Managing Your R01

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Partners in the Extramural Grants Process

- PI and the Grantee Institution

- NCI Program Staff

- NCI Grants Administration Staff

Grantee Institution and the PI

- Assures compliance with federal regulations, policies and procedures
- Monitors proper conduct of the project
- Fiscal management of the project
- Responsible for the Scientific and Technical Aspects of the grant and the day-to-day management of the project.

Program Director

Responsible for the programmatic, scientific, and/or technical aspects of grants

- Reviews post-award requests for prior approval and provides scientific input and recommends approval/disapproval
- Reviews annual progress of grants
- In the case of cooperative agreements, may have substantial programmatic involvement in the project

Grants Management Officer

Monitors administrative and fiscal aspects of the project

- The GMO is the **only** NIH official authorized to obligate NIH to the expenditure of funds - or to change funding amounts, budget/project period dates, or other terms and conditions of a grant award.

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Grants Management Specialist

The Grants Management Specialist (GMS) acts as an agent of the GMO.

- Assures compliance with laws and NIH/HHS policies and procedures
- Analyzes grant applications and budgets
- Provides technical assistance, interprets NIH policies and Institute procedures
- Awards grant funds
- Reviews and responds to grantee prior approval and rebudgeting requests

The Grants Management Specialist can…

- Answer questions about completing the SF 424, and PHS 2590

- Provide guidance on administrative and fiscal aspects of applications and awards

- Answer questions about allowable costs and prior approval requirements

- Help navigate NIH grants management information on the Web

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MANAGING YOUR AWARD

- Expanded Authorites

- Reporting Requirements

- Financial Conflict of Interest

- Close-out Requirments

Expanded Authorities

What does it mean?

Under expanded authorities, the grantee institution has the authority to take certain actions on grants without agency prior approval.

Expanded Authorities

- 1st 12-month No-Cost Extension of a project period
- Rebudgeting unrestricted funds between budget categories, if not an indication of a change in the scope of the project
- Carryover of unexpended unrestricted funds from one budget period to the next
- Transferring performance of work to a 3rd party or changing a 3rd party, if not an indication of a change in scope and the third party is not a foreign organization

Prior Approval

NCI prior approval is required for, but not limited to, the following (send requests to both the PD and GMS):

- Second or subsequent No-Cost Extension
- Change of PI Change of grantee institution
- Addition of a foreign component
- Undertaking activities disapproved or restricted as a term of award
- Need for additional NIH funds
- Carryover of restricted funds if required by term of award
- Retention of research grant funds when a career award (K) is made
- Change in scope

Prior Approval

Actions Likely to Indicate a Change in Scope

- Change in aims
- Shift in research emphasis
- Change in use of human subjects or animals
- Significant change in key personnel
- Significant rebudgeting (deviation of a single category committed costs >25% of total costs awarded)
- Application of new technology

Prior Approval

Of particular note:

- Significant reduction in the level of effort of key personnel requires NCI prior approval
  - Significant is defined as a 25% or more reduction in effort
  - PI is **always** defined as key personnel
  - Other key personnel would need to be specifically named in the terms of the notice of grant award

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Multiple PI/PD Initiative

- NIH began the multiple PI/PD initiative in 2007.
- Until now – that option could only be requested in competing applications and was dependent upon a favorable peer review of the leadership plan along with other parts of the application

Multiple PI/PD Initiative

- NIH is in the process of the changing the policy to allow post-award PD/PI changes with the prior approval of the Grants Management Officer.

- A notice will soon be published in the NIH Guide for Grants and Contracts that will explain the requirements for requesting such a change.

Prior Approval

All requests for NCI approval must be:

- Submitted in writing

- Submitted no later than 30 days before the proposed change

- Signed by the business official

- Sent to both Program and Grants Management

- Only responses to prior approval requests signed by the NCI GMO are valid.

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Prior Approval

Prior Approval via E-mail:

- E-mail requests must be sent **through the grantee business official** and must include:
  - ✓ Complete Grant Number
  - ✓ Grantee Name
  - ✓ Principal Investigator Name
  - ✓ PI's phone and fax number
  - ✓ Clear explanation of the request with appropriate scientific justification

A Rule of Thumb

Whenever contemplating post award changes and are uncertain about the need for prior approval, consult **in advance** with:

- Your Office for Sponsored Research
- Written policies and regulations (e.g.: NIH Grants Policy Statement)
- NIH Grants Management Specialist

Reporting Requirements

- Annual Progress Reports
  - PHS Form 2590
  - Due 45-60 days prior to the anniversary date
  - For R-series grants, the annual progress report is a streamlined process
    - Changes in Other Support?
    - Significant changes in Level of Effort?
    - Estimated unobligated balance >25%?
    - Progress report
    - List of publications

Reporting Requirements

– Beginning in FY 2011, NIH requires electronic submission of all SNAP applications.

– eSNAP applications are due 45 days prior to the anniversary date

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-093.html

Financial Conflict of Interest

- Revised Regulations on FCOI were published in the Federal Register August 25, 2011

- http://www.gpo.gov/fdsys/pkg/FR-2011-21633.pdf

- Implementation no later than 365 days after publication of the final rule in the Federal Register, i.e. August 24, 2012.

Financial Conflict of Interest

Major Areas Addressed in new regulations

- Definition of Significant Financial Interest (SFI)
- Extent of Investigator Disclosure
- Information Reported to PHS Awarding Component (e.g. NIH)
- Information made accessible to the public
- Investigator Training

Financial Conflict of Interest

- Significant Financial Interest (SFI)
    - Minimum threshold of $5,000 generally applies to payments and/or equity interests
    - Includes any equity interest in non-publicly traded entities
    - Exclusions include income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an Institution of higher education.
    - Excludes income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

Financial Conflict of Interest

- Investigator Disclosure

    - All SFIs related to Investigators' institutional responsibilities

    - Institutions responsible for determining whether SFIs relate to PHS-funded research and are financial conflicts of interest (FCOI)

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Financial Conflict of Interest

- Reporting to PHS Awarding Component (NIH)

  - Previous requirements, plus:
    - Name of the entity with which the Investigator has a FCOI
    - Value of the financial interest
    - Nature of FCOI, e.g. equity, consulting fees, honoraria, and description of how FCOI relate to PHS-funded research
    - A description of how the financial interest relates to PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research
    - Key elements of the Institution's management plan

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CLOSEOUT: Final Reports

REMINDER

Failure to submit timely and accurate closeout reports may affect future funding!

- Final Progress Report
- Final Invention Report
- Financial Status Report

90-day requirement is a term and condition of all NIH grant awards!

Grantees are strongly encouraged to submit closeout documents electronically through the eRA Commons

eRA Commons
Profile Maintenance

- PIs have an obligation to keep information in their Personal Profile current.

- Profile maintenance is especially critical for researchers applying for early stage and new investigator status

- Profile data used in other electronic processes (e.g., Summary Statements, eNotifications)
  - Degrees
  - Position Titles
  - Adresses – e-mail and postal