Policy and Compliance: Working Together Like Hand in Glove

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Who: Congress

• Creates policy through passing laws (See Chapter 4, NIH Grants Policy Statement, Public Policy Requirements—most of these requirements stem from Federal laws; see also assurances list in the application instructions. Examples—Civil Rights, Stem cells)

• Many laws are influenced by general public

• Creates policy by including it in NIH’s Appropriation language (e.g., Salary cap); NIH publishes annual updates

• Creates policy in special Appropriations—ARRA & Sandy included special reporting requirements that are tied to the funds
Who: The Public & Grantees

• The public can lobby Congress (e.g., stem cell research, fetal tissue research)

• Both the public & grantees can influence policy directly at the agency level (e.g., Public Access Policy, Genomic Data Sharing, etc.)

• Grantees work in partnership to develop new or improve existing policy (e.g., Federal Demonstration Partnership [FDP]; Expanded Authorities—started as FDP Terms, are now Standard NIH Terms of Award)
• Examples of Fed-wide Initiatives
    • Most of the 1999 PL 106-107 activities were subsumed under RBM
  – Example of Fed-wide forms/formats:
    • The SF424(R&R)—Example of Fed-wide Applications
    • Research Performance Progress Report (RPPR)—Example of Federal-wide Progress Report
  – Most Fed-wide initiatives are technically implemented through OMB; but use an agency as the “sponsor” on behalf of the other participating Federal agencies
Who: Office of Management & Budget (OMB)

- Federal Office that oversees and coordinates the Administration's procurement, financial management, information, and regulatory policies by helping to improve administrative management, to develop better performance measures and coordinating mechanisms, and to reduce any unnecessary burdens on the public

- Issue guidance to agencies through OMB Circulars and other Memoranda (e.g. Uniform Guidance)
Who: Department of Health and Human Services (DHHS)

• DHHS Regulations
  – Many regulations implement Federal law or OMB-issued guidance; e.g., 45 CFR Pt 75 implements 2 CFR Part 200 (Uniform Guidance)
  – Regulations generally cover applicability & future effect, and have the force and effect of law
  – Target Audience = DHHS agencies, recipient community

• Examples of HHS vs UG Differences
  – All grant award transactions in FY2016 and beyond will be in PMS Subaccounts
  – NIHs Closeout requirements changed
Who: The NIH

• Agency level implementation of Fed-wide & HHS polices
  – HHS: Subaccounts & Closeout
  – Fed-wide: RPPR & FRPPR

• Agency level initiatives
  – Biomedical Workforce Development initiatives
    • IDPs
    • Biosketch

• Efforts coordinated by the Office of Extramural Research with working group members from NIH ICs
• New Policy/Procedures announced in the NIH Guide for Grants & Contracts, then incorporated into the NIH Grants Policy Statement
• May also see IC-specific and/or grant-specific requirements on the Notice of Award
Where do I start?
NIH Grants Policy Statement!

Annual Updates
Generally Posted each
October
NIH Grants Policy Statement (GPS)

• Provides, in a single document, policy requirements that serve as terms & conditions of NIH grant awards

• **Part I:** General Information—glossary, definitions, roles & responsibilities, application/review process, information sources

• **Part IIA:** Generally applicable terms & conditions
• **Part IIB:** Separate sections on specific terms
  – Multiple PD/PI
  – Construction Grants
  – Kirschstein-NRSA (Fs & Ts)
  – Career Awards (Ks)
  – Modular Applications & Awards
  – Conference Grants
  – Consortium Agreements
  – Foreign Institutions
  – Federal Grantees
  – For-Profit Organizations
  – Patient Care Costs

• **Part III:** Provides points of Contact information

• **Authors:** Coordinated by OPERA, input from NIH staff & grantees

• **Target Audience:** NIH Staff & Grantees
Application & Progress Report Instructions

U.S. Department of Health and Human Services
Public Health Service

SF424 (R&R) Application Guide
For NIH and Other PHS Agencies

NIH Research Performance Progress Report (RPPR) Instruction Guide
Evolution of New Policy: Research Performance Progress Report

**Who:** Recipients

**Who:** White House/OSTP—Fed-wide initiative under the auspices of the Research Business Models (RBM) Subcommittee

- Research Performance Progress Report (RPPR)
  - Mandated by OMB and OSTP
  - Developed by the Research Business Models (RBM) Subcommittee
  - Federal-wide uniform research and research-related progress report
  - Objectives included:
    - reduce administrative burden on grantees
    - standardize information required by federal agencies

- NIH RPPR:
  - Replaced PHS 2590 and PHS 416-9 (Fs)
Planning:

• Developed internal NIH working group to lead the effort
  – Developed Milestones and Implementation Timeline (phased approach)
  – Worked with eRA to develop the Electronic RPPR Format

• Formal & informal input from grantee community and NIH
  – Federal Register (March and June 2012);
  – Used FDP and other connections to grantees
  – Input from NIH via functional groups

• Developed Pilot for Spring 2012;

• Available for use by Recipients: Phase 1 implemented Fall 2012 and phase II implemented Fall 2014.

• October 17, 2014 – RPPR use is mandatory for all NIH progress reports
Implementation Included:

- Frequent meetings with RPPR Working Group
- Developing Electronic RPPR format (eRA) and Progress Report Instructions
- Revising FOA text to include new format
- Updating Policy Source Documents; e.g., NIHGPS
- Developing Communications—websites FAQs, Presentations
- Webinar training for NIH Staff (10/2012)
- Training for recipient community via professional meeting

• All along kept NIH staff apprised via functional groups
What About Compliance?
Compliance Requirements
(the not so small print)
Compliance Requirements

When submitting an application, the AOR certifies that the applicant organization:

- will comply with all applicable assurances and certifications referenced in the application
- has the ability to provide appropriate administrative and scientific oversight of the project
- agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application
- is responsible for verifying conformity with the most current guidelines for all administrative, fiscal, and scientific information in the application, including the F&A (indirect) cost rate
- all of the information in the application is true and that the applicant institution will comply with any resulting award
Compliance Requirements

• Applicants for and recipients of NIH grant funds, whether such funds are received through a grant, indirectly under a contract or consortium agreement, or by a fiscal agent acting on another organization’s behalf, or as student assistance under a training grant, are responsible for and must adhere to all applicable Federal statutes, regulations, and policies, including income tax regulations.

• Applicants may be required to provide proof of organizational eligibility

• Applications also must demonstrate compliance (or intent to comply), through certification or other means, with a number of public policy requirements

• By accepting a federal grant (drawing down funds), the recipient agrees to comply with Federal requirements and terms and conditions of award and to provide stewardship and science as described in the application
With every progress report (RPPR), the SO (or PD/PI with delegated authority), certifies:

- that the grantee organization is in compliance with the terms and conditions specified in the Notice of Award and Grants Policy Statement, and verifies the accuracy and validity of all administrative, fiscal, and scientific information in the progress report
- the grantee organization will be accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the progress report
- that deliberate withholding, falsification, or misrepresentation of information could result in administrative actions such as withdrawal of a progress report, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.
Roles and Responsibilities

• Grantees are required to comply

• NIH is required to monitor and provide oversight
Compliance requirements are included in:

- Assurances and certifications
- Terms and Conditions of grant award, including special terms of award
- NIH Grants Policy Statement
Consequences of Noncompliance

• Enhanced oversight/review
  – Increased reporting
  – Corrective action plans
• Recovery of unallowable costs
• Withholding of future awards
• Suspension/debarment/exclusion
• Criminal and Civil Penalties
• Loss of future funding
• Institution scientific reputation
Common Contributors to Noncompliance

• Insufficient knowledge of grant compliance requirements
• Failure to ensure that terms and conditions flow down to subrecipients
• Deficient subrecipient monitoring
• Inaccurate and untimely reporting (e.g., closeout)
• Lack of internal controls (e.g., outdated policies) and internal oversight
• Inadequate management systems (e.g., financial management, other support)
• NIH generally will afford the grantee an opportunity to correct deficiencies before taking action unless public health or welfare concerns require immediate action.

• In some cases even if a grantee is taking corrective action, NIH may take proactive actions to protect the Federal government’s interests.

• A grantee’s failure to comply with the terms and conditions of award, including confirmed instances of research misconduct, may cause NIH to take one or more actions, depending on the severity and duration of the non-compliance.

• NIH will undertake any such action in accordance with applicable statutes, regulations, and policies.
Used when:

- History of poor performance
- Is not financially stable
- Has a management system that does not meet standards
- Has not conformed to terms and conditions of award
- Is not otherwise responsible

Additional conditions may include items such as the following:

- Requiring payments as reimbursements rather than advance payments;
- Withholding authority to proceed to the next phase until receipt of evidence of acceptable performance within a given period of performance;
- Requiring additional, more detailed financial reports;
- Requiring additional project monitoring;
- Requiring technical or management assistance; or
- Requiring additional prior approvals

Additional requirements are removed once the condition has been corrected.

These actions are not appealable
• Failure to materially comply with terms and conditions of award

• Enforcement actions include:
  – Temporarily withhold cash payments pending correction of deficiency
  – Disallow all or part of the cost of the activity or action not in compliance
  – Wholly or partly suspend or terminate an award
  – Withhold further awards for the project

• Federal-wide Debarment and Suspension

• Enforcement actions, except those that are temporary, are appealable
What Can You Do?
Elements of an Effective Compliance Program

• Identify the source of grants compliance requirements and understand them
• Maintain current, written policies and procedures (involve your compliance team!)
• Consider training and education program
• Develop and implement effective management systems and internal controls that include a review function
• Practice proactive compliance
  • Review and test to identify and improve noted weaknesses
In Summary…

OPERA serves as your Policy, Compliance, Education and Outreach arm, here to support and advise our internal NIH staff and external grantee community on complex policy and compliance matters.

How to Contact Us…

Division of Grants Policy:
• GrantsPolicy@mail.nih.gov

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