

Reminder of Financial Conflict of Interest Requirements for All NIH-Supported Institutions

Notice Number: NOT-OD-05-013

Key Dates

Release Date: December 6, 2004

Issued by

National Institutes of Health (NIH), (<http://www.nih.gov/>)

This Notice is intended as a reminder of the financial conflict of interest (FCOI) requirements for all institutions and contractors that receive from the National Institutes of Health (NIH) grants or contract support to conduct research. Although the FCOI requirements summarized here are longstanding, the world of scientific collaboration has changed and is continuing to change very quickly. New and more complex types of relationships are emerging and with them potential FCOIs. In light of these evolving financial relationships, institutions and contracting organizations that receive NIH support to conduct research are hereby reminded of the requirement to identify and manage the FCOIs of all NIH-supported investigators and to comply with the associated reporting requirements.

As you know, the Code of Federal Regulations (CFR) 42, Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding Is Sought and 45 CFR Part 94.1, Responsible Prospective Contractors, promote objectivity in research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements, or contracts will not be biased by a conflicting financial interest of an investigator. It therefore requires that institutions seeking NIH support for research have a written administrative process to identify and manage FCOI. Institutions must inform investigators of the conflict of interest policy and of their individual responsibilities.

Further, the grantee or contractor must:

1. Inform the relevant Institute or Center Chief Grants Management Officer* or Chief Contracting Officer**, as appropriate, of the existence of any FCOI before spending any NIH funds awarded under a new award. Conflicts identified during the award period must be reported within 60 days of identifying them. These reports must indicate whether the FCOI has been managed, reduced, or eliminated.
2. Make additional information available to NIH upon request.

Please review the information provided at this website: http://grants.nih.gov/grants/policy/coi/nih_review.htm. It contains an NIH assessment of how FCOI procedures are being implemented across 300 of NIH's top funded grantee institutions and provides helpful suggestions for resolving and managing these conflicts.

If you have any questions related to FCOI regulations involving NIH funded grants, cooperative agreements, or contracts, please send your question to FCOICompliance@mail.nih.gov. Please do not send any FCOI notifications to this mailbox.

Thank you for your attention to these important issues.

* Chief Grants Management Officer list: http://grants.nih.gov/grants/stafflist_gmos.htm

** Chief Contracting Officer list: http://oamp.od.nih.gov/chief_cos1.html

Weekly TOC for this Announcement NIH Funding Opportunities and Notices



Department of Health
and Human Services



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PUBLICATION OF "FINANCIAL CONFLICT OF INTEREST - OBJECTIVITY IN RESEARCH:
INSTITUTIONAL POLICY REVIEW"

RELEASE DATE: February 10, 2003

NOTICE: NOT-OD-03-026

National Institutes of Health (NIH)

The National Institutes of Health (NIH) is pleased to announce the publication of "Financial Conflict of Interest: Objectivity in Research - NIH Review of Institutional Conflict of Interest Policies" (http://grants.nih.gov/grants/policy/coi/nih_review.htm). The document is available on the Conflict of Interest website (<http://grants.nih.gov/grants/policy/coi/index.htm>), which is linked to the Office of Extramural Research (OER) homepage (<http://grants.nih.gov/grants/OER.htm>) under Grants Topics/Grants Policy and Guidance (<http://grants.nih.gov/grants/policy/policy.htm>).

During 2002, the National Institutes of Health requested 300 institutions to provide a copy of their policy on financial conflict of interest 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 purpose of the review was to allow the NIH the opportunity to: (1) develop a broad view of how these policies are implemented by an array of institutions; and (2) provide a reasonable assessment of compliance with the provisions of the PHS regulation. The information in this document is based on the review of a representative sample of over 100 policies from a mix of institutions consisting of public and private academic institutions, public and private research institutions, hospitals, and large and small for-profit organizations.

The document is organized in three sections: (1) Findings; (2) Helpful Suggestions and Areas of Concern; and (3) Other Issues to Consider. The first section provides specific information related to the review of the policies. The second section provides helpful suggestions for consideration when developing a financial conflict of interest policy and areas of concern that were noted during the review. The third section provides additional issues for consideration when revising or enhancing current financial conflict of interest policies with the intent of improving compliance with Federal regulations.

NIH is making this document available to the broader biomedical research community as an educational tool to promote awareness of and compliance with Federal financial conflict of interest regulations. For additional resources related to financial conflict of interest, please visit the following links:

OER Conflict of Interest page:
<http://grants.nih.gov/grants/policy/coi>

NIH Grants Policy Statement (3/01), Financial Conflict of Interest:
http://grants.nih.gov/grants/policy/nihgps_2001/part_iaa_1.htm#Toc504811782

Proactive Compliance Site Visits FY 2000-FY 2002: A Compendium of Findings and Observations:
http://grants.nih.gov/grants/compliance/compendium_2002.htm

INQUIRIES

Questions about financial conflict of interest may be directed to the Division of Grants Compliance and Oversight staff at (301) 435-0949.

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