Fostering a Culture of Compliance

National Institutes of Health Education and Outreach Seminar

Atlanta, Georgia
May 13, 2004
Fostering a Culture of Compliance

National Institutes of Health
Education and Outreach Seminar

AGENDA
May 13, 2004

8:30 -- 8:45  Opening Remarks
             NIH's Compliance Program – Fostering a Culture of Compliance

8:45 -- 9:45  The Administration and Science Partnership
             Grants Management for Administrators and Principal Investigators
             NIH Research Contracts

AT-RISK ISSUES FOR THE BIOMEDICAL RESEARCH COMMUNITY

9:45 -- 10:15  Financial Management of Sponsored Projects

10:15 -- 10:30  BREAK

10:30 -- 11:00  Financial Conflict of Interest

11:00 -- 11:30  Administering and Overseeing Clinical Research

11:30 -- 12:00  Extramural Intellectual Property

1:00 -- 2:30  iEdison Workshop
Fostering a Culture of Compliance

NIH Education and Outreach Seminar
Atlanta, Georgia
May 13, 2004

Division of Grants Compliance and Oversight

- Division within the Office of Policy for Extramural Research Administration, OER
- Emphasis on external and internal compliance
- Proactive Compliance Site Visits
  - Initiated in FY2000

FY 2004 Budget
$28.04 Billion

- Training 3%
- Research 9%
- Research Centers
- Other Research
- Research Project Grants 55%
- 28.04 Billion
**NIH Proactive Compliance Site Visits: Purpose**

- To assess the level of understanding of certain Federal/NIH requirements
- To assist in ensuring compliance with NIH requirements

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**NIH Proactive Compliance Site Visits: Goals**

- Nurture partnership relationship with biomedical research community
- Increase educational outreach
- Enhance administrative oversight of sponsored research
- Renew institutional commitment to compliance
- Minimize or eliminate incentives of noncompliance
- Increase NIH's level of confidence in grantees' ability to effectively manage NIH sponsored project funds

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**NIH Proactive Compliance Site Visits: Characteristics**

- Non-invasive/Non-adversarial
- Mutual information exchange - emphasis on partnership
- Not an investigation/not an audit
- No reports
- No NIH approval
Proactive Compliance Site Visit
Summary: FY2000-FY2003

31 institutions:
- 24 universities/medical schools
- 5 non-profits (3 ARI institutions)
- 2 hospitals

Geographic diversity
Expanded education-outreach seminar

A Look at FY2004...
- Georgia State University
- Emory University
- Carnegie Mellon University
- University of Pittsburgh
- Roswell Park Cancer Center
- State University of New York at Buffalo

Outcome
- Proactive Compliance Site Visits: A Compendium
  - Subject Matter Focus
  - Regulations/Policies/Guidelines
  - Summary Observations
  - Examples of Compliance in Action
- Available on Grants Compliance and Oversight Page
  http://grants.nih.gov/grants/compliance/compliance.htm
Questions?

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Administration
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Who is Eligible for an NIH Grant?

In general, NIH grants may be awarded to organizations that are:

- Domestic or foreign;
- Public or private;
- Non-profit or for-profit

- Eligible organizations include:
  - Governments (including Federal institutions);
  - Institutions of higher education;
  - Hospitals; and
  - Individuals
Essential Documents

- NIH Grants Policy Statement
- NIH Guide to Grants and Contracts
  http://grants.nih.gov/grants/guide/index
- PHS 398 Application
- PHS 2590 Application
  http://grants.nih.gov/grants/4forms.htm

What Happens When NIH Receives Your Grant Application?

- Receipt - Center for Scientific Review (CSR) reviews application for completeness and eligibility
- Application number assigned
- Referral - Application is assigned to a CSR Integrated Review Group (IRG) or to an Institute/Center
- Review - IRGs review about 70% of all applications submitted to the NIH
- Notice of assignment sent to you in 4 - 6 weeks
- If not, contact the CSR Referral Office (301-487-0719)

Have You Reviewd My Application Yet?

The NIH received over 64,000 DHHS applications (approximately 16,000 per round) in FY 2003
Who Reviews What?
(by NIH Support Mechanisms)

CSR

Institutes/Centers

Research Project Grant (R01)
Clinical Research Program (P30)
ScaIe Research (P20)
Epidemiological Branch (P20)
Clinical Trials Network (HTX)
General Clinical Research Centers (RH, R2)
Research Training (T32, K22, K24, M44)
Research Research (K02, K04, T32, K22)
Academic Research Training Award (T90)
Supplemental Research Support
United States (D10)
Grants (D15)

The NIH Extramural Management Team

Scientific Review
Administrator

- Performs administrative and technical review of applications and is initial point of contact for applicants
- Overall responsibility for the peer review process
- Manages study section activities
- Selects study sections
- Prepares summary statements
- Provides information about the review process and study section recommendations
Program Official

- Responsible for programmatic, scientific, and technical aspects of assigned grants
- Identifies areas of scientific importance and develops research programmes and initiatives to meet the mission of the NIH Institute/Center
- Participates in site visits
- Monitors scientific progress
- Important contact for principal investigators

A Program Official Can:

- Find the right program and institute for your research
- Suggest the most appropriate grant award mechanism
- Provide technical assistance during the development of the application
- Provide information related to study sections

Grants Management Officer

- Responsible for the business management of the grant award
- Only NIH official authorized to obligate NIH to the expenditure of funds or to change the funding, duration, or other terms and conditions of award
- Focal point for prior approval requests
- Interprets and ensures compliance with federal regulations, policies, and procedures
Grants Management Specialist

- Acts for the Chief Grants Management Officer
- Monitors financial and administrative aspects of projects
- Analyzes grant applications prior to award
- Reviews and responds to grantees' inquiries and requests
- Interprets and ensures compliance with Federal regulations, policies, and procedures

A Grants Management Specialist Can:

- Answer questions about completing the PHS 398
- Provide guidance on administrative and fiscal aspects of applications and awards
- Help you navigate NIH grants management information on the web

The Grantee Institution Team

- Institution
- Authorized Official
- Principal Investigator
- Administrator

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Authorized Organizational Official

- Designated representative of the grantee organization in matters related to the award and administration of its NIH grants, including those that require NIH approval or changes in award terms and conditions.
- Signature of this official is required for all official correspondence to NIH.

Authorized Organizational Official

This Official's signature on the grant application:
- Certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application.
- Assures that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the grant-supported project or activities resulting from the application.
- Attests to the fact that all information contained in the application is true and complete and is in conformance with Federal and organizational requirements.

The Principal Investigator is responsible for the scientific aspects of the grant and for the day-to-day management of the project.
Principal Investigator (PI)

- Responsible for ensuring compliance with financial and administrative requirements for the grant award
- NIH encourages the PI to maintain contact with:
  - NIH Program Official regarding scientific or technical issues of the project
  - NIH Grant Management Officials concerning business and administrative aspects of the award

Principal Investigator

Works closely with organization officials to:

- Create and maintain necessary documentation, including both technical and administrative reports
- Prepare justifications
- Ensure Federal support of research findings is appropriately acknowledged in publications, announcements, news programs, etc.
- Comply with organizational as well as Federal requirements

Research Administrator

- Acts as a local agent of the Authorized Organizational Official and/or PI
- Is a counterpart to the NIH Grants Management Specialist
- Provides essential grant-related support
- Cannot assume responsibilities assigned to the Authorized Organizational Official or the PI
A Few Reminders

- Grants are awarded to organizations, not Principal Investigators.
- Recipients of NIH grant funds must comply with all applicable Federal statutes, regulations, and policies.
- By drawing funds from the HHS payment management system, grantees agree to the terms and conditions of the grant award.
- The NIH Grants Policy Statement is a term and condition of every NIH grant award.

What If You Have a Question?
(a rule of thumb)

- Can your question be answered:
  - At your organization? (Office of Sponsored Research)
  - By reading the Notice of Grant Award and/or the NIH Grants Policy Statement?
  - At NIH by the Grants Management Officer or Program Officer indicated on the Notice of Grant Award?

Useful Information Sources

- NIH Office of Extramural Research
  http://grants.nih.gov/grants/wen.htm
- Welcome Wagon Letter
  http://grants.nih.gov/arts/funding/welcomewagon.htm
- Grants Policy Question?
  Call the Division of Grants Policy, Office of Policy for Extramural Research Administration (OPERA) at 301-496-9494 or send an email to: grantsinfo@nih.gov
- For general grants information call 301-496-0114 or send an email to: grantsinfo@nih.gov
Other Opportunities to Learn About NIH

- NIH Regional Seminars
  http://grants.nih.gov/grants/seminars.htm

- SRA National Meeting – October 23 - 27, 2004
  in Salt Lake City, Utah
  http://www.scranational.org/newweb/default.cfm

- NCURA National Meeting – October 31 – November 3, 2004 in Washington, DC
  http://www.ncura.edu

Questions?

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Grants Management for Administrators and Principal Investigators

Marcia Hahn

"Expanded" Expanded Authorities

Applied to All Mechanisms
- NIH standard terms
- Automatic carryover is specified on the NGA (Yes/No)
- Must all follow specific program guidelines (Career & RSRA Awards)
- Effective October 1, 2001 for awards issued on or after October 1, 2001
- NIH Guide, September 26, 2001:

Change in Scope
Requires Prior Approval

Actions likely to be considered a change in scope:
- Change in the specific aims specified at the time of award
- Any change from the approved use of animals or human subjects
- Shifting research emphasis from one disease area to another
- Applying new technology, e.g., changing assays from those applied to a different type of assay
- Transferring performance of substantive programmatic work to a 3rd party, if change of scope OR if consortium IS foreign (always)
- Significant Rebudgeting (may be a change of scope indicator)
**Change in Status of PI and Other "Key" Personnel**

Requirements Prior Approval

- Must notify NIH if the PI or other personnel listed in the NGA will:
  - withdraw from the project entirely
  - be absent 3 months or more
  - reduce time devoted to the project by 25% or more
- Must request approval of a substitute prior NGA designated personnel
- Must notify the awarding office GMO in writing if grantee wishes to terminate the project if it cannot make suitable alternate arrangements

**Change of Grantee Institution**

Requires Prior Approval

NIH approval is required for the transfer of a grant-supported project from one institution to another.

- Request must include:
  - Reinquiting Statement (key)
  - Final invention statement and certification
  - Final SRIR within 90 days
  - Grant application (PHS 398) from the proposed grantee
- NIH may request additional information

**Restrictions on NGA**

Requires Prior Approval

- Any deviation from specific terms or conditions stated in the NGA or from the terms and conditions included in the NIH Grants Policy Statement
- Activities disapproved or restricted as a condition of the award
Important Reminders

Other Support
- Provide as part of "Just in Time" Information
- List ALL financial resources, Federal, Non-Federal, Commercial or institutional, in direct support of the recipient's research endeavors, including but not limited to: 
  - Subcontracts agreements, contracts, and/or institutional awards
  - Project grants, and/or grants and/or grants are not included
- Used to review potential overlap—scientific, budgetary, or commitment
- Grants must report changes in other support as part of the annual progress report
- Reminder: On Campus and Up-To-Date Other Support
  NIH Guide, 2/13/2010:

Timely Non-Competing Grant Progress Reports
- A recent OIG study concluded that major contributing factors to late non-competing awards were a lack of and/or incomplete progress reports
- OAS system sends email notifications to PIs and Admins via OAS Alerts
  - Two weeks after the due date for overdue reports
- Commons-registered institutions and PIs
  - Have access to the latest information through the Commons Status system
  - Also have access to NIH-supported facsimile via State
- All awardees access a website to determine which progress reports are due:
  http://rex.nih.gov/icorn/ncr_e_report_due.jsp
- NIH Guide Notice: NOT-OD-14-014, August 5, 2013
Timely Closeout Final Reports

Failure to submit timely final reports may affect future funding to the organization.

These documents are due within 90 days of the project end date:
- Final Financial Status Report (FSR)
- Final Invention Statement and Certification
- Final Progress Report

Application Reminders

- Revised Policy, Amended Applications
  - No longer any time limit on submission of amended applications
  - Limit of 2 revisions per letter in effect
  - Applies to all NIH extramural funding mechanisms
  - NIH Notice ENV May 7, 2003

- Revised Policy, Re-submissions (since 9/10/2005)
  - Un-funded TFA applications—require an NEW investigator initiated AID
  - Previously un-funded investigator-initiated applications submitted in response to an RFA should be re-submitted as NEW applications
  - Un-funded applications re-submitted for a particular grant mechanism that submitted for a sufficient number of non-competitive applications

Application Reminders

- UNSOLICITED APPLICATIONS THAT REQUEST $500,000 OR MORE IN DIRECT COSTS
  - Prior approval required at least 90 weeks prior to the anticipated submission.
  - NIH Notice October 10, 2004

- DATA SHARING Policy (since 10/1/2004)
  - Applications requesting $500,000 or more of direct costs in any year that fail to include a plan for sharing that research data, or state why data sharing is not possible.
  - NIH Notice February 26, 2003

- Application Delivery Changes
  - Different zip code for counter-US Postal Service mailing
  - Eliminated code for hosp-except
  - NIH GUIDE NOTICES April 22, 2003
Other Reminders

- Salary Limitation (now $175,700)
  - Salary caps can change, see actual base salaries
- F&A Costs for Foreign & International Organizations (F&A allowed)
- Policy on Direct Cost Changes for IRB Review
- JACUC Approval Now "Just-in-Time"

Hot Topics

NIH Roadmap

- Lays out a vision for a more efficient and productive system of medical research
- Identifies critical roadblocks and knowledge gaps that constrain rapid advances in biomedical research progress
- Three themes:
  - New Pathways to Discovery
  - Multidisciplinary Research Teams of the Future
  - Re-engineering the Clinical Research Enterprise
- Roadmap Website:
  http://nihroadmap.nih.gov/index.asp
- FY2004 Applications expected to be funded
  September 2004
- Watch website & NIH Guide for FY2005 Initiatives
Revised NIH Grants Policy Statement

Published December 1, 2003
New NIH Grants Policy Statement includes:
- Revisions to NIH policies since March 2001
- Clarifications
- Public Policy Changes (e.g., Patent Act, Select Agent, HIPAA, Human Embryonic Stem Cells)
- An Index

NIH Guide notice that highlights specific changes:
NIH Grants Policy Statement (2003 revision)

Revised Grants Policy Statement
(A Closer Look at Changes of Note)

- Audit: Improved for A-133 audits have increased from $20,000 to $50,000 for fiscal years ending after 12/31/02
- Closeout related work: NIH now applies for performance-based closeout of all NIH recipients. To
  avoid loss of funds, a grantee must either complete or transfer all unspent funds with any restricted
  funds
- Key Personnel: Help prevent dilution of the contributions of key personnel. Use meaningful
  definitions and criteria for the term "Key Personnel" and for allowing comparable or additional
  personnel
- Consortium awards: Principal investigator is responsible for ensuring that acceptable agreements
  must be signed by the institution, contractor, collaborating principal investigator, or
  subcontractor, if any, that specifies the responsibilities of the parties involved, intellectual property, and
  data sharing requirements
Revisions to the PHS 398 and 2590 Forms

PHS 398 Revision
(Spring 2004)

- Extensively rewritten with a focus on clarity, simplicity, & plain language
- Reorganized into 3 Parts
  - Part I: Instructions (now are truly just application instructions)
  - Part II: Supplement instructions for Preparing the Human Subjects Section of the Research Plan
  - Part III: Impcis, Assurances, Definitions & Other Information

PHS 398 Revision
(Spring 2004)

- Fully incorporates all application-related policy changes implemented since the 591 version
- Existing forms will be accepted until new sheet iscome available (OMB OMBXeye expected Spring 2004)
- Notable changes:
  - Page 5: Adding "Offsite Data Indicators"
  - From Page 7: Description now includes separate instruction to P1 to clearly describe public health importance
  - Crossed Reregistered line for Riew, Cost Information
  - Added new section for "Other Significant Contributors"
  - Nutrition: amendment to scientific approach for assessment of the project & not conflicting measurable effect
PHS 2590 Revision
(Spring 2004)

- included information on electronic submission via e-SNAP
- Incorporation of refined definition of Key Personnel & new category "Other Significant Collaborators"
- For SNAP
  - Snap Question #1 (Changes in Other Support) modified instructions to not include submission of complete Other Support Forms if changes in active support are noted
  - Snap Question #5 (Changes in level of effort). Clarified applicability— is in other personal support in NIA

NIH eRA Commons

NIH eRA Commons Registration

- Open to All Institutions
- Authorized Official should register the institution
- See if your institution is already registered at: http://era.nih.gov/assistance/ptr_com_org_list.xls
Commons Functionality:
E-SNAP

Electronic submission of non-competing SNAP Progress Reports through web interface
Open to all FDP Institutions January 2004
Expected to open to all summer 2004
Allowing potential business process redesign so interested grantees are required to sign an agreement before participating

Commons Functionality:
E-SNAP

Difference from Paper Submission

- 45 day submission deadline (vs 60 days with hard copy)
- Incorporates centrally stored grantee information (in its Institutional Profile) and PI information (in its Personal Data Page)
- If publications that are available electronically, can include link rather than submit hard copy reprint
- Key Personal Data Page- System stores previous submission to allow easy update in future yrs

Commons Functionality:
E-SNAP

Difference from Paper Submission (cont'd)

- Testing business process change by submission of R1S and/or ACCC approval dates
- Approval dates will not be required at time of e-SNAP submission. Instead, grantees agree to submit approval dates at time of submission. NIH will use this to ensure full compliance. NIH expects the data to help support a permanent change in the business process, i.e., eliminating the need for routine resubmission for SNAP progress reports
- Retrospective data collection will be required until NIH has collected a random sample from a larger population of partnering grantees
Commons Functionality
New Features (11/03)

Submit Extensions
- Grantees can now submit an extension to NIH of the
  under-budgeted portion of the final budget period to
  a previously approved competing segment
- Automatically update budget/project period-end
dates in the NIH database
- Automatically generate e-mail notifications to
  assigned NIH staff and the grantee institution
- Have until the current budget/project end date to
  submit (15 day window required for hard-copy
  notifications has been eliminated for electronic
  notifications.)

Commons Functionality
New Features (cont'd)

- Just-In-Time Submission
  - Currently allows only a single submission per
    grantee on or before the due date (Future
    enhancement will allow multiple submissions)
  - Grantees can now electronically submit the 4 data
    elements included in the just-in-time submission
    - IACUC approval date
    - IRB approval date
    - Other sponsor page for key personnel
    - Human Subjects education information for key
      personnel involved with human subjects

Resources
- Revised "Grants Administration/Information Sources" is
  now available at:
  - Provides up-to-date contact information for GrantsAdministration
    through all NIH ICs
- Contact list for NIH Chief Grants Management Officers:
  http://grants.nih.gov/grants/ireferees_gmos.htm
- Need help in writing an NIH grant? - Grant Writing Tips
  Sheet:
  http://grants.nih.gov/grants/grant_tips.htm
Questions?

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Grants Management for Administrators and Principle Investigators

Resources

  Revised Terms and Conditions for NIH Awards

  Reminder to Applicants About Requirement to Submit Complete and Up-To-Date Other Support Information

- NIH Guide Notice / NOT-OD-03-054 / August 5, 2003
  Reminder and Update Status of Non-Competing Grant Progress Report Notification

  Revised NIH Policy on Submission of a Revised (Amended) Application

  Special Exception – Submission of A3 Applications During Center for Scientific Review (CSR) Reorganization

  Resubmission of Unpaid RFA Applications and Resubmission of Applications with a Changed Grant Activity Mechanism

  Revised Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs

  Final NIH Statement on Sharing Research Data

  Reminder and Clarification – Delivery of Competing Grants, Cooperative Agreement, and Fellowship Applications

- NIH Guide Notice / NOT-OD-04-034 / March 11, 2004
  Change in 2004 Salary Limitation on Grants, Cooperative Agreements, and Contracts
  Allowability of Facilities and Administrative (F&A) Costs for Foreign and International Organizations

  NIH Policy on Direct Cost Charges for IRB Review

- NIH Guide Notice / NOT-OD-02-064 / August 8, 2002
  Laboratory Animal Welfare: Change in PHS Policy on Human Care and Use of Laboratory Animals


  Publication of the Revised NIH Grants Policy Statement (Rev. 12/03): Policy Changes, Clarifications, and Enhancements
In October 1988, NIH implemented Expanded Authorities for its research grant mechanisms. In an effort to bring some consistency to the management of NIH's grant portfolio and to further streamline the administration of NIH awards, NIH is expanding these authorities (with the exception of automatic carryover of unobligated balances) to include all grant mechanisms.

Effective October 1, 2001 (awards issued on or after October 1, 2001), the authorities currently known as Expanded Authorities will become standard terms and conditions for all NIH grant awards. The mechanisms that currently do not have routine automatic carryover of unobligated balances are centers (P50, P60, P55, etc.); cooperative agreements (U's); National Research Service Awards (T's and F's); Phase I SEIR & STTR (R41,R44); clinical trials (regardless of mechanism) and awards to individuals. In most cases, carryover of unobligated balances for these mechanisms will continue to require prior approval of NIH staff. However, awarding office discretion may be used to authorize the automatic carryover authority for these grant activities and cooperative agreements on an individual or group award basis. The terms and conditions of individual awards will reflect the disposition of unobligated balances and other terms that an Institute or Center may place on an award that are project specific.

Where there are separate program guidelines (National Research Service Awards, Career Awards, and Requests for Applications), the policies under those guidelines must be followed. For example, the program guidelines for NASA awards have specific policy requirements concerning the reprogramming of stipends and tuition and fees, and career award program guidelines have specific minimum effort requirements for the career awards. These program guidelines are not changed by the new NIH standard terms and conditions.

The NIH Grants Policy Statement will be revised to reflect the change in NIH terms and conditions.

Questions concerning the new NIH implementation should be addressed to the NIH grants management staff identified on the notice of grant award.

NIH Guide: REMINDER TO APPLICANTS ABOUT REQUIREMENT TO SUBMIT COMPLETE AN... Page 1 of 2

RELEASE DATE: February 13, 2003

NOTICE: NOT-OD-03-029

National Institutes of Health (NIH)

NIH requires submission of complete and up-to-date "other support" information before an award can be made. Other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included. Applicants should not include information on other support in the PHS 398 competitive grant application submission, but should be prepared to follow "just-in-time" procedures to submit current other support information upon the request of NIH Institute/Center staff when the application is under consideration for funding. Grantees must also report any changes in other support as a part of the annual progress report.

Information on other support assists awarding agency staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and only funds necessary to the conduct of the approved project are included in the award. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source.

Commitment overlap occurs when a person's time commitment exceeds 100 percent, whether or not salary support is requested in the application. While information on other support is only requested for key personnel (excluding consultants), no individuals on the project may have commitments in excess of 100 percent.

Scientific overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source.

The Institute/Center scientific program and grants management staff review other support information prior to award. Resolution of overlap occurs at the time of award in conjunction with applicant, institution officials, the principal investigator, and awarding agency staff. NIH staff continue to monitor changes to other support information throughout the project as part of the annual progress reviews.

Return to Volume Index

Return to NIH Guide Main Index

This Notice updates the NIH extramural community on the status of non-competing grant progress report notification.

Historically, NIH reminded grantees about the submission of a progress report by mailing a pre-printed face page. In August 2002 NIH announced a modification of this business process and discontinued this mailing (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-066.html). Since that time, the NIH Office of Extramural Research has hosted a website of Non-Competing Progress Report due date information. Located at: http://era.nih.gov/userreports/pd_due.cfm, grantee officials query using their Institutional Profile Number (IPF) to return a list of "due" progress reports. If an official is not certain of the IPF, a companion query is also available at the site to help determine the appropriate IPF. Grantee officials are encouraged to review this list at least once a month. Several months of "due" information are in the query at all times and records drop off of the list as NIH receives the progress reports. New records are added on/around the 30th of each month.

For grantees institutions and principal investigators (PIs) registered in the eRA Commons, the progress report due information is available in the Commons Status system. Commons-registered institutions and PIs also have access to pre-populated face pages via Status. For more information on the NIH Commons, see: https://commons.era.nih.gov/CREPGG/1/index.jsp.

In an effort to improve the timely submission of non-competing progress reports, NIH recently implemented two separate e-mail reminders to the PI. An initial reminder is sent two months prior to the due date. Approximately two weeks after the due date, a follow-up reminder is sent for those progress reports that are overdue.

Progress reports should continue to be mailed directly to the NIH awarding Institute/Center. A list of Institute/Center mailing addresses for progress reports is found at: http://grants.nih.gov/grants/type5_mailing_addresses.htm.

The instructions in the PHS 2590 (Non-competing Progress Report) and HS 416-9 (Individual Kirschstein-NRSA Fellowship Progress Report) have been updated to include information on this change in business process. Revised PHS 2590 Instructions are located at: http://grants.nih.gov/grants/funding/2590/section_1.html and http://grants.nih.gov/grants/funding/2590/section_5.html.


Questions concerning the web query or access through the Commons should be addressed to the eRA Helpdesk: e-mail: Commons@od.nih.gov. Questions concerning submission of progress reports should be directed to the specific NIH Institute/Center.
NIH Guide: REVISED NIH POLICY ON SUBMISSION OF A REVISED (AMENDED) APPLICATION  Page 1 of 2

REVIEWED NIH POLICY ON SUBMISSION OF A REVISED (AMENDED) APPLICATION

RELEASE DATE: May 7, 2003 (Also see NOT-OD-03-041)

NOTICE: NOT-OD-03-041

National Institutes of Health (NIH)

In June 27, 1997 the NIH issued a notice in the NIH Guide for Grants and Contracts (see http://grants.nih.gov/grants/guide/notice-files/NOT9-011.html) that limited the number of revised or amended applications permitted as well as the time window during which those amended applications would be received. This announcement reiterates the NIH policy on the number of amended applications permitted but eliminates the two-year restriction on the receipt of those applications.

Accordingly, the NIH will not consider any A3 or higher amendment to an application for extramural support. But, beginning on the date of this announcement, there is no longer a time limit for the submission of the first and second revisions (A1 and A2). This policy applies to all NIH extramural funding mechanisms.

In submitting a revised application, it is worth noting that, a lengthy time after the initial submission may be marked by significant advances in the scientific field and the comments of the reviewers may no longer be relevant. Principal investigators and their institutions need to exercise their best judgment in determining the advisability of submitting a revised application after several years have elapsed.

The policy limiting the number of revisions was established following analysis of data indicating that investigators who receive initial funding for an amended application have a lower success rate in obtaining support for a follow-on competing application. The likelihood of subsequent success decreased with an increasing number of amendments. After three reviews, it was felt that it was time for investigators to take a fresh approach to their research proposals.

Investigators who have submitted three versions of an application and have not been successful often ask NIH staff how different the next application submitted has to be to be considered a new application. It is recognized that investigators are trained in a particular field of science and are not likely to make drastic changes in their research interests, however, a new application following three reviews is expected to be substantially different in content and scope with more significant differences than are normally encountered in a revised application. Simply wording the title and Specific Aims or incorporating minor changes in response to comments in the previous Summary Statement does not constitute a substantial change in scope or content. Changes to the Research Plan should produce a significant change in direction and approach for the research project. Thus, a new application would include substantial changes in all sections of the Research Plan, particularly the Specific Aims and the Research Design and Methods sections.

In the referral process, NIH staff look at all aspects of the application, not just the title and abstract. Requesting review by a different review committee does not affect the implementation of this policy. When necessary, previous applications are analyzed for similarities to the present one. Thus, identical applications or those with only minor changes will not be accepted for review.

Inquiries:


4/20/2004
NIH Guide SPECIAL EXCEPTION – SUBMISSION OF A3 APPLICATIONS DURING CENTER FOR
SCIENTIFIC REVIEW (CSR) REORGANIZATION

RELEASE DATE: September 22, 2003

NOTICE: NOT-GD-03-065

National Institutes of Health (NIH)

Present NIH policy allows consideration of revised applications for only two additional versions (A1 and A2). The policy (https://grants.nih.gov/grants/guide/notice-files/NOT-GD-03-041.html) was established following analysis of data indicating that investigators who receive initial funding for an amended application have a lower success rate in obtaining support for a follow-on competing application. The likelihood of subsequent success decreased with an increasing number of amendments. After three reviews, it was felt that it was time for investigators to take a fresh approach to their research proposals.

The most common situation is for revised applications to be reviewed by the same committee that reviewed the previous version, but this is not always the case. Because of the reorganization of Integrated Review Groups and their component study sections in the Center for Scientific Review at NIH, some investigators may be concerned that amended applications may be assigned to a new study section. This reorganization is a special circumstance that warrants offering applicants in a particular category an additional review opportunity. Accordingly, NIH has decided to allow a third (A3) revision for applications that meet all of the following criteria:

6. They were reviewed in their first revision (A1) in a to-be-disbanded study section and not funded.
6. They were reviewed in a newly created study section as the second revision (A2) and not funded.
6. A note citing this opportunity appears on the summary statement of A2 application.

This will allow all amended applications to have their final two reviews within the reorganized CSR review committees. This opportunity applies only to the identified applications; other A3 applications will not be accepted for review consistent with NIH policy as stated above.

For questions, please contact:

Division of Receipt and Referral
Center for Scientific Review
301-435-0715; 301-480-1987 (fax)

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The majority of grant applications submitted to NIH each year are investigator-initiated. However, the Institutes and Centers of NIH also solicit grant applications on specific topics through the use of Requests for Applications (RFAs). With this notice the NIH is changing its practice regarding resubmissions of three categories of grant applications. Those categories include:

1. Applications that were originally submitted in response to an RFA and then resubmitted as an investigator-initiated application.
2. Applications that were originally submitted as investigator-initiated applications and subsequently resubmitted in response to an RFA.
3. Applications that were originally submitted using one grant mechanism and subsequently resubmitted using a different grant mechanism (for example, an application that was originally an R01 and then is resubmitted as an R21).

Since an RFA often has special considerations of eligibility, scientific scope, and review criteria, it is felt that most unfunded applications should be resubmitted as NEW applications. Similarly, a change of grant mechanism (from an R01 to an R21 or from an R03 to R01, for example) usually involves a change of eligibility criteria, application characteristics, dollar limits, time limits, or review criteria. This also suggests that consideration as a new application is the most appropriate course. Because the application will be new, it will be easier to conform to the new application requirements, which should advantage the applicant in the review process. Additionally, submission of a new application will allow the applicant to fully benefit from the NIH policy that allows an applicant to submit two revisions within two years [see http://grants.nih.gov/grants/policy/amendedapps.htm].

NEW APPLICATIONS: The new application must be submitted on the scheduled due dates for new applications [see http://grants.nih.gov/grants/funding/submissionschedule.htm]. It must not include an introduction describing the changes and improvements made; and the text must not be marked to indicate the changes. While the investigator may still benefit from the previous review, the application is not to state explicitly how. The reviewers will not be provided with the previous summary statement. The investigator will be allowed to submit the new application and up to two revised versions of this application, should that be necessary.

POLICY: This general policy on application resubmission, stated below, applies to all grant mechanisms that might be solicited via an RFA and to instances where there is a change in mechanism. There may, however, be exceptions to this policy, which will be clearly identified in the original RFA or in a follow-up RFA.

1. When an application that was submitted in response to an RFA is not funded and the investigator wishes to resubmit an application on this topic as an investigator-initiated application, it is to be submitted as a NEW application, unless provisions for
NIH Guide: RESUBMISSION OF UNPAID RFA APPLICATIONS AND RESUBMISSION OF APPLI... Page 2 of 2

submission of a revised application are clearly delineated in the RFA. In addition, if a subsequent RFA specifically solicits revisions of unfunded applications from a previous RFA, the instructions in the second RFA should be followed. In all other cases, applications submitted in response to an RFA and then resubmitted as an investigator-initiated application must be submitted as a NEW application.

2. When a previously unfunded application, originally submitted as an investigator-initiated application is to be submitted in response to an RFA, it is to be prepared as a NEW application.

3. When an unfunded application that was reviewed for a particular research grant mechanism (for example, R01) is to be submitted for a different grant mechanism (for example, R03), it is to be prepared as a NEW application.

This change in policy is effective for applications submitted on or after May 10, 2003 so it includes all applications going to January 2004 councils.

For further information please contact:

1) grantsInfo
Office of Extramural Research
301-435-0714
301-480-0525 (fax)
granteinfo@nih.gov

2) Division of Receipt and Referral
Center for Scientific Review
301-435-0715
301-480-1987 (fax)
6701 Rockledge Drive
Room 2030, MSC 7720
Bethesda, MD 20892-7720 (20817 for courier delivery)

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NIH Guide: REVISED POLICY ON THE ACCEPTANCE FOR REVIEW OF UNSOLICITED APPLICATIONS REQUESTING $500,000 OR MORE IN DIRECT COSTS

Release Date: October 16, 2001
NOTICE: NOT-OD-02-004

National Institutes of Health

The National Institutes of Health (NIH) is updating its policy on the acceptance of applications requesting direct costs of $500,000 or more for any one year. Effective with the January 1, 2002 receipt date, applicants must seek agreement to accept assignment from Institute/Center staff at least 6 weeks prior to the anticipated submission of any application requesting $500,000 or more in direct costs for any year.

BACKGROUND

The NIH supports research projects with large budgets but needs to consider such awards as early as possible in the budget and program planning process. Regardless of the merit of the application or the budget justification, unanticipated requests for unusually high amounts of direct costs are difficult for NIH to manage. It is in the best interest of all parties if applicants anticipating large direct costs to contact the appropriate NIH program staff as early as possible to ensure that an Institute/Center would be willing to accept the application.


The current policy advises an applicant planning to submit an investigator-initiated new, competing continuation, competing supplement, or any amended/revised version of the original application requesting $500,000 or more in direct costs for any year to contact Institute or Center program staff before submitting the application. Discussions with program staff should occur as plans for the study are being developed. However, that notice does not specify a timeframe for this process.

This revised policy requires applicants to seek agreement from Institute/Center staff at least 6 weeks prior to the anticipated submission of any application requesting $500,000 or more in direct costs for any year. If staff is contacted less than 6 weeks before submission, there may be insufficient time to make a determination about assignment prior to the intended submission date. If the requested dollars are significantly greater than $500,000, then approval should be sought even earlier.

This policy does not apply to applications submitted in response to RFAs or in response to other Announcements that include specific budgetary limits. However, such applications must be responsive to any budgetary limits specified, or they will be returned to applicants without review.

PROCEDURES

An applicant planning to submit a grant application with $500,000 or more in direct costs for any year is required to contact in writing or by telephone NIH Institute or Center program staff. This contact should be made during the development process of the application but no later than 6 weeks before the anticipated submission date. If the Institute or Center is willing to accept assignment of the application.


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for consideration of funding, the staff will notify the Center for Scientific Review before the application is submitted.

The Principal Investigator must include a cover letter with the application. That cover letter must identify the program staff member and Institute or Center that has agreed to accept assignment of the application.

An application received without indication of prior staff concurrence and identification of program staff contacted will be returned to the applicant without review. Therefore, NIH strongly encourages applicants to contact Institute or Center staff at the earliest possible time.

INQUIRIES

For additional information about this policy, the program staff at any Institute or Center may be contacted. Applicants who are uncertain about which Institute or Center may have the greatest interest in the research for which support is sought should contact:

Division of Receipt and Referral
Center for Scientific Review
National Institutes of Health
Telephone: (301) 435-0715
FAX: (301) 480-1987


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NIH Guide: FINAL NIH STATEMENT ON SHARING RESEARCH DATA

FINAL NIH STATEMENT ON SHARING RESEARCH DATA

RELEASE DATE: February 26, 2003

NOTICE: NOT-OD-03-032

National Institutes of Health (NIH)

As part of NIH's long-standing policy to share and make available to the public the results and accomplishments of the activities that it funds, NIH announced and invited comments on a draft statement about the sharing of final research data on March 1, 2002. Since that time, NIH has received and reviewed many thoughtful comments from a range of scientific organizations and over 150 individuals. Additionally, during the comment period, HHS published final modifications for the STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION, the "Privacy Rule," of the Health Insurance Portability and Accountability Act (HIPAA), available at http://www.hhs.gov/ocr/. The Privacy Rule is a federal regulation that governs how certain health care providers, health care clearinghouses, and health plans, known as "covered entities," use and disclose identifiable health information. NIH has carefully considered the comments and the Privacy Rule, and issues the following statement on data sharing:

NIH reiterates its support for the concept of data sharing. We believe that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. The NIH endorses the sharing of final research data to serve these and other important scientific goals. The NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. Starting with the October 1, 2003 receipt date, investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why data sharing is not possible.

As indicated above, all investigator-initiated applications with direct costs greater than $500,000 in any single year will be expected to address data sharing in their application. Applicants are encouraged to discuss their data sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application as described at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html.

Applicants are reminded that agreement to accept assignment of applications over $500,000 must be obtained at least six weeks in advance of the anticipated submission date. Instructions related to the data sharing policy as it is applied to applications and proposals responding to a specific Request for Application (RFA) or Request for Proposals (RFP) will be described in the specific solicitation. In some cases, Program Announcements (PA) may request data sharing plans for applications that are less than $500,000 direct costs in any single year. Reviewers will not factor the proposed data-sharing plan into the determination of scientific merit or priority score. Program staff will be responsible for overseeing the data sharing policy and for assessing the appropriateness and adequacy of the proposed data-sharing plan.

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule. As NIH stated in the March 1, 2002 draft data sharing statement (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-035.html), the rights and privacy of people who participate in NIH-sponsored research must be protected at all times. Thus, data intended for


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broad use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data sharing is limited, applicants should explain such limitations in their data sharing plans.

The final NIH statement on data sharing is largely the same as stated in the March 1, 2002 draft with the following exceptions:

- The effective start date has been changed from January 1, 2003 to October 1, 2003 receipt date.

- This policy applies to applicants seeking $500,000 or more in direct costs in any year of the project period. Such applicants are expected to contact IC program staff prior to submission and are also expected to include a data-sharing plan in their application stating how they will share the data or, if they cannot share the data, why not. Applicants responding to an RFA or RFP will find instructions related to data sharing in the specific announcement.

- Several groups and individuals objected to sharing of research data prior to publication. As noted earlier, NIH recognizes that the investigators who collect the data have a legitimate interest in benefiting from their investment of time and effort. We have therefore revised our definition of "the timely release and sharing" to be no later than the acceptance for publication of the main findings from the final data set. NIH continues to expect that the initial investigators may benefit from first and continuing use but not from prolonged exclusive use.

For more information on data sharing, please see our website at http://grants.nih.gov/grants/policy/data_sharing/.

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REMINDER AND CLARIFICATION - DELIVERY OF COMPETING GRANT, COOPERATIVE AGREEMENT, AND FELLOWSHIP APPLICATIONS

RELEASE DATE: April 22, 2001

NOTICE: NOT-OD-03-040 (Also see NOT-OD-02-012)

National Institutes of Health (NIH)

The Division of Receipt and Referral, Center for Scientific Review, National Institutes of Health, would like to inform investigators submitting grant applications that the Zip Code 20817 specified in the grant application instructions for “Courier” delivery should not be used for Express Mail through the United States Postal Service (USPS). The USPS does not deliver packages directly to the 6701 Rockledge Drive address but instead forwards them to the main mail facility of the NIH. If the “Courier” zip code is used with USPS, the application may be initially sent to a non-NIH mail facility and later routed to NIH.

Thus, when tracking your package it will be noted that it was forwarded to another zip code (20892). That is normal procedure and the package will be forwards back to the Rockledge address though there will be a delay.

Consequently, all applications sent via the United States Postal Service for Express or regular mail should use the following address:

Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive MSC 7110
Bethesda, MD 20892-7110

All applications sent via a courier delivery service should use this address:

Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive
Bethesda, MD 20817

Applications may not be delivered by individuals to the Center for Scientific Review but must be sent via a courier delivery service or the USPS.

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4/20/2004
NIH Guide: CHANGE IN 2004 SALARY LIMITATION ON GRANTS, COOPERATIVE AGREEMENTS, AND CONTRACTS

RELEASE DATE: March 11, 2004
NOTICE: NOT-OD-04-034

National Institutes of Health (NIH)
(www.nih.gov)

This notice provides updated information on the FY 2004 salary limitation.

On March 3, 2004, an Executive Order (EO) was signed to implement a retroactive pay increase for Federal employees. This EO, which implements the pay raise approved by Congress in January, applies to certain rates of Federal pay including Executive Level salaries. As a result, the Executive Level I salary level increased, effective January 1, from $174,500 to $176,700.

Consistent with NIH’s implementation of the FY 2004 salary limitation, if grant awards (competing or non-competing) have already been issued in FY 2004, no adjustments will be made. However, rebudgeting is allowable. Additional details on NIH’s implementation of the salary limitation can be found at "Salary Limitation in Grants, Cooperative Agreements, and Contracts."

INQUIRIES

Questions concerning this notice or other policies relating to grants or contracts should be directed to the grants management or contracts management office in the appropriate NIH Institute or Center.


4/20/2004
NIH Guide: ALLOWABILITY OF FACILITIES AND ADMINISTRATIVE (F&A) COSTS FOR FOREIGN AND INTERNATIONAL ORGANIZATIONS

Release Date: March 29, 2001
NOTICE: NOT-OD-01-028

National Institutes of Health

In the past, Department of Health and Human Services (DHHS) policy prohibited the provision of facilities & administrative (F&A) costs on foreign and international awards. As a result, the National Institutes of Health (NIH) and the extramural community have had concerns that by not providing some allowance for F&A costs to these organizations, valuable research opportunities may be lost.

Effective October 2001 (FY 2002), NIH will provide limited F&A costs to foreign and international organizations. The provision of F&A costs to foreign and international organizations is to support the costs of compliance with DHHS and NIH requirements including but not limited to, the protection of human subjects, the welfare of animals, financial conflict of interest, and invention reporting.

This implementation will affect new and competing continuation awards. Established commitment levels on non-competing continuation awards will not be adjusted; however, funds may be rebudgeted to cover these costs. The F&A costs should be requested in competing applications and may not exceed eight percent of total direct costs less equipment. Also, domestic organizations that submit applications with a foreign or international consortium may request eight percent of total direct costs less equipment, for the consortium. NIH will not support the acquisition of, or provide for depreciation on any capital expenses (facilities), or normal general operations related to foreign and international organizations.

Affected applicants that have already submitted applications request these costs at the time any potential award is negotiated.

INQUIRIES

Additional questions regarding the implementation of F&A costs to foreign and international organizations may be directed to the NIH Division of Grants Policy at (301) 435-0949 or the Grants Management Specialist identified on the NIH Notice of Grant Award.

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NIH Guide: NIH POLICY ON DIRECT COST CHARGES FOR IRB REVIEW

RELEASE DATE: May 22, 2003

NOTICE: NOT-OD-03-042

National Institutes of Health (NIH):

This is a reminder that no costs associated with the review of human research protocols by an Institutional Review Board (IRB) may be charged as direct costs for NIH-funded research involving human participants, unless such costs are not included in the institution's facilities and administrative rate (F&A). This policy is consistent with OMB Circular A-21 which requires that "all costs incurred for the same purpose, in like circumstances, are either direct costs only or F&A (indirect) costs only with respect to final costs objectives."

The NIH recognizes the increased compliance costs associated with human subjects protection and is addressing this issue through the Human Subject Research Enhancement Program. The NIH continues to explore the feasibility of alternative approaches to further address this issue.

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National Institutes of Health (NIH)

In the March 28, 2002, Federal Register (and the April 5, 2002, NIH Guide for Grants and Contracts), the NIH announced that it was considering a change in the PHS Policy on Humane Care and Use of Laboratory Animals to allow institutions to provide IACUC approval in a "just-in-time" fashion prior to award, as is now permitted for NIH approval. The comment period ended on May 28, 2002, and responses from the research community and institutional officials were overwhelmingly in favor of this change. Consequently, the NIH now announces that beginning with applications submitted for the October 1, 2002, receipt date (and any other receipt dates that result in applications being reviewed for May/June 2003 Councils), IACUC "just-in-time" will be in effect. That is, institutions will be permitted flexibility in the timing of IACUC review relative to submission of an application.

The NIH wants to emphasize certain principles and expectations of the "just-in-time" process for IACUC review and approval.

- The fundamental PHS Policy requirement that no award may be made without an approved Assurance and without verification of IACUC approval remains in effect. This change only affects the timing of the submission of the verification of that review.

- This change is intended to permit flexibility and discretion on the part of the institution. It is not a requirement that IACUC approval be deferred. Institutional officials retain the discretion to require IACUC approval prior to peer review in certain circumstances of their choosing if they so desire.

- Under no circumstances may an IACUC be pressured to approve a protocol, or be overruled on its decision to withhold approval. NIH peer review groups will continue to address the adequacy of animal usage and protections in their review of an application, and will continue to raise concerns about animal welfare issues. However, in no way is peer review intended to supersede or serve as a replacement for IACUC approval. An institution that elects to use IACUC "just-in-time" bears the responsibility for supporting the role of the IACUC.

- It remains incumbent upon investigators to be totally forthcoming and timely in conveying to their IACUCs any modifications related to project scope and animal usage that may result from the NIH review and award process. Should an institution find that one of its investigators disregards his/her responsibilities, the institution may, for example, determine that all animal protocols from that investigator be subject to IACUC approval before it will permit submission of an application from that investigator.

- The existing PHS Policy requirement that modifications required by the IACUC be submitted to the NIH with the verification of IACUC approval remains in effect, and it remains the responsibility of institutions to communicate any IACUC-imposed changes to NIH staff.

- The NIH understands its responsibility to ensure that institutions are given adequate notice to allow for timely IACUC review prior to award, and will take appropriate internal measures to fulfill its responsibility to establish timely feedback.


4/20/2004
An announcement is published in the Federal Register (67 FR 51289), giving the precise language change and citation in the PHS Policy.

To see the Federal Register Notice in HTML format, go to: http://wwwgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=fr07aug02-109.

To see the Federal Register Notice in PDF format, go to: http://wwwgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=fr07aug02-109.pdf.

INQUIRIES
For questions or further information, contact:
Anthony Denscy, Ph.D.
Senior Advisor for Policy
Office of Extramural Research
National Institutes of Health
Building 1, Room 154
Bethesda, MD 20892
301/496-5127 (phone)
301/496-3469 (fax)
e-mail: denscy@od.nih.gov
New Pathways to Discovery
- Building Blocks, Biological Pathways, and Networks
- Molecular Libraries and Imaging
- Structural Biology
- Bioinformatics and Computational Biology
- Nanomedicine

Research Teams of the Future
- High-Risk Research
- Interdisciplinary Research
- Public-Private Partnerships

Re-engineering the Clinical Research Enterprise
- Re-engineering the Clinical Research Enterprise

What's New
- Meeting: Nanomedicine Project Launch and Planning — May 4
- Meeting: NIH Roadmap Briefing
- NIH Director’s Pioneer Award
- Addendum to RFA-PRM-04-005, “National Technology Centers for Networks and Pathways” — Page Limits and Budget Pages
- RFTOP-PRM-169 Inventory and Evaluation of Clinical Research Networks
- Meeting: Chemistry and Biology: Partners in Decoding the Genome

http://nihroadmap.nih.gov/
NIH Roadmap Overview
September 2003

History and Purpose

Soon after becoming the Director of the National Institutes of Health (NIH), in May 2002, Elias A. Zerhouni, M.D. convened a series of meetings to chart a "roadmap" for medical research in the 21st century. The purpose was to identify major opportunities and gaps in biomedical research that no single institute at NIH could tackle alone but that the agency as a whole must address to make the biggest impact on the progress of medical research. The opportunities for discoveries have never been greater, but the complexity of biology remains a daunting challenge. NIH is uniquely positioned to catalyze changes that must be made to transform our new scientific knowledge into tangible benefits for people.

Developed with input from meetings with more than 300 nationally recognized leaders in academia, industry, government, and the public, the NIH Roadmap provides a framework of the priorities the NIH as a whole must address in order to optimize its entire research portfolio. It lays out a vision for a more efficient and productive system of medical research. It identifies the most compelling opportunities in three main areas: new pathways to discovery, research teams of the future, and re-engineering the clinical research enterprise.

Initiatives under the NIH Roadmap will help enable the agency to sustain its historic record of cutting-edge contributions that are central to extending the quality of healthy life for people in this country and around the world.

Steps in the Process

The process of crafting the Roadmap—from vision to implementation—is described in the following sections.

The first step in the Roadmap process involved a series of five meetings in which Dr. Zerhouni and Directors of the various NIH Institutes led invited participants through lively discussions about the most compelling initiatives that the NIH should pursue over the next 10 years that will have the most profound impact on the progress of medical research, both in the United States and worldwide. Participants were asked:

- What are today’s scientific challenges?
- What are the roadblocks to progress?
- What do we need to do to overcome roadblocks?
- What can’t be accomplished by any single institute—but is the responsibility of NIH as a whole?
During each meeting, participants were asked to step into the NIH Director’s role and to prioritize different research areas.

NIH Leadership Forum Meets to Define Action Plan

The priority areas identified through the Roadmap meetings formed the basis for the discussions at the 2002 NIH Leadership Forum — an annual retreat for NH Institute and Center Directors. The Forum participants were organized into five groups to address the major themes that emerged from the roadmap meetings. Dr. Zerhouni charged the groups with critically assessing the input from the roadmap meetings — What can be done? What can’t be done? What needs to be done? When can it be done? What is realistic?

In addition, Dr. Zerhouni asked the groups to consider compelling arguments for each proposed initiative and to assess the impact, feasibility, appeal to a wide constituency, and potential for real advances in medical research. Dr. Zerhouni stressed that he was not looking for “business as usual under another name.” Instead, the groups should come up with exciting, enabling ideas and actions that can be clearly articulated to a wide audience. The groups identified short and long-term activities and actions; other activities that should be addressed in the future; and areas of science hindered by specific roadblocks. At the end of the day, each group had identified 3-5 major, trans-NIH themes for further consideration.

Working Groups Develop Initial Blueprints for Action

In the months after the Forum, the new ideas were further refined. The development of proposed Roadmap initiatives required systematic analysis and planning. In the spring of 2003, a series of Institute Director-chaired Working Groups of NIH staff, along with ad hoc outside advisors, were formed. Thus, the action plans developed by the Working Groups served as the initial blueprints for building the medical research enterprise of tomorrow.

Each working group presented their top initiatives at the 2003 NIH Budget Retreat, attended by the NIH Director and Institute and Center Directors. The group examined the initiatives and weighed them in the context of several broad criteria:

- Is the initiative truly transformative — will it dramatically change how or what biomedical research is conducted in the next decade?
- Would the outcomes from the initiative be used by and synergize the work of many NIH Institutes and Centers?
- Can the NIH afford NOT to do it?
- Will the initiative be compelling to our stakeholders, especially the public?
- Does the initiative position the NIH as unique — doing something that no other entity can or will do?
Implementation Groups

The Roadmap working groups were grouped into nine Implementation Groups. These nine groups devised implementation plans for the next stage of the Roadmap. These plans included timelines, milestones, mechanisms for coordination, need for inventories, staffing needed for program implementation.

Major NIH Roadmap Themes

The NIH Roadmap is an integrated vision to deepen our understanding of biology, stimulate interdisciplinary research teams, and reshape clinical research to accelerate medical discovery and improve people’s health. Most of the initiatives will begin in FY 2004. Other initiatives will start in FY 2005 and beyond, depending upon the budget and other emerging needs. The three NIH Roadmap themes are as follows:

New Pathways to Discovery

This theme of the NIH Roadmap addresses the need to advance our understanding of the daunting complexity of biological systems. Future progress in medicine will require a quantitative understanding of the many interconnected networks of molecules that comprise our cells and tissues, their interactions, and regulation. We need to more precisely know the combination of molecular events that lead to disease if we hope to truly revolutionize medicine. New Pathways to Discovery also sets out to build a better “toolbox” for medical research in the 21st century.

To fully capitalize on the recent completion of the human genome sequence and many recent discoveries in molecular and cell biology, the research community needs wide access to technologies, databases and other scientific resources that are more sensitive, more robust and more easily adaptable to researchers’ individual needs. Among the resources to be established are libraries of chemical molecules that may provide: probes of biological networks; imaging probes for molecular and cellular events; improved computational infrastructure for biomedical research; nanotechnology devices capable of viewing and interacting with basic life processes; and potential targets for new therapies.

These initiatives will provide a solid scientific foundation for new strategies for diagnosing, treating, and preventing disease. Implementation groups in this area are:

- Building Blocks, Biological Pathways, and Networks
- Molecular Libraries & Molecular Imaging
- Structural Biology
- Bioinformatics and Computational Biology
- Nanomedicine
Research Teams of the Future

The scale and complexity of today’s biomedical research problems increasingly demands that scientists move beyond the confines of their own discipline and explore new organizational models for team science. For example, imaging research often requires radiologists, physicists, cell biologists, and computer programmers to work together on integrated teams. Many scientists will continue to pursue individual research projects; however, they will be encouraged to make changes in the way they approach the scientific enterprise. NIH wants to stimulate new ways of combining skills and disciplines in both the physical and biological sciences. The Director’s Innovator Award will encourage investigators to take on creative, unexplored avenues of research that carry a relatively high potential for failure, but also possess a greater chance for truly groundbreaking discoveries. In addition, novel partnerships, such as those between the public and private sectors, will be encouraged to accelerate the movement of scientific discoveries from the bench to the bedside.

As part of its theme, Research Teams of the Future, the NIH Roadmap seeks to encourage scientists and scientific institutions to test alternative models for conducting research. Implementation groups in this area are:

- Interdisciplinary Research
- High-Risk Research – Director’s Innovator Award
- Public-Private Partnerships

Re-engineering the Clinical Research Enterprise

Ideally, basic research discoveries are quickly transformed into drugs, treatments or methods for prevention. Such translation lies at the very heart of NIH’s mission. Although NIH has been historically successful by funding medical research that has helped to transform once acute and lethal diseases into more chronic ones, it has become clear to the scientific community that our country will need to recast its entire system of clinical research if we are to remain as successful as in the past.

Over the years, clinical research that helps discover mechanisms of disease, prevention, diagnosis, or treatment has become more difficult to conduct. Yet the exciting discoveries we are currently making require us to conduct even more efficiently the complex clinical studies required to make rapid medical progress and to further inform our basic science efforts. This is undoubtedly the most challenging, but critically important, area identified through the NIH roadmap process.

At the core of this vision is the need to develop new partnerships of research with organized patient communities, community-based physicians, and academic researchers. This also includes the need to build better integrated networks of academic centers linked to a qualified body of community-based physicians who care for sufficiently large groups of patients interested in working with researchers to quickly develop and test new interventions. This vision will require
new paradigms in how clinical research information is recorded, new standards for clinical research protocols, modern information technology platforms for research, new models of cooperation between NIH and patient advocates, and new strategies to re-energize our clinical research workforce.

Re-engineering the Clinical Research Enterprise is intended to address these pressing needs by promoting the better integration of existing clinical research networks, encouraging the development of technologies to improve the assessment of clinical outcomes, harmonizing regulatory processes, and enhancing training for clinical researchers. A major goal of this initiative is to more fully involve and empower the public in the research process.

Implementation groups in this area are:

- Harmonization of Clinical Research Regulatory Processes
- Integration of Clinical Research Networks
- Clinical Research Informatics: National Electronic Clinical Trials and Research System (NECTAR)
- Regional Translation Research Centers
- Enabling Technologies for Improved Assessment of Clinical Outcomes
- Enhance Clinical Research Training in the Medical Scientist Training Program and Multidisciplinary Training
- Create a National Clinical Research Corps

Taken together, the components of these initiatives are part of a well-thought out national portfolio of research to meet the health demands of the 21st century.

More information about the NIH Roadmap can be found at: http://nihroadmap.nih.gov. Further information about the NIH can be found at its Web site: www.nih.gov.

###
The National Institutes of Health (NIH) is pleased to announce the publication of the revised NIH Grants Policy Statement (NHGPS, rev. 12/03). The NHGPS (12/03) is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after December 1, 2003. This revision supersedes, in its entirety, the NIH Grants Policy Statement (03/01) as its standard term and condition of award. However, the March 2001 NHGPS continues to be the standard term and condition for all NIH grants and cooperative agreements with budget periods that began between March 1, 2001 and November 30, 2003.

The NHGPS provides both up-to-date policy guidance that serves as NIH standard terms and conditions of awards for grants and cooperative agreements, and extensive guidance to individuals that are interested in NIH grants.

The NHGPS (rev. 12/03) incorporates NIH policy changes since March 2001, public policy changes, policy clarifications, as well as document enhancements. Sections of the revised policy statement have been rewritten to provide clarity; however, the overall policies in these sections have not changed. The document is available in the following electronic formats: KML and PDF. Links to the 10/98 and 3/01 NHGPS will remain the same.

NIH will publish interim grants policy changes through the issuance of NIH Guide Notices. Each change will be described, including its applicability and effective date; and the necessary language to implement it as a term or condition of award provided.

Policy changes that are implemented with the 12/03 NHGPS include:
- Closely related work: the option for grantees to pursue prior approval to account for multiple projects under a single cost objective has been eliminated. NIH will now apply the relatedness provision ofOMB circular A-21 (C., 4., d., (3)) to all NIH recipients which states if a specific cost can not be reasonably allocated to a specific project; it can be charged to any of the benefiting projects on any reasonable basis.
- Cost transfers: policy now states that transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are unallowable.
- Cost overruns: included a definition to the glossary that states: "Any amount charged in excess of the Federal share of costs for the project period (competitive segment)."

Below are examples of NIH policy changes that have occurred since March 2001. Please note that the list below should not be considered all-inclusive; therefore, please refer to the NIH Guide for Grants and Contracts for details on other changes since March 2001.

Expanded Authorities: Application of expanded authorities as a standard term and condition to all NIH awards.

Examples of the latest changes in the application submission policies:

http://grants.nih.gov/grants/guide/notice-files/NOT-00-009.html

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NIH Guide: PUBLICATION OF THE REVISED NIH GRANTS POLICY STATEMENT (REV. 12/03)... Page 2 of

- NIH will continue to accept no more than two revised applications after the submission of the original application; however, the two year limitation has been eliminated.
- Resubmission of Application policy changed to allow grantees to resubmit unfunded applications as new applications in the following instances: 1) unsuccessful applications for an RFA can be resubmitted as a new investigator-initiated application; 2) previously unsuccessful investigator-initiated applications can be resubmitted as a new response to an RFA as a new application; and 3) unfunded applications that are reviewed for one research grant mechanism may be resubmitted for a different grant mechanism and should be prepared as a new application.
- Data Sharing: Implementation of the NIH data-sharing policy.
- Just-in-Time procedures: Expanded to include option to submit IACUC approval.
- NRSA Section Highlights:
  - In accordance with the amendment of the Public Health Service Act, NIH renamed the National Research Service Awards to the Ruth L. Kirschstein National Research Service Awards.
  - Includes the regulatory changes of NRSA part-time training.
  - Audit: Threshold for A-133 audits has increased from $300,000 to $500,000 for fiscal years ending on or after 12/31/2003.

Public Policy Changes that are discussed in the 12/03 NIRGPs:

- Stem Cell Research
- USA PATRIOT Act
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- HIPAA Privacy Rule

Policy Clarifications since March 2001:

- Clinical Practice Compensation (Institutional Base Salary): Compensation may be considered is the institutional base salary as long as all criteria are met: 1) clinical practice must be guaranteed by the university; 2) clinical practice must be reported on the university’s appointment form and paid by the university; and 3) clinical practice effort must be included and accounted for in the university’s effort reporting.
- Key Personnel: Expanded definition to describe the contribution of key personnel as “measurable” whether of not salaries are requested. Zero percent effort and “as needed” are not acceptable for individuals that the grantee identifies as key personnel.
- PI Eligibility: Elaborated on eligibility criteria for certain mechanisms/programs, no change in policy.
- A discussion on the unallowable of patent costs has been added to the NIRGPs. The policy now states that invention, patent, or Licensing Costs are unallowable as either direct or F&A costs because the creation of intellectual property is not a requirement of NIH grant awards. Such costs include licensing or option fees, attorney’s fees for preparing or submitting patent application, patent maintenance, or recordation of patent-related information.
- Consortium Written Agreements: Outlined that it is the responsibility of the grantees to include applicable requirements of the policy statement in their written agreements and highlighted that agreements must also include a reference to the financial conflict of interest policy, intellectual property, and data sharing requirements.

Document Enhancements:


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NIH Guide: PUBLICATION OF THE REVISED NIH GRANTS POLICY STATEMENT (REV. 12/03)...

- NIA Grants Policy Statement and the PHS 398 application glossaries have been merged, where appropriate.
- Other Support Policy: Previously located in the PHS 398 application has been included in the NIA Grants Policy Statement.
- Glossary included in a table format.
- Select items of Cost section included in a table format.
- Bayh-Dole Inventions reporting requirements are now included in a table format.
- Cross-referencing Notes with eRA: NIH Grants Policy Statement role titles have been cross-referenced with the NIH eRA role titles, e.g.: Authorized organizational official (also known as the signing official).
- Abbreviations and acronyms are used throughout the policy statement without parentheticals; therefore, readers should refer to the master list to identify unfamiliar terms abbreviations and/or acronyms.
- Index included.

ADDITIONAL INQUIRIES

Additional questions about the NINGPS may be directed to the NIH Division of Grants Policy at (301) 435-0949 or the Grants Management Specialist that is identified on the NIH Notice of Grant Award.

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4/20/2004
NIH RESEARCH CONTRACTS

Greg Pryor

NIH Research Contracts

What are they?
How do you find out about them?
How are they awarded?
Should you try to get one?

Contracts: What Are They?

- The Federal Acquisition Regulation (FAR) defines contracts as mutually binding legal relationships obligating the seller to furnish supplies or services and the buyer to pay for them.
- Contracts are subject to protests, claims, terminations for default or convenience, and penalties for nonperformance.
Contracts: What Are They?

- Not a grant
- Used when the primary purpose is to acquire goods or services for the direct use or benefit of the Government
- Usually results from an offer made by a bidder or offeror and acceptance of that offer by the Government
- Government initiates the Statement of Work
- Greater Government control/execution of project

Contracts: What Are They?

- Contracting Process:
  1. Sealed bidding: involves competitive bids, public opening, and award
  2. Contracting by negotiation
     - Most R&D projects will be negotiated
- Types of Contracts:
  1. Fixed-price agreement to deliver services at the price specified for a price that cannot be changed
  2. Cost-reimbursement used when uncertainties exist such that cost of performance cannot be estimated with sufficient reliability to use a fixed-price contract
- Most R&D projects are cost-reimbursement

Grants & Acquisition at the NIH

Approximate obligations in billions of dollars in 2002

<table>
<thead>
<tr>
<th>Year</th>
<th>Obligations</th>
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<tbody>
<tr>
<td>1999</td>
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<tr>
<td>2000</td>
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<tr>
<td>2001</td>
<td>57.0</td>
</tr>
<tr>
<td>2002</td>
<td>60.5</td>
</tr>
</tbody>
</table>
Similarities to Grants

- Peer review of concepts and proposals
- Team Approach to Contract Management
  - Contracting Officer/Contract Specialist and Project Officer
- Scientific Review Administrators
- Required compliance with regulations and policies, such as animal welfare, human subject protection, and fiscal management
- Submission of technical progress reports
Differences Between Contracts and Grants

- Federal Acquisition Regulation, Health and Human Services Acquisition Regulation, and population policies
- Proposals are evaluated against technical evaluation criteria created for that project
- Will likely involve negotiation and opportunity to submit revised proposals after negotiations are concluded
- Subject to public policy initiatives and socio-economic programs

How Do I Find Out About Contracts?

- Plans to award contracts and notice of awarded contracts exceeding $25,000 are published in the Federal Business Opportunities - http://www.fbo.gov
- NIH RFPs: http://nihod.nih.gov/contracts/rfps/mainpage.nsf
- Electronic Guide to NIH Acquisition: http://end-map.ccmp.od.nih.gov
Modified Information from RFP Web Site

- RFP: NIH-MAID-OADS-04-04. Microbicide Design and Development Teams
- Issue Date: 03-19-2004
- Proposal Due Date: 06-13-2004
- Contact Person: Donald E. Coli
  dcolie@nait.nih.gov
  301/496-0802
- If you plan to submit an offer, please notify the contact person listed in the RFP to ensure that you receive any additional information. Proposal submission forms are listed in each RFP, and are available electronically from the CFDA Forms and Attachments page, or from the NIH RFP Directory.

Sample Technical Evaluation Criteria

1. Technical Approach - 40 Points
   Suitability and feasibility; methods and procedures

2. Scientific Relevance - 20 Points
   Soundness of the scientific rationale of the proposed concept; rationale of the likelihood of obtaining goal

3. Qualifications and Availability of Proposed Scientific and Management Staff - 20 Points
   Leadership and Management Structure; Scientific and Technical Staff; Subcontractors

4. Facilities and Resources - 30 Points
   Documented availability and adequacy of facilities, equipment, and resources

Should You Try to Get an NIH Contract?

- Keep in mind that in FY2002 the NIH awarded $1.4 billion for research contracts
- Preparing a proposal requires individual and institutional resources
- You must realistically assess your chances of winning a contract
Look at a request for proposals in which you may be interested. It contains all the information needed to prepare a proposal.

Will you be able to convince peer reviewers that you have a good approach, that you understand the problem?

How will your personnel, especially your key personnel, do in an evaluation?

How will your facilities score?

If you are not successful, request a debriefing to find out why you were not selected for award and to get information that will help you compete better in the future.

Additional Information


Valuable information is also available through the Office of Extramural Research Web site http://grants1.nih.gov/grants/new.htm.

Questions?

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Financial Management of Sponsored Projects

Rose A. Farace

What is Financial Management?

- Responsible
  - Accounting of sponsored project expenses AND program income
  - Monitoring
  - Reporting

Accounting

- Requires that:
  - Separate account be established for each project
  - Program income be identified and accounted for by project
  - Cost Sharing be accounted for
  - All expenses be appropriately documented
Accounting (cont’d)

Requires that:
- Program income is used in accordance with the appropriate alternative
- Expenses are charged in accordance with:
  - NGA/Contract Document
  - NIH Grant Policy Statement
  - Salary Rate, Inflation
  - Cost Accounting Standards
  - OMB Circulars

What are Office of Management and Budget (OMB) Circulars?

- OMB Circulars set standards among Federal agencies for the administration of grants and contracts
- Federal agencies are required to implement OMB Circulars

Which OMB Circulars Apply?

- A-110 - Uniform Administrative Requirements for Grants and Agreement with Universities, Hospitals and Other Non-Profit Organizations (administrative)
- A-21 - Cost Principles for Educational Institutions (costing)
- A-133 - Audits of States, Local Governments, and Non-Profit Organizations (audit requirements)

All OMB Circulars may be found online at:
http://www.whitehouse.gov/omb/circulars/
OMB Circular A-110

Prescribes:
- Preaward requirements
- Postaward requirements
  - Standards for financial management systems
  - Payment methods/cash management
  - Closeout procedures

OMB Circular A-21

- Establishes principles for determining costs applicable to grants, contracts, and other agreements
  - Direct costs
  - F&A/Indirect costs
  - Selected items of cost
    - Allowable/unallowable costs
    - Time and effort reporting

OMB Circular A-133

- Establishes audit requirements:
  - Non-Federal entities that exceed $500,000 or more in Federal awards in a year shall have a single (organization-wide) or program-specific audit
- Audits are required annually
- Audit costs are typically recovered as part of indirect costs
What about the Cost Accounting Standards?

- They apply to commercial and non-profit organizations
- Are intended to achieve uniformity and consistency in measuring, assigning, and allocating costs to sponsored projects
- Can be found in the Federal Acquiescence Regulation, 48 CPR Chapter 9
  (online at http://www.fedweb.gov/)

What is Financial Management Again??

- Responsible:
  > accounting
  > monitoring
  > reporting

  of sponsored project expenses AND program income

Monitoring

- Requires that:
  > There is good evidence of project expenses
  > Only reasonable, allocable, and allowable costs are charged to sponsored projects
Reasonable
Allocable
Allowable
and
Consistently applied

What does “reasonable” mean?

A cost is considered to be reasonable if the nature of the goods or services and the amount involved reflects the action a prudent person would have taken at the time the decision was made to incur the cost.

Example: Reasonable or Not?

Grant requirement: Microscope that has features A, B, and C.

Price Quotes:
1. XYZ Inc. Model A1: $5,000 has features A, B, & C
2. RTR Co. Model B2: $4,975 has features A, B, & C
3. Top of the Line, Inc. Model C3: $8,975 has features A, B, C, D, & E

Features D & E are not needed, so the purchase of Model C3 from the third quote would not be reasonable.
What does “allocable” mean?

- A cost is allocable if the goods or services involved are chargeable or assignable to a sponsored agreement in accordance with relative benefits received.

Example: Allocable or Not?

The RTTR model 82 microscope purchased in the example above was used solely for work under an National Cancer Institute (NCI) project. By the time payment was due, it was estimated that the NCI award was fully expended. The PI decided to charge the microscope to the National Eye Institute (NEI) grant. The NEI grant received no benefit from the microscope. The charge to the NEI grant is therefore unallocable.

What does “allowable” mean?

- A cost is allowable if it is reasonable, allocable, and conforms to the cost principles and the sponsored agreement AND is not prohibited by law or regulation.
Examples of A-21 Expressly Unallowable Costs

- Alcoholic beverages
- Alumni activities
- Food, gift expenses
- Personal use of institution furnished autos
- Donations and contributions
- Entertainment costs
- Fines and penalties
- Memberships and dues in social clubs

What does “consistently applied” mean?

- A cost is consistently applied when a cost incurred for the same purpose in like circumstances is consistently charged, i.e., always charged as either a direct cost or an indirect cost.

Example: Consistently Applied or Not?

A University has office supplies and postage stamps as indirect costs. A lab was running low on these items and (O&P) sent for the university to provide them. The lab bought the items and charged them directly to the NIH account. Such a direct charge to the award is inconsistent and therefore unallowable. Such a charge would, in effect, result in charging the award twice for the same items—once directly and again when the F&A rate is applied to the project expenses.
Monitoring (cont'd)

- Requires that:
  - Actual Expenses are reviewed for accuracy
  - Actual expenses are compared with budget
  - Discrepancies are corrected in a timely manner (e.g., cost transfers)
  - Prior approvals are obtained when required
  - There is good oversight of subrecipient expenses (Prime's responsibility)

What is Financial Management Again???

Responsible:
- accounting
- monitoring
- reporting

of sponsored project expenses AND program income

Reporting

Requires that financial reports be submitted:
- Accurately (reported expenses and income must agree with institutional accounting records)
- Timely (report submission must adhere to sponsor's deadlines)
Reporting (cont’d)
- Reports for grants:
  - Financial Status Report (FSR). Use SF 269A (short form); however, if there is program income which must be reported, must use SF 269 (long form)
  - Must be submitted NLT 90 days after the end of the budget period unless
  - SNAP - then must be submitted NLT 90 days after the end of the project period

Why Financial Management?
Ensures that:
- Grant and subgrant funds are used for their intended purpose
- Only reasonable, allocable, allowable, and consistently applied expenses are charged to sponsored projects

Why Financial Management? (cont’d)
- Most NIH awards are cost reimbursement (as opposed to fixed price)
  - What does “cost reimbursement” mean?
    - The institution will be reimbursed for reasonable, allowable and allocable costs that are incurred and accurately accounted for
  - What does “cost reimbursement” mean?
    - The institution will be automatically entitled to receive or draw funds in the full amount of the award
Why Financial Management? (cont'd)

<table>
<thead>
<tr>
<th>Accountable to:</th>
<th>Get the most research possible for the funds provided</th>
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<tbody>
<tr>
<td>Taxpayer's</td>
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<tr>
<td>Congress</td>
<td></td>
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<tr>
<td>Don't want to read or hear about inappropriate use of research funds</td>
<td></td>
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</tbody>
</table>

Reminder

- Having a good financial management system in place is required for receipt of Federal grants or contract awards

What's at Risk?

- Audit findings/cost disallowances/refunds
- Special Terms and Conditions on NSGs
- Requirement for Corrective Action Plan
What’s at Risk? (cont’d)

- Spinal monitoring by NIH
- Temporary withholding of payments
- Withholding of future awards
- Possible criminal/civil/administrative penalties in cases of fraud

Conclusion

- In conjunction with having a good financial management system:
  - Read, understand and follow the grant or contract terms and conditions
  - Review, understand and follow Federal and Institutional policies
  - Read, understand and follow applicable cost principles
  - Work with your institution’s sponsored project officials and NIH’s grant/contract officials if you have questions

Questions?

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Office of Acquisition Management and Policy, NIH, HHS
301-496-4401
rfda@nih.gov
Financial Management of
Sponsored Projects

Resources

- 45 CFR 74.20 - 28
- 45 CFR 74.50 - 53
- OMB Circular A-21 (excerpt)
- OMB Circular A-110 (excerpt)
- Requirements for Program Income Accountability
TITLE 45--PUBLIC WELFARE
AND HUMAN SERVICES

PART 74--UNIFORM ADMINISTRATIVE REQUIREMENTS FOR AWARDS AND SUBAWARDS TO INSTITUTIONS

Subpart C--Post-Award Requirements

Sec. 74.20 Purpose of financial and program management.

Source: 59 FR 43760, Aug. 25, 1994, unless otherwise noted.

Financial and Program Management

Sections 74.21 through 74.28 prescribe standards for financial management systems, methods for making payments, and rules for satisfying cost sharing and matching requirements, accounting for program income, budget revision approvals, making audits, determining allowability of cost, and establishing fund availability.
TITLe 45--PUBLIC WELFARE
AND HUMAN SERVICES

PART 74--UNIFORM ADMINISTRATIVE REQUIREMENTS FOR AWARDS AND SUBAWARDS TO INSTITU

Subpart C--Award Requirements

Sec. 74.21 Standards for financial management systems.

(a) Recipients shall relate financial data to performance data and
develop

unit cost information whenever practical. For awards that support
research, unit cost information is usually not appropriate.

(b) Recipients’ financial management systems shall provide for the
following:

1. Accurate, current and complete disclosure of the financial
results of each HHS-sponsored project or program in accordance with the
reporting requirements set forth in Sec. 74.22. If the HHS awarding
agency requires reporting on an accrual basis from a recipient that
maintains its records on other than an accrual basis, the recipient
shall not be required to establish an accrual accounting system. These
recipients may develop such accrual data for their reports on the basis
of an analysis of the documentation on hand.

2. Records that identify adequately the source and application of
funds for HHS-sponsored activities. These records shall contain
information pertaining to Federal awards, authorizations, obligations,
unobligated balances, assets, outlays, income, and interest.

3. Effective control over and accountability for all funds, property and other assets. Recipients shall adequately safeguard all
such assets and assure they are used solely for authorized purposes.

4. Comparison of outlays with budget amounts for each award.
When ever appropriate, financial information should be related to
performance and unit cost data. (Unit cost data are usually not
appropriate for awards that support research.)

5. Written procedures to minimize the time elapsed between the
transfer of funds to the recipient from the U.S. Treasury and the
issuance or redemption of checks, warrants or payments by other means
for program purposes by the recipient. To the extent that the provisions
of the Cash Management Improvement Act (CMIA) (Pub. L. 101-153) and its
implementing regulations, “Rules and Procedures for Funds Transfers,”
(31 CFR part 205) apply, payment methods of State agencies,
instrumentalities, and fiscal agents shall be consistent with CMIA
Treasury-State agreements, or the CMIA default procedures codified at 31
CFR 205.9(c).

6. Written procedures for determining the reasonableness,
allocability and allowability of costs in accordance with the provisions
of the applicable Federal cost principles and the terms and conditions of the award.

http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=45&PART=74&SECTION=21... 4/26/2004
(7) Accounting records, including cost accounting records, that are supported by source documentation.

(c) Where the Federal Government guarantees or insures the repayment of money borrowed by the recipient, the HHS awarding agency, at its discretion, may require adequate bonding and insurance if the bonding and insurance requirements of the recipient are not deemed adequate to protect the interest of the Federal Government.

(d) The HHS awarding agency may require adequate fidelity bond coverage where the recipient lacks sufficient coverage to protect the Federal Government's interest.

(e) Where bonds are required in the situations described in Sec. 74.21(c) and (d), the bonds shall be obtained from companies holding certificates of authority as acceptable sureties, as prescribed in 31 CFR Part 223, "Surety Companies Doing Business with the United States."

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TITLE 45--PUBLIC WELFARE
AND HUMAN SERVICES

PART 74--UNIFORM ADMINISTRATIVE REQUIREMENTS FOR AWARDS AND SUBAWARDS TO INSTITU

Subpart C--Post-Award Requirements

Sec. 74.22 Payment.

(a) Unless inconsistent with statutory program purposes, payment methods shall minimize the time elapsing between the transfer of funds from the U.S. Treasury and the issuance of redemption of checks, warrants, or payment by other means by the recipient. Payment methods of State agencies or instrumentalities shall be consistent with Treasury-State CMIA agreements, or the CMIA default procedures codified at 31 CFR 205.3, to the extent that either applies.

(b)(1) Recipients will be paid in advance, provided they maintain or demonstrate the willingness to maintain:

(1) Written procedures that minimize the time elapsing between the transfer of funds and disbursement by the recipient; and

(2) Financial management systems that meet the standards for fund control and accountability as established in Sec. 74.21.

(2) Unless inconsistent with statutory program purposes, cash advances

[[Page 206]]

to a recipient organization shall be limited to the minimum amounts needed and be timed to be in accordance with the actual, immediate cash requirements of the recipient organization in carrying out the purpose of the approved program or project. The timing and amount of cash advances shall be as close as is administratively feasible to the actual disbursements by the recipient organization for direct program or project costs and the proportionate share of any allowable indirect costs.

(c) Whenever possible, advances will be consolidated to cover anticipated cash needs for all awards made by all HHS awarding agencies to the recipient.

(1) Advance payment mechanisms include electronic funds transfer, with Treasury checks available on an exception basis.

(2) Advance payment mechanisms are subject to 31 CFR part 205.

(3) Recipients may submit requests for advances and reimbursements at least monthly when electronic fund transfers are not used.

(d) Requests for Treasury check advance payment shall be submitted as PHS-270, "Request for Advance or Reimbursement," or other forms as may be authorized by HHS. This form is not to be used when Treasury check advance payments are made to the recipient automatically through the use of a pretermined payment schedule or if precluded by special HHS-wide instructions for electronic funds transfer.

(e) Reimbursement is the preferred method when the requirements in paragraph (b) of this section cannot be met. The HHS awarding agency may

http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=45&PART=74&SECTION=22... 4/26/2004
also use this method on any construction agreement, or if the major portion of the construction project is accomplished through private market financing or Federal loans, and the HHS assistance constitutes a minor portion of the project.

1. When the reimbursement method is used, HHS will make payment within 30 days after receipt of the billing, unless the billing is improper.

2. Recipients may submit a request for reimbursement at least monthly when electronic funds transfers are not used.

4. If a recipient cannot meet the criteria for advance payments and the HHS awarding agency has determined that reimbursement is not feasible because the recipient lacks sufficient working capital, HHS may provide cash on a working capital advance basis. Under this procedure, HHS advances cash to the recipient to cover its estimated disbursement needs for an initial period generally geared to the recipient’s disbursing cycle. Thereafter, HHS reimburses the recipient for its actual cash disbursements. The working capital advance method of payment will not be used for recipients unwilling or unable to provide timely advances to their subrecipient to meet the subrecipient’s actual cash disbursements.

4. Unless inconsistent with statutory program purposes, to the extent available, recipients shall disburse funds available from repayments and interest earned on a revolving fund, program income, rebates, refunds, contract settlements, audit recoveries and interest earned on such funds before requesting additional cash payments.

41. Unless otherwise required by statute, the HHS awarding agency will not withhold payments for proper charges made by recipients at any time during the project period unless paragraph (h) (1) or (2) of this section applies:

1. A recipient has failed to comply with the project objectives, the terms and conditions of the award, or HHS awarding agency reporting requirements.

2. The recipient or subrecipient is delinquent in a debt to the United States. Under such conditions, the HHS awarding agency may, upon reasonable notice, inform the recipient that payments shall not be made for obligations incurred after a specified date until the conditions are corrected or the indebtedness to the Federal Government is liquidated. (See 45 CFR part 30).

4. Standards governing the use of banks and other institutions as depositaries of funds advanced under awards are as follows.

1. Except for situations described in paragraph (h) (2) of this section, HHS will not require separate depository accounts for funds provided to a recipient.

[Page 207]

or establish any eligibility requirements for depositaries for funds provided to a recipient. However, recipients must be able to account for the receipt, obligation and expenditure of funds.

1. Consistent with the national goal of expanding the opportunities for women-owned and minority-owned business enterprises, recipients are encouraged to use women-owned and minority-owned banks (a bank which is owned at least 50 percent by women or minority group members).

1. Recipients shall maintain advances of Federal funds in interest bearing accounts, unless one of the following conditions apply:

1. The recipient receives less than $10,000 in Federal awards per year.

2. The best reasonably available interest bearing account would not

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be expected to earn interest in excess of $250 per year on Federal cash balances.

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected Federal and non-
Federal cash resources.

(1) For those entities where CMA and its implementing regulations
do not apply (see 31 CFR part 205), interest earned on Federal advances
deposited in interest bearing accounts shall be remitted annually to the
Department of Health and Human Services, Payment Management System, P.O.
Box 6021, Rockville, MD 20852. Recipients with Electronic Funds Transfer
capability should use an electronic medium such as the FEDWIRE Deposit
System. Interest amounts up to $250 per year may be retained by the
recipient for administrative expense. State universities and hospitals
shall comply with CMA, as it pertains to interest. If an entity subject
to CMA uses its own funds to pay pre-award costs for discretionary
awards without prior written approval from the NHS awarding agency, it
waives its right to recover the interest under CMA. (See
Sec. 74.25(d)).

(m) CMS-270, Request for Advance or Reimbursement. Recipients shall
use the CMS-270 to request advances or reimbursement for all programs
when electronic Funds transfer or predetermined advance methods are not
used. NHS shall not require recipients to submit more than an original
and two copies.

(n) Recipients and subrecipients are not required to use forms CMS-
270 and 272 in connection with subaward payments.

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Subpart C—Post-Award Requirements

Sec. 74.23 Cost sharing or matching.

(a) To be accepted, all cost sharing or matching contributions, including cash and third party in-kind, shall meet all of the following criteria:
(1) Are verifiable from the recipient's records;
(2) Are not included as contributions for any other federally-assisted project or program;
(3) Are necessary and reasonable for proper and efficient accomplishment of project or program objectives;
(4) Are allowable under the applicable cost principles;
(5) Are not paid by the Federal Government under another award, except where authorized by Federal statute to be used for cost sharing or matching;
(6) Are provided for in the approved budget; and
(7) Conform to other provisions of this part, as applicable.

(b) Uncovered indirect costs may be included as part of cost sharing or matching.

(c) Values for recipient contributions of services and property shall be established in accordance with the applicable cost principles. If the HHS awarding agency authorizes recipients to donate buildings or land for construction/facilities acquisition projects or long-term use, the value of the donated property for cost sharing or matching shall be the lesser of:
(1) The certified value of the remaining life of the property recorded in the recipient's accounting records at the time of donation; or
(2) The current fair market value, however, when there is sufficient justification, the HHS awarding agency may approve the use of the current fair market value of the donated property, even if it exceeds the certified value at the time of donation to the project.

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(d) Volunteer services furnished by professional and technical personnel, consultants, and other skilled and unskilled labor may be counted as cost sharing or matching if the services are an integral and necessary part of an approved project or program. Rates for volunteer services shall be consistent with those paid for similar work in the recipient's organization. In those instances in which the required skills are not found in the recipient's organization, rates shall be consistent with those paid for similar work in the labor market in which the recipient competes for the kind of services involved. In either case, fringe benefits consistent with those paid that are reasonable,

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allowable, and allocable may be included in the valuation.

(e) When an employer other than the recipient furnishes the services of an employee, these services shall be valued at the employee's regular rate of pay (plus an amount of fringe benefits that are reasonable, allowable, and allocable, but exclusive of overhead costs), provided these services are in the same skill for which the employee is normally paid.

(f) Donated supplies may include such items as expendable property, office supplies, laboratory supplies or workshop and classroom supplies. Value assessed to donated supplies included in the cost sharing or matching share shall be reasonable and shall not exceed the fair market value of the property at the time of the donation.

(g) The method used for determining cost sharing or matching for donated equipment, buildings and land for which title passes to the recipient may differ according to the purpose of the award, if paragraphs (g)(1) or (2) of this section applies:

(1) If the purpose of the award is to assist the recipient in the acquisition of equipment, buildings or land, the total value of the donated property may be claimed as cost sharing or matching.

(2) If the purpose of the award is to support activities that require the use of equipment, buildings or land, normally only depreciation or use charges for equipment and buildings may be made. However, the full value of equipment or other capital assets and fair rental charges for land may be allowed, provided that the awarding agency has approved the charges.

(h) The value of donated property shall be determined in accordance with the usual accounting policies of the recipient, with the following qualifications.

(1) The value of donated land and buildings shall not exceed its fair market value at the time of donation to the recipient as established by an independent appraiser (e.g., certified real property appraiser or General Services Administration representative) and certified by a responsible official of the recipient.

(2) The value of donated equipment shall not exceed the fair market value of equipment of the same age and condition at the time of donation.

(3) The value of donated space shall not exceed the fair rental value of comparable space as established by an independent appraisal of comparable space and facilities in a privately-owned building in the same locality.

(4) The value of loaned equipment shall not exceed its fair rental value.

(i) The following requirements pertain to the recipient's supporting records for in-kind contributions from third parties.

(1) Volunteer services shall be documented and, to the extent feasible, supported by the same methods used by the recipient for its own employees, including time records.

(2) The basis for determining the valuation for personal service, material, equipment, buildings and land shall be documented.

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Subpart C—Post-Award Requirements

Sec. 74.24 Program income.

(a) The standards set forth in this section shall be used to account for program income related to projects financed in whole or in part with Federal funds.

(b) Except as provided below in paragraph (h) of this section, program income earned during the project period shall be retained by the recipient and, in accordance with the terms and conditions of the award, shall be used in one or more of the following ways:

1. Added to funds committed to the project or program, and used to further eligible project or program objectives;

2. Used to finance the non-Federal share of the project or program;

3. Deducted from the total project or program allowable cost in determining the net allowable costs on which the Federal share of costs is based.

(c) When the NIH awarding agency authorizes the disposal of program income as described in Paragraph (b)(1) or (b)(3) of this section, program income in excess of any limits stipulated shall be used in accordance with paragraph (b)(3) of this section.

(d) In the event that the NIH awarding agency does not specify in the terms and conditions of the award how program income is to be used, paragraph (b)(3) of this section shall apply automatically to all projects or programs except research. For awards that support performance of research work, paragraph (b)(1) of this section shall apply automatically unless:

1. The NIH awarding agency indicates in the terms and conditions of the award another alternative; or

2. The recipient is subject to special award conditions under Sec. 74.14(e).

3. The recipient is a commercial organization (see Sec. 74.82).

(e) Unless the terms and conditions of the award provide otherwise, recipients shall have no obligation to the Federal Government regarding program income earned after the end of the project period.

(f) Costs incident to the generation of program income may be deducted from gross income to determine program income, provided these costs have not been charged to the award.

(g) Proceeds from the sale of property shall be handled in accordance with the requirements of the Property Standards. (See Secs. 74.30 through 74.37, below.)

(h) The Patent and Trademark Laws Amendments, 35 U.S.C. section 200-

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apply to inventions made under an award for performance of experimental, developmental, or research work. Unless the terms and conditions for the award provide otherwise, recipients shall have no obligation to HHS with respect to program income earned from license fees and royalties for copyrighted material, patents, patent applications, trademarks, and inventions made under an award. However, no scholarship, fellowship, training grant, or other funding agreement made primarily to a recipient for educational purposes will contain any provision giving the Federal agency rights to inventions made by the recipient.
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Sec. 74.25 Revision of budget and program plans.

(a) The budget plan is the financial expression of the project or program as approved during the award process. It may include either the sum of the Federal and non-Federal shares, or only the Federal share, depending upon HHS awarding agency requirements. It shall be related to performance for program evaluation purposes whenever appropriate.

(b) Recipients are required to report deviations from budget and program plans, and request prior approvals for budget and program plan revisions, in accordance with this section. Except as provided at Secs. 74.4, 74.14, and this section, HHS awarding agencies may not impose other prior approval requirements for specific items.

(c) For nonconstruction awards, recipient shall obtain prior approvals from the HHS awarding agency for one or more of the following program or budget related reasons.

(1) Change in the scope or the objective of the project or program (even if there is no associated budget revision requiring prior written approval).

(2) Change in the project director or principal investigator or other key persons specified in the application or award document.

(3) The absence for more than three months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.

(4) The need for additional Federal funding.


(6) The transfer of funds allotted for training allowances (direct payment to trainees) to other categories of expense.

(7) Unless described in the application and funded in the approved award, the subaward, transfer or contracting out of any work under an award. This provision does not apply to the purchase of supplies, material, equipment or general support services.

(8) The inclusion of research patient care costs in research awards made for the performance of research work.

(d) Except for requirements listed in paragraphs (c)(1) and (c)(4) of this section, the HHS awarding agency is authorized, at its option,
to waive cost-related and administrative prior written approvals required by this part and its appendices. Additional waivers may be granted authorizing recipients to do any one or more of the following:

(1) Incur pre-award costs up to 90 calendar days prior to award, or more than 90 calendar days with the prior approval of the HHS awarding agency. However, all pre-award costs are incurred at the recipient's risk; the HHS awarding agency is under no obligation to reimburse such costs if for any reason the applicant does not receive an award or if the award to the recipient is less than anticipated and inadequate to cover such costs.

(2) Initiate a one-time extension of the expiration date of the award of up to 12 months unless one or more of the conditions identified at paragraphs (d)(2)(i), (ii), and (iii) of this section apply. For one-
time extensions, the recipient must notify the HHS awarding agency in writing, with the supporting reasons and revised expiration date, at least 10 days before the date specified in the award. This one-time extension may not be exercised either by recipients or HHS awarding agencies separately for the purpose of using unobligated balances. Such extensions are not permitted where:

(1) The terms and conditions of award prohibit the extension; or

(ii) The extension requires additional Federal funds; or

(iii) The extension involves any change in the approved objectives or scope of the project.

(3) Carry forward unobligated balances to subsequent funding periods.

(4) For awards that support performance of research work, unless the HHS awarding agency provides otherwise in the award, the award is subject to Sec. 74.14 or subpart F of this Part, the prior approval requirements described in paragraphs (d)(1)-(3) of this section are automatically waived (i.e., recipients need not obtain such prior approvals). However, extension of award expiration dates must be approved by the HHS awarding agency if one of the conditions in paragraph (d)(2) of this section applies.

(e) The HHS awarding agencies may not permit any budget changes in a recipient's award that would cause any Federal appropriation to be used for purposes other than those consistent with the original purpose of the authorization and appropriation under which the award was funded.

(f) For construction awards, recipients shall obtain prior written approval promptly from the HHS awarding agency for budget revisions whenever:

(1) The revision results from changes in the scope or the objective of the project or program;

(2) The need arises for additional Federal funds to complete the project; or

(3) A revision is desired which involves specific cost for which prior written approval requirements apply in keeping with the applicable cost principles listed in Sec. 74.27.

(g) When an HHS awarding agency makes an award that provides support for both construction and nonconstruction work, it may require the recipient to obtain prior approval before making any fund or budget transfers between the two types of work supported.

(h) For both construction and nonconstruction awards, recipients shall notify the HHS awarding agency in writing promptly whenever the amount of Federal authorized funds is expected to exceed the needs of the recipient for the project period by more than $5,000 or five percent of the Federal award, whichever is greater. This notification shall not be required if an application for additional funding is

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submitted for a continuation award.

(1) Within 30 calendar days from the date of receipt of the request for budget revisions, HHS awarding agencies shall notify the recipient whether its requested budget revisions have been approved. If the requested revision is still under consideration at the end of 30 calendar days, the HHS awarding agency must inform the recipient in writing of the date when the recipient may expect a decision.

(2) When requesting approval for budget changes, recipients shall make their requests in writing.

(k) All approvals granted in keeping with the provisions of this section shall not be valid unless they are in writing, and signed by at least one of the following HHS officials:

(1) The Head of the HHS Operating or Staff Division that made the award or subordinate official with proper delegated authority from the Head, including the Head of the Regional Office of the HHS Operating or Staff Division that made the award; or

(2) The responsible Grants Officer of the HHS Operating or Staff Division that made the award or an individual duly authorized by the Grants Officer.

(1) No other prior approval requirements for specific items may be imposed unless a class deviation has been approved by OMB.

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AND NON-FEDERAL AGENCIES

Subpart C--Post-Award Requirements

Sec. 74.26 Non-Federal audits.

(a) Recipients and subrecipients that are institutions of higher education or other non-profit organizations (including hospitals) shall be subject to the audit requirements contained in the Single Audit Act Amendments of 1996 (31 U.S.C. 7501-7507) and revised OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations." (b) State and local governments shall be subject to the audit requirements contained in the Single Audit Act Amendments of 1996 (31 U.S.C. 7501-7507) and revised OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations." (c) For-profit hospitals not covered by the audit provisions of revised OMB Circular A-133 shall be subject to the audit requirements of the Federal awarding agencies. (d) (1) Recipients and subrecipients that are commercial organizations (including for-profit hospitals) have two options regarding audits: (i) a financial related audit (as defined in the Government Auditing Standards, GPO Stock #020-000-00-265+) of a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one HHS program; or, if awards are received under multiple HHS programs, a financial related audit of all HHS awards in accordance with Government Auditing Standards; or (ii) an audit that meets the requirements contained in OMB Circular A-133.

(2) Commercial organizations that receive annual HHS awards totaling less than OMB Circular A-133's audit requirement threshold are exempt from requirements for a non-Federal audit for that year, but records must be available for review by appropriate officials of Federal agencies.


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Subpart C--Post-Award Requirements

Sec. 74.27 Allowable costs.

(a) For each kind of recipient, there is a particular set of Federal principles that applies in determining allowable costs. Allowability of costs shall be determined in accordance with the cost principles applicable to the entity incurring the costs. Thus, allowability of costs incurred by State, local or federally-recognized Indian tribal governments is determined in accordance with the provisions of OMB Circular A-87, "Cost Principles for State and Local Governments."

The allowability of costs incurred by nonprofit organizations (except for those listed in Attachment C of Circular A-122) is determined in accordance with the provisions of OMB Circular A-122, "Cost Principles for Nonprofit Organizations" and paragraph (b) of this section. The allowability of costs incurred by institutions of higher education is determined in accordance with the provisions of OMB Circular A-21, "Cost Principles for Educational Institutions."
The allowability of costs incurred by hospitals is determined in accordance with the provisions of appendix E of this part, "Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals."
The allowability of costs incurred by commercial organizations and those nonprofit organizations listed in Attachment C to Circular A-122 is determined in accordance with the provisions of the Federal Acquisition Regulation (FAR) at 48 CFR part 31, except that independent research and development costs are unallowable.

(b) OMB Circular A-122 does not cover the treatment of bid and proposal costs or independent research and development costs. The following rules apply to these costs for nonprofit organizations subject to that Circular:

(1) Bid and proposal costs. Bid and proposal costs are the immediate costs of preparing bids, proposals, and applications for Federal and non-Federal awards, contracts, and other agreements, including the development of scientific, cost, and other data needed to support the bids, proposals, and applications. Bid and proposal costs of the current accounting period are allowable as indirect costs. Bid and proposal costs of past accounting periods are unallowable in the current period.

However, if the recipient's established practice is to treat these costs by some other method, they may be accepted if they are found to be reasonable and equitable. Bid and proposal costs do not include independent research and development costs covered by paragraph (b)(2) of this section, or pre-award costs covered by OMB Circular A-122.

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Attachment B, paragraph 33 and Sec. 74.25(d)(1).

(2) Independent Research and Development costs. Independent research and development is research and development which is conducted by an organization, and which is not sponsored by Federal or non-Federal awards, contracts, or other agreements. Independent research and development shall be allocated its proportionate share of indirect costs on the same basis as the allocation of indirect costs to sponsored research and development. The cost of independent research and development, including their proportionate share of indirect costs, are unallowable.
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Sec. 74.28  Period of availability of funds.

Where a funding period is specified, a recipient may charge to the award only allowable costs resulting from obligations incurred during the funding period and any pre-award costs authorized by the awarding agency pursuant to Sec. 74.25(d)(1).

Property Standards
Sec. 74.50 Purpose of reports and records.

Sections 74.51 through 74.53 set forth the procedures for monitoring and reporting on the recipient's financial and program performance and the necessary standard reporting forms. They also set forth record retention requirements.
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Sec. 74.51 Monitoring and reporting program performance.

(a) Recipients are responsible for managing and monitoring each project, program, subaward, function or activity supported by the award. Recipients shall monitor subawards to ensure that subrecipients have met the audit requirements as set forth in Sec. 74.26.

(b) The HHS awarding agency will prescribe the frequency with which the performance reports shall be submitted. Except as provided in paragraph (f) of this section, performance reports will not be required more frequently than quarterly or, less frequently than annually. Annual reports shall be due 30 calendar days after the award year; quarterly or semi-annual reports shall be due 30 days after the reporting period. The HHS awarding agency may require annual reports before the anniversary dates of multiple year awards in lieu of these requirements. The final performance reports are due 90 calendar days after the expiration or termination of the award.

(c) If inappropriate, a final technical or performance report will not be required after completion of the project.

(d) Performance reports shall generally contain, for each award, brief information on each of the following:

1) A comparison of actual accomplishments with the goals and objectives established for the period, the findings of the investigator, or both. Whenever appropriate and the output of programs or projects can be readily quantified, such quantitative data should be related to cost data for computation of unit costs.

2) Reasons why established goals were not met, if appropriate.

3) Other pertinent information including, when appropriate, analysis and explanation of cost overruns or high unit costs.

(e) Recipients shall submit the original and two copies of performance reports.

(f) Recipients shall immediately notify the HHS awarding agency of developments that have a significant impact on the award-supported activities. Also, notification shall be given in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

(g) HHS may make site visits, as needed.

(h) The HHS awarding agency complies with the applicable report clearance requirements of 5 CFR part 1320, "Controlling Paperwork Burdens on the Public," when requesting performance data from recipients.

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recipients.
(a) The following forms are used for obtaining financial information from recipients:

(1) SF-269 or SF-269A, Financial Status Report.

(1) The HHS awarding agency will require recipients to use either the SF-269 (long form) or SF-269A to report the status of funds for all nonconstruction projects or programs. The SF-269 shall always be used if income has been earned. The awarding agency may, however, waive the SF-269 or SF-269A requirement when the PMS-270, Request for Advance or Reimbursement, or PMS-272, Report of Federal Cash Transactions, will provide adequate information to meet its needs, except that a final SF-269 or SF-269A shall be required at the completion of the project when the PMS-270 is used only for advances.

(ii) If the HHS awarding agency requires accrual information, the recipient’s accounting records are not normally kept on the accrual basis, the recipient shall not be required to convert its accounting system, but shall develop such accrual information through best estimates based on an analysis of the documentation on hand.

(iii) The HHS awarding agency will determine the frequency of the Financial Status Report for each project or program, considering the size and complexity of the particular project or program. However, the report will not be required more frequently than quarterly or less frequently than annually except under Sec. 74.14. A final report shall be required at the completion of the agreement.

(iv) Recipients shall submit the SF-269 and SF-269A (an original and two copies) no later than 30 days after the end of each specified reporting period for quarterly and semi-annual reports, and 90 calendar days for annual and final reports. Extensions of reporting due dates may be approved by the HHS awarding agency upon request of the recipient.

(b) PMS-272, Report of Federal Cash Transactions.

(1) When funds are advanced to recipients, the HHS awarding agency requires each recipient to submit the PMS-272 and, when necessary, its continuation sheet, PMS-272A through G. The HHS awarding agency uses this report to monitor cash advanced to recipients and to obtain disbursement information for each agreement with the recipients.

(iii) Recipients shall submit the original and two copies of the PMS-272 15 calendar days following the end of each quarter. The HHS awarding agency may require a monthly report from those recipients receiving advances totaling $1 million or more per year.

(iv) The HHS awarding agency may waive the requirement for submission of the PMS-272 for any one of the following reasons: (A) When
monthly advances do not exceed $15,000 per recipient, provided that such advances are monitored through other forms contained in this section; (B) If, in HHS' opinion, the recipient's accounting controls are adequate to minimize excessive Federal advances; or, (C) When

the electronic payment mechanisms provide adequate data.

(b) When the HHS awarding agency needs additional information or more frequent reports, the following shall be observed.

1. When additional information is needed to comply with legislative requirements, the HHS awarding agency will issue instructions to require recipients to submit that information under the 'Remarks' section of the reports.

2. When HHS determines that a recipient's accounting system does not meet the standards in Sec. 74.21, additional pertinent information to further monitor awards may be obtained, without regard to Sec. 74.4, upon written notice to the recipient until such time as the system is brought up to standard. In obtaining this information, the HHS awarding agencies comply with report clearance requirements of 5 CFR part 1320, "Controlling Paperwork Burdens on the Public."

3. The HHS awarding agency may accept the identical information from a recipient in machine readable format or computer printouts or electronic outputs in lieu of prescribed formats.

4. The HHS awarding agency may provide computer or electronic outputs to recipients when such action expedites or contributes to the accuracy of reporting.

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Subpart C--Post-Award Requirements

Sec. 74.53 Retention and access requirements for records.

(a) This section sets forth requirements for record retention and access to records for awards to recipients.

(b) Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report. The only exceptions are the following:

(1) If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

(2) Records for real property and equipment acquired with Federal funds shall be retained for 3 years after final disposition.

(3) When records are transferred to or maintained by the HHS awarding agency, the 3-year retention requirement is not applicable to the recipient.

(4) Indirect cost rate proposals, cost allocations plans, etc., as specified in Sec. 74.53(g).

(c) Copies of original records may be substituted for the original records if authorized by the HHS awarding agency.

(d) The HHS awarding agency will request transfer of certain records to its custody from recipients when it determines that the records possess long term retention value. However, in order to avoid duplicate recordkeeping, the HHS awarding agency may make arrangements for recipients to retain any records that are continuously needed for joint use.

(e) HHS awarding agencies, the HHS Inspector General, the U.S. Comptroller General, or any of their duly authorized representatives, have the right of timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to the awards, in order to make audits, examinations, excerpts, transcripts and copies of such documents. This right also includes timely and reasonable access to a recipient's personnel for the purpose of interview and discussion related to such documents. The rights of access in this paragraph are not limited to the required retention period, but shall last as long as records are retained.

(f) Unless required by statute, the HHS awarding agency will not place restrictions on recipients that limit public access to the records of recipients that are pertinent to an award, except when the HHS awarding agency can demonstrate that such records shall be kept confidential and would have been exempted from disclosure pursuant to

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the Freedom of Information Act, 5 U.S.C. 552, if the records had belonged to the HHS awarding agency.

(g) Paragraphs (g)(1) and (g)(2) of this section apply to the following types of documents, and their supporting records: Indirect cost rate computations or proposals, cost allocation plans, and any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback rates or composite fringe benefit rates).

(1) If the recipient submits to the Federal Government or the subrecipient submits to the recipient the proposal, plan, or other computation to form the basis for negotiation of the rate, then the 3-year retention period for its supporting records starts on the date of such submission.

(2) If the recipient is not required to submit to the Federal Government or the subrecipient is not required to submit to the recipient the proposal, plan, or other computation for negotiation purposes, then the 3-year retention period for the proposal, plan, or other computation and its supporting records starts at the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

Termination and Enforcement

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Office of Management and Budget

CIRCULAR A-21 (Revised 8/8/00)

CIRCULAR NO. A-21
Revised

TO THE HEADS OF EXECUTIVE DEPARTMENTS AND ESTABLISHMENTS

SUBJECT: Cost Principles for Educational Institutions

1. Purpose. This Circular establishes principles for determining costs applicable to grants, contracts, and other agreements with educational institutions. The principles deal with the subject of cost determination, and make no attempt to identify the circumstances or dictate the extent of agency and institutional participation in the financing of a particular project. The principles are designed to provide that the Federal Government bears its fair share of total costs, determined in accordance with generally accepted accounting principles, except where restricted or prohibited by law. Agencies are not expected to place additional restrictions on individual items of cost. Provision for profit or other increment above cost is outside the scope of this Circular.


3. Applicability.

   a. All Federal agencies that sponsor research and development, training, and other work at educational institutions shall apply the provisions of this Circular in determining the costs incurred for such work. The principles shall also be used as a guide in the pricing of fixed price or lump sum agreements.

   b. In addition, Federally Funded Research and Development Centers associated with educational institutions shall be required to comply with the Cost Accounting Standards, rules and regulations issued by the Cost Accounting Standards Board, and set forth in 48 CFR part 99, provided that they are subject thereto under defense related contracts.

4. Responsibilities. The successful application of cost accounting principles requires development of mutual understanding between representatives of educational institutions and of the Federal Government as to their scope, implementation, and interpretation.
5. **Attachment.** The principles and related policy guides are set forth in the Attachment, “Principles for determining costs applicable to grants, contracts, and other agreements with educational institutions.”

6. **Effective date.** The provisions of this Circular shall be effective October 1, 1979, except for subsequent amendments incorporated herein for which the effective dates were specified in these revisions (47 FR 33658, 51 FR 20908, 51 FR 43487, 56 FR 50224, 58 FR 39996, 61 FR 20880, 63 FR 29786, 63 FR 57332, and 65 FR 48356). The provisions shall be implemented by institutions as of the start of their first fiscal year beginning after that date. Earlier implementation or a delay in implementation of individual provisions, is permitted by mutual agreement between an institution and the cognizant Federal agency.

7. **Inquiries.** Further information concerning this Circular may be obtained by contacting the Office of Federal Financial Management, Office of Management and Budget, Washington, DC 20503, telephone (202) 395-3993.

Attachment

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**PRINCIPLES FOR DETERMINING COSTS APPLICABLE TO GRANTS, CONTRACTS, AND OTHER AGREEMENTS WITH EDUCATIONAL INSTITUTIONS**

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6. Commencement and convocation costs
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11. Defense and prosecution of criminal and civil proceedings, claims, appeals and patent infringement
12. Depreciation and use allowances
13. Donations and contributions
14. Employee morale, health, and welfare costs and credits
15. Entertainment costs
16. Equipment and other capital expenditures
17. Executive lobbying costs
18. Fines and penalties
19. Goods or services for personal use
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27. Material costs
28. Memberships, subscriptions and professional activity costs
29. Patent costs
30. Plant security costs
31. Preagreement costs
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33. Profits and losses on disposition of plant equipment or other capital assets
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37. Recruiting costs
38. Rental cost of buildings and equipment
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Exhibit A - List of Colleges and Universities Subject to Section 1.12.f of Circular A-21
Exhibit B - Listing of Institutions that are eligible for the utility cost adjustment
Exhibit C - Examples of "major project" where direct charging of administrative or clerical staff salaries may be appropriate

Appendix A - CASP's Cost Accounting Standards (CAS)
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Appendix C - Documentation Requirements for Facilities and Administrative (F&A) Rate Proposals

http://www.whitehouse.gov/omb/circulars/a021/print/a021.html
Office of Management and Budget

CIRCULAR A-110
(REVISED 11/19/93, As Further Amended 9/30/99)

CIRCULAR NO. A-110 Revised

TO THE HEADS OF EXECUTIVE DEPARTMENTS AND ESTABLISHMENTS

SUBJECT: Uniform Administrative Requirements for Grants and Agreements
With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations

1. Purpose. This Circular sets forth standards for obtaining consistency and uniformity among Federal agencies in the administration of grants to and agreements with institutions of higher education, hospitals, and other non-profit organizations.


3. Policy. Except as provided herein, the standards set forth in this Circular are applicable to all Federal agencies. If any statute specifically prescribes policies or specific requirements that differ from the standards provided herein, the provisions of the statute shall govern.

The provisions of the sections of this Circular shall be applied by Federal agencies to recipients. Recipients shall apply the provisions of this Circular to subrecipients performing substantive work under grants and agreements that are passed through or awarded by the primary recipient, if such subrecipients are organizations described in paragraph 1.

This Circular does not apply to grants, contracts, or other agreements between the Federal Government and units of State or local governments covered by OMB Circular A-102, "Grants and Cooperative Agreements with State and Local Governments," and the Federal agencies' grants management common rule which standardized and codified the administrative requirements Federal agencies impose on State and local grantees. In addition, subawards and contracts to State or local governments are not covered by this Circular. However, this Circular applies to subawards made by State and local governments to organizations covered by this Circular. Federal agencies may apply the
provisions of this Circular to commercial organizations, foreign governments, organizations under the jurisdiction of foreign governments, and international organizations.

4. Definitions. Definitions of key terms used in this Circular are contained in Section __2 in the Attachment.

5. Required Action. The specific requirements and responsibilities of Federal agencies and institutions of higher education, hospitals, and other non-profit organizations are set forth in this Circular. Federal agencies responsible for awarding and administering grants to and other agreements with organizations described in paragraph 1 shall adopt the language in the Circular unless different provisions are required by Federal statute or are approved by OMB.

6. OMB Responsibilities. OMB will review agency regulations and implementation of this Circular, and will provide interpretations of policy requirements and assistance to insure effective and efficient implementation. Any exceptions will be subject to approval by OMB, as indicated in Section __4 in the Attachment. Exceptions will only be made in particular cases where adequate justification is presented.

7. Information Contact. Further information concerning this Circular may be obtained by contacting the Office of Federal Financial Management, Office of Management and Budget, Washington, DC 20503, telephone (202) 395-3993.

8. Termination Review Date. This Circular will have a policy review three years from date of issuance.

9. Effective Date. The standards set forth in this Circular which affect Federal agencies will be effective 30 days after publication of the final revision in the Federal Register. Those standards which Federal agencies impose on grantees will be adopted by agencies in codified regulations within six months after publication in the Federal Register. Earlier implementation is encouraged.

Attachment

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Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations

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http://www.whitehouse.gov/omb/circulars/a110/a110.html
# Requirements for Program Income Accountability

(Page 122, NIH GPS 12/1/2003)

## Use and Applicability of Program Income Alternatives

<table>
<thead>
<tr>
<th>Program income alternative</th>
<th>Use of program income</th>
<th>Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additive Alternative</td>
<td>Added to funds committed to the project or program and used to further eligible project or program objectives.</td>
<td>Applies to all NIH awards unless there is a concern with the recipient or activity or the program requires a different alternative.</td>
</tr>
<tr>
<td>Deductive Alternative</td>
<td>Deducted from total allowable costs of the project or program to determine the NIH allowable costs on which the Federal share of costs will be based.</td>
<td>Available for use by NIH programs on an exception basis.</td>
</tr>
<tr>
<td>Combination Alternative</td>
<td>Uses all program income up to (and including) $25,000 as specified under the additive alternative and any amount of program income exceeding $25,000 under the deductive alternative.</td>
<td>Available for use by NIH programs on an exception basis.</td>
</tr>
<tr>
<td>Matching Alternative</td>
<td>Used to satisfy all or part of the non-Federal share of a project or program.</td>
<td>Available for use by NIH programs that require matching.</td>
</tr>
</tbody>
</table>
Financial Conflict of Interest

Greg Pryor

Promoting Objectivity is the Goal

Institutions must establish standards to ensure there is no reasonable expectation that the design, conduct, or reporting of PHS funded research is biased by a conflicting financial interest of an investigator.

Where to Find the PHS Regulations

For Grants and Cooperative Agreements -
- 42 CFR Part 50 Subpart F - "Responsibility of Applicants for Promoting Objectivity in Research"

For Contracts -
- 45 CFR Part 94 - "Responsible Prospective Contractors"

Note: The regulations became effective on October 1, 1995
Applicability of Financial COI Regulations

To be applicable, three elements must exist:
1. Public Health Service (PHS) funds
2. Research - as defined in the regulation
3. Investigator - specific definition

(Note: The regulations do not apply to Phase I SBIR or STTR projects)

The Big View

Institutions must:
- Maintain a written, enforce financial COI policy for researchers/investigators
- Ensure that investigators are informed of the regulations, the policy, and the reporting responsibilities

The Big View (cont’d)

- Designate an Official (DO) to solicit and review Financial Disclosure Statements from investigators planning to participate in the research
- Ensure that by the time of application submission, the DO has received Financial Disclosure Statements from investigators
- Report any and all components the existence of financial COIs and that the financial COIs are managed, reduced, or eliminated
Key Terms

1. Investigator: PI and anyone responsible for the design, conduct, or reporting of NIH-funded research (includes Investigator's spouse & dependent children for financial reporting purposes)

2. Significant Financial Interest (SFI): "Anything of Monetary Value" (However, exclusions include salary at the applicant institution and equity Interest not exceeding $10,000 and 5% ownership)

Key Terms (cont'd)

Financial Disclosure Statement: A listing of Investigators' SFIs (and those of higher spouse and dependent children):
- (i) that would reasonably appear to be affected by the research; and
- (ii) in entities whose financial interests would reasonably appear to be affected by the research (e.g., stock)
Required to be updated annually or as new SFIs occur

When Does a Financial COI Exist?

When the Institutional Designated Official reasonably determines that a COI could directly and significantly affect the design, conduct, or reporting of the NIH-funded research:
Ways to Manage, Reduce or Eliminate Conflicts
(examples offered in the regulations)

Institutions may:
- Publicly disclose the SFs (most common)
- Monitor research by independent reviewers
- Modify research plan
- Direct the SF
- Sever relationship(s) that create conflict(s)

Selected Information
- March 2000 NIH initiates a series of Proactive Compliance Site Visits to assess institutional understanding of Federal policies and regulations, to minimize or eliminate noncompliance, and to nurture productive partnerships between the NIH and its grantee institutions.
- Financial Conflicts of Interest is a publication on the site visits.
- Compendium of Findings and Alternatives for Fiscal Year 2000 to Fiscal Year 2002 is available at https://grants.nih.gov/grants/guide/awards/notice.htm
- August 2000 NER conference on Human Subject Protection and Financial Conflict of Interest.

Selected Information
- January 2001 draft interim guidance issues by HHS.
- January 2001 NIH requests policy on Financial Conflict of Interest from the top 200 funded institutions.
Selected Information


Selected Information

- September 2002 NIH Conflict of Interest Workshop, designed as an interactive process that would allow participants to share experiences and to discuss strategies involving ethics, implementation, and monitoring of policies.

- Discussion of the importance of identifying and managing conflicts of interest.

- Session 2: individual communique of the workshop.

- Forum: invited research scientists, university administrators, and representatives from professional organizations that have taken leadership roles in drafting guidelines for NIH projects, such as the AAMC and AAU, and senior staff from the Institutes and Offices of the NIH.

http://oarc.nih.gov/organizational/index.cfm

Selected Information


- Winter 2002 COSE Report on "Recognizing and Managing Personal Financial Conflicts of Interest"

- March 2003 HHS publishes new guidance for IRBs, investigators, and research institutions to ensure compliance with the regulations for human subjects research conducted or supported by HHS, as regulated by the FDA. Effective period secreted on May 30, 2003
More Information?

- Conflict of Interest Information Resources Available on the Web
  http://grants1.nih.gov/grants/off/did/tic/research.htm

- FAQ - Federal Register - July 3, 1998
  http://www.nih.wrl.com/faq/fg/gap.htm

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Financial Conflict of Interest

Resources

- 42 CFR Part 50 Subpart F – Responsibility of Applicants for Promoting Objectivity in Research
- 45 CFR Part 94 – Responsible Prospective Contractors
PART 50--POLICIES OF GENERAL APPLICABILITY--Table of Contents

Subpart F--Responsibility of Applicants for Promoting Objectivity in Research for Which Grants or Cooperative Agreements are Made


Source: 60 FR 35815, July 11, 1995; 60 FR 39076, July 31, 1995, unless otherwise noted.

Sec. 50.601 Purpose.

This subpart promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under NIH grants or cooperative agreements will be biased by any conflicting financial interest of an investigator.

Sec. 50.602 Applicability.

This subpart is applicable to each Institution that applies for NIH grants or cooperative agreements for research and, through the implementation of

this subpart by each Institution, to each investigator participating in such research (see Sec. 50.604(a)); provided, that this subpart does not apply to SBIR Program Phase I applications. In those few cases where an individual, rather than an institution, is an applicant for NIH grants or cooperative agreements for research, NIH Awarding Components will make case-by-case determinations on the steps to be taken to ensure that the design, conduct, and reporting of the research will not be biased by any conflicting financial interest of the individual.

Sec. 50.603 Definitions.

As used in this subpart:

HRD means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency).

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by NIH, or proposed for such funding. For purposes of the requirements of this subpart relating to financial interests,
'Investigator' includes the Investigator's spouse and dependent children.

PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options or other ownership interests), and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:

1. Salary, royalties, or other remuneration from the applicant institution;
2. Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;
3. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
4. Income from service on advisory committees or review panels for public or nonprofit entities;
5. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity, or
6. Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed $10,000.

Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) program, which was established by Pub. L. 102-564.

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Sec. 50.604 Institutional responsibility regarding conflicting interests of investigators.

Each institution must:
(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this subpart and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subgrantees, contractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such

entities comply with this subpart, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the institution that will enable the Institution to comply with this subpart.

(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each investigator who is planning to participate in PHS-funded research.

(c)(1) Require that by the time an application is submitted to PHS each investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):
   (1) That would reasonably appear to be affected by the research for which PHS funding is sought; and
   (ii) In entities whose financial interests would reasonably appear to be affected by the research.
   (2) All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
   (d) Provide guidelines consistent with this subpart for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
   (e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.
   (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
   (g) Certify, in each application for the funding to which this subpart applies, that:
   (1) There is an effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS.
   (2) Prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accordance with this subpart; and, for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced or eliminated, at least on an interim basis, within sixty days of that identification.
   (3) The Institution agrees to make information available, upon request, to the PHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and
   (4) The Institution will otherwise comply with this subpart.

Sec. 50.605 Management of conflicting interests.

[a] The designated official(s) must: Review all financial disclosures and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest would directly and significantly affect


4/26/2004
funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;
(2) Monitoring of research by independent reviewers;
(3) Modification of the research plan;
(4) Disqualification from participation in all or a portion of the research funded by the PHS;
(5) Divestiture of significant financial interests; or
(6) Severance of relationships that create actual or potential conflicts.
(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

Sec. 50.606 Remedies.

(a) If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review of, site, all records pertinent to compliance with this subpart. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this subpart. The PHS Awarding Component may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this subpart, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

Sec. 50.607 Other HHS regulations that apply.

Several other regulations and policies apply to this subpart. They include, but are not necessarily limited to:

42 CFR part 50, subpart D--Public Health Service grant appeals procedure
45 CFR Part 16--Procedures of the Departmental Grant Appeals Board

45 CFR part 74---Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments

45 CFR part 76---Government-wide debarment and suspension (non-procurement)

45 CFR part 79---Program Fraud Civil Remedies

45 CFR part 92---Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments

http://grants.nih.gov/grants/compliance/42 CFR 50 Subpart F.htm

4/26/2004
TITLE 45--PUBLIC WELFARE
AND HUMAN SERVICES

PART 94--RESPONSIBLE PROSPECTIVE CONTRACTORS--Table of Contents

Sec. 94.1 Purpose.

This part promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under PHS contracts will be biased by any conflicting financial interest of an investigator.
TITLE 45—PUBLIC WELFARE
AND HUMAN SERVICES

PART 94—RESPONSIBLE PROSPECTIVE CONTRACTORS—Table of Contents

Sec. 94.2 Applicability.

This part is applicable to each institution that seeks PHS funding for research and, through the implementation of this part, to each investigator who participates in such research (see Sec. 94.4(a)); provided that this part does not apply to SBIR Program Phase I applications.
TITLE 45--PUBLIC WELFARE
AND HUMAN SERVICES

PART 94--RESPONSIBLE PROSPECTIVE CONTRACTORS--Table of Contents

Sec. 94.2 Definitions.

As used in this part:
Contractor means an entity that provides property or services for
the direct benefit or use of the Federal Government.
HHS means the United States Department of Health and Human Services,
and any component of the Department to which the authority involved may
be delegated.
Institution means any public or private entity or organization
(excluding a Federal agency)
(1) That submits a proposal for a research contract whether in
response to a solicitation from the PHS or otherwise, or
(2) That assumes the legal obligation to carry out the research
required under the contract.
Investigator means the principal investigator and any other person
who is responsible for the design, conduct, or reporting of a research
project funded by PHS, or proposed for such funding. For purposes of the
requirements of this part relating to financial interests,
"Investigator" includes the Investigator's spouse and dependent
children.
PHS means the Public Health Service, an operating division of the
U.S. Department of Health and Human Services, and any component of the
PHS to which the authority involved may be delegated.
PHS Awarding Component means an organizational unit of the PHS that
funds research that is subject to this part.
Public Health Service Act or PHS Act means the statute codified at 42
U.S.C. 201 et seq.
Research means a systematic investigation designed to develop or
contribute to generalizable knowledge relating broadly to public health,
including behavioral and social-sciences research. The term encompasses
basic and applied research and product development. As used in this
part, the term includes any such activity for which funding is available
from a PHS Awarding Component, whether authorized under the PHS Act or
other statutory authority.
Significant financial interest means anything of monetary value,
including but not limited to, salary or other payments for services
(e.g., consulting fees or honoraria; equity interests (e.g., stocks,
stock options or other ownership interests); and intellectual property
rights (e.g., patents copyrights and royalties from such rights). The
term does not include:
(1) Salary, royalties, or other remuneration from the applicant
institution;
(2) Any ownership interests in the institution, if the institution
is an applicant under the SBIR program;
(3) Income from seminars, lectures, or teaching engagements
sponsored by public or nonprofit entities;

(4) Income from service on advisory committees or review panels for public or nonprofit entities;

(5) An equity interest that when aggregated for the investigator and the investigator’s spouse and dependent children, meets both of the following tests: Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or

(6) Salary, royalties or other payments that when aggregated for the investigator and the investigator’s spouse and dependent children over the next twelve months, are not reasonably expected to exceed $10,000.

Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the awarding components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this part, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.
TITLE 45--PUBLIC WELFARE
AND HUMAN SERVICES

PART 94--RESPONSIBLE PROSPECTIVE CONTRACTORS--Table of Contents

Sec. 94.4 Institutional responsibility regarding conflicting interests of investigators,

Each Institution must:
(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this part and inform each investigator of that policy, the investigator's reporting responsibilities, and of these regulations. If the institution carries out the PHS-funded research through subcontractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this part, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this part.

(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(c)(1) Require that by the time an application is submitted to PHS, each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):
(i) that would reasonably appear to be affected by the research for which PHS funding is sought; and
(ii) in entities whose financial interests would reasonably appear to be affected by the research.

(2) All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with this part for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for three years after final payment or, when applicable, for the other time periods specified in 48 CFR part 4, subpart 4.7.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each contract proposal, that:
(1) there is in effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS;
(2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the

existence of any conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accordance with this part; and, for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification.

(3) the Institution agrees to make information available, upon request, to the PHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and

(4) the Institution will otherwise comply with this part.

[60 FR 35817, July 11, 1995; 60 FR 35076, July 31, 1995]
 TITLE 45--PUBLIC WELFARE
AND HUMAN SERVICES

PART 94--RESPONSIBLE PROSPECTIVE CONTRACTORS--Table of Contents

Sec. 94.5 Management of conflicting interests.

(a) The designated official(s) MUST: Review all financial disclosures and determine whether a conflict of interest exists, and is so, what actions should be taken by the institution to manage, reduce, or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;
(2) Monitoring of the research by independent reviewers;
(3) Modification of the research plan;
(4) Disqualification from participation in all or a portion of the research funded by the PHS;
(5) Divestiture of significant financial interests, or;
(6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

[60 FR 35813, July 11, 1995; 60 FR 39277, July 31, 1995]
(a) If the failure of an investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a review of all records pertinent to compliance with this part. HHS may require submission of the records or review them on site. To the extent permitted by law HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this part. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with a conflicting interest that was not disclosed or managed as required by this part, the Institution must require disclosure of the conflicting interest in each public presentation of the results of the research.

[60 FR 35817, July 11, 1995; 60 FR 39077, July 31, 1995]
Administering and Overseeing Clinical Research
A Collaborative Activity
Dennis O. Dixon, Ph.D.

Partners
- Investigator(s)
- Institution
- IRB
- Sponsors such as NIH and Industry
- FDA
- External Committees

Key Issues
- Adverse Events
- Data and Safety Monitoring
- Data Sharing
Adverse Events

- Responsibility of Investigator
- Responsibility of Safety Monitor
- Responsibility of IRB
- Responsibility of Data and Safety Monitoring Board in multicenter trials

Data and Safety Monitoring

- Minimize risk to study participants
  - Adverse event monitoring
  - Outcome evaluation
  - Stop study when objective met (or cannot be met)
- Assure integrity of study protocol
  - Design remains appropriate
  - Data of high quality; enrollment adequate

Data and Safety Monitoring
Regulations, Guidelines

- 45 CFR 46 (Common Rule), administered by HHS Office of Human Research Protections
- NIH Policies
  - All trials need a plan — describe in application
  - Phase III trials must use a DMPB
  - Notify IRBs of DMPB recommendations
- (Recombinant DNA Research)
Data and Safety Monitoring Approaches

IRB and investigator
Plus, often:
• Independent DSMB or
• Internal group or
• Designated monitor

Possible Monitoring Plan for Phase II Trial

• Recruit a committee with at least some external members (identify by name)
• Follow the protocol plans (content and schedule) for interim analysis and review
• Restrict access to interim trends
• Notify the IRB of results (conclusions only)

Data Sharing

Allows scientists to expedite the translation of research results into:
• Knowledge
• Products
• Procedures
to improve human health
Data Sharing

- Important goals
  - Ensuring openness to scientific inquiry
  - Encouraging diversity of analysis and opinion
  - Promoting new research not originally envisioned
  - Supporting studies on data collection methods and measurements
  - Facilitating education of new researchers

Data Sharing

- Data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data
- All applications submitted to NIH on or after October 1, 2003, in which direct costs of $500,000 or more are requested in any one year must include a plan for sharing final research data or stating why not possible

Questions?

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Administering and Overseeing
Clinical Research

Resources

  NIH Policy for Data and Safety Monitoring
- NIH Guide Notice / OD-00-038 / June 5, 2000
  Further Guidance on a Data and Safety Monitoring for Phase I and Phase II Trials
- NIH Guide Notice / January 11, 1999
  Guidance on Reporting Adverse Events to Institutional Review Boards for
  NIH-Supported Multicenter Clinical Trials
- HIPPA Privacy Rules and Its Impact on Research – Educational Materials
  Final NIH Statement on Sharing Research Data
CODE OF FEDERAL REGULATIONS

TITLE 45
PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
OFFICE FOR PROTECTION FROM RESEARCH RISKS

PART 46
PROTECTION OF HUMAN SUBJECTS

* * *

Revised November 13, 2001
Effective December 13, 2001

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Subpart A -- Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)

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46.204 Research involving pregnant women or fetuses.
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Subpart C — Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

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46.302 Purpose.
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46.304 Composition of Institutional Review Boards where prisoners are involved.
46.305 Additional duties of the Institutional Review Boards where prisoners are involved.
46.306 Permitted research involving prisoners.

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46.403 IRB duties.
46.404 Research not involving greater than minimal risk.
46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

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TITLE 45
CODE OF FEDERAL REGULATIONS
PART 46
PROTECTION OF HUMAN SUBJECTS

** **

Revised June 18, 1991
Effective August 19, 1991

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http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

4/26/2004
§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each Department or Agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

(1) Research that is conducted or supported by a Federal Department or Agency, whether or not it is regulated as defined in §46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a Federal Department or Agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an Institutional Review Board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:  

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or Agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or Agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the Department or Agency be not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be

applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a Department or Agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the Department or Agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the Department or Agency head, notices of these actions as they occur will be published in the Federal Register or will be otherwise published as provided in Department or Agency procedures.

(i) Unless otherwise required by law, Department or Agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes or research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the Department or Agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services (DHHS), and shall also publish them in the Federal Register or in such other manner as provided in Department or Agency procedures.  

1 Institutions with DHHS-approved assurances on file will abide by provisions of Title 45 CFR Part 46 Subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR Part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

§46.102 Definitions.

(a) Department or Agency head means the head of any Federal Department or Agency and any other officer or employee of any Department or Agency to whom authority has been delegated.

(b) Institution means any public or private entity or Agency (including Federal, State, and other agencies).

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(c) **Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.

(d) **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) **Research subject to regulation,** and similar terms are intended to encompass those research activities for which a Federal Department or Agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a Federal Department or Agency solely as part of the Department’s or Agency’s broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains

1. data through intervention or interaction with the individual, or
2. identifiable private information.

**Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) **IRB** means an Institutional Review Board established in accord with and for the purposes expressed in this policy.

(h) **IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

(i) **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated
in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) Certification means the official notification by the institution to the supporting Department or Agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§46.103 Assuring compliance with this policy — research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a Federal Department or Agency shall provide written assurance satisfactory to the Department or Agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual Department or Agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, National Institutes Health, DHHS, and approved for Federalwide use by that office. When the existence of an DHHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to Department and Agency heads shall also be made to the Office for Protection from Research Risks, National Institute of Health, DHHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Department or Agency head that the research has been reviewed and approved by an IRB for which the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall be at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to Department- or Agency-supported or regulated research and need not be applicable to any research exempted or waived under §46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB’s review and recordkeeping duties.

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(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc.; sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Department or Agency head, unless in accord with §46.103(a) of this policy, the existence of a DHHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the Department or Agency head prescribes.

(d) The Department or Agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the Department or Agency and such experts or consultants engaged for this purpose as the Department or Agency head determines to be appropriate. The Department or Agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Department or Agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Department or Agency head may limit the period during which any particular approved

assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a Federal Department or Agency and not otherwise exempted or waived under §§46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §§46.103 of this policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the Department or Agency to which the application or proposal is submitted. Under no condition shall research covered by §§46.103 of the policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the Department or Agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§§46.104–46.106 [Reserved]

§46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution’s consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

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(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§46.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in §46.103(b)(4) and to the extent required by §46.103(b)(5).

(b) Except when an expedited review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to

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observe or have a third party observe the consent process and the research.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, DHHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

1. some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

2. minor changes in previously approved research during the period of one year or less for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Department or Agency head may restrict, suspend, terminate, or choose not to authorize an institution’s or IRB’s use of the expedited review procedure.

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to
subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the

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investigator, appropriate institutional officials, and the Department or Agency head.  
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the Department or Agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in §46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Department or Agency at reasonable times and in a reasonable manner.  
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§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the

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subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

2. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3. any additional costs to the subject that may result from participation in the research;

4. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

6. the approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

2. the research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. the research involves no more than minimal risk to the subjects;

2. the waiver or alteration will not adversely affect the rights and welfare of the

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(3) the research could not practically be carried out without the waiver or 
alteration, and

(4) whenever appropriate, the subjects will be provided with additional pertinent 
information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any 
applicable Federal, State, or local laws which require additional information to be disclosed 
in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide 
emergency medical care, to the extent the physician is permitted to do so under applicable 
Federal, State, or local law.

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§46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be 
documented by the use of a written consent form approved by the IRB and signed by the 
subject or the subject's legally authorized representative. A copy shall be given to the person 
signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the 
following:

(1) A written consent document that embodies the elements of informed consent 
required by §46.116. This form may be read to the subject or the subject's legally 
authorized representative, but in any event, the investigator shall give either the 
subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed 
consent required by §46.116 have been presented orally to the subject or the 
subject's legally authorized representative. When this method is used, there shall 
be a witness to the oral presentation. Also, the IRB shall approve a written 
summary of what is to be said to the subject or the representative. Only the short 
form itself is to be signed by the subject or the representative. However, the 
watch shall sign both the short form and a copy of the summary, and the person 
actually obtaining consent shall sign a copy of the summary. A copy of the 
summary shall be given to the subject or the representative, in addition to a copy 
of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form 
for some or all subjects if it finds either:

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(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Department or Agency.

§46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the Department or Agency, and final approval given to the proposed change by the Department or Agency.

§46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The Department or Agency head will evaluate all applications and proposals involving human subjects submitted to the Department or Agency through such officers and employees of the Department or Agency and such experts and consultants as the Department or Agency head determines to be appropriate. This evaluation will take into consideration

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the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the Department or Agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§46.121 [Reserved]

§46.122 Use of Federal funds.

Federal funds administered by a Department or Agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§46.123 Early termination of research support: Evaluation of applications and proposals.

(a) The Department or Agency head may require that Department or Agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Department or Agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the Department or Agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or have directed the scientific and technical aspects of an activity has/have, in the judgment of the Department or Agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

§46.124 Conditions.

With respect to any research project or any class of research projects the Department or Agency head may impose additional conditions prior to or at the time of approval when in the judgment of the Department or Agency head additional conditions are necessary for the protection of human subjects.

Subpart B Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research


§46.201 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.

(b) The exemptions at Sec. 46.101(b)(1) through (6) are applicable to this subpart.

(c) The provisions of Sec. 46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in Sec. 46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.202 Definitions.

The definitions in Sec. 46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) Fetus means the product of conception from implantation until delivery.

(d) Neonate means a newborn.

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.

(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given

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the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

§46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

§46.204 Research involving pregnant women or fetuses.

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or

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neonate;

(g) For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate

§46.205 Research involving neonates.

(a) Neonates of uncertain viability and necivable neonates may be involved in research if all of the following conditions are met:

(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

(2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

(3) Individuals engaged in the research will have no part in determining the viability of a neonate.

(4) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

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(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

(1) Vital functions of the neonate will not be artificially maintained;

(2) The research will not terminate the heartbeat or respiration of the neonate;

(3) There will be no added risk to the neonate resulting from the research;

(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of Sec. 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of Sec. 46.204 or Sec. 46.205 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:

(1) That the research in fact satisfies the conditions of Sec. 46.204, as applicable; or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

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§46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "DHHS" means the Department of Health and Human Services.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a
particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) the research under review represents one of the categories of research permissible under §46.306(a)(2);

(2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) the information is presented in language which is understandable to the subject population;

(6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary
may require, that the duties of the Board under this section have been fulfilled.

§46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) the institution responsible for the conduct of the research has certified to the Secretary that the institutional Review Board has approved the research under §46.305 of this subpart; and

(2) in the judgment of the Secretary the proposed research involves solely the following:

(A) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

(D) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

§46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (i) of §46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator (s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of Subpart A are applicable to this subpart.

§46.402 Definitions.

The definitions in §46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.
(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§46.404 Research not involving greater than minimal risk.

DHHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) the risk is justified by the anticipated benefit to the subjects;

(b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) the risk represents a minor increase over minimal risk;

(b) the intervention or procedure presents experiences to subjects that are reasonably

http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

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commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

DHHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, and

(b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or (2) the following:

(i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) the research will be conducted in accordance with sound ethical principles;

(iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

§46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child,
as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirements under circumstances in which consent may be waived in accord with §46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §46.406 and §46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§46.409 Wards.

(a) Children who are wards of the State or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

1. related to their status as wards; or

2. conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.
NIH POLICY FOR DATA AND SAFETY MONITORING

Release Date: June 10, 1998

National Institutes of Health

Policy

It is the policy of the NIH that each Institute and Center (IC) should have a system for the appropriate oversight and monitoring of the conduct of clinical trials to ensure the safety of participants and the validity and integrity of the data for all NIH-supported or conducted clinical trials. The establishment of the data safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that pose potential risk to the participants. The data and safety monitoring functions and oversight of such activities are distinct from the requirement for study review and approval by an Institutional Review Board (IRB).

Background

A clinical trial entails a relationship between participants and investigators, both of whom must fulfill certain obligations for the effort to succeed. Participants must be fully informed of the study requirements throughout the conduct of the trial and should comply with the requirements of the research protocol or be allowed the opportunity to withdraw from participation. The investigators must protect the health and safety of participants, inform participants of information relevant to their continued participation, and pursue the research objectives with scientific diligence.

Although there are potential benefits to be derived from participation in clinical research, the IRBs and the NIH must ensure, to the extent possible, the safety of study participants and that they do not incur undue risk and that the risks versus benefits are continually reassessed throughout the study period.

With this issuance, the NIH reaffirms the 1979 policy [NIH GUIDE, Volume 5, No. 8, June 5, 1979] developed by the NIH Clinical Trials Committee. Among its recommendations was the concept that "every clinical trial should have provision for data and safety monitoring." The Committee further acknowledged that "a variety of types of monitoring may be anticipated depending on the nature, size, and complexity of the clinical trial. In many cases, the principal investigator would be expected to perform the monitoring function."

In 1994, the Office of Extramural Research established the Committee on Clinical Trial Monitoring to review the oversight and management practices of the ICs for phase III clinical trials. One of the outcomes of this Committee's review was a strong recommendation that "all trials, even those that pose little likelihood of harm, should consider an external monitoring body." This policy affirms the Committee's recommendations concerning DSMBs.

Principles of monitoring data and safety

All clinical trials require monitoring -- Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicologic, and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness and comparative trials (phase III); etc.

Monitoring should be commensurate with risks -- The method and degree of monitoring needed is related to the degree of risk involved. A monitoring


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Committee is usually required to determine safe and effective conduct and to recommend conclusion of the trial when significant benefits or risks have developed or the trial is unlikely to be concluded successfully. Risk associated with participation in research must be minimized to the extent practical.

Monitoring should be commensurate with size and complexity. Monitoring may be conducted in various ways or by various individuals or groups, depending on the size and scope of the research effort. These exist on a continuum from monitoring by the principal investigator or NIH program staff in a small phase I study to the establishment of an independent data and safety monitoring board for a large phase III clinical trial.

Practical and Implementation Issues:

Oversight of Monitoring

This policy provides each IC with the flexibility to implement the requirement for data and safety monitoring as appropriate for its clinical research activities. Thus, IC staff may either conduct or sponsor the monitoring of data and safety of ongoing studies or delegate such responsibilities to a grantee or contractor. Oversight of monitoring activities is distinct from the monitoring itself and should be the responsibility of the IC regardless of whether the monitoring is performed by NIH staff or is delegated. Oversight of monitoring must be done to ensure that data and safety monitoring plans are in place for all interventional trials, that the quality of these monitoring activities is appropriate to the trial(s), and that the IC has been informed of recommendations that emanate from monitoring activities.

Institutes and Centers Responsibilities

Though ICs may perform a variety of roles in data and safety monitoring and its oversight, the following are the minimum responsibilities of sponsoring ICs.

Prepare or ensure the establishment of a plan for data and safety monitoring for all interventional trials.

Conduct or delegate ongoing monitoring of interventional trials.

Ensure that monitoring is timely and effective and that those responsible for monitoring have the appropriate expertise to accomplish its mission.

Oversee monitoring activities.

Respond to recommendations that emanate from monitoring activities.

Performance of Data and Safety Monitoring

The ICs will ensure the integrity of systems for monitoring trial data and participant safety, although they may delegate the actual performance to the grantee or contractor. Monitoring must be performed on a regular basis, and conclusions of the monitoring reported to the IC. Recommendations that emanate from monitoring activities should be reviewed by the responsible official in the IC and addressed. The ICs also have the responsibility of informing trial investigators concerning the data and safety monitoring policy and procedures. Considerations such as who shall perform the monitoring activities, the composition of the monitoring group (if a group is to be used), the frequency and character of monitoring meetings (e.g., open or closed, public or private), and the frequency and content of meeting reports should be a part of the monitoring plans. IRBs should be provided feedback on a regular basis, including findings from adverse-event reports, and recommendations derived from data and safety
monitoring.

Monitoring activities should be conducted by experts in all scientific disciplines needed to interpret the data and ensure patient safety. Clinical trial experts, biostatisticians, bioethicists, and clinicians knowledgeable about the disease and treatment under study should be part of the monitoring group or be available if warranted.

Ideally, participants in monitoring outcomes of a trial are in no way associated with the trial. For trials that are conducted as part of a cooperative group, a majority of the individuals monitoring outcome data should be external to the group. ICs should require policies that evaluate whether the participants have conflicts of interest with or financial stakes in the research outcome; and when these conflicts exist, policies must exist to manage these in a reasonable manner.

Generally, data and safety monitoring boards meet first in open session, attended by selected trial investigators as well as NIH program staff or project officers and perhaps industry representatives, and then in closed session where they review emerging trial data. When "masked" data are presented or discussed, no one with a proprietary interest in the outcome should be allowed. Participants in the review of "masked" or confidential data and discussions regarding continuance or stoppage of the study should have no conflict of interest with or financial stake in the research outcome. However, if there is an open session, they could be present.

Confidentiality must be maintained during all phases of the trial including monitoring, preparation of interim results, review, and response to monitoring recommendations. Besides selected NIH program staff, other key NIH staff, and trial biostatisticians, usually only voting members of the DSMB should see interim analyses of outcome data. Exceptions may be made under circumstances where there are serious adverse events, or whenever the DSMB deems it appropriate.

Individuals or groups monitoring data and safety of interventional trials will perform the following activities:

- Review the research protocol and plans for data and safety monitoring.
- Evaluate the progress of interventional trial(s), including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome. Monitoring should also consider factors external to the study when interpreting the data, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study.
- Make recommendations to the IC, IRB, and investigators concerning continuation or conclusion of the trial(s).
- Protect the confidentiality of the trial data and the results of monitoring.

Examples of Monitoring Operations

The following provides examples of appropriate types of monitoring and oversight for different types of studies. These are illustrative only. The ICs must develop and implement monitoring activities and oversight of those activities appropriate to the study, population, research environment, and the degree of risk involved.


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Phase I: A typical phase I trial of a new drug or agent frequently involves relatively high risk to a small number of participants. The investigator and occasionally others may have the only relevant knowledge regarding the treatment because these are the first human uses. An IC may require the study investigator to perform continuous monitoring of participant safety with frequent reporting to IC staff with oversight responsibility.

Phase II: A typical phase II trial follows phase I studies and there is more information regarding risks, benefits and monitoring procedures. However, more participants are involved and the toxicity and outcomes are confounded by disease process. An IC may require monitoring similar to that of a phase I trial or supplement that level of monitoring with individuals with expertise relevant to the study who might assist in interpreting the data to ensure patient safety.

Phase III: A phase III trial frequently compares a new treatment to a standard treatment or to no treatment, and treatment allocation may be randomly assigned and the data masked. These studies usually involve a large number of participants followed for longer periods of treatment exposure. While short-term risk is usually slight, one must consider the long term effects of a study agent or achievement of significant safety or efficacy differences between the control and study groups for a masked study. An IC may require a DSMB to perform monitoring functions. This DSMB would be composed of experts relevant to the study and would regularly assess the trial and offer recommendations to the IC concerning its continuation.

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Department of Health and Human Services
National Institutes of Health (NIH)
9000 Rockville Pike
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FURTHER GUIDANCE ON A DATA AND SAFETY MONITORING FOR PHASE I AND PHASE II TRIALS

Release Date: June 5, 2000

NOTICE: OD-00-038

National Institutes of Health

Policy: Beginning with the October 2000 receipt date, investigators must submit a monitoring plan for phase I and II clinical trials to the funding Institute and Center (IC) before the trial begins.

Background

In June 1998, the National Institutes of Health (NIH) issued a policy on data and safety monitoring (https://grants.nih.gov/grants/guide/notice-files/not98-084.html) that requires oversight and monitoring of all intervention studies to ensure the safety of participants and the validity and integrity of the data. The policy further elaborates that monitoring should be commensurate with risks and with the size and complexity of the trials. The NIH already requires data and safety monitoring, generally, in the form of Data and Safety Monitoring Boards (DSMBs) for phase III clinical trials. For earlier trials (phase I and II), a DSMB may be appropriate if the studies have multiple clinical sites, are blinded (masked), or employ particularly high-risk interventions or vulnerable populations.

This document provides further guidance for monitoring of phase I and II trials. This guidance does not take the place of Institutional Review Board (IRB) guidelines, Food and Drug Administration (FDA) requirements, or special NIH guidelines e.g., NIH Guidelines for Research Involving Recombinant DNA Molecules. Specifically, phase I and II gene transfer trials must comply with additional requirements imposed by the latter NIH Guidelines, e.g., reporting of adverse events to the Office of Biotechnology Activities.

Monitoring plan

For phase I and II clinical trials, investigators must submit a general description of the data and safety monitoring plan as part of the research application. This plan will be reviewed by the scientific review group and any comments and concerns will be included in an administrative note in the summary statement. A detailed monitoring plan, however, must be included as part of the protocol and submitted to the local IRB and reviewed and approved by the funding Institute and Center (IC) before the trial begins. We strongly encourage the IRB to review the plan. Each IC should have a system for appropriate oversight and monitoring of the conduct of clinical trials to ensure the safety of participants and the validity and integrity of the data. IC oversight of the monitoring activities is distinct from the monitoring itself. Oversight of monitoring must be done to ensure that monitoring plans are in place for all phase I or II trials and that the IC is informed of recommendations and any necessary actions that emanate from the monitoring activities.

At a minimum, all monitoring plans must include a description of the reporting mechanisms of adverse events to the IRB, the FDA and the NIH. Investigators must ensure that the NIH is informed of actions, if any, taken by the IRB as a result of its continuing review. ICs have the flexibility to determine the reporting requirements of adverse events.


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The reporting requirement to the NIH may range from individual adverse event reports to summary reports from the monitoring group. In specific cases where the funding IC is the sponsor of the test agent, i.e. holder of the Investigational New Drug (IND) application, investigators must submit individual adverse event reports to the IC (as sponsor) in accordance with FDA regulations. Occasionally, there are phase I or II trials that have established safety monitoring committees. In these cases, summary reports of the committees' discussions of adverse events must be submitted to the IC and IRB. The reporting requirements for adverse events, as approved by the ICs, are in addition to the annual progress reports to the NIH for type 5 awards (non-competitive awards).

The overall elements of the monitoring plan may vary depending on the potential risks, complexity, and nature of the trial. In phase I and II trials, factors of factors influence risk. A phase I trial of a new drug or agent may involve increasing risk, to a small number of participants, as the drug is escalated in dosage. For phase II trials, there is sometimes information about risks in normal subjects, but risk may be increased as more participants are involved and the toxicity and outcomes may be confounded by the disease process. In situations involving potentially high risks or special populations, investigators must consider additional monitoring safeguards.

For many phase I and phase II trials, independent DSMBs may not be necessary or appropriate when the intervention is low risk. Continuous, close monitoring by the study investigator may be an adequate and appropriate format for monitoring, with prompt reporting of toxicity to the IRB, FDA and/or NIH. In some instances, the study investigator or the IRB may determine that an independent individual may be needed for monitoring. In studies of small numbers of subjects, toxicity may more readily become apparent through close monitoring of individual patients, while in larger studies risk may better be assessed through statistical comparisons of treatment groups.

For multisite phase I and II trials, study investigators should organize a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and the IRBs. The frequency of the summary reports will depend on the nature of the trials. Additional NIH guidance for reporting adverse events for multisite clinical trials with a DSMB has been published in 1999. (See http://grants.nih.gov/grants/guide/notices-files/not99-107.html)

Grantee institutions with a large number of clinical trials may develop standard monitoring plans for phase I and II trials. Thus, individual study investigators will be able to include the IRB-approved monitoring plan in their submission to the NIH. However, such plans should always be evaluated for appropriateness to the particular investigation.

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GUIDANCE ON REPORTING ADVERSE EVENTS TO INSTITUTIONAL REVIEW BOARDS FOR NIH-SUPPORTED MULTICENTER CLINICAL TRIALS

Release Date: June 11, 1999

National Institutes of Health

Effective July 1, all multi-site trials with data safety monitoring boards are expected to forward summary reports of adverse events to each IRB involved in the study. This action in no way reduces the responsibilities of individual IRBs to address such reports coming to them from the site over which they have responsibility. NIH program staff will ensure that this language appears in new solicitations for clinical trials and is broadly disseminated to current principal investigators with appropriate follow-up.

This National Institutes of Health (NIH) document provides guidance to investigators engaged in NIH-supported multi-center clinical trials to promote effective reporting of adverse events to the appropriate IRBs. The mechanism for reporting should be optimized to protect study participants from research risks, while at the same time reducing the regulatory burden on these committees. It is recognized that multiple parties, e.g., NIH, Food and Drug Administration (FDA), or industrial sponsors, must be notified of adverse events. However, this document provides guidance specifically for IRB notification. The NIH is directing principal investigators to report adverse events by identifying the DSMB to the IRB and ensuring reports of assessments of adverse events are transmitted from the DSMB to each IRB.

Background

In response to a congressional request to streamline and reduce unnecessary Federal regulations that govern the conduct of extramural scientific research, the NIH recently published a report "NIH Initiative to Reduce Regulatory Burden" following extensive interviews and focus group meetings with the research community (http://grants.nih.gov/grants/policy/regulatoryburden/index.html). Among the five major areas of focus, the report identified the reporting of adverse events to the IRB for multicenter clinical trials as burdensome and confusing. Some of the confusion stems from the different regulations governing the NIH and the FDA in this area.

Federal regulations (45 CFR Part 46, Subpart A), shared by 17 Departments and Agencies as the Common Rule, require written procedures and policies for ensuring reporting of "unanticipated problems" involving risks to participants to the IRB, appropriate institutional officials, and the Department or Agency Head. Under a different set of regulations, 21 CFR 312, the FDA requires the sponsor to notify the FDA and participating investigators of any adverse event associated with the use of a test article that is "both serious and unexpected." The reporting of adverse events is in addition to, and does not supplant, periodic reports to the IRB at intervals appropriate to the degree of risk in the study, generally, an annual report.

Definitions

The definitions and reporting requirements for adverse events differ between the two Federal regulations. The notification requirements described in the Common Rule define adverse events as "unanticipated problems" involving risks to study participants or others. Generally,


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the funding Institutes and Centers establish operational definitions of adverse events that apply to the particular trial. The National Cancer Institute (NCI), for example, defines adverse drug reactions in its clinical trials involving antineoplastic agents, as: (1) previously unknown toxicities; and (2) life-threatening or fatal toxicities regardless of whether or not previously unknown. Toxicity criteria are generally included in the protocols.

The FDA, in Federal regulations 21 CFR Part 312, defines adverse events as any untoward medical occurrence that may present itself during treatment or administration with a pharmaceutical product, and which may or may not have a causal relationship with the treatment. In the guideline entitled "Clinical Safety Data Management: Definitions and Standards for Expanded Reporting", the Agency further clarifies and defines serious adverse events stemming from a drug study as any untoward medical occurrence that at any dose results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; creates persistent or significant disability/incapacity, or a congenital anomaly/birth defects (http://www.fda.gov/cder/guidance/iche3.pdf).

Issues

For multicenter clinical trials, an IRB may receive individual adverse event reports from sites other than its own. Such off-site reports may not be presented in a useful format and duplicate reports are received, sometimes, months apart. The receipt of reports that are not aggregated (no numerators or denominators are included) and that come from disparate sources contributes to confusion and added workload of the IRB. More importantly, the format of the reports jeopardizes the IRB's ability to make an informed judgment on the appropriate action, if any, to be taken.

Investigator Responsibility

An investigator is responsible for knowing the policies of the local IRB, adhering to these policies, and maintaining a copy of the policies in the study file. An investigator is also responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events. For NIN-supported multicenter clinical trials, investigators do not necessarily report these events to off-site IRBs as long as the local IRB has been notified. In lieu of receiving individual adverse event reports from each of the clinical sites, the IRBs should receive from the investigator a written summary report whenever a data safety monitoring board (DSMB) review has taken place (see below). It should be noted that these summary reports do not replace other reporting requirements to the local IRBs, e.g., annual reports.

Any protocol submitted for IRB approval should both identify the DSMB (not members' names), if any, that will be reviewing interim results, and include a brief description of the monitoring plan as well as procedures for transmitting the DSMB's summary reports to the IRB.

Communication between Data Safety Monitoring Board and IRB

DSMBs play an essential role in protecting the safety of participants, and assuring integrity of the study. They accomplish the former by being familiar with the protocol, preparing appropriate analyses, and periodically reviewing the developing outcomes and safety data. They


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accomplish the latter by reviewing data on such aspects as participant enrollment, site visits, study procedures, forms completion, data quality, losses to follow-up, and other measures of adherence to protocol. The Board makes recommendations based on those data, regarding appropriate protocol and operational changes. DSMBs (and the investigators) monitor toxicity and discuss any concern in this regard. The DSMB monitoring function is above and beyond the oversight traditionally provided by IRBs and as such is particularly important for multicenter trials.

Typically, the study statisticians and the investigators, along with the DSMB, develop monitoring guidelines. However, for some trials, the study statisticians and the investigators develop interim monitoring guidelines that are reviewed as part of the protocol review process by the Institutes and Centers.

In the recent re-issuance of the policy for data and safety monitoring (NIH Guide for Grants and Contracts, June 12, 1998), the NIH clearly addressed the need for communication between the DSMB and IRB. Once a DSMB is established, each IRB should be informed of the operating procedures with regard to data and safety monitoring (e.g., who, what, when, and how monitoring will take place). This information will serve to assure the IRB that the safety of the research participants is appropriately monitored. If the IRB is not satisfied with the monitoring procedures, it should request modifications. While it is recognized that it may not be possible to satisfy every IRB completely, IRB comments should be considered seriously.

The DSMB’s summary report should provide feedback at regular and defined intervals to the IRBs. The Institutes and Centers should ensure that there is a mechanism in place to distribute the report to all participating investigators for submission to their local IRB. For example, at each meeting of the DSMB, the executive secretary should send a brief summary report to each investigator. The report should document that a review of data and outcomes across all centers took place on a given date. It should summarize the Board’s review of the cumulative toxicities reported from all participating sites without specific disclosure by treatment arm. It should also inform investigators of the study the Board’s conclusion with respect to progress or need for modification of the protocol. The investigator is required to transmit the report to the local IRB.

IRB Responsibilities

An IRB has the authority to suspend or terminate approval of research at its site that has been associated with unexpected serious harm to participants. When an IRB takes such action, it is required to provide a statement of reasons for the action and to promptly report this action to the investigator, appropriate institutional officials, the Department or Agency head, Office for Protection from Research Risks (OPRR), and the FDA if an investigational new drug or device is involved. For studies that have a DSMB, the investigator should forward summary reports to the IRB as soon as they are received; it is within the purview of the IRB to request this information. IRBs could make reporting contingent on IRB approval for specific studies that are deemed appropriate. An IRB should communicate concerns to the DSMB and/or the Institute sponsoring the study if it believes that the safety of study participants is in jeopardy.

Implementation:


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The NIH program staff will review multicenter clinical trials with the following expectations:

A. Investigators submitting a protocol for IRB review must identify the DSMB involved, if any. They must describe plans for monitoring adverse events.

B. Investigators must submit a written summary of DSMB periodic review to their IRB.

C. When a study is conducted in multiple sites, the funding institutions and Centers must assure that there is a mechanism in place to distribute the report to all participating investigators for submission to their local IRB.

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Overview

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule is the first comprehensive Federal protection for the privacy of personal health information. Research organizations and researchers may or may not be covered by the HIPAA Privacy Rule. This website provides information on the Privacy Rule for the research community.

HIPAA Resources

- The Privacy Rule - Final Modification (PDF/RTF)
- Office for Civil Rights HIPAA Information (Medical Privacy Home Page)
- Office for Civil Rights HIPAA Guidance (PDF/RTF)
- Office for Civil Rights Summary of the HIPAA Privacy Rule (PDF/RTF)
- Center for Medicare & Medicaid Services HIPAA Information (Covered Entity Decision Tool)

http://privacyruleandresearch.nih.gov/

4/26/2004
FINAL NIH STATEMENT ON SHARING RESEARCH DATA

RELEASE DATE: February 26, 2003

NOTICE: NOT-OD-03-032

National Institutes of Health (NIH)

As part of NIH's long-standing policy to share and make available to the public the results and accomplishments of the activities that it funds, NIH announced and invited comments on a draft statement about the sharing of final research data on March 1, 2002. Since that time, NIH has received and reviewed many thoughtful comments from a range of scientific organizations and over 150 individuals. Additionally, during the comment period, NIH published final modifications for the STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION, the "Privacy Rule," of the Health Insurance Portability and Accountability Act (HIPAA), available at http://www.hhs.gov/ocr/. The Privacy Rule is a federal regulation that governs how certain health care providers, health care clearinghouses, and health plans, known as "covered entities," use and disclose identifiable health information. NIH has carefully considered the comments and the Privacy Rule, and issue the following statement on data sharing:

NIH reaffirms its support for the concept of data sharing. We believe that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. The NIH endorses the sharing of final research data to serve these and other important scientific goals. The NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. Starting with the October 1, 2003, receipt date, investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why data sharing is not possible.

As indicated above, all investigator-initiated applications with direct costs greater than $500,000 in any single year will be expected to address data sharing in their application. Applicants are encouraged to discuss their data sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application as described at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html. Applicants are reminded that agreement to accept assignment of applications over $500,000 must be obtained at least six weeks in advance of the anticipated submission date. Instructions related to the data sharing policy as it is applied to applications and proposals responding to a specific Request for Application (RFA) or Request for Proposals (RFP) will be described in the specific solicitation. In some cases, Program Announcements (PA) may request data sharing plans for applications that are less than $500,000 direct costs in any single year. Reviewers will not factor the proposed data-sharing plan into the determination of scientific merit or priority score. Program staff will be responsible for overseeing the data sharing policy and for assessing the appropriateness and adequacy of the proposed data-sharing plan.

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule. As


4/26/2004
NIH Guide: FINAL NIH STATEMENT ON SHARING RESEARCH DATA

NIH stated in the March 1, 2002 draft data sharing statement (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-035.html), the rights and privacy of people who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data sharing is limited, applicants should explain such limitations in their data sharing plans.

The final NIH statement on data sharing is largely the same as stated in the March 1, 2002 draft with the following exceptions:

- The effective start date has been changed from January 1, 2003 to October 1, 2003 receipt date.
- This policy applies to applicants seeking $500,000 or more in direct costs in any year of the project period. Such applicants are expected to contact IC program staff prior to submission and are also expected to include a data-sharing plan in their application stating how they will share the data or, if they cannot share the data, why not. Applicants responding to an RFA or RFP will find instructions related to data sharing in the specific announcement.
- Several groups and individuals objected to sharing of research data prior to publications. As noted earlier, NIH recognizes that the investigators who collect the data have a legitimate interest in benefiting from their investment of time and effort. We have therefore revised our definition of "the timely release and sharing" to be no later than the acceptance for publication of the main findings from the final data set. NIH continues to expect that the initial investigators may benefit from first and continuing use but not from prolonged exclusive use.

For more information on data sharing, please see our website at http://grants.nih.gov/grants/policy/data_sharing/.

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Return to NIH Guide Main Index


4/26/2004
Extramural Intellectual Property: Meeting the Objectives of the Bayh-Dole Act

George Stone, Ph.D.

Stewardship of Federal Funds

- How funds will be expended
  - Fiscal management
  - Programmatic assessment
- How research will be conducted
  - Research integrity
  - Conflict of interests
- How research outcomes will benefit the public
  - Encourage abatement of intellectual property
  - Share outcomes to spawn new research ideas

Bayh-Dole Act of 1980

- gave \textit{grantee organizations/contractors} the \textit{right} to \textit{invent} or \textit{inventions} arising from \textit{Federal funding agreements}
  - \textit{Required} pursuit of tech. transfer \textit{opportunities}
  - \textit{Government retains license to practice the invention}
- \textit{Result} = \textit{commercialization/application of Federally funded inventions}
What is an Invention (per Bayh-Dole)?

- 37 CFR Section 401.14 standard patent rights clauses.
  - (a) Definitions:
    - (1) Invention means any invention or discovery which is patentable under Title 35 of the United States Code...;
  - (2) Subject invention means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this grant or contract...
  - Does not include copyrightable materials, e.g. books.
  - Includes software, deemed patentable as of late '80s

Invention Reporting Requirements of Grantee/Contractor

*NH Grant Policy Statement - Section II:
Administrative Requirements (per 37 CFR Section 401.14d)

- Implement Employee Agreements as needed
- Disclose Each Invention w/ within 60 days
- Resolve Election of Title within 2 years
- File Patent within 1 yr. of election
- Provide Licenses to the Gov't upon title election
- Indicate Gov't Support on Patent with patent application
- Share Royalties With Inventor when available
- License Small Businesses where feasible
- Produce Manufacturing in U.S. as required
- Report Invention Utilization annually

Responsibilities of Funding Agencies per Bayh-Dole

- Maintain confidentiality for benefit of grantee/contractor/inventor
- Ensure acknowledgement of government license to invention
- Facilitate transfer of technology
- Ensure equal access to invenwole property
- "March in" to provide licensee to responsible applicant
- Restrict title in exceptional circumstances
- Encourage wide dissemination of research tools
- Ensure compliance of 37 CFR Section 401.14
- Oversight of printed organization reporting
- Education of grantee organization community
Bayh-Dole Requirements
Compliance Rules for both Genentech and the NIH

What are research tools?
- "Targets" and "Tools" for scientific discovery
- Wide variety of resources: labs, receptors, animal models, libraries, computer software and databases
- Broad access & availability needed
- Patented or unpatented
- Examples of Research Tools
  - O2 dopamine receptor: screening
  - Immunized liver cells: disease model
  - ERK mice: screening
  - Basement membranes: reagent sales
  - C protein antibodies: reagent sales

1998 NIH Director's Working Group
Recommendations for NIH
- Promote free dissemination of research tools without legal arrangements
- Further use of IRBMTAs
- Review and strengthen current policies
- Establish "research tools forum"
- Develop guidelines for extramural MTAs and licensing
New Guidelines For Recipients of NIH Grants & Contracts

- Guidelines published in Federal Register, December 23, 1999, [84 FR72090]
- Principles for:
  - ensuring academic freedom and publication
  - publication delays (<60 days) unacceptable
  - minimizing administrative impediments
  - use of Unit I+C, simple inter-agreement
  - Implementing Bayh-Dole Act
  - research tools recognized to fulfill Bayh-Dole requirements
  - disseminating research resources
  - avoid restrictions on new tool distribution

Bayh-Dole Requirements

Compliance Roles for Inventive Organization and the NIH

Inventor — Grantee Organization

Invention Disclosure

Research Tradestone

ROYALTIES

PATENT

LICENSE

LICENSE

LICENSE

Inventor

Grantee Organization

Inventor Disclosure

Time Frame

Research Transfer

Royalties

License

Publication

Patent

Invention

License

Product

http://nedison.gov

- Secure, Interactive Web-Based System for Bayh-Dole Policy and Reporting Compliance
- Didactic Content to Inform Inventors & grantee/contractor organizations
- If CTEQ Act
- Invention Policy Issues
- Invention Reporting Procedures/Forms
- Submission of Invention Report Records to any of 21 participating Federal Agencies
- NSF, NIH, NIAID, NIH, NIDCD, NIDDK, NCMRR, NLM, AHA, USDA, FDA, EPA, USAF, DOE, DOD, NASA, NAVY, ARMY, and VA
- Submission via browser or computer-to-computer datalstream
- Used by >400 grantee/contractor organizations
Questions?

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Edison Help Desk
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Extramural Intellectual Property

Resources

- 37 CFR 401
- Extramural Invention Reporting Compliance Responsibilities – Electronic (iEdison) and Paper Mechanisms
- Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research (Federal Register)
- Invention Reporting to the NIH: 20 Questions
37 CFR 401

37 CFR 401 Menu

- Sec. 401.1 Scope.
- Sec. 401.2 Definitions.
- Sec. 401.3 Use of the standard clauses at Sec. 401.14.
- Sec. 401.4 Contractor appeals of exceptions.
- Sec. 401.5 Modification and tailoring of clauses.
- Sec. 401.6 Exercise of march-in rights.
- Sec. 401.7 Small business preference.
- Sec. 401.8 Reporting on utilization of subject inventions.
- Sec. 401.9 Retention of rights by contractor employee inventor.
- Sec. 401.10 Government assignment to contractor of rights in invention of government Employee.
- Sec. 401.11 Appeals.
- Sec. 401.12 Licensing of background patent rights to third parties.
- Sec. 401.13 Administration of patent rights clauses.
- Sec. 401.14 Standard patent rights clauses.
- Sec. 401.15 Deferred determinations.
- Sec. 401.16 Electronic filing.

Sec. 401.1 Scope.

(a) Traditionally, there have been no conditions imposed by the government on research performers while using private facilities which would preclude them from accepting research funding from other sources to expand, to aid in completing or to conduct separate investigations closely related to research activities sponsored by the government. Notwithstanding the right of research organizations to accept supplemental funding from other sources for the purpose of expediting or more comprehensively accomplishing the research objectives of the government sponsored project it is clear that the ownership provisions of these regulations would remain applicable in any invention "conceived or first actually reduced to practice in performance" of the project. Separate accounting for the two funds used to support the project in this case is not a determining factor.

(1) To the extent that a non-government sponsor established a project which, although closely related, falls outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities, inventions made in performance of the non-government sponsored project would not be subject to the conditions of these regulations. An example of such related but separate projects would be a government sponsored project having research objectives to expand scientific understanding in a field and a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology. The time relationship in conducting the two projects and the use of new fundamental knowledge from one in the performance of the other are not important.
determinants since most inventions rest on a knowledge base built up by numerous independent research efforts extending over many years. Should such an invention be claimed by the performing organization to be the product of non-government sponsored research and be challenged by the sponsoring agency as being reportable to the government as a "subject invention", the challenge is appealable as described in Sec. 401.11(d).

(2) An invention which is made outside of the research activities of a government-funded project is not viewed as a "subject invention" since it cannot be shown to have been "conceived or first actually reduced to practice" in performance of the project. An obvious example of this is a situation where an instrument purchased with government funds is later used, without interference with or cost to the government-funded project, in making an invention all expenses of which involve only non-government funds.

(b) This part implements 35 U.S.C. 202 through 204 and is applicable to all Federal agencies. It applies to all funding agreements with small business firms and nonprofit organizations executed after the effective date of this part, except for a funding agreement made primarily for educational purposes. Certain sections also provide guidance for the administration of funding agreements which predate the effective date of this part. In accordance with 35 U.S.C. 212, no fellowship, scholarship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

(c) The March-in and Appeals procedure in Secs. 401.8 and 401.11 shall apply to any march-in or appeal proceeding under a funding agreement subject to Chapter 18 of Title 35, U.S.C., initiated after the effective date of this part even if the funding agreement was executed prior to that date.

(d) At the request of the contractor, a funding agreement for the operation of a government-owned facility which is in effect on the effective date of this part shall be promptly amended to include the provisions required by Secs. 401.3(a) unless the agency determines that one of the exceptions at 35 U.S.C. 202(a)(v) through (vi) Sec. 401.3(a)(v) through (vi) of this part is applicable and will be applied. If the exception at Sec. 401.3(a)(v) is determined to be applicable, the funding agreement will be promptly amended to include the provisions required by Sec. 401.3(c).

(e) This regulation supersedes OMB Circular A-124 and shall take precedence over any regulations dealing with ownership of inventions made by small businesses and nonprofit organizations which are inconsistent with it. This regulation will be followed by all agencies pending amendment of agency regulations to conform to this part and amended Chapter 18 of Title 35. Only deviations requested by a contractor and not inconsistent with Chapter 18 of Title 35, United States Code, may be made without approval of the Secretary. Modifications or tailoring of clauses as authorized by Sec. 401.6 or Sec. 401.3, when alternative provisions are used under Sec. 401.3(a)(v) through (vi), are not considered deviations requiring the Secretary's approval. Three copies of proposed and final agency regulations supplementing this part shall be submitted to the Secretary at the office set out in Sec. 401.16 for approval for consistency with this part before they are submitted to the Office of Management and Budget (OMB) for review under Executive Order 12291 or, if no submission is required to be made to OMB, before their submission to the Federal Register for publication.

(f) In the event an agency has outstanding prime funding agreements that do not contain patent flow-down provisions consistent with this part or earlier Office of Federal Procurement Policy regulations (OMB Circular A-124 or OMB Bulletin 91-22), the agency shall take appropriate action to ensure that small business firms or nonprofit organizations that are subcontractors under any such agreements and that received its subcontractors after July 1,
1981, receive rights in their subject inventions that are consistent with Chapter 18 and this part.

(g) This part is not intended to apply to arrangements under which nonprofit organizations, small business firms, or others are allowed to use government-owned research facilities and normal technical assistance provided to users of those facilities, whether on a reimbursable or nonreimbursable basis. This part is also not intended to apply to arrangements under which sponsors reimburse the government or facility contractor for the contractor employee's time in performing work for the sponsor. Such arrangements are not considered "funding agreements" as defined at 35 U.S.C. 201(b) and Sec. 401.2(a) of this part.

Sec. 401.2 Definitions.

As used in this part--

(a) The term funding agreement means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal government. This term also includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as defined in the first sentence of this paragraph.

(b) The term contractor means any person, small business firm or nonprofit organization which is a party to a funding agreement.

(c) The term invention means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant, which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(d) The term subject invention means any invention of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(e) The term practical application means to manufacture in the case of a composition of product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

(f) The term made when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(g) The term small business firm means a small business concern as defined at section 2 of Pub. L. 85-638 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this part, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.5 will be used.

(h) The term nonprofit organization means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.
(i) The term Chapter 18 means Chapter 18 of Title 35 of the United States Code.

(ii) The term Secretary means the Assistant Secretary of Commerce for Technology Policy.

(k) The term electronically filed means any submission of information transmitted by an electronic or optical-electronic system.

(l) The term electronic or optical-electronic system means a software-based system approved by the agency for the transmission of information.

(m) The term patent application or "application for patent" includes a provisional or nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(2) and (a)(3), respectively, or an application for patent in a foreign country or in an international patent office.

(n) The term initial patent application means a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3).

Sec. 401.3 Use of the standard clauses at Sec. 401.14.

(a) Each funding agreement awarded to a small business firm or nonprofit organization (except those subject to 35 U.S.C. 212) shall contain the clause found in Sec. 401.14(a) with such modifications and tailoring as authorized or required elsewhere in this part. However, a funding agreement may contain alternative provisions --

(1) When the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government; or

(2) In exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of Chapter 18 of Title 35 of the United States Code; or

(3) When it is determined by a government authority which is authorized by statute or executive order to conduct foreign intelligence or counterintelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security to such activities; or

(4) When the funding agreement includes the operation of the government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department’s nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor’s right to elect title to a subject invention are limited to inventions occurring under the above two programs.

(b) When an agency exercises the exceptions at Sec. 401.3(a)(2) or (3), it shall use the standard clause at Sec. 401.14(a) with only such modifications as are necessary to address the exceptional circumstances or concerns which led to the use of the exception. For example, if the justification relates to a particular field of use or market, the clause might be modified along lines similar to those described in Sec. 401.14(b). In any event, the clause should provide the contractor with an opportunity to receive greater rights in accordance with the procedures at Sec. 401.15. When an agency justifies and exercises the exception at Sec. 401.3(a)(2) and uses an alternative provision in the funding agreement on the basis of national security, the provision shall provide the contractor with the right to elect ownership to any invention made under such funding agreement as provided by the Standard Patent Rights Clause found at Sec. 401.14(a) if the invention is not classified by the agency within six months of the date it is reported to the agency, or within the same time period the Department of Energy does not, as authorized by regulation, law or Executive order or implementing
regulations thereto, prohibit unauthorized dissemination of the invention. Contracts in support of DOE's naval nuclear propulsion program are exempted from this paragraph.

(c) When the Department of Energy exercises the exception at Sec. 401.3(a)(4), it shall use the clause prescribed at Sec. 401.14(b) or substitute thereto with such modification and tailoring as authorized or required elsewhere in this part.

(d) When a funding agreement involves a series of separate task orders, an agency may apply the exception at Sec. 401.3(a)(2) or (3) to individual task orders, and it may structure the contract so that modified patent rights provisions will apply to the task order even though the clauses at either Sec. 401.14(a) or (b) are applicable to the remainder of the work. Agencies are authorized to negotiate such modified provisions with respect to task orders added to a funding agreement after its initial award.

(e) Before utilizing any of the exceptions in Sec. 401.3(a) of this section, the agency shall prepare a written determination, including a statement of facts supporting the determination, that the conditions identified in the exception exist. A separate statement of facts shall be prepared for each exceptional circumstance determination, except that in appropriate cases a single determination may apply to both a funding agreement and any subcontracts issued under it or to any funding agreement to which such an exception is applicable. In cases where Sec. 401.3(a)(2) is used, the determination shall also include an analysis justifying the determination. This analysis should address with specificity how the alternate provisions will better achieve the objectives set forth in 35 U.S.C. 200. A copy of each determination, statement of facts, and, if applicable, analysis shall be promptly provided to the contractor or prospective contractor along with a notification to the contractor or prospective contractor of its rights to appeal the determination of the exception under 35 U.S.C. 202(b)(4) and Sec. 401.4 of this part.

(f) Except for determinations under Sec. 401.3(a)(3), the agency shall also provide copies of each determination, statement of fact, and analysis to the Secretary. These shall be sent within 30 days after the award of the funding agreement to which they pertain. Copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration if the funding agreement is with a small business firm. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy and recommend corrective actions.

(g) To assist the Comptroller General of the United States to accomplish his or her responsibilities under 35 U.S.C. 202, each Federal agency that enters into any funding agreements with nonprofit organizations or small business firms shall accumulate and, at the request of the Comptroller General, provide the Comptroller General or his or her duly authorized representative the total number of prime agreements entered into with small business firms or nonprofit organizations that contain the patent rights clause in this part or under OMB Circular A-124 for each fiscal year beginning with October 1, 1982.

(h) To qualify for the standard clause, a prospective contractor may be required by an agency to certify that it is either a small business firm or a nonprofit organization. If the agency has reason to question the status of the prospective contractor as a small business firm, it may file a protest in accordance with 13 CFR 121.9. If questions involving nonprofit status, it may require the prospective contractor to furnish evidence to establish its status as a nonprofit organization.

Sec. 401.4 Contractor appeals of exceptions.

(a) In accordance with 35 U.S.C. 202(b)(4) a contractor has the right to an administrative
review of a determination to use one of the exceptions at Sec. 401.3(a)(1) through (4) if the contractor believes that a determination is either contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency. Paragraph (b) of this section specifies the procedures to be followed by contractors and agencies in such cases. The assertion of such a claim by the contractor shall not be used as a basis for withholding or delaying the award of a funding agreement or for suspending performance under an award. Pending final resolution of the claim the contract may be issued with the patent rights provision proposed by the agency; however, should the final decision be in favor of the contractor, the funding agreement will be amended accordingly and the amendment made retroactive to the effective date of the funding agreement.

(b)

(1) A contractor may appeal a determination by providing written notice to the agency within 30 working days from the time it receives a copy of the agency’s determination, or within such longer time as an agency may specify in its regulations. The contractor’s notice should specifically identify the basis for the appeal.

(2) The appeal shall be decided by the head of the agency or by his/her designee who is at a level above the person who made the determination. If the notice raises a genuine dispute over the material facts, the head of the agency or the designee shall undertake, or refer the matter to, fact-finding.

(3) Fact-finding shall be conducted in accordance with procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may rely upon. A transcripted record shall be made and shall be available at cost to the contractor upon request. The requirements for a transcribed record may be waived by mutual agreement of the contractor and the agency.

(4) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended decision. A copy of the findings of fact and recommended decision shall be sent to the contractor by registered or certified mail.

(5) Fact-finding should be completed within 45 working days from the date the agency receives the contractor’s written notice.

(6) When fact-finding has been conducted, the head of the agency or designee shall base his or her decision on the facts found, together with any argument submitted by the contractor, agency officials or any other information in the administrative record. In cases referred for fact-finding, the agency head or the designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. The agency head or the designee may hear oral arguments after fact-finding provided that the contractor or contractor’s attorney or representative is present and given an opportunity to make arguments and rebuttal. The decision of the agency head or the designee shall be in writing and, if it is unfavorable to the contractor shall include an explanation of the basis of the decision. The decision of the agency or designee shall be made within 30 working days after fact-finding or, if there was no fact-finding, within 45 working days from the date the agency received the contractor’s written notice. A contractor adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Claims Court, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand, or modify as appropriate, the determination.
of the Federal agency.

Sec. 401.5 Modification and tailoring of clauses.

(a) Agencies should complete the blank in paragraph (q)(2) of the clauses at Sec. 401.14 in accordance with their own or applicable government-wide regulations such as the Federal Acquisition Regulation. In grants and cooperative agreements (and in contracts, if not inconsistent with the Federal Acquisition Regulation) agencies wishing to apply the same clause to all subcontractors as is applied to the contractor may delete paragraph (q)(2) of the clause and delete the words “to be performed by a small business firm or domestic nonprofit organization” from paragraph (q)(1). Also, if the funding agreement is a grant or cooperative agreement, paragraph (q)(3) may be deleted. When either paragraph (q)(2) or paragraphs (q) (2) and (3) are deleted, the remaining paragraph(s) or paragraphs should be renumbered appropriately.

(b) Agencies should complete paragraph (i), “Communications,” at the end of the clauses at Sec. 401.14 by designating a central point of contact for communications on matters relating to the clause. Additional instructions on communications may also be included in paragraph (l).

(c) Agencies may replace the italicized words and phrases in the clauses at Sec. 401.14 with those appropriate to the particular funding agreement. For example, “contractor” could be replaced by “grant,” “contractor” by “grantee,” and “contracting officer” by “grants officer.” Depending on its use, “Federal agency” can be replaced either by the identification of the agency or by the specification of the particular office or official within the agency.

(d) When the agency head or duly authorized designee determines at the time of contracting with a small business firm or nonprofit organization that it would be in the national interest to acquire the right to sublicense foreign governments or international organizations pursuant to any existing treaty or international agreement, a sentence may be added at the end of paragraph (b) of the clause at Sec. 401.14 as follows:

This license will include the right of the government to sublicense foreign governments, their nationals, and international organizations, pursuant to the following treaties or international agreements: .........................

The blank above should be completed with the names of applicable existing treaties or international agreements, agreements of cooperation, memoranda of understanding, or similar arrangements, including military agreements relating to weapons development and production. The above language is not intended to apply to treaties or other agreements that are in effect on the date of the award but which are not listed. Alternatively, agencies may use substantially similar language relating the government's rights to specific treaties or other agreements identified elsewhere in the funding agreement. The language may also be modified to make clear that the rights granted to the foreign government, and its nationals or an international organization may be for additional rights beyond a license or sublicense if so required by the applicable treaty or international agreement. For example, in some exclusive licensees or even the assignment of title in the foreign country involved might be required. Agencies may also modify the language above to provide for the direct licensing by the contractor of the foreign government or international organization.

(e) If the funding agreement involves performance over an extended period of time, such as the typical funding agreement for the operation of a government-owned facility, the following language may also be added:

The agency reserves the right to unilaterally amend this funding agreement to identify specific treaties or international agreements entered into or to be entered into by the government after the effective date of this funding agreement and
effectuate those license or other rights which are necessary for the government to meet its obligations to foreign governments, their nationals and international organizations under such treaties or international agreements with respect to subject inventions made after the date of the amendment.

(f) Agencies may add additional subparagraphs to paragraph (f) of the clauses at Sec. 401.14 to require the contractor to do one or more of the following:

(1) Provide a report prior to the close-out of a funding agreement listing all subject inventions or stating that there were none.

(2) Provide, upon request, the filing date, patent application number and title; a copy of the patent application; and patent number and issue date for any subject invention in any country in which the contractor has applied for a patent.

(3) Provide periodic (but no more frequently than annual) listings of all subject inventions which were disclosed to the agency during the period covered by the report.

(g) If the contract is with a nonprofit organization and is for the operation of a government-owned, contractor-operated facility, the following will be substituted for paragraph (g)(3) of the clause at Sec. 401.14(a):

(3) After payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, the balance of any royalty or income earned and retained by the contractor during any fiscal year on subject inventions under this or any successor contract containing the same requirement, up to any amount equal to five percent of the budget of the facility for that fiscal year, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility. If the balance exceeds five percent, 75 percent of the excess above five percent shall be paid by the contractor to the Treasury of the United States and the remaining 25 percent shall be used by the contractor only for the same purposes as described above. To the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

(h) If the contract is for the operation of a government-owned facility, agencies may add the following at the end of paragraph (f) of the clause at Sec. 401.14(a):

(5) The contractor shall establish and maintain active and effective procedures to ensure that subject inventions are promptly identified and timely disclosed and shall submit a description of the procedures to the contracting officer so that the contracting officer may evaluate and determine their effectiveness.

Sec. 401.6 Exercise of march-in rights.

(a) The following procedures shall govern the exercise of the march-in rights of the agencies set forth in 35 U.S.C. 203 and paragraph (i) of the clause at Sec. 401.14.

(b) Whenever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor in writing of the information and request informal written or oral comments from the contractor as well as information relevant to the matter. In the absence of any comments from the contractor within 30 days, the agency may, at its discretion, proceed with the procedures below. If a comment is received within 30 days, or later if the agency has not initiated the procedures below, then the
agency shall, within 60 days after it receives the comment, either initiate the procedures below or notify the contractor, in writing, that it will not pursue march-in rights on the basis of the available information.

(c) A march-in proceeding shall be initiated by the issuance of a written notice by the agency to the contractor and its assignee or exclusive licensee, as applicable and if known to the agency, stating that the agency is considering the exercise of march-in rights. The notice shall state the reasons for the proposed march-in in terms sufficient to put the contractor on notice of the facts upon which the action would be based and shall specify the field or fields of use in which the agency is considering requiring licensing. The notice shall advise the contractor (assignee or exclusive licensee) of its rights, as set forth in this section and in any supplemental agency regulations. The determination to exercise march-in rights shall be made by the head of the agency or his or her designee.

(d) Within 30 days after the receipt of the written notice of march-in, the contractor (assignee or exclusive licensee) may submit in person, in writing, or through a representative, information or argument in opposition to the proposed march-in, including any additional specific information which raises a genuine dispute over the material facts upon which the march-in is based. If the information presented raises a genuine dispute over the material facts, the head of the agency or designee shall undertake or refer the matter to another official for fact-finding.

(e) Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency. Any portion of the march-in proceeding, involving a fact-finding hearing that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government except where such release is authorized by the contractor (assignee or licensee).

(f) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended determination. A copy of the findings of fact shall be sent to the contractor (assignee or exclusive licensee) by registered or certified mail. The contractor (assignee or exclusive licensee) and agency representatives will be given 30 days to submit written arguments to the head of the agency or designee; and, upon request by the contractor oral arguments will be held before the agency head or designee that will make the final determination.

(g) In cases in which fact-finding has been conducted, the head of the agency or designee shall base his or her determination on the facts found, together with any other information and written or oral arguments submitted by the contractor (assignee or exclusive licensee) and agency representatives, and any other information in the administrative record. The consistency of the exercise of march-in rights with the policy and objectives of 35 U.S.C. 200 shall also be considered. In cases referred for fact-finding, the head of the agency or designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. Written notice of the determination whether march-in rights will be exercised shall be made by the head of the agency or designee and sent to the contractor (assignee of exclusive licensee) by certified or registered mail within 90 days after the completion of fact-finding or 90 days after oral
arguments, whichever is later, or the proceedings will be deemed to have been terminated and thereafter no march-in based on the facts and reasons upon which the proceeding was initiated may be exercised.

(h) An agency may, at any time, terminate a march-in proceeding if it is satisfied that it does not want to exercise march-in rights. (1) The procedures of this part shall also apply to the exercise of march-in rights against inventors receiving title to subject inventions under 35 U.S.C. 202(d) and, for that purpose, the term "contractor" as used in this section shall be deemed to include the inventor.

(j) An agency determination unfavorable to the contractor (assignee or exclusive licensee) shall be held in abeyance pending the exhaustion of appeals or petitions filed under 35 U.S.C. 203(2).

(k) For purposes of this section the term exclusive licensee includes a partially exclusive licensee.

(l) Agencies are authorized to issue supplemental procedures not inconsistent with this part for the conduct of march-in proceedings.

Sec. 401.7 Small business preference.

(a) Paragraph (b)(4) of the clauses at Sec. 401.14 implements the small business preference requirement of 35 U.S.C. 202(c)(7)(D). Contractors are expected to use efforts that are reasonable under the circumstances to attract small business licensees. They are also expected to give small business firms that meet the standard outlined in the clause a preference over other applicants for licenses. What constitutes reasonable efforts to attract small business licensees will vary with the circumstances and the nature, duration, and expense of efforts needed to bring the invention to the market. Paragraph (b)(4) is not intended, for example, to prevent nonprofit organizations from providing larger firms with a right of first refusal or other options in inventions that relate to research being supported under long-term or other arrangements with larger companies. Under such circumstances it would not be reasonable to seek and give a preference to small business licensees.

(b) Small business firms that believe a nonprofit organization is not meeting its obligations under the clause may report their concerns to the Secretary. To the extent deemed appropriate, the Secretary will undertake informal investigation of the concern, and, if appropriate, enter into discussions or negotiations with the nonprofit organization to the end of improving its efforts in meeting its obligations under the clause. However, in no event will the Secretary intervene in ongoing negotiations or contractor decisions concerning the licensing of a specific subject invention. All the above investigations, discussions, and negotiations of the Secretary will be in coordination with other interested agencies, including the Small Business Administration; and in the case of a contract for the operation of a government-owned, contractor operated research or production facility, the Secretary will coordinate with the agency responsible for the facility prior to any discussions or negotiations with the contractor.

Sec. 401.8 Reporting on utilization of subject inventions.

(a) Paragraph (b) of the clauses at 401.14 and its counterpart in the clause at Attachment A to OMB Circular A-164 provides that agencies have the right to require contractors to report on the contractor or utilization of inventions. Agencies exercising this right should accept such information, to the extent feasible, in the format that the contractor normally prepares it for its own internal purposes. The prescription of forms should be avoided. However, any forms or standard questionnaires that are adopted by an agency for this purpose must comply with the requirements of the Paperwork Reduction Act. Copies shall be sent to the Secretary.
(b) In accordance with 35 U.S.C. 202 (c)(5) and the terms of the clauses at 401.14, agencies shall not disclose such information to persons outside the government. Contractors will continue to provide confidential markings to help prevent inadvertent release outside the agency.

Sec. 401.9 Retention of rights by contractor employee inventor.

Agencies which allow an employee/inventor of the contractor to retain rights to a subject invention made under a funding agreement with a small business firm or nonprofit organization contractor, as authorized by 35 U.S.C. 202(d), will impose upon the inventor at least those conditions that would apply to a small business firm contractor under paragraphs (d)(1) and (3); (f)(4); (h)(1); (i); and (l) of the clause at Sec. 401.14(a).

Sec. 401.10 Government assignment to contractor of rights in invention of government Employee.

In any case when a Federal employee is a co-inventor of any invention made under a funding agreement with a small business firm or nonprofit organization and the Federal agency employing such co-inventor transfers or reassigns the right it has acquired in the subject invention from its employee to the contractor as authorized by 35 U.S.C. 202(e), the assignment will be made subject to the same conditions as apply to the contractor under the patent rights clause of its funding agreement. Agencies may add additional conditions as long as they are consistent with 35 U.S.C. 201-206.

Sec. 401.11 Appeals.

(a) As used in this section, the term standard clause means the clause at Sec. 401.14 of this part and the clauses previously prescribed by either OMB Circular A-124 or OMB Bulletin 81-22.

(b) The agency official initially authorized to take any of the following actions shall provide the contractor with a written statement of the basis for his or her action at the time the action is taken, including any relevant facts that were relied upon in taking the action.

(1) A refusal to grant an extension under paragraph (c)(4) of the standard clauses.

(2) A request for a conveyance of title under paragraph (d) of the standard clauses.

(3) A refusal to grant a waiver under paragraph (i) of the standard clauses.

(4) A refusal to approve an assignment under paragraph (k)(1) of the standard clauses.

(5) A refusal to grant an extension of the exclusive license period under paragraph (k)(2) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22.

(c) Each agency shall establish and publish procedures under which any of the agency actions listed in paragraph (b) of this section may be appealed to the head of the agency or designee. Review at this level shall consider both the factual and legal basis for the actions and its consistency with the policy and objectives of 35 U.S.C. 200-206.

(d) Appeals procedures established under paragraph (c) of this section shall include administrative due process procedures and standards for fact-finding at least comparable to those set forth in Sec. 401.6 (e) through (g) whenever there is a dispute as to the factual basis for an agency request for a conveyance of title under paragraph (d) of the standard clause, including any dispute as to whether or not an invention is a subject invention.
(e) To the extent that any of the actions described in paragraph (b) of this section are subject to appeal under the Contract Disputes Act, the procedures under the Act will satisfy the requirements of paragraphs (c) and (d) of this section.

Sec. 401.12 Licensing of background patent rights to third parties.

(a) A funding agreement with a small business firm or a domestic nonprofit organization will not contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the agency head and a written justification has been signed by the agency head. Any such provision will clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The agency head may not delegate the authority to approve such provisions or to sign the justification required for such provisions.

(b) A Federal agency will not require the licensing of third parties under any such provision unless the agency head determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve practical application of the subject invention or work object. Any such determination will be on the record after an opportunity for an agency hearing. The contractor shall be given prompt notification of the determination by certified or registered mail. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

Sec. 401.13 Administration of patent rights clauses.

(a) In the event a subject invention is made under funding agreements of more than one agency, at the request of the contractor or on their own initiative the agencies shall designate one agency as responsible for administration of the rights of the government in the invention.

(b) Agencies shall promptly grant, unless there is a significant reason not to, a request by a nonprofit organization under paragraph (k)(2) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22 inasmuch as 35 U.S.C. 202(c)(7) has since been amended to eliminate the limitation on the duration of exclusive licenses. Similarly, unless there is a significant reason not to, agencies shall promptly approve an assignment by a nonprofit organization to an organization which has as one of its primary functions the management of inventions when a request for approval has been necessitated under paragraph (k)(1) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22 because the patent management organization is engaged in or holds a substantial interest in other organizations engaged in the manufacture or sale of products or the use of processes that might utilize the invention or be in competition with embodiments of the invention. As amended, 35 U.S.C. 202(c)(7) no longer contains this limitation. The policy of this subsection should also be followed in connection with similar proposals that may be required under Institutional Patent Agreements, other patent rights clauses, or waivers that predate Chapter 18 of Title 35, United States Code.

(c) The President's Patent Policy Memorandum of February 18, 1983, states that agencies should protect the confidentiality of invention disclosure, patent applications, and utilization reports required in performance or in consequence of awards to the extent permitted by 35 U.S.C. 205 or other applicable laws. The following requirements should be followed for funding agreements covered by and predating this part 401.

(1) To the extent authorized by 35 U.S.C. 205, agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention for a reasonable time in order for a patent application to be
filed. With respect to subject inventions of contractors that are small business firms or nonprofit organizations, a reasonable time shall be the time during which an initial patent application may be filed under paragraph (c) of the standard clause found at Sec. 401.14(a) or such other clause may be used in the funding agreement. However, an agency may disclose such subject inventions under the FOIA, at its discretion, after a contractor has elected not to retain title or after the time in which the contractor is required to make an election if the contractor has not made an election within that time. Similarly, an agency may honor a FOIA request at its discretion if it finds that the same information has previously been published by the inventor, contractor, or otherwise. If the agency plans to file a suit when the contractor has not elected title, it may, of course, continue to avail itself of the authority of 35 U.S.C. 205.

(2) In accordance with 35 U.S.C. 205, agencies shall not disclose or release for a period of 18 months from the filing date of the patent application to third parties pursuant to requests under the Freedom of Information Act, or otherwise, copies of any document which the agency obtained under this clause which is part of an application for patent with the U.S. Patent and Trademark Office or any foreign patent office filed by the contractor (or its assignee, licensees, or employees) on a subject invention to which the contractor has elected to retain title. This prohibition does not extend to disclosure to other government agencies or contractors of government agencies under an obligation to maintain such information in confidence.

(3) A number of agencies have policies to encourage public dissemination of the results of work supported by the agency through publication in government or other publications of technical reports of contractors or others. In recognition of the fact that such publication, if it included descriptions of a subject invention could create bars to obtaining patent protection, it is the policy of the executive branch that agencies will not include in such publication programs copies of disclosures of inventions submitted by small business firms or nonprofit organizations, pursuant to paragraph (c) of the standard clause found at Sec. 401.14(a), except that under the same circumstances under which agencies are authorized to release such information pursuant to FOIA requests under paragraph (c)(1) of this section, agencies may publish such disclosures.

(4) Nothing in this paragraph is intended to preclude agencies from including in the publication activities described in the first sentence of paragraph (c)(3), the publication of materials describing a subject invention to the extent such materials were provided as part of a technical report or other submission of the contractor which were submitted independently of the requirements of the patent rights provisions of the contract. However, if a small business firm or nonprofit organization notifies the agency that a particular report or other submission contains a disclosure of a subject invention to which it has elected title or may elect title, the agency shall use reasonable efforts to restrict its publication of the material for six months from date of its receipt of the report or submission or, if earlier, until the contractor has filed an initial patent application. Agencies, of course, retain the discretion to delay publication for additional periods of time.

(5) Nothing in this paragraph is intended to limit the authority of agencies provided in 35 U.S.C. 205 in circumstances not specifically described in this paragraph.

Sec. 401.14 Standard patent rights clauses. (a) The following is the standards patent rights clause to be used as specified in Sec. 401.13(a).

Patent Rights (Small Business Firms and Nonprofit Organizations)

(a) Definitions
(1) **Invention** means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(2) **Subject Invention** means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(3) **Practical Application** means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

(4) **Made when used in relation to any invention** means the conception or first actual reduction to practice of such invention.

(5) **Small business Firm** means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

(6) **Nonprofit Organization** means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (25 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(b) **Allocation of Principal Rights**

The Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 202.

With respect to any subject invention in which the Contractor retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(c) **Invention Disclosure, Election of Title and Filing of Patent Application by Contractor**

(1) The contractor will disclose each subject invention to the Federal Agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a
manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the Contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor.

(2) The Contractor will elect in writing whether or not to retain title to any such invention by notifying the Federal agency within two years of disclosure to the Federal agency. However, in any case where publication, on sale or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The contractor will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after publication, on sale, or public use. The contractor will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the agency, be granted.

(d) Conditions When the Government May Obtain Title

The contractor will convey to the Federal agency, upon written request, title to any subject invention as follows:

(1) If the contractor fails to disclose or elect title to the subject invention within the times specified in (g), above, or elects not to retain title; provided that the agency may only request title within 60 days after learning of the failure of the contractor to disclose or elect within the specified times.

(2) In those countries in which the contractor fails to file patent applications within the times specified in (g) above; provided, however, that if the contractor has filed a patent application in a country after the times specified in (c) above, but prior to its receipt of the written request of the Federal agency, the contractor shall continue to retain title to that country.

(3) In any country in which the contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(e) Minimum Rights to Contractor and Protection of the Contractor Right to File

(1) The contractor will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the contractor fails to disclose the invention within the times specified in (g) above. The contractor's license extends to its domestic subsidiary and affiliates, if any, within the corporate structure of which the contractor is a party and includes the right to grant sublicenses of the same scope to the extent the
contractor was legally obligated to do so at the time the contract was awarded. The license is transferable only with the approval of the Federal agency except when transferred to the successor of that party of the contractor's business to which the invention pertains.

(2) The contractor's domestic license may be revoked or modified by the funding Federal agency to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions at 37 CFR part 404 and agency licensing regulations (if any). This license will not be revoked in that field of use or the geographical area in which the contractor has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the funding Federal agency to the extent the contractor, its licensees, or the domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the funding Federal agency will furnish the contractor a written notice of its intention to revoke or modify the license, and the contractor will be allowed thirty days (or such other time as may be authorized by the funding Federal agency for good cause shown by the contractor) after the notice to show cause why the license should not be revoked or modified. The contractor has the right to appeal, in accordance with applicable regulations in 37 CFR part 404 and agency regulations (if any) concerning the licensing of Government-owned inventions, any decision concerning the revocation or modification of the license.

(f) Contractor Action to Protect the Government's Interest

(1) The contractor agrees to execute or to have executed and promptly deliver to the Federal agency all instruments necessary to

(i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the contractor elects to retain title, and

(ii) convey title to the Federal agency when requested under paragraph (d) above and to enable the government to obtain patent protection throughout the world in that subject invention.

(2) The contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the contractor each subject invention made under contract in order that the contractor can comply with the disclosure provisions of paragraph (c), above, and to execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by (c)(1), above. The contractor shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The contractor will notify the Federal agency of any decisions not to
continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of the response period required by the relevant patent office.

(4) The contractor agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention."

(5) The contractor agrees to provide a final invention statement and certification prior to the close-out listing all subject inventions or stating that there were none.

(6) The contractor will provide the patent application filing date, serial number and title, copy of the page of the patent application with the statement identified in (4) above (and upon request, a copy of the patent application); and patent number and is due date for any subject invention in any country in which the grantee institution has applied for patent.

(g) Subcontracts

(1) The contractor will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental development or research work to be performed by a small business firm or domestic nonprofit organization. The subcontractor will retain all rights provided for the contractor in this clause, and the contractor will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(2) The contractor will include in all other subcontracts, regardless of tier, for experimental developmental or research work the patent rights clause required by (c)(1) of section 25B, and/or the Federal Acquisition Regulation (FAR).

(3) In the case of subcontracts, at any tier, when the prime award with the Federal agency was a contract (but not a grant or cooperative agreement), the agency, subcontractor, and the contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Federal agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (i) of this clause.

(h) Reporting on Utilization of Subject Inventions

The Contractor agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify. The contractor also agrees to provide additional reports as may be requested by the agency in connection with any matching-proceeding undertaken by the agency in accordance with paragraph (i) of this clause. As required by 35 U.S.C. 202(c)(5), the agency agrees it will not disclose such information to persons outside the government.
without permission of the contractor.

(i) Preference for United States Industry

Notwithstanding any other provision of this clause, the contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency upon a showing by the contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(j) March-in Rights

The contractor agrees that with respect to any subject invention in which it has acquired title, the Federal agency has the right in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such a request the Federal agency has the right to grant such a license itself if the Federal agency determines that:

1. Such action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.
2. Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee or their licensees;
3. Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee or licensees; or
4. Such action is necessary because the agreement required by paragraph (i) of this clause has not been obtained or waived or because a license of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(k) Special Provisions for Contracts with Nonprofit Organizations

If the contractor is a nonprofit organization, it agrees that:

1. Rights to a subject invention in the United States may not be assigned without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions, provided that such assignee will be subject to the same provisions as the contractor;
2. The contractor will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the agency deems it appropriate) when the subject invention is assigned in accordance with 35
U.S.C. 202(e) and 37 CFR 401.10;

(3) The balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, will be utilized for the support of scientific research or education; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject invention that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the contractor determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the contractor agrees that the Secretary may review the contractor's licensing program and decisions regarding small business applicants, and the contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary when the Secretary's review discloses that the contractor could take reasonable steps to implement more effectively the requirements of this paragraph (d)(4).

(l) Communication

All NIH-related disclosures, elections, confirmatory licenses to the government, face page of a patent application, waivers, and other routine communications should be sent to:

National Institutes of Health
Chief, Extramural Inventions and Technology Resources Branch
6705 Rockledge Drive, Room 1140A
MSC 7980
Bethesda, MD 20892-7980
(301) 435-1986
Fax: (301) 480-0272

For other awarding components, please follow their instructions. In most cases, invention information and communications should be sent to the Grants Management Officer.

The NIH electronic Edison extramural invention reporting system can be accessed through the Web (http://era.info.nih.gov/). This electronic reporting system has been designed to facilitate reporting compliance, timeliness, and reduce paperwork. Edison also has an e-mail address (mailto:Edison@od.nih.gov).

Sec. 401.1f Deferred determinations.

(a) This section applies to requests for greater rights in subject inventions made by contractors when deferred determination provisions were included in the funding agreement because one of the exceptions at Sec. 401.3(e) was applied, except that the Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations or this section. A contractor requesting greater rights should include with its request information on its plans and intentions to bring the invention to practical application. Within 90 days after receiving a request and supporting information, or sooner if a statutory bar to patenting is imminent, the agency should seek to make a determination. In any event, if a bar
to patenting is imminent, unless the agency plans to file on its own, it shall authorize the contractor to file a patent application pending a determination by the agency. Such a filing shall normally be at the contractor's own risk and expense. However, if the agency subsequently refuses to allow the contractor to retain title and elects to proceed with the patent application under government ownership, it shall reimburse the contractor for the cost of preparing and filing the patent application.

(b) If the circumstances of concern which originally led the agency to invoke an exception under Sec. 401.3(a) are not applicable to the actual subject invention or are no longer valid because of subsequent events, the agency should allow the contractor to retain title to the invention on the same conditions as would have applied if the standard clause at Sec. 401.14(a) had been used originally, unless it has been licensed.

(c) If paragraph (b) is not applicable the agency shall make its determination based on an assessment whether its own plans regarding the invention will better promote the policies and objectives of 35 U.S.C. 200 than will contractor ownership of the invention. Moreover, if the agency is concerned only about specific uses or applications of the invention, it shall consider leaving title in the contractor with additional conditions imposed upon the contractor's use of the invention for such applications or with expanded government license rights in such applications.

(d) A determination not to allow the contractor to retain title to a subject invention or to restrict or condition its title with conditions differing from those in the clause at Sec. 401.14(a), unless made by the head of the agency, shall be appealable by the contractor to an agency official at a level above the person who made the determination. This appeal shall be subject to the procedures applicable to appeals under Sec. 401.11 of this part.

Sec. 401.16 Electronic filing.

Unless otherwise requested or directed by the agency,

(a) The written report required in (c)(1) of the standard clause in Sec. 401.14(a) may be electronically filed;

(b) The written election required in (c)(2) of the standard clause in Sec. 401.14(a) may be electronically filed; and

(c) The close-out report in (f)(1) and the information identified in (f)(2) and (f)(3) of Sec. 401.5 may be electronically filed.
# Extramural Invention Reporting Compliance Responsibilities

## Electronic (iEdison) and Paper Mechanisms

<table>
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<tr>
<th>Action</th>
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<td>Employee Agreement to Disclose All Inventions: The agreement to be obtained by the grantee/contractor organization is that the employee will abide by the terms of the patent rights clause.</td>
<td>At time of employment – term of employment.</td>
<td>Grantee/contractor organizations must have policies in place regarding ownership of intellectual property, including conflict of interest issues.</td>
<td>401.14(a)(3)</td>
<td>401.14(a)(2) 401.14(d)(1) Submission of the invention report may be done electronically by uploading either a PDF, TIFF, or text file through iEdison. Alternatively the document can be faxed to the lead agency, or submitted through U.S. mail.</td>
</tr>
<tr>
<td>Rights to Inventions on Subcontracts: Subcontractors retain rights to their subject inventions.</td>
<td>Within 2 months of inventor’s initial report to the grantee/contractor organization.</td>
<td>There is no single format for disclosing the invention to the government. The communication should include: the title of the invention, date of any public disclosure, names of all inventors, source(s) of federal funding (i.e. grant or contract number), a written description of the invention in technical detail. The invention disclosure should ideally be signed by the inventor(s) at the very least signed by a grantee/contractor institutional official.</td>
<td>401.14(a)(1) 401.14(a)(2)</td>
<td></td>
</tr>
<tr>
<td>Election of Title to Invention: Grantee/contractor organization must notify the federal agency sponsor</td>
<td>Within 2 years of reporting the invention to the lead federal agency sponsor.</td>
<td></td>
<td>401.14(b) 401.14(c)(2) 401.14(f)(1) Election of title handled electronically using iEdison, otherwise a signed paper document is required.</td>
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[https://s-edison.info.nih.gov/iEdison/timeline.jsp](https://s-edison.info.nih.gov/iEdison/timeline.jsp)
that it will retain ownership of the invention and take steps to commercialize the invention.

Confidentiality License: The grantee/contractor organization must provide a nonexclusive, nontransferable, irrevocable, paid-up license for the government to practice or have the invention practiced on its behalf throughout the world.

Commensurate with report of any initial patent filing, unless the invention is being licensed as an unpatented biological, reagent or research tool.

401.146(1)

Submission of the confidentiality license may be done electronically by uploading either a PDF or TIFF file through Edison. Alternatively, the signed document can be faxed to the lead agency, or submitted through U.S. mail.

See http://edison.gov/Edison/licensing.jsp

Nonelection of Title to Invention: Grantee/contractor organization must notify the federal sponsor that it will not retain ownership of the invention.

Within 2 years of reporting to federal agency sponsor.

Effectively a waiver to the government. After further review the federal agency sponsor may elect title on behalf of the government. Title does not actually vest with the government until the government elects to retain title.

401.146(2)

401.146(4)

Handed electronically through Edison, otherwise a signed hard-copy request is required.

Assignment of Invention Rights to the Inventor: The inventor may request assignment of invention rights. Agencies support requests of this type to vary, in all cases, documentation is required. Within 2 years of reporting to the grantee/contractor organization, waiver rights to the invention and the inventor(s) wishes to retain the invention rights.

At the time the grantee/contractor organization waives not to pursue the invention and the inventor requests right in the invention.

First, the grantee/contractor organization must elect not to retain rights in the invention. Second, the inventor must request the assignment of rights, agree to all terms associated with invention reporting as detailed in 37 CFR 401, and must pursue commercialization of the invention through patent filing or licensing as a research tool. Specific procedures for any agency should be determined prior to initiating the request.

For NIH, see Inventor Certification.

401.146(1)

non-profit

Initial Patent Application: The grantee/contractor organization must inform the government of the initial patent application that relates to any subject invention. The patent application must include a government support clause.

Within 1 year after each event of title, unless there is an extension.

Time frame may vary if invention becomes public.

401.146(3)

401.293

The term initial patent application means a nonprovisional U.S. national application for patent as defined in 37 CFR 1.63(c).

The notification must include the patent application number and filing date assigned by the USPTO. A copy of the full application is not required.

Assignment to Third Party: Documentation necessary when a

If assignment is approved, third party must pursue commercialization of the invention.

401.146(3)

401.146(4) for non-profit.

Note the Extent of information available about this process varies according to agency. Consult agency online for details.

https://s-n&ciadmin.info.nih.gov/Edison/timeline.jsp

4/26/2004
grantees/contractors wishes to assign invention rights to third party. If the grantees/contractor is a non-profit, the government must approve the assignment. For profit or small business grantees/contractors do not need to seek approval. If the rights are assigned, new rights holder assumes the same reporting responsibilities as the grantees/contractor organization.

Issued Patent: Grantees/contractors must provide federal agency sponsor with patent issue date, number, title or patent, and evidence of government support clause.

At the time of issue. Patent must include government support clause.

401.15(c)(2)
401.14(c)(4)

All issued patent information can be received using iEdison. Evidence of inclusion of government support clause may be provided electronically via a PDF or TIFF file through iEdison. Alternatively, a hard copy may be submitted via fax or U.S. mail.

Request for Extension of Time: An extension of up to two years may be requested for election of title, or one year for filing a patent application.

Prior to any statutory bar. Extension of 2 years for title election and one year for patent application are preapproved for funded inventions. Additional extensions need written approval from the federal agency sponsor.

401.14(c)(4)

Can be requested electronically if using iEdison; otherwise request must be in writing.

Discontinuance of Patent Application, Payment of Maintenance Fees, or Defense in a Reexamination or Opposition proceeding on a Patent: Grantee/contractor must notify federal agency sponsor of changes in patent status.

At anytime in the process, but prior to established deadlines. Relevant information and documents (e.g., patent application or patent) must be provided such that a determination to protect government interests can be made. The federal agency sponsor has the option to pursue the patent application or the patent if not being properly pursued or maintained. Any change in status must be reported at least 30 days prior to pending PTO office actions.

401.14(f)(3)
401.6

Indication may be made via iEdison or through written correspondence.

Annual Utilization Report: For agencies that require utilization reporting the report is for all subject inventions that have had title elected or are licensed without a patent. Report includes stage of development, date of first commercial sale or use, number and type of licenses, gross income, licensing to small business status of U.S. manufacturing and identification of any FDA-approved product names.

Annually for agencies that require utilization reports. Not all agencies require invention utilization reports. When in doubt, organization should consult the lead agency on the invention in question. For NIH grantees/contractor, establishes a 12 month reporting cycle beginning in the month of their choosing. Information requirements defined in iEdison.

401.14(b)

Can be submitted electronically using iEdison, otherwise submission of the same data may be made in writing.

Final Invention Statement Due within 90 days if no inventions occurred

401.50(d)
The completed form must be submitted

https://s-edison.info.nih.gov/iEdison/timeline.jsp
and Certification: Report adverse effects, CER, and NC during the award period, a negative report must be submitted. The report is to be submitted to the awarding unit, grants or contracts management office.

For general information contact:

Extramural Inventions and Technology Resources Branch, OPERA, NIH
6705 Rockledge Drive Room 1040 MSC 7980
Bethesda, MD 20892-7980
(301) 435-1986
FAX (301) 480-0272

E-mail: edison@od.nih.gov

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E-mail the NIH administrator | OMB Burden Statement | iEdison Privacy Notice

https://s-edison.info.nih.gov/iEdison/timeline.jsp

4/26/2004
Federal Register Notice
published on Thursday, December 23, 1999

[64 FR 72090]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES: FINAL NOTICE

AGENCY: National Institutes of Health (NIH), Public Health Service, DHHS

SUMMARY:
On May 25, 1999 the National Institutes of Health (NIH) published for public comment in the Federal Register a proposed policy entitled SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Contracts [64 FR 26205]. This policy is designed to provide recipients of NIH funding with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with federal funds and is intended to assist recipients in complying with their obligations under the Bayh-Dole Act and NIH funding policy. Comments on the Principles and Guidelines were requested by August 21, 1999. This Notice presents the final Principles and Guidelines together with NIH's response to the public comments received.

BACKGROUND:
The present policy represents part of the overall implementation of recommendations made by the Advisory Committee to the Director (ACD) to Dr. Harold Varmus, Director, NIH. Dr. Varmus requested that a Working Group of the ACD look into problems encountered in the dissemination and use of proprietary research tools, the competing interests of intellectual property owners and research users underlying these problems, and possible NIH responses. One of the recommendations in the Report was that NIH issue guidance to the recipients of NIH funding.

PURPOSE:
The present policy is a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines providing specific information to patent and license professionals and sponsored research administrators for implementation. The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining 1) reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools), and 2) restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help Recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding agreements. It is also hoped that these Principles and Guidelines will be adopted by the wider research community so that all biomedical research and development can be synergistic and accelerated.
COMMENTS AND AGENCY RESPONSE:

The National Institutes of Health (NIH) recognizes the importance of public involvement in the development of policy and sought widespread comment and participation by the various stakeholders in the biomedical research and development communities regarding the proposed policy. To this end, NIH sought comment not only from NIH grantees, but also from academic, not-for-profit, government, and private sector participants in biomedical research and development. In order to involve as many stakeholders as possible in the comment process, the proposed policy was advertised and comments solicited in a wide variety of venues. In addition to its publication on May 25, 1999, in the Federal Register, the proposed policy was made available on several different websites including the Federal Register Online, numerous NIH websites (Edison, NIH Office of Technology Transfer, NIH Office of Extramural Research and the NIH Director's Policy Forum), the Association of University Technology Managers (AUTM) website and Recombinant Capital's Signals Magazine. The proposed policy was also advertised on a variety of e-mail lists (including Techno-L) as well as in direct letters and e-mail to various stakeholders. In addition, the proposed policy was profiled in articles appearing in articles in a variety of journals and magazines, including Science, Nature and Nature Biotechnology.

In response to the May 25 proposal, NIH received 45 letters, each of which contained one or more comments. Comments were received from academic institutions, scientific foundations, pharmaceutical companies, biotechnology companies (including providers of research instruments, biological reagents and genomic data), an industry trade association, professional societies, individual researchers and other individual commenters. Below is NIH’s response to comments offered, organized by the section of the proposed policy to which they pertain.

Introduction

Several commenters suggested that sponsored research administrators be included within the target audience to which this policy is addressed. This suggestion has been adopted in the final policy.

Several commenters suggested that the policy be promulgated in accordance with regulatory process or withdrawn. Several other commenters suggested that as a policy the Principles/Guidelines are not enforceable as law and that NIH should issue them as a regulation to ensure compliance. The NIH does not believe that a regulation, enforceable as law, is required at this time to facilitate sharing and access to research tools for its Recipients. Although the final policy is issued as a grants policy, to be incorporated into the NIH Grants Policy Statement, the NIH has not precluded the possibility of engaging in the regulatory process if widespread problems continue in access to NIH-funded research tools by NIH Recipients. In addition, on a case-by-case basis, the expectations set forth in the Principles and Guidelines may be imposed as specific requirements of NIH funding awards where the Recipient has failed to demonstrate sufficient progress in implementing the Principles and Guidelines.

Some commenters suggested that the policy should not be applicable to all projects that include NIH grant funds, but that NIH should set a minimum level of NIH funding that would trigger application of the policy. NIH has determined that the establishment of such a threshold would not be consistent with NIH’s objective of ensuring that broad availability of research tools.
One commenter expressed concern that the proposed policy, if applied to recipients of Small Business Innovation Research (SBIR) grants, would place SBIR recipients under conflicting directives. The commenter suggests that because SBIR recipients are required, as a condition of their grant, to focus on the commercialization of technology, they would be unable to disseminate research tools with the minimal intellectual property encumbrances advocated by the proposed policy. SBIR Recipients, like other NIH grantees, are subject to the dual obligations of disseminating unique research resources while promoting utilization, commercialization and public availability of their inventions. The NIH does not see a conflict between these obligations. The NIH invites its SBIR grantees to consult with their project officer in the event they encounter difficulty in the interpretation or implementation of this policy, either in general or with respect to particular unique research resources developed under their grant.

Principles

1. Ensure Academic Freedom and Publication

Several commenters suggested that language be added to the guidelines to prohibit recipients from making coauthorship a condition of providing research tools. There appears to be general consensus within the research community that authorship is property based upon significant intellectual contribution to the published paper. In most cases, simply making available research materials will not, in the absence of other contributions, justify coauthorship. (See e.g., Responsible Science, Volume I: Ensuring the Integrity of the Research Process, Panel on Scientific Responsibility and the Conduct of Research, National Academy Press, 1992, p. 52). The final policy as been amended to reflect this view.

Several commenters expressed concern that the definition of "Recipient" in the proposed policy might not include individuals or entities receiving NIH funds through "cooperative agreements." The policy is applicable to cooperative agreements and has been clarified in the Principles and Guidelines.

2. Ensure Appropriate Implementation of the Bayh-Dole Act

Virtually all commenters requested clarification on how this policy would preserve incentives for the development and commercialization of research tools that are ultimately sold as products to the research community. The policy has been clarified to ensure that where patent protection is necessary for development of a research tool as a potential product for sale and distribution to the research community, Recipients are not discouraged from seeking such protection, but should license the intellectual property in a manner that maximizes the potential for broad distribution of the research tool. The policy is not intended to require Recipient scientists to develop or maintain tools for widespread distribution, to discourage development of research tool products, nor to set or influence the price for research tools that are commercial products.

3. Minimize Administrative Impediments to Academic Research

One commenter suggested that reach-through rights should not be discouraged because they are sometimes helpful to Recipients by allowing them to obtain materials and equipment at reduced or nominal upfront cost. NIH is aware of this rationale for a Recipient agreeing to reach-through but finds that such practices contribute not only to specific restriction of access to subsequent tools arising out of the NIH-funded work, but also to the general proliferation of multiple ties and competing interests that is the source of the current access problems. NIH does not support the coupling of procurement with intellectual property rights and restrictions.
and expects Recipients to ensure that NIH-funded tools are not restricted as a result of such agreements. Therefore, Recipients should engage in such interactions on an infrequent, case-by-case, and highly controlled and monitored basis.

4. Ensure Dissemination of Research Resources Developed with NIH Funds

Numerous comments were received concerning the conditions under which research tools developed with NIH funds be transferred to other entities. The comments reflected the wide range of opinions present within the life sciences community on this point. On the one hand, some commenters urged that transfer of research tools to for-profit entities be certified under the same terms as transfers to nonprofits/academic institutions. These commenters argue that because of the increasingly important role research tools play in the discovery and development of new therapeutic compounds, it is critical that these tools be made available to for-profit entities free of onerous contractual provisions. They argue that by adopting a transfer policy similar to that proposed for transfers to academic laboratories, NIH will ensure that the public will reap the benefit of its investment in government research in the form of new and improved pharmaceuticals. Other commenters opposed the general idea that the terms for transferring tools to for-profit entities should be identical to those for transfers of tools to academic and non-profit organizations. They argue that the fundamental differences in mission between for-profit entities and academic institutions justify different treatment with respect to the terms under which each obtains and uses tools.

In the final policy, the NIH has left considerable discretion to Recipients in determining how to achieve the principle of ensuring appropriate distribution of NIH-funded tools. As articulated by the policy, imposing reach-through royalty terms as a condition of use of a research tool is inconsistent with this principle. When transferring an NIH-funded research tool to a for-profit entity that intends to use the tool for its own internal purposes, Recipients are entitled to capture the value of their invention. Arrangements such as execution or annual fees are an appropriate way for Recipients to do so. Royalties on the sale of a final product that does not embody the tool, or other reach-through rights directed to a final product that does not embody the tool, discourage use of tools and are not appropriate in these circumstances. Royalties on the sale of final products are more appropriate to situations where a for-profit entity seeks to commercialize the tool, e.g., by developing a marketable product or service, or incorporating the tool into a marketable product or service.

Appendix A Guidelines for Implementation

The final policy has been clarified with regard to NIH intent in attaching the more specific Guidelines to the general Principles. The Principles set forth the policy that NIH is issuing to its funding Recipients to assist them in fulfilling the dual obligations imposed by NIH grants policy with respect to the dissemination of unique research resources, and the Bayh-Dole Act with respect to utilization, commercialization and public availability of government funded inventions. These dual obligations must be thoughtfully managed. The Guidelines provide further information, model language, and suggested strategies for implementing the Principles. The model language and strategies provided by the Guidelines are not intended as the sole means by which Recipients may implement the articulated Principles. It is the nature of advancing science and technology to present unique factual circumstances, and NIH expects that Recipients will determine the most appropriate means to achieve the Principles for unique technologies when the Guidelines do not provide a workable strategy.
Several commenters suggested that research tools be better defined and that more examples be used to assist in determining whether the policy should be applied and if so, what licensing strategy is appropriate. For example, one commenter suggested that the policy draw a distinction between "broad platform technologies" and "product-specific technologies" when determining whether an exclusive license is appropriate. The final policy provides clarification of the criteria that Recipients might apply in determining how to handle a particular technology.

One commenter requested that the definition of research tools be expanded to include diagnostic genetic tests performed with "home-brew" reagents. The commenter suggested that the patenting and exclusive licensing of such tests is having a deleterious effect on clinical education, clinical research, and patient care. NIH declines to expand the definition of research tools to include diagnostic genetic tests. Where such tests are patented and licensed to for-profit entities, academic medical centers wishing to use such licensed tests in their clinical programs should negotiate terms of use with the commercial licensee.

Many commenters were of the opinion that the thirty-day time limit for disclosure of research findings was too short. The final policy has been amended to state that a delay of 30-60 days is generally viewed as reasonable. This amendment is in accord with previous NIH guidance on sponsored research agreements, Developing Sponsored Research Agreements: Considerations for Recipients of NIH Research Grants and Contracts, 59 FR 55674.

Comments were received in favor of adopting the Simple Letter Agreement as a free-standing, one page, uniform material transfer agreement. If used by the NIH intramural program and NIH grantees, commenters believe that the majority of transfers among and between not-for-profits and government laboratories would be greatly simplified. In response to specific comments, the Simple Letter Agreement has been significantly edited and updated. Recipients are encouraged to adopt the Simple Letter Agreement as their institution's model Material Transfer Agreement (MTA), and are expected to use the terms of the Simple Letter Agreement, or no more restrictive terms, for transfers of unpatented materials developed with NIH funding to other NIH grantees.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara McGarey, J.D., NIH Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Fax: (301) 492-3257; E-mail: NIHOTT@od.nih.gov.

/ls/
Maria C. Freire, Ph.D.,
Director, Office of Technology Transfer
National Institutes of Health

Certified to be a true copy of the original document

SHARING BIOMEDICAL RESEARCH RESOURCES:
Principles and Guidelines for Recipients of NIH Research Grants and Contracts

INTRODUCTION
The National Institutes of Health is dedicated to the advancement of health through science. As a public sponsor of biomedical research, NIH has a dual interest in accelerating scientific discovery and facilitating product development. In 1997, Dr. Harold Varmus, Director, NIH requested that a Working Group of the Advisory Committee to the Director look into problems encountered in the dissemination and use of unique research resources, the competing interests of intellectual property owners and research tool users, and possible NIH responses. The Working Group found that intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. One of the recommendations of the Working Group was that NIH issue guidance to its funding recipients to help them achieve the appropriate balance. That guidance is provided in this two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation. A copy of the full Report of the Working Group, with more detailed background information, is available at the NIH website, www.nih.gov/welcome/forum, or from the NIH Office of the Director.

The term "unique research resource" is used in its broadest sense to embrace the full range of tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines. The terms "research tools" and "materials" are used throughout this document interchangeably with "unique research resources." Databases and materials subject to copyright, such as software, are also research tools in many contexts. Although the information provided here may be applicable to such resources, the NIH recognizes that databases and software present unique questions which cannot be fully explored in this document.

PRINCIPLES

1. Ensure Academic Freedom and Publication

Academic research freedom based upon collaboration, and the scrutiny of research findings within the scientific community, are at the heart of the scientific enterprise. Institutions that receive NIH research funding through grants, cooperative agreements or contracts ("Recipients") have an obligation to preserve research freedom, safeguard appropriate authorship, and ensure timely disclosure of their scientists’ research findings through, for example, publications and presentations at scientific meetings. Recipients are expected to avoid signing agreements that unduly limit the freedom of investigators to collaborate and publish, or that automatically grant co-authorship or copyright to the provider of a material.

Reasonable restrictions on collaboration by academic researchers involved in sponsored research agreements with an industrial partner that avoid conflicting obligations to other industrial partners, are understood and accepted. Similarly, brief delays in publication may be appropriate to permit the filing of patent applications and to ensure that confidential information obtained from a sponsor or the provider of a research tool is not inadvertently disclosed. However, excessive publication delays or requirements for editorial control,
approval of publications, or withholding of data all undermine the credibility of research results and are unacceptable.

2. **Ensure Appropriate Implementation of the Bayh-Dole Act**

When a Recipient's research work is funded by NIH, the activity is subject to various laws and regulations, including the Bayh-Dole Act (35 U.S.C. 200 et seq.). Generally, Recipients are expected to maximize the use of their research findings by making them available to the research community and the public, and through their timely transfer to industry for commercialization.

The right of Recipients to retain title to inventions made with NIH funds comes with the corresponding obligations to promote utilization, commercialization, and public availability of these inventions. The Bayh-Dole Act encourages Recipients to patent and license subject inventions as one means of fulfilling these obligations. However, the use of patents and exclusive licenses is not the only, nor in some cases the most appropriate, means of implementing the Act. Where the subject invention is useful primarily as a research tool, inappropriate licensing practices are likely to thwart rather than promote utilization, commercialization and public availability of the invention.

In determining an intellectual property strategy for an NIH-funded invention useful primarily as a research tool, Recipients should analyze whether further research, development and private investment are needed to realize this primary usefulness. If it is not, the goals of the Act can be met through publication, deposit in an appropriate database or repository, widespread non-exclusive licensing or any other number of dissemination techniques. Restrictive licensing of such an invention, such as to a for-profit sponsor for exclusive internal use, is antithetical to the goals of the Bayh-Dole Act. Where private sector involvement is desirable to assist with maintenance, reproduction, and/or distribution of the tool, or because further research and development are needed to realize the invention's usefulness as a research tool, licenses should be crafted to fit the circumstances, with the goal of ensuring widespread and appropriate distribution of the final tool product. Exclusive licensing of such an invention, such as to a distributor that will sell the tool or to a company that will invest in the development of a tool from the nascent invention, can be consistent with the goals of the Bayh-Dole Act.

3. **Minimize Administrative Impediments to Academic Research**

Each iteration in a negotiation over the terms of a license agreement or materials transfer agreement delays the moment when a research tool may be put to use in the laboratory. Recipients should take every reasonable step to streamline the process of transferring their own research tools freely to other academic research institutions using either no formal agreement, a cover letter, the Simple Letter Agreement of the Uniform Biological Materials Transfer Agreement (UBMTA), or the UBMTA itself. The Appendix contains an updated free-standing version of the Simple Letter Agreement that is strongly encouraged for transfers of unpatented research materials among Recipients.

Where they have not already done so, Recipients should develop and implement clear policies which articulate acceptable conditions for acquiring resources, and refuse to yield on unacceptable conditions. NIH acknowledges the concern of some for-profit organizations that the concept of purely academic research may be diluted by the close ties of some not-for-profit organizations with for-profit entities, such as research sponsors and spin-off companies in which such organizations take equity. Of concern to would-be providers is the loss of control over a proprietary research tool that, once shared with a not-for-profit Recipient
for academic research, results in commercialization gains to the providers’ for-profit competitors. Recipients must be sensitive to this legitimate concern if for-profit organizations are expected to share tools freely.

For-profit organizations, in turn, must minimize the encumbrances they seek to impose upon not-for-profit organizations for the academic use of their tools. Reach-through royalty or product rights, unreasonable restraints on publication and academic freedom, and improper valuation of tools impede the scientific process whether imposed by a not-for-profit or for-profit provider of research tools. While these Principles are directly applicable only to recipients of NIH funding, it is hoped that other not-for-profit and for-profit organizations will adopt similar policies and refrain from seeking unreasonable restrictions or conditions when sharing materials.

4. Ensure Dissemination of Research Resources Developed with NIH Funds

Progress in science depends upon prompt access to the unique research resources that arise from biomedical research laboratories throughout government, academia, and industry. Ideally, these new resources flow to others who advance science by conducting further research. Prompt access can be accomplished in a number of ways, depending on the type of resource that has been developed, whether it has broad or specific uses, and whether it is immediately useful or private sector investment is needed to realize its usefulness. The goal is widespread, timely distribution of tools for further discovery. When research tools are used only within one or a small number of institutions, there is a great risk that fruitful avenues of research will be neglected.

Unique research resources arising from NIH-funded research are to be made available to the scientific research community. Recipients are expected to manage interactions with third parties that have the potential to restrict Recipients’ ability to disseminate research tools developed with NIH funds.² For example, a Recipient might use NIH funds with funds from one or more third party sponsors, or acquire a research tool from a third party provider for use in an NIH-funded research project. Either situation may result in a Recipient incurring obligations to a third party that conflict with Recipient’s obligations to the NIH. To avoid inconsistent obligations, Recipients are encouraged to share these Principles with potential co-sponsors of research projects and third party providers of materials.

Recipients should also examine and, where appropriate, simplify the transfer of materials developed with NIH funds to for-profit institutions for internal use by those institutions. NIH endorses distinguishing internal use by for-profit institutions from the right to commercial development and sale or provision of services. In instances where the for-profit institution is seeking access for internal use purposes, Recipients are encouraged to transfer research tools developed with NIH funding to such institutions without seeking option rights or royalties on the final product.

² Research tools obtained or derived from human tissues constitute a special case. Certain restrictions on the use and further dissemination of such tools may be appropriate to ensure consistency with donor consent and human subjects protection. See 45 C.F.R. Part 46.
SUMMARY

Access to research tools is a prerequisite to continuing scientific advancement. Ensuring broad access while preserving opportunities for product development requires thoughtful, strategic implementation of the Bayh-Dole Act. The NIH urges Recipients to develop patent, license, and material sharing policies with this goal in mind, realizing both product development as well as the continuing availability of new research tools to the scientific community.

APPENDIX

GUIDELINES FOR IMPLEMENTATION

The following Guidelines provide specific information, strategies, and model language for patent and license professionals and sponsored research administrators at Recipient institutions to assist in implementing the Principles or Obtaining and Disseminating Biomedical Resources. Recipients are encouraged to use the strategies below, other strategies developed at their own institutions, or any other appropriate means of achieving the Principles.

Guidelines for Disseminating Research Resources Arising Out of NIH-Funded Research

Definition of Research Tools

- The definition of research tools is necessarily broad, and it is acknowledged that the same material can have different uses, being a research tool in some contexts and a product in others. In determining how an NIH-funded resource that falls within the definition should be handled, Recipients should determine whether: 1) the primary usefulness of the resource is as a tool for discovery rather than an FDA-approved product or integral component of such a product; 2) the resource is a broad, enabling invention that will be useful to many scientists (or multiple companies in developing multiple products), rather than a project or product-specific resource; and 3) the resource is readily usable or distributable as a tool rather than the situation where private sector involvement is necessary or the most expedient means for developing or distributing the resource. Recipients should ensure that their intellectual property strategy for resources fitting one or more of the above criteria enhances rather than restricts the ultimate availability of the resource. If Recipient believes private sector involvement is desirable to achieve this goal, Recipient should strategically license the invention under terms commensurate with the goal.

Use of Simple Letter Agreement

- Recipients are expected to ensure that unique research resources arising from NIH-funded research are made available to the scientific research community. The majority of transfers to not-for-profit entities should be implemented under terms no more restrictive than the UBMTA. In particular, Recipients are expected to use the Simple Letter Agreement provided below, or another document with no more restrictive terms, to readily transfer unpatented tools developed with NIH funds to other Recipients.
for use in NIH-funded projects. If the materials are patented or licensed to an exclusive provider, other arrangements may be used, but commercialization option rights, royalty through, or product reach-through rights back to the provider are inappropriate.

- Similarly, when for-profit entities are seeking access to NIH-funded tools for internal use purposes, Recipients should ensure that the tools are transferred with the fewest encumbrances possible. The Simple Letter Agreement may be expanded for use in transferring tools to for-profit entities, or simple internal use license agreements with execution or annual use fees may be appropriate.

- Simple Letter Agreement for the Transfer of Materials

In response to the RECIPIENT's request for the MATERIAL [insert description] the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.
2. THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.
3. The MATERIAL will be used for teaching or not-for-profit research purposes only.
4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching or not-for-profit research purposes only.
5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.
6. Any MATERIAL delivered pursuant to this Agreement is understanded to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the Material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider.
7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.
8. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested, the amount will be indicated here. [insert fee] The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.
PROVIDER INFORMATION and AUTHORIZED SIGNATURE

Provider Scientist: ____________________________
Provider Organization: ____________________________
Address: ____________________________
Name of Authorized Official: ____________________________
Title of Authorized Official: ____________________________

Certification of Authorized Official: This Simple Letter Agreement __ has / __ has not [check one] been modified. If modified, the modifications are attached.

Signature of Authorized Official: ____________________________ Date: ____________

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient Scientist: ____________________________
Recipient Organization: ____________________________
Address: ____________________________
Name of Authorized Official: ____________________________
Title of Authorized Official: ____________________________
Signature of Authorized Official: ____________________________ Date: ____________

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

Recipient Scientist: ____________________________ Date: ____________

Ensuring Consistent Obligations

• Recipients must ensure that obligations to other sources of funding of projects in which NIH funds are used are consistent with the Bayh-Dole Act and NIH funding requirements. Unique research resources generated under such projects are expected to be made available to the research community. Recipients are encouraged to share these Guidelines with potential co-sponsors. Any agreements covering projects in which NIH funds will be used along with other funds are expected to contain language to address the issue of dissemination of unique research resources. Examples of possible language follow. The paragraphs are presented in a "mix and match" format:

"The project covered by this agreement is supported with funding from the National Institutes of Health. Provider agrees that upon publication, unpatented unique research resources arising out of this project may be freely distributed."

"In the event an invention is primarily useful as a research tool, any option granted shall either be limited to a non-exclusive license or the terms of any resulting exclusive license shall include provisions that ensure that the research tool will be available to the academic research community on reasonable terms."
"Provider agrees that Recipient shall have the right to make any materials and inventions developed by Recipient in the course of the collaboration (including materials and inventions developed jointly with Provider, but not including any Provider materials or parts thereof) or Provider sole inventions available to other scientists at not-for-profit organizations for use in research, subject to Provider’s independent intellectual property rights."

"Subject to Recipient’s obligations to the U.S. government, including 37 CFR Part 401, the NIH Grants Policy Statement, and the NIH Guidelines for Obtaining and Disseminating Biomedical Research Resources, Recipient grants to Sponsor the following rights:..."

Limiting Exclusive Licenses to Appropriate Field of Use

- Exclusive licenses for research tools (where no further research and development is needed to realize the invention’s usefulness as a tool) should generally be avoided except in cases where the licensee undertakes to make the research tool widely available to researchers through unrestricted sale, or the licensor retains rights to make the research tool widely available. When an exclusive license is necessary to promote investment in commercial applications of a subject invention that is also a research tool, the Recipient should ordinarily limit the exclusive license to the commercial field of use, retaining rights regarding use and distribution as a research tool. Examples of possible language include:

"Research License" means a nontransferable, nonexclusive license to make and to use the Licensed Products or Licensed Processes as defined by the Licensed Patent Rights for purposes of research and not for purposes of commercial manufacture, distribution, or provision of services, or in lieu of purchase, or for developing a directly related secondary product that can be sold. Licensor reserves the right to grant such nonexclusive Research Licenses directly or to require Licensee to grant nonexclusive Research Licenses on reasonable terms. The purpose of this Research License is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the Licensed Patent Rights, however, Licensor shall consult with Licensee before granting to commercial entities a Research License or providing to them research samples of the materials.”

"Licensor reserves the right to provide the Biological Materials and to grant licenses under Patent Rights to not-for-profit and governmental institutions for their internal research and scholarly use.”

"Notwithstanding anything to the contrary in this agreement, Licensor shall retain a paid-up, nonexclusive, irrevocable license to practice, and to sublicense other not-for-profit research organizations to practice, the Patent Rights for internal research use.”

"The grant of rights provided herein is subject to the rights of the United States government pursuant to the Bayh-Dole Act and is limited by the right of the Licensor to use Patent Rights for its own research and educational purposes and to freely distribute Materials to not-for-profit entities for internal research purposes.”
"Licensee reserves the right to supply any or all of the Biological Materials to academic research scientists, subject to limitation of use by such scientists for research purposes and restriction from further distribution."

"Licensee reserves the right to practice under the Patent Rights and to use and distribute to third parties the Tangible Property for Licensee’s own internal research purposes."

Guidelines For Acquiring Research Resources For Use in NIH-Funded Research

Prompt Publication

- Agreements to acquire materials for use in NIH-funded research are expected to address the timely dissemination of research results. Recipients should not agree to significant publication delays, any interference with the full disclosure of research findings, or any undue influence on the objective reporting of research results. A delay of 30-90 days to allow for patent filing or review for confidential proprietary information is generally viewed as reasonable.

Definition of Materials

- Under the Bayh-Dole Act and its implementing regulations, agreements to acquire materials for use in NIH-funded projects cannot require that title to resulting inventions be assigned to the provider. For this reason, definitions of "materials" that include all derivatives or modifications are unacceptable. Other unacceptable variations include definitions of "materials" that include any improvements, or any other materials that could not have been made without the provided material. Conversely, it is important for providers of materials to be aware that a Recipient does not gain any possession or interest in a provider's material by virtue of the Recipient using the material in an NIH-funded activity. Examples of acceptable definitions for "materials" include:

  "Materials" means the materials provided as specified in this document."

  "Materials" means the materials provided as specified in this document. Materials may also include Unmodified Derivatives of the materials provided, defined as substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the original material, such as subclones of unmodified cell lines, purified or fractionated subsets of the original material, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line."

  "Materials" means the materials provided as specified in this document. Materials may also include Progeny and Unmodified Derivatives of the materials provided. Progeny is an unmodified descendant from the original material, such as virus from virus, cell from cell, or organism from organism. Unmodified Derivatives are substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the original material, such as subclones of unmodified cell lines, purified or fractionated subsets of the original material, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line."

  "Materials" means the material being transferred as specified in this document.
Materials shall not include: (a) Modifications, or (b) other substances created by the recipient through the use of the Material which are not Modifications, Progeny, or Unmodified Derivatives. Progeny is an unmodified descendant from the Material, such as virus from virus, cell from cell, or organism from organism. Unmodified Derivatives are substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the original Material, such as subclones of unmodified cell lines, purified or fractionated subsets of the original Material, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line. [Source: Uniform Biological Materials Transfer Agreement; terms defined therein]

Ensuring Consistent Obligations

- Recipients are expected to avoid signing agreements to acquire research tools that are likely to restrict Recipients' ability to promote broad dissemination of additional tools that may arise from the research. This might occur when an agreement gives a provider an exclusive license-option to any new intellectual property arising out of the project. A new transgenic mouse developed during the project could fall under this license option and become unavailable to third party scientists as a result. Examples of agreements to examine include material transfer agreements (MTAs), memoranda of understanding (MOU), research or collaboration agreements, and sponsored research agreements. Recipients should consider adopting standard language to place in such agreements to address this issue. The following are examples of possible language to include in MTAs, sponsored research agreements, and other agreements that either acquire materials from or co-mingled funds with non-government sources. The paragraphs are presented in a "hit and match" format:

"The project covered by this agreement is supported with funding from the National Institutes of Health. Provider agrees that after publication, unpatented unique research resources arising out of this project may be freely distributed."

"In the event an invention is primarily useful as a research tool, any option granted shall either be limited to a non-exclusive license or the terms of any resulting exclusive license shall include provisions which ensure that the research tool will be available to the academic research community on reasonable terms."

"Provider agrees that Recipient shall have the right to make any materials and inventions developed by Recipient in the course of the collaboration (including materials and inventions developed jointly with Provider, but not including any Provider materials or parts thereof) or Provider sole inventions available to other scientists at not-for-profit organizations for use in research, subject to Provider’s independent intellectual property rights."

"Subject to Recipient's obligations to the U.S. government, including 37 CFR Part 401, the NIH Grants Policy Statement, and the NIH Guidelines for Obtaining and Disseminating Biomedical Research Resources, Recipient grants to Sponsor the following rights:..."

Grantback and Option Rights

- Agreements to acquire materials from for-profit entities for use in NIH-funded research
may provide a grant back of non-exclusive, royalty-free rights to the provider to use improvements and new uses of the material that, if patented, would infringe any patent claims held by the provider. They may also provide an option for an exclusive or non-exclusive commercialization license to new inventions arising directly from use of the material. These should be limited to circumstances where the material sought to be acquired is unique, such as a patented proprietary material, and not reasonably available from any other source. A non-exclusive "grant-back" might be used, for example, to protect a for-profit entity that provides a proprietary compound from being blocked from using new uses or improvements of that compound discovered during the NIH-funded project. In providing license options, Recipients must ensure that licenses granted to providers under such options are consistent with Bayh-Dole requirements, including the preference for U.S. industry requirements and reservation of government rights under 37 C.F.R. Part 401.

- In determining the scope of license or option rights that are granted in advance to a provider of materials, Recipient should balance the relative value of the provider's contribution against the value of the rights granted, cost of the research, and importance of the research results. The rights granted to providers should be limited to inventions that have been made directly through the use of the materials provided. In addition, Recipients should reserve the right to negotiate license terms that will ensure: 1) continuing availability to the research community if the new invention is a unique research resource, 2) that the provider has the technical and financial capability and commitment to bring all potential applications to the marketplace in a timely manner; and 3) that if an exclusive license is granted, the provider will provide a commercial development plan and agree to benchmarks and milestones for any fields of use granted.

- It is expected that agreements to acquire NIH-funded materials from not-for-profit entities for use in NIH-funded research will not include commercialization option rights, royalty reach-through, or product reach-through rights back to the provider. Such materials should be acquired under the Simple Letter Agreement or UMBTA, or, if the materials are patented, a simple license agreement that does not request reach-through to either future products or royalties. If the providing not-for-profit organization is constrained in sharing the material due to a pre-existing sponsored research agreement or license, NIH expects the not-for-profit provider to negotiate a suitable resolution with the private research sponsor or licensee. The co-mingling of NIH and sponsored research funds is allowed, however. Recipient is responsible for ensuring that conditions on the use of the sponsored funds do not interfere with the open dissemination of research tools.

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A "20-20" VIEW OF INVENTION REPORTING TO THE NATIONAL INSTITUTES OF HEALTH

A "20-20" VIEW OF INVENTION REPORTING TO THE NATIONAL INSTITUTES OF HEALTH
Adapted and updated from: NIH GUIDE, Volume 24, Number 33, September 22, 1995
P.T. 34; K.W. 1014006
National Institutes of Health

INVENTION REPORTING TO THE NIH: 20 QUESTIONS
THE DISCUSSION OF 20 QUESTIONS TO ASSIST IN THE UNDERSTANDING OF BAYH-DOLE ACT-RELATED INVENTION AND PATENT REPORTING.

1. WHAT FEDERAL STATUTES AND REGULATIONS COVER PATENT AND INVENTION ISSUES?

The regulations codified at 37 CFR Part 401, "Rights to Inventions made by Nonprofit Organizations and Small Business Firms" apply to all grantees and contactors, including universities and other non-firms. The Department of Commerce has been designated the responsible Federal agency for these regulations as they emanated from Public Law 96-620 (November 8, 1984), which amended Public Law 95-517 (December 12, 1980), more commonly known as the Bayh-Dole Act. This law amended Title 35 USC, by adding Chapter 18, Section 200-212. Other regulations that address these issues are OMB Circular A-124 (February 10, 1982) and a February 18, 1983 Presidential Memorandum on "Government Patent Policy" in 37 CFR 401. The Presidential Memorandum was incorporated into the text of OMB A-124 on March 24, 1984. It was not until 1987 that all of these provisions were finalized in rulemaking and published by the Department of Commerce.

2. WHAT IS THE BAYH-DOLE ACT AND WHY IS IT IMPORTANT?

The Bayh-Dole Act encourages researchers to patent and market their inventions by guaranteeing patent rights. This Act automatically grants first rights to a patent for an invention fully or partially funded by a Federal
agency to the awardee organization. To obtain these benefits, however, the inventor and the organization have several reporting requirements that protect the rights of the Government. This landmark legislation is important because it gives nonprofit organizations and small business firms the right to elect to retain title to inventions. The objectives are to: use the patent system to promote utilization of inventions arising from Federally supported research; encourage maximum participation of small business firms in Federally supported research and development efforts; promote collaboration between commercial and nonprofit organizations; ensure that inventions made by nonprofit organizations and small business firms are used in a manner that promotes free competition and enterprise; promote commercialization and public availability of inventions made in the United States by United States industry and labor; and ensure that the Government obtains sufficient rights in Federally supported inventions to prevent the unreasonable use of inventions.


37 CFR 401.14 requires organizations to establish a written agreement with all employees to disclose promptly each subject invention made under a Federally sponsored program and to execute all papers necessary to file patent applications. By its acceptance of an NIH award, a grantee or contractor organization agrees to obtain written agreements from its employees and:

- Promptly report inventions to the NIH.
- Elect, in writing, within two years, whether or not to retain title.
- File a patent application within one year of electing title.
- Acknowledge Government support in the patent application and send page of application containing Federal support clause.
- Provide the Government with a royalty free license to the invention; the confirmatory license should be sent to the Office of Policy for Extramural Research Administration (OPERA), NIH.
- Make reasonable efforts to attract small business licensees.
- Provide annual reports on the utilization of the invention, including date of first commercial sale or use and gross royalties received.
- Agree that exclusive licensee will manufacture the invention substantially within the United States, if it is to be used or sold in the U.S.

4. WHY PATENT?

Patent protection gives the owner of the patent the right to exclude others from making, using, offering to sell, selling, or importing into the United
States the invention during the lifetime of the patent, thus protecting the incentive for commercial development of the invention. However, it does not give the public the right to use the invention if it is claimed by another's patent. A company will be more willing to make the investment needed to commercialize an invention if it can eliminate or decrease competition. When a patent is licensed and successfully commercialized, it can lead to royalties for the organization and the inventor, economic development for the Nation, and improvements in the public health. Patent protection is the key component of technology transfer. Of the legal options available, including trademarks, trade names, copyrights, and licensing, patenting is probably the most crucial to commercializing research results. More than 200 years ago, the Constitutional Convention included in the U.S. Constitution the power "to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Almost 90 years later, President Lincoln addressed the importance of patenting, when he said, "the patent system has added the fuel of interest to the fire of genius."

5. DO THE REQUIREMENTS FOR INVENTION REPORTING AND COMPLIANCE WITH BAYH-DOLE VARY FOR DIFFERENT TYPES OF ORGANIZATIONS?

Bayh-Dole legislation, which was also extended to large businesses by the 1983 Presidential Memorandum, applies to all grantees and contractors funded by the U.S. Government. Non-profit organizations are subject to three provisions in addition to those that apply to all organizations:

- Nonprofit organizations cannot assign rights to an invention to a third party, unless it is an invention management organization, without permission from the Federal funding component;
- Royalties must be shared with the inventor and the remainder used for scientific research and education; and,
- Nonprofit organizations must give preference to small businesses when licensing the inventions.

6. WHAT ARE THE RESPONSIBILITIES OF A PRIME Awardee VIs-A-Vis FLOWING DOWN BAYH-DOLE REQUIREMENTS TO SUBGRANTEEES/SUBCONTRACTORS UNDER FEDERAL AWARDS?

In accordance with 37 Part 401.14g, prime grantees and contractors are required to include the Standard Patent Rights Clause (401.14) in all subcontracts, regardless of tier, for experimental, developmental, or research work to be performed. That clause requires subawardees to report directly to NIH on any inventions developed with Federal funding. It is suggested that the prime awardee include a clause in its written agreement with the subawardee that also requires notification to the prime when an invention is made. This will ensure that prime awardees have accurate information to complete questions concerning inventions on the competing and noncompeting applications and the final invention statement.
7. WHAT IS THE FIRST STEP IN THE INVENTION REPORTING PROCESS AND WHO TAKES THAT FIRST STEP?

The first step, if the inventor believes he/she has an invention/discovery, is to report it promptly to the organization's technology transfer office, the office of sponsored research, or the institutional administrative official responsible for technology transfer. The employee/investigator is required to report any invention in accordance with the terms of the employee agreement he/she signed. (Note: Organizations are required, as a condition of Federal funding, to enter into employee agreements with all appropriate staff.) After the inventor reports the invention in-house, the appropriate office is then responsible for reporting the invention to the Government, as well as providing support to the inventor for fulfilling the administrative requirements for securing a patent and negotiating license agreements if the invention is deemed to have commercial value.

8. WHAT ADDITIONAL STEPS ARE INCLUDED IN THE INVENTION REPORTING PROCESS AND WHEN ARE THEY TO BE TAKEN?

The awardee organization is responsible for the following:

- Invention disclosure to the NIH, in writing, within 2-months of the inventor’s initial report to the organization

- Election of title to invention — within 2-years of disclosure to NIH. Sometimes election is made at the time of disclosure of the invention. (For inventions disclosed to the public, notification of the NIH 60-days prior to the statutory bar date, which is usually one year after the date of publication, sale, or public use.)

- Non-election of title to invention (For inventions not disclosed to the public, notification of the NIH at least 60-days prior to the end of the 2-year period after disclosure.)

- Patent application — within one-year of election of title or publication, whichever is earlier, provision to the NIH of the confirmatory license and the page of the patent application that contains the Federal support clause

- Issued patent — provision to the NIH of the patent number and issue date at time of issuance of the patent

- Annual utilization report (See Question 13) — every year subsequent to filing a patent

- Final invention statement — prior to closeout of the NIH grant or contract. This form (HHS 568) is to be submitted directly to the awarding component (See Term 9).

- Unless otherwise specified, the information should be sent to the Office of Policy for Extramural Research Administration (OPERA), NIH.
9. WHAT HAPPENS IF THE ORGANIZATION DECIDES NOT TO ELECT TITLE ON THE INVENTION?

The awardee has two years after it discloses an invention to the NIH to determine if it wants to take title and file a patent application. If the organization does not choose to elect title, it must notify the NIH. Under these circumstances, the NIH has the option to take title. The Government evaluates the invention to determine whether patenting and further development is in the public interest, because of potential commercial interest or health benefit. If the NIH chooses to elect title, the inventor is guaranteed a portion of any royalty.

10. WHAT IF THE NIH ALSO DECIDES NOT TO ELECT TITLE? CAN THE INVENTOR GET TITLE?

Under these circumstances, after NIH consults with the awardee, title may be given to the inventor if it is requested. If the inventor takes title, he/she must abide by the Patent Rights Clause, found at 37 CFR 401.14.

11. HOW DOES THE GOVERNMENT BENEFIT, IF THE ORGANIZATION ELECTS TO RETAIN TITLE TO AN INVENTION?

The government must be granted a "nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world" (37 CFR 401.14.6.b; see also "Confirmatory License" in the accompanying terms). The Government does not get a share of the royalties, but the public does benefit if a useful invention is developed, reaches the market, and becomes accessible to those who need it.

12. IS THERE ANY HARM IN AN INVENTOR PUBLICLY DISCLOSING AN INVENTION BEFORE REPORTING IT TO THE TECHNOLOGY TRANSFER OFFICE?

Yes. Inventions should be reported to the awardee organization prior to publication or presentation at any open meeting, since failure to do so may result in loss of the rights to the awardee organization, inventor, and the Federal government in the invention. Most foreign patent rights are immediately lost upon publication or other public disclosure, unless a patent application is already on file. In addition, statutes preclude obtaining United States patent protection after one year from the date of a publication that discloses the invention.

13. WHAT IS THE PURPOSE OF THE ANNUAL INVENTION UTILIZATION REPORT?

An annual Invention Utilization Report is required for all inventions for which a patent application has been filed or that have been licensed, but not
14. WHY WOULD AN AWARDEE ORGANIZATION NOT PROPERLY REPORT SUBJECT INVENTIONS TO THE GOVERNMENT AND WHAT ARE THE CONSEQUENCES OF FAILING TO COMPLY WITH BAYH-DOLE REPORTING?

Failure to report inventions appropriately is usually caused by "ignorance of the law" or a misunderstanding of the legislation and its implementing regulations. An additional concern that may contribute to a failure to report is based on the incorrect premise that the Government will inappropriately interfere with the commercialization of subject inventions. In fact, the Bayh-Dole Act provides very few restrictions on commercial development. As long as Government funded inventions are reported and commercially viable inventions are being reasonably developed by the organization (which is in everyone's interest), Government involvement is limited to retaining its confirmatory license. On the other hand, failure to comply with the reporting requirements of the Patent Rights Clause can result in loss of the recipient's rights to an invention (37 CFR 401.14(d)) or the use of the Government's right to march-in. In addition, the latest version of the grant application form PHS 398 (rev. 5/95) includes a penalty clause for the improper reporting of an invention or failure to report an invention.

15. WHEN AN AWARDEE LICENSES A COMPANY TO USE AN INVENTION DEVELOPED WITH FEDERAL FUNDS, WHAT INFORMATION OR REQUIREMENTS MUST BE INCLUDED RELATIVE TO THE GOVERNMENT'S RIGHTS IN THE INVENTION?

The financial aspects of the license are between the awardee organization and the licensee. However, the awardee must inform the licensee that the Federal government has a nonexclusive right to make or use the invention for Government purposes. In addition, if the licensee is awarded exclusive rights to the invention, the awardee must inform the licensee that it is obligated to manufacture the invention substantially in the U.S., if it will be sold or used in the U.S.

16. WHO HAS THE RIGHTS TO DATA DEVELOPED UNDER NIH GRANTS?
Under the grant mechanism, recipient institutions have custody of and primary rights to data developed, subject to the Government's right of access.

17. WHAT HAPPENS TO AN INVENTION WHEN THE INVENTOR/PRINCIPAL INVESTIGATOR TRANSFERS TO A NEW INSTITUTION?

The invention belongs to the awardee organization. The Bayh-Dole Act requires that there be employee agreements in place at the awardee organizations that obligate inventors to assign title to Federally-supported inventions to the organization. In return, the inventor receives a portion of any royalties. If the inventor moves to a new organization, the rights to existing patents usually remain with the former organization, although the inventor remains entitled to a share of the royalties. However, depending on the stage of development of the invention, an inventor or the organization, with NIH permission, may negotiate a transfer of rights to the new organization.

18. ARE ROYALTIES FROM PATENTED INVENTIONS CONSIDERED PROGRAM INCOME?

Yes, but they are not considered general program income. Thus, if no specific footnote appears on the Notice of Grant Award pertaining to royalty or other income from patents or inventions, its inclusion as program income for the purposes of the financial status report is not required. However, such income must be reported on the annual utilization report submitted each year by awardee organizations. It is important to note that, according to the Bayh-Dole Act, a portion of royalties must go to the inventor and the balance must be used to support scientific research and education.

19. HOW DO ORGANIZATIONS SATISFY THE FEDERAL LAW THAT REQUIRES Awardees TO REPORT INVENTIONS AND PATENTS THAT RESULT FROM NIH FUNDING AGREEMENTS AND WHAT IS NIH DOING TO ENSURE AND FACILITATE COMPLIANCE?

All awardee organizations are to use Form HHS 568 - "Final Invention Statement and Certification" to closeout a grant or contract. The completed Form should be sent directly to the grants or contracts office of the awarding component. The NIH has developed an on-line information management system based on a client-server database in which common files are established and data is viewed or modified. The system was deployed in 1995 and named 'Edison' (see "Edison" in accompanying list of "20-20" terms) and includes features that will significantly decrease the amount of work needed for an organization to fulfill the reporting requirements. NIH may obtain title to inventions that are not properly reported and elected.
20. WHAT IF AN INVENTOR IS UNSURE THAT HE/SHE HAS MADE A SUBJECT INVENTION? WHAT IF THE INVENTOR AND/OR ORGANIZATIONAL OFFICIAL HAVE A QUESTION OF A GENERAL NATURE? WHOM CAN THEY CONTACT FOR ADDITIONAL INFORMATION?

Inventors should be aware that publication prior to filing a patent application will immediately destroy patent rights in most foreign countries. Also, if the awardee organization elects rights, but neglects to file a patent application or tell the Government such action has been taken, a loss of patent rights for the organization, the inventor, and the Government may result. NIH may obtain title if the patent application is not timely filed. An inventor should work closely with organizational technology transfer personnel. Awardee organizations are encouraged to obtain a copy of 37 CFR 401, which is available through OPERA, NIH.

Additional assistance can be obtained from the grants management and contracts management offices of the awarding component. For situations beyond the scope of the organizational technology transfer official or the grants or contracts management officers, Extramural Inventions and Technology Resources Branch, OPERA, NIH, should be contacted. The phone number is 301-480-1886. General information and access to Interagency Edison is available on the world wide web at (http://iedison.gov).

INVENTION REPORTING TO THE NIH: 20 TERMS
20 INVENTION REPORTING TERMS WITH WHICH EVERY NIH Awardee SHOULD BE FAMILIAR.

1. ASSIGNMENT.
Transfer of title or ownership in patent rights in the form of a written assignment document. By law, an inventor has initial ownership of an invention. However, awardee organizations are required by the Bayh-Dole Act to have in place employee agreements requiring an inventor to "assign" or give ownership of an invention to the organization upon acceptance of Federal funds.

2. BAYH-DOLE ACT.
Enacted on December 12, 1980 The Patent & Trademark Act (Public Law 96-517) created a uniform patent policy among Federal agencies that fund research. Bayh-Dole enables small businesses and non-profit organizations, including universities, to retain title to materials and products they invent under Federal funding. Subsequent amendments created uniform licensing guidelines and expanded the law's purview to include all Federally-funded contractors (Public Law 88-617).
3. CONFIRMATORY LICENSE.

Acknowledges right of retention by the U.S. government of a "nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the U.S. the subject invention throughout the world." Such a license is always retained by the U.S. government when the awardee elects title to an invention, regardless of the title holder's licensing strategy. License agreements for Federally-funded technology must include a clause addressing the Government's rights and interests, i.e., "The Licensee acknowledges that the U.S. Government has certain rights in this invention under 37 CFR 401 including a non-exclusive, non-transferable, paid-up license heretofore granted by the Licensor."

4. EDISON.

The electronic system for invention reporting to the NIH and other federal agencies. The system is based on a client-server database architecture in which a common file is established and data is viewed or modified in real-time. The system allows input and updates of records and includes features in its architecture that significantly decrease the amount of work presently done by awardee organizations to fulfill invention reporting requirements. The system, deployed originally in 1995, was "Edison," in recognition of the prolific American inventor. In 1997, additional agencies agreed to allow their grantees to use the Edison system to report inventions funded through their agency. At that point, the name of the system was changed to Interagency Edison (iEdison). Today, 16 agencies are participating in iEdison. Grant recipients for any of the agencies listed on the iEdison site (http://iedison.gov) may request authorization to use the electronic system for invention reporting.

5. ELECTION OF TITLE.

In accordance with 37 CFR 401 - Standard Patent Rights Clauses, the notification of the decision to retain title to an invention. The election must be in writing, or sent electronically, and is due within two years of disclosure of the invention to the NIH.

6. EXTENSION OF TIME.

In relation to disclosure, election, and filing, requests for extension of the time needed to evaluate a subject invention or identify a licensee, may, at the discretion of the agency, be granted.

7. FEDERAL SUPPORT CLAUSE.

Required language on a patent application and any patent issued for an invention arising from Federally funded activities. "This invention was made with Government support under (identify support) awarded by the PHS. The
Government has certain rights in the invention."

8. FILING.

The act of submitting a patent application to the Patent Trademark Office or its foreign counterpart. Failure to file within the one-year "grace-period" for public disclosure disqualifies the invention from patent protection in the U.S.

9. FINAL INVENTION STATEMENT AND CERTIFICATION.

Form HHS 568, due prior to close-out of a grant/contract which lists all inventions made under the grant or certifies that there were no inventions.

10. FIRST TO FILE.

System used internationally for establishing who has the right to patent an invention when more than one party is claiming a single invention. "First-to-Invent" is the system used in the United States.

11. INTELLECTUAL PROPERTY LAW.

A widely used term to designate a field of law that encompasses products of the human mind or intellect (e.g., patents, inventions, trademarks, copyrights).

12. INVENTION/SUBJECT INVENTION.

An invention is anything made by the "hand of man," that is a new, useful, and unobvious process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. The term "invention" means any invention or discovery that is or may be patentable or otherwise protectable under Title 35 of the U.S. Code. The term "subject invention" means any invention of an awardee conceived or first actually reduced to practice in the performance of work under a Government funding agreement (grant, cooperative agreement, contract).

13. INVENTION DISCLOSURE.

A written report to the NIH that includes the title, the name(s) of the inventor, a technical description of the invention, the grant/contract number(s), and date of any public disclosure. Due within two months of inventor's initial report to employer.
14. INVENTION UTILIZATION REPORT.

Annual report to NIH regarding status of commercialization of an invention for which a patent application has been filed. These reports are used to record the status of development, date of first commercial sale or use, gross royalties received by the awardee, and compliance with Bayh-Dole legislation. NIH is very lenient in accepting information in any format, provided the basic required information is submitted. Utilization reports can be submitted electronically by grantees who have an iEdison account. A paper copy of the suggested format is available from OPERA, NIH (See: utilization_reporting.jsp).

15. LICENSE.

The right to develop and practice a patent, invention, trademark, or copyright. A license is a written document granted by the owner of a patent, giving permission to another to make, use or sell articles embodying the invention.

16. MARCH-IN RIGHTS.

The government's right to require that the awardee provide nonexclusive, partially exclusive, or exclusive license, under reasonable terms, to responsible applicants. If necessary, because the awardee organization's licensee has not taken (or is not expected to take) effective steps within a reasonable time to achieve practical application of an invention or is necessary to alleviate a health or safety need.

17. PATENT.

A grant by the Federal Government to an inventor of the right to exclude others from using, selling, or making an invention during the lifetime of the patent.

18. REDUCTION TO PRACTICE.

Actual reduction to practice is the actual construction or working of the invention for its intended purpose. Constructive reduction to practice is the filing of a patent application with the Patent Trademark Office. An invention is a subject invention if it is conceived or first actually reduced to practice in the performance of work under the grant or contract.

19. STANDARD PATENT RIGHTS CLAUSE.

Details awardee obligations and responsibilities to the U.S. government with regard to Federally-supported inventions. Full text of the patent rights
clause (37 CFR 401.14) can be found on the iEdison site (37CFR401.jsp#401-1).

26. TECHNOLOGY TRANSFER.

The transfer of research results to the commercial sector or interchange between the private and public sectors.
General Reference Materials

Resources

- OER Home Page
- Getting Started at NIH
- NIH Welcome Wagon Letter to New Grantees
- Grant Writing Tip Sheet
- Listing of NIH Chief Grants Management Officers
- NIH Acronym List
- NIH Grants – General Information Glossary
  (excerpt from the NIH Grants Policy Statement)
Welcome

- Introduction to Extramural Research from Dr. Ruiz Bravo
- NIH Outreach Activities
- New Investigator/Grantee
- General Information
- Staff Directories
- OER Offices and Org Charts

NIH Guide for Grants and Contracts (NIH Funding Announcements)

- RFAs, PAs and Notices
- Most Recent Weekly Index
- LISTSERV - Weekly E-Mail
- Search the NIH Guide
- Description of the NIH Guide
- Grant & Application Submission Information

Research Training

- News
- Extramural Training Programs
- Intramural Research and Training Opportunities
- Job Links
- Career Resources
- Forms and Applications
- Training Q&A and FAQs

Grant Topics

- Funding Opportunities
- Grants Policy and Guidance
- Grants Compliance and Oversight
- Award Data
- CRISP Database
- Intellectual Property Policy
- IDEASonline: Invention Reporting
- ERA: Electronic Research Admin.
- Forms and Applications
- Human Subjects
- Lab.Animal/Stiﬀfare (OLAW)
- Peer Review Policy and Issues
- Small Business Funding Opportunities (SBIR/STTR)
- NIH Roadmap Initiatives

Related Topics

- Bioethics
- Sites of Interest

News

- Current News Flashes
- News Archives
- Search News Archives

On OER Site

[Welcome | News | NIH Guide | Grant Topics | Research Training | Related Topics]
[Accessibility | Privacy Notice | Disclaimer | Contact Us | Help/Downloading Files]

http://grants.nih.gov/grants/oer.htm

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Getting Started at NIH
Useful Links from the NIH and Related Websites

GENERAL

All About Grants at http://www.niaid.nih.gov/ncn/grants/default.htm - Includes Grant Application Basics, How to Plan a Grant Application and How to Write a Grant Application.

NIH Home Page at http://www.nih.gov - links to offices within the offices of the Director, as well as to Institute and Center websites, each of which provides valuable tools and insights into Institute specific areas of research emphasis.

Office of Extramural Research at http://grants.nih.gov/grants/oer.htm - host to quantities of information of interest to the extramural community.

POLICY

NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2003/index.htm - On-line version of up-to-date policy guidance that serves as the terms and conditions of NIH awards. This document also provides information about NIH-its organization, its staff, and its grants process. A must read!


Modular grants at http://grants.nih.gov/grants/funding/modular/modular.htm - provides policies, lists of sample applications and valuable Q & A's.

Grant Funding Program Guidelines at http://grants.nih.gov/grants/funding/funding_program.htm - Includes R03, R15, R16, R21, R34, Inclusion of Women & Minorities and Inclusion of Children guidelines.

ELECTRONIC RESEARCH ADMINISTRATION


NIH Electronic Research Administration (eRA) at http://era.nih.gov - provides information on NIH's eRA initiative, which strives for paperless electronic transfer of application and administrative information. The NIH Commons may be accessed through this site.

CRISP at http://crisp.od.nih.gov - a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions.

OTHER

A Straightforward Description of What Happens to Your Research Project Grant Application After it is Received for Peer Review at http://wwwCSR.nih.gov/review/prerev.htm - A snapshot of the process for applications reviewed in the Center for Scientific Review.

Bioethics at http://www.nih.gov/sigs/bioethics/ - a broad collage of annotated web links on education, research involving human participants and animals, medical and healthcare ethics, and the implications of applied research.


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genetics and biotechnology. This site may be useful for those looking for ways to satisfy the educational requirements for training on the protection of human research participants.

HHS Office for Human Research Protections (OHRP) at http://ohrp.osophs.dhhs.gov - this new office at the Department of Health and Human Services leads efforts for protecting human subjects in biomedical and behavioral research.

NIH Office of Laboratory Animal Welfare (OLAW) at http://grants.nih.gov/grants/olaw/index.htm - responsible for animal-related functions, including the Public Health Service Policy on Humane Care and Use of Laboratory Animals, administering an educational program for PHS-supported institutions and investigators, negotiating Animal Welfare Assurances, and evaluating compliance with the PHS Policy.

Grant Writing Tips Sheets at http://grants.nih.gov/grants/grant_tips.htm - Links to Web sites with grant writing tips.

On OER Site
[Welcome | News | NIH Guide | Grant Topics | Research Training | Related Topics]  

Site Search | Sign In | Document Index | Contact Us | Help | Downloading Files]  

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**NIH "WELCOME WAGON" LETTER**

Information for New Grantee Organizations

Updated: April 2004

This letter may also be helpful to established grantee organizations because it updates previous issues and cites new and current provisions.

While the "Welcome Wagon" letter [http://grants.nih.gov/grants/funding/welcomewagon.htm](http://grants.nih.gov/grants/funding/welcomewagon.htm) highlights or summarizes important issues, it is neither intended to nor does it serve as a substitute for the NIH GPS.

**REQUIREMENTS AND PROVISIONS**

**Terms of Award**

Acceptance of a grant award from NIH carries with it the responsibility to be aware of and comply with the terms and conditions of award. The Notice of Grant Award (NOG) states:

This award is based on the application submitted to, and as approved by, the NIH on the above-listed project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. Grant program legislation and program regulation cited in the Notice of Grant Award.

b. Restrictions on the expenditure of Federal funds in appropriation acts, to the extent those restrictions are pertinent to the award.


d. The National Institutes of Health Grants Policy Statement (NIHGPS) in effect at the beginning date of the budget period.


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The National Institutes of Health Grants Policy Statement

The NIHGPS (rev. 1/2003) is a term and condition for all NIH grant awards with budget periods beginning on or after 1/1/03. In the NIHGPS, Part II. Terms of Award contains the legally binding requirements for all grant recipients. By drawing funds from the appropriate payment system, the grantee agrees to the terms and conditions of the award. The previous edition (3/1/01) is in effect for budget periods that began on or after 3/1/01 through 12/01/03.

The NIHGPS covers policy topics such as expedited authorities, modular applications, SNAP (streamlined non-competing application process), prior approval requirements, and awards to foreign entities. A search mechanism is provided to facilitate easy access to the information that is contained within the NIHGPS.

If you do not have a copy of the NIHGPS, you may access either PDF or an HTML version at http://grants.nih.gov/grants/policy/policy.htm.

45 CFR Part 74 and 45 CFR Part 92

Regulations found at Title 45, Code of Federal Regulations (CFR), Parts 74 and 92, are the HHS rules and requirements that govern the administration of grants. Part 74 is applicable to all recipients except those covered by Part 92, which governs awards to state and local governments. As is the case for the NIHGPS, these regulations are a term and condition of award. Grant recipients must be aware of and comply with the regulations. The CFR volume that includes Parts 74 and 92 may be ordered from the following:

U.S. Government Printing Office
Superintendent of Documents
Mail Stop 8420P
Washington, D.C. 20402-8328

The 45 CFR Parts 74 and 92 may also be accessed from HHS GrantsNet at:

http://www.hhs.gov/grantsnet/

Reporting Requirements

- Financial Status Report (FSR): The FSR is submitted on Standard Form 299 (SF 299, long form) or Standard Form 299A (SF 299A, short form) as the report of expenditures documenting the financial status of the award, according to the official accounting records of the grantee organization.

For grants that are awarded under the SNAP, an FSR for each budget period must be submitted within 90 days after the close of the budget period (see NIHGPS). FSRs for grants subject to SNAP are due 90 days after the close of the competitive segment (see NIHGPS). When reporting grant-related program income, the long-form FSR (SF 299) must be used. (See NIHGPS for a further explanation of grant-related program income).

FSRs submitted to the NIH are submitted to the NIH Office of Financial Management for review and acceptance. FSRs for other PHS components other than NIH should be submitted directly to the Grants Management Office of the PHS component that made the award.

FSRs for NIH awards should be sent to:

Government Accounting Branch
Office of Financial Management
National Institutes of Health
31 Center Drive, Room 81805A, MSC 2050
Bethesda, MD 20892-2050
Tel: (301) 402-9123

 NIH has a system for the electronic transmittal of FSRs that allows participants to list currently due, and late FSRs, as


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well as to submit FSRs electronically. To register to use this system, contact the eRA Commons Help Desk at:

NIH Commons UAW Support Branch
Help Desk (866)504-9552 (Toll Free)
(301)402-7459 (Voice)
(201)451-6575 (Fax)
(901)451-5939 (TTY)
ecommons@od.nih.gov

- Progress Report: All NIH grant awards require, at a minimum, an annual progress report, which is submitted with as part of the Annual Non-Competing Progress Report (PHS Form 2590). Refer to the competing or non-competing PHS forms and instructions for the appropriate instructions. If a PHS 2590 is not submitted because continuation support is not desired, a final progress report must be submitted within 90 days after the expiration or termination of the project (see NIHGPS).

- Inventions Report: The Bayh-Dole Act (P.L. 96-517) affords Grantees the right to retain the rights to patentable inventions that were conceived or first actually reduced to practice during the course of an NIH grant award (so-called subject inventions). In accepting an award, the grantee agrees to comply with the Government-wide patent regulations found at Title 37, Codes of Federal Regulations (CFR) Part 401. A significant part of the Regulations require that the grantee report all subject inventions to the granting agency (see NIHGPS). NIH participates in the transfer of technology Electronic system (http://www.etdex.gov) and strongly encourages use of this system to comply with Bayh-Dole reporting requirements. The system allows for grantees to submit reports electronically over the Internet. In addition, the invention must be reported in continuation applications (competing or non-competing). Also, the invention must be included on the Final Invention Statement and Certification (HHS 586), which is required within 90 days following the expiration or termination of the project. (See NIHGPS) Invention reporting information should be directed as follows:

- Extramural Intellectual Property policies and Bayh-Dole-related documents or questions:
  - Extramural Inventions and Technology Resources Branch
  Office of Policy for Extramural Research Administration, OER, NIH
  6705 Rockledge Drive, MSC 7890
  Bethesda, MD 20892-7890
  TEL: (301) 435-1986
  e-mail: Edson@od.nih.gov

  - Invention report documents or questions pertaining to continuations applications should be directed to the NIH awarding Institute or Center, as specified on the NGA.

  - The Final Invention Statement and Certification should be directed to the NIH awarding Institute or Center, as specified on the Notice of Grant Award. A downloadable version of the HHS 586 is available at: http://grants.nih.gov/grants/hhs586.pdf

A more detailed discussion of reporting obligations can be found in the NIHGPS discussion on monitoring and reporting, located at http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Pintel.htm#Top54600-01

Audit Requirements

Audit requirements for Federal award recipients are defined in OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations (June 30, 1997 with revisions published June 27, 2003). A for-profit organization is required to have a non-Federal audit if, during its fiscal year, it expended a total of $300,000 or more under one or more HHS awards and at least one of those awards is an HHS grant (as a direct grant and/or under a consortium agreement). 45 CFR 74.26(c) provides for-profit organizations with two options regarding the type of audit that will satisfy the audit requirements. The grantee may either have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the Yellow Book), GPO stock # 020-000-20-265-4, of all the HHS awards; or (2) an audit that meets the requirements of OMB Circular A-133. For-profit organizations spending less than $300,000 a year (calculated as above) are not required to have an annual audit for that year but must make their grant-related records available to NIH or other designated officials for review or audit.

OMB Circular A-133 now requires auditees to submit a completed data collection form (SF-54C) with the audit reporting package to the Federal clearinghouse designated by OMB - currently the Federal Award Clearinghouse, Bureau of the Census, 2201 E. 10th Street, Jeffersonville, IN 47132. For questions concerning the submission process, located at http://grants.nih.gov/grants/funding/welcomeawagon.htm?Display=Graphics

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Protection of Human Subjects in Research

Every applicant proposing to "engage" in human subjects research is required to provide an assurance to comply with the regulations pertaining to the protection of human subjects in research (45 CFR Part 46) unless the research is exempt under 45 CFR 46.101(b).

An applicant will be "engaged" in human subjects research when its employees or agents plan to (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes (45 CFR 46.102(d), (f)).

Awards involving human subjects will only be made after Office for Human Research Protections (OHRP), NIH, has approved an Assurance of Compliance for the grantee. In addition, the grantee must provide certification, to the NIH, that the research has been reviewed and approved by Institutional Review Board (IRB) within 12 months of the budget period start date, and that the research will be subject to continuing review by the IRB.

The grantee institution bears ultimate responsibility for protecting human subjects under the award, including human subjects as all collaborating sites, and for ensuring that an assurance approved by OHRP and certification of IRB review and approval have been obtained before human subjects research can be conducted at each collaborating site.

Information is provided for the Federalwide Assurance on the OHRP website. Certification of IRB review is under "Just-in-Time" procedures.

Additional information is available regarding Financial Conflict of Interest, and Data Safety and Monitoring for clinical trials, Required Education for the protection of human research participants, and Inclusion of Women, Minorities & Children. Also, the URL for "Protecting Human Research Subjects: Institutional Review Board Guidebook" is http://ohrp.od.nih.gov/irb/irb_guidebook.htm. To obtain information concerning a human subject assurance, contact OHRP at:

Office for Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway, Suite 300
Rockville, MD 20852
Tel.: 301-443-7005
E-mail address: ohrp@od.nih.gov


In addition, OHRP provides an instructional videotape on the Protection of Human Subjects. This videotape, available free of charge, contains three components:

- Evolving Concern, Protection for Human Subjects
- Balancing Society's Mandates, IRB Review Criteria
- The Belmont Report, Basic Ethical Principles and Their Application

To obtain a copy of the videotape, contact:

For New Grantees (NIH "Welcome Wagon" Letter)  Page 5 of 10

Education Program Coordinator
Division of Human Subjects Protection
Office for Human Research Protections
Department of Health and Human Services
101 Woodton Parkway, Suite 200
Rockville, MD 20852
Tel. 301-496-7005

Care and Use of Laboratory Animals in Research

The Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) governs the use of all live vertebrate animals in research supported by the NIH. This policy provides for institutional oversight of the humane use of animal research subjects and requires that domestic institutions follow the Guide for the Care and Use of Laboratory Animals. No award involving the use of animals will be made unless the NIH Office of Laboratory Animal Welfare (OLAW) has approved an Animal Welfare Assurance and the Institutional Animal Care and Use Committee (IACUC) has approved those components of the application related to the care and use of animals. If there are performance slights or animal work will be conducted at an institution other than the awardee, that institution must also obtain the necessary Assurances. Verification of IACUC approval is under "just-in-time" procedures.

Additional information is available on the OLAW website, including the PHS Policy, a sample Animal Welfare Assurance, PHS Policy Tutorial, IACUC Guidebook and the Guide for the Care and Use of Laboratory Animals. To obtain information regarding normal welfare assurance requirements, contact:

Office of Laboratory Animal Welfare
Rockledge 1, Suite 280, MSC 7982
8705 Rockledge Drive Bethesda, MD 20892-7982
TEL: (301) 486-7163 FAX: (301) 480-2863
e-mail address: olaw@od.nih.gov

Recombinant DNA

Organizations planning to conduct research involving recombinant DNA, including human gene transfer, are required to comply with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). The NIH Guidelines can be obtained from the Web site of the NIH Office of Biotechnology Activities, which oversees their implementation, at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

Institutions subject to the NIH Guidelines must establish a standing institutional Biosafety Committee. The requirements for the composition of this committee may be found in Section IV-B-2-a of the NIH Guidelines and are summarized on the Web site of the NIH Office of Biotechnology Activities:

http://www4.od.nih.gov/oba/BC/indexxpg.htm

Investigators needing additional information should contact:

Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Bethesda, MD 20892-7985
Tel: (301) 486-9838
Fax: (301) 486-9839
e-mail address: oba@nih.gov
http://www4.od.nih.gov/oba

Office of Research Integrity

The HHS Office of Research Integrity (ORI) is responsible for implementing the assurance system related to procedures on scientific misconduct. An organization receiving NIH grant support for research is required to certify compliance with CFR 42 Part 50, Subpart A, and "Responsibilities for PHS Awardee and Applicant Institutions for Confidence in Research Integrity" at http://grants.nih.gov/grants/funding/welcomewagon.htm?Display=Graphics

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Dealing with Possible Misconduct in Science, as part of the grant application. ORI also requires an annual report (PHS 6348) detailing aggregate information on allegations, inquiries and investigations that were handled by a grantee organization. The annual report constitutes the organizational official's assurance to ORI that the organization has established internal policies and procedures and will comply with PHS regulations for reviewing, investigating and reporting allegations of misconduct in science conducted at, or sponsored by, the organization.

To obtain the above referenced forms, or for additional information regarding scientific misconduct and research integrity, contact:

**Office of Research Integrity**
Assurance Program
4510 Security Lane
Rockville, MD 20852
TEL: (301) 443-0300
FAX: (301) 594-0042

**Public Policy Requirements**

Applicants, upon signing an application requesting Federal assistance, certify compliance with a number of public policy requirements, some of which are established in or flow down from legislative or regulatory provisions. These policies govern such areas as objectivity in research, civil rights, environmental impact, bio-safety, drug-free workplace, debarment and suspension, Federal debt, and lobbying with Federal funds and are intended to ensure fairness and equity, as well as physical and other protections in activities which receive PHS financial assistance. The public policy requirements and objectives governing NIH awards are presented in the NIHGPS.

Public policy requirements concerning civil rights, handicapped individuals, sex discrimination, and age discrimination require the one-time submission of Assurance Form HHS 680, [http://www.hhs.gov/ogc/premngrnts/pfas680.pdf](http://www.hhs.gov/ogc/premngrnts/pfas680.pdf) prior to award and certification in all subsequent applications that the form (or the previous forms HHS 441, 641, 632A, and 680) has been filed.

To obtain the forms, send an email to grantsinfo@nih.gov or call GRANTSINFO at (301) 485-0714.

To inquire as to whether your organization has previously filed the HHS 680 or the previous forms, contact the DHHS Office for Civil Rights at (202) 619-0403.

**Cost Principles**

The costs of a grant-supported activity are comprised of allowable direct costs, plus the allocable portion of the organization's associated facilities and administrative (F&A) costs. Direct costs are costs that can be specifically identified with a particular project or program, while F&A costs are incurred for common or joint objectives and which therefore cannot be identified specifically with a particular project or program. The allowability, reasonableness and necessity of direct and F&A costs that may be charged to NIH grants are outlined in five sets of cost principles.

- [OMB Circular A-21](http://www.grants.gov) for Institutions of Higher Education
- [OMB Circular A-87](http://www.grants.gov) for State and Local Governments
- [OMB Circular A-122](http://www.grants.gov) for Nonprofit Organizations
- 45 CFR Part 74, Appendix E for Hospitals
- FAR 48 Subpart 31.2 for For-profit Organizations

**Facilities & Administrative Cost Rate Negotiations**

The payment of facilities & administrative (F&A) costs is based upon rates established through a formal agreement between the grantee organization and the cognizant Federal agency. The negotiated rate is applied to the direct cost base for individual grants to determine the amount of total costs to be awarded. HHS/NIH recognizes F&A cost rates applicable to research activities negotiated by other Federal agencies adjusted for the NIH treatment of independent (self-sponsored) research and development (R&D) costs. NIH does not reimburse F&A costs on grants to individuals, or agencies of the Federal Government, or on construction and conference grants. F&A is provided to foreign grantees beginning with FY 2002 based on a rate of 8%.

F&A rates are not negotiated for Phase I SBIR/STTR awards.

Administrative Standards For Grants

In addition to the cost principles, OMB has established administrative standards and audit requirements for organizations receiving Federal assistance.

OMB Circular A-102 State and Local Governments and Indian Tribes
OMB Circular A-110 Higher Education, Hospitals, and Other Nonprofit Organizations
OMB Circular A-133 Audits of States, Local Governments, and Non-Profit Organizations

- The OMB website is: http://www.whitehouse.gov/omb/
- Copies of the Office of Management and Budget (OMB) Circulars are available on the Internet at: http://www.whitehouse.gov/omb/circulars/ or by calling (202) 395-7332.

Electronic Research Administration

The NIH Commons is the means by which NIH PI's can review the current status of their grant applications and review detailed information associated with their grants. Institutional officials can see a summary view of grant applications, review the Notice of Grant Award, access the Progress Report face page, and submit electronic FSIRs. For more information, go to: https://commons.era.nih.gov/commons/. Details on the Commons registration process can be found at: https://commons.era.nih.gov/commons/registration/registration/instructions.jsp. For additional information or user support contact the help desk at commons@od.nih.gov.

Electronic Access to Grant-Related Resources over the Internet

Anyone with an Internet connection can electronically access numerous grant-related resources such as the NIHGPS, NIH Guide for Grants and Contracts, and other grant resources at the following Internet address: http://grants.nih.gov/grants/guide.htm

NIH Guide for Grants and Contracts

The NIH Guide for Grants and Contracts (NIH Guide), published daily and indexed weekly, provides information to the research community regarding NIH Program Announcements (PAs), Requests for Applications (RFAs), Requests for (Contract) Proposals (RFPs), and Notices of changes to NIH grants policy. The NIH Guide is available at: http://grants.nih.gov/grants/guide/index.htm.

NIH Extramural Research and Research Training Programs

You will find a wealth of information about NIH research and research training programs and funding opportunities on the NIH Office of Extramural Research Web site, at: http://grants.nih.gov/training/index.htm.

NIH Award Data

Data about NIH awards is available on NIH's Award Data page, located at http://grants.nih.gov/grants/awardaward.htm. This page also includes:

- CRISP (Computer Retrieval of Information on Scientific Projects)

  A searchable biomedical database of federally-supported proposed research conducted at universities, hospitals, and other research institutions. You may access the CRISP Database at: http://crisp.cit.nih.gov/. If you have questions about CRISP, you may contact the Division of Research Documentation on 301-435-0650.

- Extramural Data and Award Trends

  NIH award data presented in many formats including:
  - Research Grants Award Trends - current and long-term (historical)

If you need information or guidance about Extramural Date and Award Trends, please send an e-mail to: DSNmail@mail.nih.gov.

NIH GRANT APPLICATION INSTRUCTIONS AND FORMS

Details concerning application procedures, application forms, and dates for submission of applications may be obtained electronically by e-mail from grantsinfo@nih.gov. Activity (mechanisms) codes, organization codes, and definitions used in extramural programs can be found at http://grants.nih.gov/grants/funding/app.pdf.

Application forms used for the majority of the NIH grant programs are listed below.

- **PHS 398** Application for Public Health Service Grant (including Research Career Development Awards and Institutional National Research Service Awards): this form is used for new, competing continuation, and supplemental applications.
- **PHS 2650** Progress Report for a Public Health Service Grant (including Research Career Development Awards and Institutional National Research Service Awards): this form is used for non-competing continuation applications.
- **PHS 418-1** Application for Public Health Service Individual National Research Service Award (Fellowship)
- **PHS 418-9** Application for Public Health Service Individual National Research Service Award (Fellowship) Continuation
- **SF 424** Application for Federal Assistance used for construction programs only
- **PHS 5161-1** Application for Federal Assistance Non-Construction Programs (State and Local Government applicants only)

The PHS 398 and PHS 2650 instructions (HTML) and forms in Adobe Acrobat are available on the NIH web site (http://www.nih.gov), under "Grants and Funding Opportunities," "Grants page." If you do not have access to the Internet, you may order the forms by calling GRANTSINFO at (301) 435-0714 or sending an e-mail to grantsinfo@nih.gov.

The NIH will mail (fourth class) application materials to institutional offices of sponsored research (or equivalent) upon request. Requests should be for the anticipated number needed for six to twelve months. Requests should be made by sending e-mail to: grantsinfo@nih.gov or by calling GRANTSINFO at (301) 435-0714.

**OTHER IMPORTANT OFFICES AT NIH AND HHS**

**Payment Procedures**

Payments for grants awarded by NIH are made through the Division of Payment Management with the exception of awards to individuals, foreign organizations, and agencies of the Federal Government, which are paid by the NIH Office of Financial Management. Applicant organizations are assigned a 12-digit Employer Identification Number for payment and accounting purposes. That number is an expansion of the 8-digit Employer Identification Number assigned to an organization by the Internal Revenue Service.

The Payment Management System is administered by the Program Support Center (PSC), DHHS. Requests for downloadable forms and inquiries regarding payments should be directed to:

Division of Payment Management
P.O. Box 6021

Questions regarding payments of grants to individuals, foreign organizations, and agencies of the Federal Government should be addressed to:

Government Accounting Branch
Office of Financial Management
National Institutes of Health
31 Center Drive, Room B1101SA
Baltimore, MD 20892-1050
Tel: (301) 496-4401

**Patient Care Costs**

In instances where the proposed project represents a clinical research study, funds may be requested in a grant application for Patient Care Costs. Due to the special nature of these costs, a detailed explanation is required in the application as to how the total amount requested was determined. In situations where the amount requested for patient care results in an award that exceeds $100,000 in that category for a single budget period, the grantee organization must either have in place or take steps to develop a negotiated patient care rate agreement with HHS.

Hospitals and nonprofit organizations with questions concerning the negotiation of F&A cost rate agreements or patient care rate agreements should contact the appropriate office listed below.

**HHS Division of Cost Allocation Regional Offices**

<table>
<thead>
<tr>
<th>Region</th>
<th>Address for Grantees Located In:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, Puerto Rico, Virgin Islands</td>
</tr>
<tr>
<td>Mid-Atlantic</td>
<td>Alabama, Delaware, District of Columbia, Florida, Georgia, Kentucky, Maryland, Mississippi, North Carolina, Pennsylvania, South Carolina, Tennessee, Virginia, West Virginia</td>
</tr>
<tr>
<td>Central States</td>
<td>Arkansas, Illinois, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nebraska, New Mexico, Ohio, Oklahoma, Texas, Wisconsin</td>
</tr>
<tr>
<td>Western</td>
<td>Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming</td>
</tr>
</tbody>
</table>

For-profit organizations should contact:

Office of Acquisition Management and Policy, NIH
6100 Executive Boulevard, Room 6B55, MSC 7540
Baltimore, MD 20892-7540
Tel: (301) 496-4401


4/26/2004
Grant Writing Tips Sheets

Many NIH Institutes put out guides and tip sheets on their Web sites. These guides can be useful resources. Here are just a few.

- All About Grants - Including Grant Application Basics, How to Plan a Grant Application and How to Write a Grant Application
- Preparing Grant Applications
- Quick Guide for Grant Applications
- Tips for New NIH Grant Applicants
- Quick Guide for the Preparation of Grant Applications (Complementary and Alternative Medicine)
- Applying for an NIH Grant
- A Straightforward Description of What Happens to Your Research Project Grant Application (R01/R21) After it is Received for Peer Review
- Review Of New Investigator R21s: Guidelines for Reviewers
- ORIN/STR Policy and Grantmanship Information

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[Welcome | News | NIH Guide | Grant Topics | Research Training | Related Topics]

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[OER Home | NIH Home | Accessibility | Privacy Notice | Disclaimer]

http://grants.nih.gov/grants/grant_tips.htm

4/26/2004
<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Office</th>
<th>Phone</th>
<th>Fax</th>
<th>E-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buscher</td>
<td>Leo</td>
<td>NCI</td>
<td>436-7753</td>
<td>402-3409</td>
<td><a href="mailto:leoa@nih.gov">leoa@nih.gov</a></td>
</tr>
<tr>
<td>Buhm</td>
<td>Bruce</td>
<td>FIC</td>
<td>451-4830</td>
<td>594-1211</td>
<td><a href="mailto:mbuhm@nih.gov">mbuhm@nih.gov</a></td>
</tr>
<tr>
<td>Chik</td>
<td>Chewy</td>
<td>NIGMS</td>
<td>402-0733</td>
<td>402-1951</td>
<td><a href="mailto:chik@nih.gov">chik@nih.gov</a></td>
</tr>
<tr>
<td>Clark</td>
<td>Bryan</td>
<td>NOMHD</td>
<td>402-1365</td>
<td>402-8049</td>
<td><a href="mailto:blyrn@nih.gov">blyrn@nih.gov</a></td>
</tr>
<tr>
<td>Claycamp</td>
<td>Rebecca</td>
<td>NHLBI</td>
<td>443-2068</td>
<td>443-6685</td>
<td><a href="mailto:rclayc@nih.gov">rclayc@nih.gov</a></td>
</tr>
<tr>
<td>Cole</td>
<td>Marcello</td>
<td>NIGMS</td>
<td>384-2115</td>
<td>402-2554</td>
<td><a href="mailto:mcclay@nih.gov">mcclay@nih.gov</a></td>
</tr>
<tr>
<td>Curley</td>
<td>Nancy</td>
<td>NHLBI</td>
<td>406-3015</td>
<td>351-6735</td>
<td><a href="mailto:nclayn@nih.gov">nclayn@nih.gov</a></td>
</tr>
<tr>
<td>Daisy</td>
<td>Mary</td>
<td>NIDCR</td>
<td>594-4800</td>
<td>402-3622</td>
<td><a href="mailto:mdaisy@nih.gov">mdaisy@nih.gov</a></td>
</tr>
<tr>
<td>Fappy</td>
<td>William</td>
<td>NEI</td>
<td>451-2020</td>
<td>456-5037</td>
<td><a href="mailto:wclay@nih.gov">wclay@nih.gov</a></td>
</tr>
<tr>
<td>Dula</td>
<td>Dorothy</td>
<td>NHLBI</td>
<td>919-541-7028</td>
<td>919-541-2652</td>
<td><a href="mailto:dolly@nih.gov">dolly@nih.gov</a></td>
</tr>
<tr>
<td>Fleming</td>
<td>Gary</td>
<td>NIAID</td>
<td>443-6710</td>
<td>594-6849</td>
<td><a href="mailto:gclay@nih.gov">gclay@nih.gov</a></td>
</tr>
<tr>
<td>Fox</td>
<td>Judy</td>
<td>NIAA</td>
<td>443-4704</td>
<td>443-3891</td>
<td><a href="mailto:jclay@nih.gov">jclay@nih.gov</a></td>
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<tr>
<td>Grassim</td>
<td>Irene</td>
<td>NCHR</td>
<td>435-6644</td>
<td>460-3777</td>
<td><a href="mailto:iclary@nih.gov">iclary@nih.gov</a></td>
</tr>
<tr>
<td>Hancock</td>
<td>Annella</td>
<td>NCHD</td>
<td>496-3011</td>
<td>496-7070</td>
<td><a href="mailto:aclay@nih.gov">aclay@nih.gov</a></td>
</tr>
<tr>
<td>Kliner</td>
<td>Mary</td>
<td>NINDS</td>
<td>496-8021</td>
<td>496-0291</td>
<td><a href="mailto:aclay@nih.gov">aclay@nih.gov</a></td>
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<tr>
<td>Lowe</td>
<td>Michael</td>
<td>NINDS</td>
<td>496-8899</td>
<td>496-0202</td>
<td><a href="mailto:aclay@nih.gov">aclay@nih.gov</a></td>
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<tr>
<td>McDermott</td>
<td>Cindy</td>
<td>NENR</td>
<td>594-8854</td>
<td>490-3584</td>
<td><a href="mailto:aclay@nih.gov">aclay@nih.gov</a></td>
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<tr>
<td>Mineo</td>
<td>David</td>
<td>NCCAM</td>
<td>594-8854</td>
<td>490-5004</td>
<td><a href="mailto:aclay@nih.gov">aclay@nih.gov</a></td>
</tr>
<tr>
<td>Mineo</td>
<td>David L.</td>
<td>NIDDK</td>
<td>594-9854</td>
<td>490-6004</td>
<td><a href="mailto:aclay@nih.gov">aclay@nih.gov</a></td>
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<tr>
<td>Mowery</td>
<td>Dwight</td>
<td>NLM</td>
<td>496-4222</td>
<td>490-0421</td>
<td><a href="mailto:aclay@nih.gov">aclay@nih.gov</a></td>
</tr>
<tr>
<td>Nelson</td>
<td>Melinda</td>
<td>NIAID</td>
<td>594-3535</td>
<td>490-9440</td>
<td><a href="mailto:aclay@nih.gov">aclay@nih.gov</a></td>
</tr>
<tr>
<td>Slovis</td>
<td>Sara</td>
<td>NIMCD</td>
<td>402-0060</td>
<td>402-1770</td>
<td><a href="mailto:aclay@nih.gov">aclay@nih.gov</a></td>
</tr>
<tr>
<td>White</td>
<td>Linda C.</td>
<td>NA</td>
<td>496-4772</td>
<td>402-3782</td>
<td><a href="mailto:aclay@nih.gov">aclay@nih.gov</a></td>
</tr>
<tr>
<td>White</td>
<td>Suzanne</td>
<td>NHLBI</td>
<td>301-435-0144</td>
<td>480-5310</td>
<td><a href="mailto:aclay@nih.gov">aclay@nih.gov</a></td>
</tr>
</tbody>
</table>

Total Count = 24
NIH Acronym List

AHRO - Agency for Healthcare Research and Quality
AREA - Academic Research Enhancement Award
BECON - Bioengineering Consortium
BML - Biological Material License
BRDPI - Biomedical Research and Development Price Index
BSC - Board of Scientific Counselors
CC - Warren Grant Magnuson Clinical Center
CDuC - Centers for Disease Control and Prevention
CEL - Commercial Evaluation License
CFDA - Catalog of Federal Domestic Assistance
CFR - Code of Federal Regulations
CIT - Center for Information Technology
CRADA - Cooperative Research and Development Agreement
CRC - Cooperative Research Center
CRISP - Computer Retrieval of Information on Scientific Programs
CSR - Center for Scientific Review
DCA - Division of Cost Allocation
DHHS - Department of Health and Human Services
EA - Expanded Authorities
EIR - Employee Invention Report
ERA - Electronic Research Administration
ESA - Extramural Scientist Administrator
F & A - Facilities and Administrative Costs

http://grants.nih.gov/grants/acronym_list.htm

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FACA - Federal Advisory Committee Act
FAR - Federal Acquisition Regulations
FCTR - Federal Cash Transaction Report (SF-269 or 269A)
FDA - Food and Drug Administration
FDP - Federal Demonstration Partnership
FIC - John E. Fogarty International Center
FIRST - First Independent Research Support and Transition Award
FOA - Freedom of Information Act
FPR - Final Proposal Revision
FSR - Financial Status Report
FTE - Full-Time Equivalent
FTTA - Federal Technology Transfer Act
FTTP - Full-Time Training Position
FWA - Federal-wide Assurance
FY - Fiscal Year
GAO - General Accounting Office
GMO - Grants Management Officer
HHS - Department of Health and Human Services
HOPE - Health Omnibus Programs Extension Legislation
HRIM - High Risk/High Impact
HSA - Health Scientist Administrator
IACUC - Institutional Animal Care and Use Committee
IBRP - Introduction to Biomedical Research Program
IC - NIH Institute or Center
IMPAC - Information for Management, Planning, Analysis, and Coordination
IND - Investigational New Drug Application
IPA - Intergovernmental Personnel Act Mobility Program

http://grants.nih.gov/grants/acronym_list.htm

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IRB - Institutional Review Board
IRG - Initial Review Group
MARC - Minority Access to Research Careers Program
MBRS - Minority Biomedical Research Support Program
MERIT - Method to Extend Research in Time Award
MTA - Material Transfer Agreement
NCCAM - National Center for Complementary and Alternative Medicine
NCI - National Cancer Institute
NCMHO - National Center on Minority Health and Health Disparities
NCRR - National Center for Research Resources
NEI - National Eye Institute
NGA - Notice of Grant Award
NHGRI - National Human Genome Research Institute
NHLBI - National Heart, Lung, and Blood Institute
NIA - National Institute on Aging
NIAAA - National Institute on Alcohol Abuse and Alcoholism
MAID - National Institute of Allergy and Infectious Diseases
NIAMS - National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB - National Institute of Biomedical Imaging and Bioengineering
NICHD - National Institute of Child Health and Human Development
NIDA - National Institute on Drug Abuse
NIDCD - National Institute of Deafness and Other Communication Disorders
NIDCR - National Institute of Dental and Craniofacial Research
NIDDK - National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS - National Institute of Environmental Health Sciences
NIGMS - National Institute of General Medical Sciences
NIH - National Institutes of Health

http://grants.nih.gov/grants/acronym_list.htm
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<td>NIHGPS</td>
<td>NIH Grants Policy Statement</td>
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<td>National Institute of Mental Health</td>
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<td>NINDS</td>
<td>National Institute of Neurological Disorders and Stroke</td>
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<tr>
<td>NINR</td>
<td>National Institute for Nursing Research</td>
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<td>NLM</td>
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<td>NRSA</td>
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<td>NS</td>
<td>No Score (lower 50% of grants in study section)</td>
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<tr>
<td>NSS</td>
<td>No Study Section (in house)</td>
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<td>OD</td>
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<td>OEP</td>
<td>Office of Extramural Programs</td>
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<tr>
<td>OER</td>
<td>NIH Office of Extramural Research</td>
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<tr>
<td>OFM</td>
<td>NIH Office of Financial Management</td>
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<tr>
<td>OHRP</td>
<td>Office for Human Research Protections (previously OPRR)</td>
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<tr>
<td>OIG</td>
<td>Office of the Inspector General</td>
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<td>OLAW</td>
<td>Office of Laboratory Animal Welfare</td>
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<td>Office of Management and Budget</td>
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<td>OPERA</td>
<td>Office of Policy for Extramural Research Administration</td>
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<td>OPRR</td>
<td>Office for Protection from Research Risks (now OHRP)</td>
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<td>ORI</td>
<td>Office of Research Integrity</td>
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<td>Office of Research on Minority Health, NIH</td>
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<td>ORMWH</td>
<td>Office of Research on Minority and Women's Health, NIMD</td>
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<td>Office of Scientific Affairs</td>
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<td>Office of Tropical Medicine and International Research</td>
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NIH Acronym List

PAR - Program Announcement Reviewed in an Institute
PAS - Program Announcement with Set-aside funds
PI - Principal Investigator/Program Director/Project Director
PLA - Patent License Agreement
PHS - Public Health Service
PMS - Payment Management System
PO - Program Official
PRRR - Program Review Report Record
RCMI - Research Centers in Minority Institutions
RFA - Request For Applications (Grants)
RFP - Request For Proposals (Contracts)
RML - Rocky Mountain Laboratory
RPG - Research Project Grant
RSUM - Research Supplements for Underrepresented Minorities
SBIR - Small Business Innovation Research
SEP - Special Emphasis Panel
$SNAP - Streamlined Noncompeting Award Process
SOW - Statement Of Work
SRA - Scientific Review Administrator
SRG - Scientific Review Group
SSS - Special Study Section
STTR - Small Business Technology Transfer
WHO - World Health Organization

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http://grants.nih.gov/grants/acronym_list.htm

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### Definitions of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>alteration and renovation</td>
<td>Work that changes the interior arrangements or other physical characteristics of an existing facility or of installed equipment so that it can be used more effectively for its currently designated purpose or adapted to an alternative use to meet a programmatic requirement. Major A&amp;R (including: renovation, remodeling, or improvement) of an existing building is permitted under an NIH grant only when the authorizing statute for the program specifically allows that activity. (See &quot;Allowability of Costs/Activities—Selected Items of Cost—Alteration and Renovation&quot; and &quot;Allowability of Costs/Activities—Selected Items of Cost—Construction&quot;)</td>
</tr>
<tr>
<td>application</td>
<td>A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions. (See &quot;Application and Review Processes&quot; for detailed information about the application process, including an explanation of the types of applications.)</td>
</tr>
<tr>
<td>approved budget</td>
<td>The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH and permissible revisions made by the grantee. The approved budget consists of Federal (grant) funds and, if required by the terms and conditions of the award, non-Federal participation in the form of matching or cost sharing. The approved budget specified in the NGA may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grantee in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.</td>
</tr>
<tr>
<td>authorized organizational official</td>
<td>The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This official is equivalent to the SO in NIH's eRA Commons.</td>
</tr>
<tr>
<td>award</td>
<td>The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.</td>
</tr>
<tr>
<td>awarding office</td>
<td>The NIH IC responsible for the award, administration, and monitoring of particular grants.</td>
</tr>
<tr>
<td>budget period</td>
<td>The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.</td>
</tr>
<tr>
<td>capital expenditure</td>
<td>The cost of an asset (land, building, equipment), including the cost to put it in place. A capital expenditure for equipment includes the net invoice price and the cost of any modifications, attachments, accessories, or auxiliary apparatus to make it usable for the purpose for which it was acquired. Other charges, such as taxes, in-transit insurance, freight, and installation, may be included in capital expenditure costs in accordance with the recipient’s regular accounting practices consistently applied regardless of the source of funds. (See “Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Capital Expenditures.”)</td>
</tr>
<tr>
<td>clinical research</td>
<td>Patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, but does not include in vitro studies that use human tissues that cannot be linked to a living individual. Studies falling under 45 CFR 46.101(a) (4) are not considered clinical research for purposes of this definition.</td>
</tr>
</tbody>
</table>
| clinical trial | A biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases:  
  Phase I. Testing in a small group of people (e.g., 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects).  
  Phase II. Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety.  
  Phase III. Study to determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use.  
  Phase IV. Studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use. |
<p>| competitive segment | The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a competing continuation award. |
| consortium agreement | A formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. (See “Consortium Agreements” in Part 11, Subpart B.) |
| contract under a grant | A written agreement between a grantee and a third party to acquire routine goods or services. |
| Consultant | An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. Consultants also include firms that provide professional advice or services. (See &quot;Allowability of Costs/Activities—Selected Items of Cost—Consultant Services&quot;) |
| Cooperative Agreement | A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities. |
| Co-Investigator | An individual involved with the PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered &quot;key personnel.&quot; The designation of a co-investigator, if applicable, does not affect the PI's roles and responsibilities as specified in the NIHGPS. |
| Cost Overrun | Any amount charged in excess of the Federal share of costs for the project period (competitive segment). |
| Cost Sharing | See &quot;matching or cost sharing&quot; in this section. |
| Direct Costs | Costs that can be specifically identified with a particular project or activity. |
| Domestic Organization | A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities. |
| Equipment | An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds $5,000 or the capitalization threshold established by the organization, whichever is less. |
| Expanded Authorities | Operating authorities provided to grantees that waive the requirement for NIH prior approval for specified actions (see &quot;Administrative Requirements—Changes in Project and Budget—Expanded Authorities&quot;). |
| Facilities and Administrative Costs | Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs also are known as &quot;indirect costs.&quot; |
| Federal Demonstration Partnership | A cooperative initiative among some Federal agencies, including NIH, selected organizations receiving Federal funding for research, and certain professional associations. Its efforts include demonstration projects intended to simplify and standardize Federal requirements in order to increase research productivity and reduce administrative costs. |
| Federal Institution | A Cabinet-level department or independent agency of the executive branch of the Federal government or any component organization of such a department or agency. |</p>
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>fee</td>
<td>An amount, in addition to actual allowable costs, paid to an organization providing goods or services consistent with normal commercial practice. This payment is also referred to as &quot;profit.&quot; (See &quot;Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs—Allowable Costs and Fee—Profit or Fee.&quot;)</td>
</tr>
<tr>
<td>financial assistance</td>
<td>Transfer by Nih of money or property to an eligible entity to support or stimulate a public purpose authorized by statute.</td>
</tr>
<tr>
<td>foreign component</td>
<td>The performance of any significant scientific element or segment of a project outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the grantee that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Foreign travel for consultation is not considered a foreign component. (See &quot;Grants to Foreign Institutions, International Organizations, and Domestic-U.S. Grants with Foreign Components.&quot;)</td>
</tr>
<tr>
<td>foreign institution</td>
<td>An organization located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed PI.</td>
</tr>
<tr>
<td>for-profit organization</td>
<td>An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. Such organizations are also referred to as &quot;commercial organizations.&quot;</td>
</tr>
<tr>
<td>full-time appointment</td>
<td>The number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.</td>
</tr>
<tr>
<td>grant</td>
<td>A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH IC anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.</td>
</tr>
<tr>
<td>grant-supported project or activity</td>
<td>Those activities specified or defined in a grant application or in a subsequent submission that are approved by an NIH IC for funding, regardless of whether Federal funding constitutes all or only a portion of the financial support necessary to carry them out.</td>
</tr>
<tr>
<td>Grants Management Officer</td>
<td>An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. Only GMOs are authorized to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH IC that awards grants has one or more GMOs with responsibility for particular programs or awards.</td>
</tr>
<tr>
<td>Grants Management Specialist</td>
<td>An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award.</td>
</tr>
<tr>
<td>hospital</td>
<td>A non-profit or for-profit hospital or a medical-care provider component of a non-profit organization (for example, a foundation). The term includes all types of medical, psychiatric, and dental facilities, such as clinics, infirmaries, and sanatoria.</td>
</tr>
<tr>
<td>human subject</td>
<td>A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. (See <em>(Regulations Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects)</em>)</td>
</tr>
<tr>
<td>indirect costs</td>
<td>See <em>(facilities and administrative costs)</em>.</td>
</tr>
<tr>
<td>Institute or Center</td>
<td>The NIH organizational component responsible for a particular grant program or set of activities. The terms &quot;NIH IC&quot; or &quot;awarding office&quot; are used throughout this document to designate a point of contact for advice and interpretation of grant requirements and to establish the focal point for requesting necessary prior approvals or changes in the terms and conditions of award. In the latter case, the terms refer specifically to the designated GMO.</td>
</tr>
<tr>
<td>institutional base salary</td>
<td>The annual compensation paid by an organization for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds. (See <em>(Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages)</em>)</td>
</tr>
<tr>
<td>international organization</td>
<td>An organization that identifies itself as international or intergovernmental and has membership from, and represents the interests of, more than one country, without regard to whether the headquarters of the organization and location of the activity are inside or outside of the United States.</td>
</tr>
<tr>
<td>matching or cost sharing</td>
<td>The value of third party in-kind contributions and the portion of the costs of a federally assisted project or program not borne by the Federal government. Matching or cost sharing may be required by law, regulation, or administrative decision of an NIH IC. Costs used to satisfy matching or cost-sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.</td>
</tr>
<tr>
<td>modular application</td>
<td>A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review of the application, award, and post-award administration.</td>
</tr>
<tr>
<td>monitoring</td>
<td>A process whereby the programmatic and business management performance aspects of a grant are assessed by reviewing information gathered from various required reports, audits, site visits, and other sources.</td>
</tr>
<tr>
<td>new investigator</td>
<td>An individual who has not previously served as a PI on any PHS-supported research project other than a small grant (RO3), an Academic Research Enhancement Award (PR15), an exploratory development grant (R21), or certain research career awards directed principally to physicians, dentists, or veterinarians at the beginning of their research careers (K01, K08, and K12). Current or past recipients of Independent Scientist and other non-mentored career awards (K02 and K04) are not considered &quot;new investigators.&quot;</td>
</tr>
<tr>
<td>Notice of Grant Award</td>
<td>The legally binding document that notifies the grantee and others that an award has been made, contains or references all terms and conditions of the award, and documents the obligation of Federal funds. The award notice may be in letter format and may be issued electronically.</td>
</tr>
<tr>
<td>organization</td>
<td>A generic term used to refer to an educational institution or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.</td>
</tr>
<tr>
<td>other support</td>
<td>Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.</td>
</tr>
<tr>
<td>Phase III clinical trial</td>
<td>As defined by NIH, a broadly based prospective Phase III clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included. (See &quot;clinical trial.&quot;)</td>
</tr>
<tr>
<td>Principal Investigator/Program Director/Project Director</td>
<td>An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and NIH for the proper conduct of the project or activity.</td>
</tr>
<tr>
<td>prior approval</td>
<td>Written approval from the designated GMO required for specified post-award changes in the approved project or budget. Such approval must be obtained before undertaking the proposed activity or spending NIH funds (see &quot;Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements&quot;).</td>
</tr>
<tr>
<td>priority score</td>
<td>A numerical rating of an application that reflects the scientific merit of the proposed research relative to stated evaluation criteria.</td>
</tr>
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</table>

6
<table>
<thead>
<tr>
<th>term</th>
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</tr>
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<tbody>
<tr>
<td>profit</td>
<td>See “fee.”</td>
</tr>
<tr>
<td>program</td>
<td>A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization’s mission or some specific program–related aspect of that mission. For the NIH’s “program” refers to those NIH programs that carry out their missions through the award of grants or cooperative agreements to other organizations.</td>
</tr>
<tr>
<td>program income</td>
<td>Gross income earned by a grantee that is directly generated by the grant–supported project or activity or earned as a result of the award (see “Administrative Requirements—Management Systems and Procedures—Program Income”).</td>
</tr>
<tr>
<td>Program Official</td>
<td>The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.</td>
</tr>
<tr>
<td>progress report</td>
<td>Periodic, usually annual, report submitted by the grantee and used by NIH to assess progress and, except for the final progress report of a project period, to determine whether to provide funding for the budget period subsequent to that covered by the report.</td>
</tr>
<tr>
<td>project period</td>
<td>The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a competing continuation award, and non-competitive extensions.</td>
</tr>
<tr>
<td>real property</td>
<td>Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment.</td>
</tr>
<tr>
<td>recipient</td>
<td>The organizational entity or individual receiving a grant or cooperative agreement. See “grantee.”</td>
</tr>
<tr>
<td>research</td>
<td>A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. Also termed “research and development.”</td>
</tr>
<tr>
<td>research: misconduct</td>
<td>Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.</td>
</tr>
<tr>
<td>significant rebudgeting</td>
<td>A threshold that is reached when expenditures in a single direct cost budget category deviates (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant rebudgeting is one indicator of change in scope.</td>
</tr>
<tr>
<td>small business</td>
<td>A business that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States; and</td>
</tr>
</tbody>
</table>
concern

is organized for profit, is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, more than 500 employees; and meets other regulatory requirements established by the SBA at 13 CFR 121.

State government

The government of any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any U.S. territory or possession, or any agency or instrumentality of a State exclusive of local governments. For purposes of NIH grants, federally recognized Indian tribal governments generally are considered State governments. State institutions of higher education and State hospitals are not considered State governments for HHS's general administrative requirements for grants and the NIHGPS.

stipend

A payment made to an individual under a fellowship or training grant in accordance with preestablished levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.

suspension

Temporary withdrawal of a grantee's authority to obligate grant funds, pending either corrective action by the grantee, as specified by NIH, or a decision by NIH to terminate the award. This meaning of the term "suspension" differs from that used in conjunction with the debarment and suspension process (see "Public Policy Requirements and Objectives—Ethical and Safe Conduct in Science and Organizational Operations—Debarment and Suspension" and "Administrative Requirements—Enforcement Actions").

termination

Permanent withdrawal by NIH of a grantee's authority to obligate previously awarded grant funds before that authority would otherwise expire, including the voluntary relinquishment of that authority by the grantee.

terms and conditions of award

All legal requirements imposed on a grant by NIH, whether based on statute, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The NGA may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate post-award administration of the grant, conserve grant funds, or otherwise protect the Federal government's interests.

total project costs

The total allowable cost (both direct costs and F&A costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

United States

The 50 States, territories, and possessions of the United States, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.

withholding of support

A decision by NIH not to make a non-competing continuation award within the current competitive segment.
1. Did you find the seminar useful?
   Yes ☐ No ☐ Somewhat ☐

2. Did you find the seminar relevant?
   Yes ☐ No ☐ Somewhat ☐

3. Did you learn anything new?
   Yes ☐ No ☐ Somewhat ☐

4. Were the topics thoroughly covered?
   Yes ☐ No ☐ Somewhat ☐

5. Will the printed materials be useful to you in carrying out your job roles and responsibilities?
   Yes ☐ No ☐ Somewhat ☐

6. Was the seminar length:
   About right ☐ Too long ☐ Too short ☐

7. The opportunities to ask questions were:
   About right ☐ Too long ☐ Too short ☐

Additional Comments:

Please place this completed survey in the designated boxes outside the conference room. Thank you!