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Financial Conflict of Interest: Objectivity in Research

Updated: July 18, 2002

Introduction

Dr. Wendy Baldwin, Deputy Director for Extramural Research, National Institutes of Health (NIH), requested 300 institutions to provide a copy of their policy on conflict of interest (COI) as described in Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought* (For NIH contractors, the corollary regulation is Title 45 CFR Part 94, *Responsible Prospective Contractors*) The intent of the regulation is to promote "objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator."

The purpose of the request for copies of institutional policies was not to endorse or critique individual policies, but, rather, to develop a broad view of how these policies are implemented by an array of institutions. To provide a reasonable assessment of compliance with the provisions of the PHS regulation, a representative sample of over 100 policies was selected for review. The sample consisted of a mix of public and private academic institutions, public and private research institutions, hospitals, and large and small for-profit organizations.

General Observations

The regulation does not prescribe the format that institutional COI policies must present to its audience. Thus, they come in all forms. However, we found that generally, institutions have developed policies that reflect a serious desire to inform and assist their investigators in complying with the regulation. Some policies provide more helpful information than others. As a result, our review process has enabled us to present below our findings, suggestions, and policy items for consideration so that institutions may ensure continued comprehensive compliance with the regulation.

Requirements of the PHS Regulation

The regulation requires that each institution applying for PHS grants and cooperative agreements for research must:

- Maintain a written, enforced policy on conflict of interest that:
 - Complies with the regulation;
 - Informs each Investigator of the institution's policy;
 - Informs each Investigator of his or her reporting responsibilities; and
 - Informs each Investigator of the regulation.

I. FINDINGS

The following are aspects of these policies that would benefit from clarification:

- 96 percent did not mention the Small Business Innovation Research (SBIR) program in the policy document(s).
- 86 percent did not define "Research."
- 52 percent did not identify the applicable PHS regulation.
- 47 percent did not address "records management."
- 74 percent did not state agreement to make conflict information available to HHS.

Other observations could indicate that the procedures underlying these policies were not widely known:

- 45 percent did not require the reporting of the conflict to the PHS awarding component that issued the award.
- 54 percent did not mention compliance regarding subgrantees/contractors/collaborators.
- 76 percent did not require notification to the awarding component within 60 days regarding conflicting interest identified subsequent to initial report.
- 68 percent did not indicate that if investigator has biased the research, the institution would promptly notify the awarding component of corrective action taken or to be taken.
- 87 percent did not state that if HHS determines that a PHS-funded project to evaluate a drug, medical device or treatment was conducted by an investigator with a conflict that was not disclosed or managed, the institution must require investigators to disclose the conflict in each public presentation of the results of the research.

II. HELPFUL SUGGESTIONS and AREAS of CONCERN

We believe that policies separating COI from other policies through a distinct part, appendix, or document are the most compliant with the PHS regulation and provide the greatest benefit to Investigators and others who fall under the requirements of that regulation. Of course, institutions may have their own broader conflict of interest policies or have State policies to which they also adhere. In those cases, it may be more difficult to highlight the PHS requirements. Each section of 42 CFR Part 50, Subpart F for PHS grants and cooperative agreements (and 45 CFR Part 94 for contracts) should be included within such instructions. A complete, single Institutional policy document, replete with citations and web links to supporting Institutional policies and procedures and Federal and state regulations, provides the greatest source of information and guidance to Investigators and others as they traverse the various requirements that comprise the "research compliance" arena, including financial COI.

The following suggestions are provided for consideration.

Helpful Suggestions

- Address directly the PHS regulation by developing the COI policy as a complete, self-contained document with citations and web links to supporting policies, procedures, and Federal and state regulations, as appropriate.
- State an issuance or effective date for the policy, including revisions.
- Identify a contact point within the institution that Investigators and others may contact for questions and discussion.
- Specify that the policy applies to Investigators participating in PHS research, as defined by PHS regulation, including subgrantee/contractor/collaborating Investigators, but excluding applications for Phase I support under the SBIR and Small Business Technology Transfer (STTR) programs.
- Define, as a minimum, the terms "Investigator," "PHS Awarding Component," "Research," "Significant Financial Interest," and "SBIR."
- Specify the Investigator's reporting responsibilities to the institution (what needs to be reported and to whom) and cite the PHS regulation that assigns these responsibilities to the institution and Investigator.
- Identify an institutional official(s) to solicit and review financial disclosure statements from Investigators submitted annually or as new reportable interests are obtained.
- Provide guidelines for the designated official(s) to identify conflicting interests and to take appropriate action to ensure that conflicting interests will be managed, reduced, or eliminated. (Examples of conditions or restrictions are contained in the PHS regulation.)
- Specify that records of all financial disclosures and all actions taken by the institution will be maintained for at least three years from the date of submission of the final expenditures report.
- Identify the enforcement mechanisms available to the institution and provide for sanctions where appropriate.
- Provide a "Reporting" section that specifies that the institution must report:
 - any conflicting interest to the PHS awarding component that issued the award prior to expending any funds; and
 - any interest identified as conflicting subsequent to the initial report within 60 days of that identification.
- Specify that the institution:
 - agrees to make conflict information available, upon request, to HHS;
 - will, if the Investigator has biased the research, promptly notify the PHS awarding component of the corrective action taken or to be taken; and
 - if HHS determines that a PHS-funded project to evaluate a drug, medical device or treatment was conducted by an investigator with a conflict that was not disclosed or managed, require Investigators to disclose the conflict in each public presentation of the results of the research.

Areas of Concern

- Diffuse policy on COI that is integrated with other institutional policies, such as ethics, purchase of goods and services, use of resources for personal activities, and consulting.
- Increased burden on Investigators and others by forcing them to go to other places to obtain information on requirements mentioned in the COI policy document but not contained in that document nor electronically "hot linked" to others (e.g., references to policies and procedures regarding Board of Regents, Faculty Handbook, and Intellectual Property).
- Confused COI policy that is not clear in its applicability and terminology; for example, the term "Investigator" is not used, but the policy is applicable to all "faculty" and covers their "professional judgment in exercising any University duty or responsibility or in the conducting or reporting of research."
- Vague language or statements in COI policies, such as those presented below. Although they may allude to the broader legal environment in which this policy falls, these references do not provide useful guidance.
 - "The University's policy is to comply with all laws and regulations affecting its activities."
 - "Employees accepting grants or contracts must be knowledgeable of the granting and contracting organization's conflict of interest policy and agree to abide by it."
 - "In addition to the guidelines and processes described below, some funding agencies of the federal government require grantees to conform with other disclosure and conflict of interest resolution procedures. A list of these agencies and the specifics of the requirements and procedures ("Guidelines for Investigator Financial Disclosure") are available from the Office of Sponsored Research."
 - "... intends, by this policy, to comply with applicable federal and state requirements."
 - "Any regulations promulgated by a governmental agency will be incorporated by reference in this policy."
 - "Any changes in the federal requirements will supersede the relevant provisions of this policy."
 - "Faculty disclosures shall also ... occur at such other times as may be required by law or federal regulation."
 - "To the extent required by law, the dean or his/her designee shall report conflict disclosures and their resolution to appropriate governmental agencies."
 - "It shall be the responsibility of each Disclosure Review Committee to keep and maintain in a secure manner such files that may be required to comply with federal regulations on conflict of interest."

III. OTHER ISSUES TO CONSIDER

In view of the discussion above, we encourage each institution to take a fresh look at its COI policy and revise or enhance its provisions accordingly. To assist in this endeavor, below are items that should be considered in the construction or revision of conflict of interest policies (keyed to sections of the PHS regulation):

- (50.601) A brief, opening "Introduction" or "Purpose" section indicating the intent of the PHS regulation (Title 45 CFR Part 50, Subpart F), that is, to promote "objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator."
- (50.603) A "Definitions" section that defines, as a minimum, these terms: "Investigator"; "PHS Awarding Component"; "Research"; "Significant Financial Interest"; and "Small Business Innovation Research (SBIR)."
- (50.604) An "Institutional Responsibilities" section that, at a minimum, provides these instructions:
 - Informs each Investigator of the Institution's policy and his or her "disclosure" reporting obligations, including time frames for doing so;
 - Identifies an Institutional official(s) to determine the existence of conflicting interests and to take actions to ensure that they will be managed, reduced, or eliminated;
 - Provides for retention of records "for at least three years from the date of submission of the final expenditures report" or other dates as specified in 45 CFR 74.53(b);
 - Establishes adequate enforcement mechanisms and sanctions where appropriate;

- Requires the Institution to certify, in each PHS application for funding, that:
 - The Institution has in effect a written and enforced process to identify and manage, reduce, or eliminate conflicting interests;
 - Prior to expending any funds under the award, the Institution will report to the PHS Awarding Component the existence of a conflicting interest and assure that it has been managed, reduced, or eliminated, AND, for any interest identified as conflicting subsequent to the Institution's initial report, a report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within 60 days; and
 - Upon request, the Institution agrees to make information available to HHS regarding all conflicting interests and how those interests have been managed, reduced, or eliminated.
- (50.605) A Review of Disclosure Forms" section that provides:
 - Guidelines for the designated official(s) to identify conflicting interests and take actions to ensure that they will be managed, reduced, or eliminated; and
 - Provides examples of conditions or restrictions that might be imposed to manage conflicts of interest.
- (50.606) A "Non-compliance" section that provides:
 - If the failure of the Investigator to comply with the Institution's policy has biased the research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken;
 - That the Institution agrees to make information on conflicting interests available to HHS and how those interests have been managed, reduced, or eliminated; and
 - If HHS determines that a PHS-funded project of clinical research, whose purpose was to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an investigator with a conflicting interest that was not disclosed or managed, the Institution must require the Investigator(s) to disclose the conflicting interest in each public presentation of the results of the research.

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