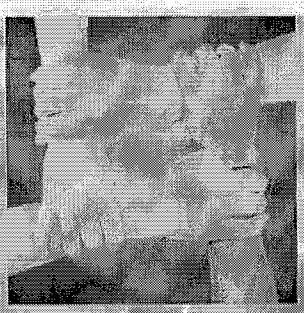
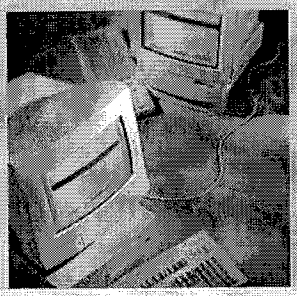


NIH GRANTS
Policy Statement



(Revised December 1, 2003)

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

December 1, 2003

Standards of Conduct

NIH requires grantees to establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties. These safeguards must be reflected in written standards of conduct. Except as provided below, NIH does not require a grantee to establish separate standards of conduct if it maintains such standards for its non-grant-supported activities, as long as those standards are consistent with State and local laws and cover, at a minimum, expected conduct in regard to financial interests, gifts, gratuities and favors, nepotism, and such other areas as political participation and bribery. The standards also must do the following:

- Address the conditions under which outside activities, relationships, or financial interests are proper or improper.
- Provide for advance notification of outside activities, relationships, or financial interests to a responsible organizational official.
- Include a process for notification and review by the responsible official of potential or actual violations of the standards.
- Specify the nature of penalties that the grantee may impose. These penalties would be in addition to any penalties that NIH or a cognizant Federal agency may impose for infractions that also violate the terms or conditions of award.

The grantee is not required to submit its general standards of conduct to NIH for review or approval. However, a copy must be made available to each of its officers, each employee and consultant working on the grant-supported project or activity, each member of the governing board, if applicable, and, upon request, to NIH. The grantee is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the IC CGMO if the infraction is related to an NIH award. (A listing of the NIH CGMOs is available at http://grants.nih.gov/grants/stafflist_gmos.htm.) If a suspension or separation action is taken by a grantee against a PI or other key personnel under an NIH grant, the grantee must request prior approval of the proposed replacement as specified in "Administrative Requirements—Changes in Project and Budget—Prior-Approval Requirements."

Financial Conflict of Interest

NIH requires grantees and investigators to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought." That subpart promotes objectivity in research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will not be biased by any conflicting financial interest of an investigator. These requirements do not apply to Phase I of the SBIR/STTR programs.

The signature of the AOO on the face page of the application serves as certification of compliance with the requirements of 42 CFR Part 50, Subpart F. Under those requirements the organization must do the following:

- Have a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought
- Before spending any NIH funds awarded under a new award, inform the CGMO of the existence of any conflicting financial interests it identified of the type covered by 42 CFR 50.605
- When informing the CGMO that a financial conflict of interest has been identified, ensure that the interest has been addressed in accordance with the regulations by indicating whether the conflict has either been managed, reduced, or eliminated
- Continue to make similar reports on subsequently identified conflicts within 60 days of identifying them
- Make additional information available to NIH, upon request, as to how it handled conflicting interests in accordance with the regulations.

As described in the regulations, examples of how financial conflicts of interest might be addressed include the following:

- Public disclosure of significant financial interests
- Monitoring of research by independent reviewers
- Modification of the research plan
- Disqualification from participation in all or a portion of the research funded by PHS
- Divestiture of significant financial interests
- Severance of relationships that create actual or potential conflicts.

Grantees also must ensure that consortium agreements address whether the consortium participant's employees will be subject to the financial conflict of interest requirements of the consortium participant or to those of the grantee (see "Consortium Agreements" in Subpart B of this part).

Some IRBs also consider investigator financial conflict of interest in their deliberations, although they are not required to do so (see "Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Human Subjects").

Following are some strategies used by IRBs:

- Make IRB members aware of the organization's conflict of interest policies and procedures.
- Include a statement in the informed consent form that all clinical investigators comply with the organizational guidelines.
- Ask investigators to complete a short questionnaire about whether they—or any person responsible for the design, conduct, or reporting of research—have an economic interest in or act as an officer or a director of any outside entity whose financial interest could reasonably appear to be affected by the research.
- Instruct IRB members during their orientation on how to identify and respond to a perceived financial, academic, or other conflict of interest.

Suggestions for grantees to consider when implementing the requirements of this regulation are available in the NIH publication, *Financial Conflict of Interest–Objectivity in Research: Institutional Policy Review*, available on the NIH website at http://grants.nih.gov/grants/policy/coi/nih_review.htm.

Debarment and Suspension

HHS regulations published in 45 CFR Part 76 implement the government-wide debarment and suspension system for HHS' non-procurement transactions. "Non-procurement transactions" include grants, cooperative agreements, scholarships, fellowships, and loans. Accordingly, applicants for NIH grants ("primary covered transactions"), including applicants for Kirschstein-NRSA individual fellowships, are required to certify[6] that, to the best of their knowledge and belief, they and their principals (including PIs and other key personnel)

- are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
- have not, within the 3-year period preceding the application, been convicted of, or had a civil judgment rendered against them for
  - committing fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction;
  - violating a Federal or State antitrust statute;
  - embezzlement, theft, forgery, bribery, falsification or destruction of records; or

[6] This certification is accomplished by the signature of the AOO on the application. States need only certify as to their principals.