

INTERIM
Conflict of Interest Policy for RISD Researchers
Working Under Federal Grants and Cooperative Agreements

1. Scope of this policy

This policy on conflict of interest for researchers was developed to comply with 42 CFR 50.601 et seq., the implementing regulations for applicants seeking funding through Public Health Service (PHS) grants or cooperative agreements for research and with the requirements of the National Science Foundation (NSF). These regulations are also used by the National Institutes of Health in monitoring regulatory compliance with their grant procedures. According to the regulations, the goal of the PHS regulations 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."

RISD maintains this policy and commits to inform each Investigator of the Investigator's reporting responsibilities and of the regulations requiring the policy. If RISD carries out the federally funded research through subgrantees, contractors, or collaborators, RISD will take reasonable steps to ensure that Investigators working for such entities comply with this subpart, either by requiring those Investigators to comply with this policy or by requiring the entities to provide assurances to RISD that will enable compliance with the implementing regulations.

2. Institutional official

RISD designates the Associate Provost for Academic Affairs as the institutional official who solicits and reviews financial disclosure statements from each Investigator who is planning to participate in federally funded research.

3. Required disclosure

By the time an application is submitted to either PHS or NSF, each Investigator who is planning to participate in the funded research is required to submit to the Associate Provost or his or her designee a listing of his or her known Significant Financial Interests (and those of his or her spouse and dependent children):

- (i) That would reasonably appear to be affected by the research or educational activity for which funding is sought; and
- (ii) In entities whose financial interests would reasonably appear to be affected by the research or educational activity.

Disclosure is not required if the application is for a subaward under the National Institutes of Health SBIR/STTR Phase I funding.

All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained. No funds may be expended until the process of identifying and managing any conflicts is complete.

If the Investigator has no Significant Financial Interests to disclose, the Investigator is required to certify the lack of such interests.

4. Guidelines for identifying conflicts of interest

The Associate Provost or his or her designee will review all financial disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by RISD to manage, reduce or eliminate such conflict of interest.

A conflict of interest exists when the Associate Provost reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

- (1) public disclosure of significant financial interests;
- (2) monitoring of research by independent reviewers;
- (3) modification of the research plan;
- (4) disqualification from participation in all or a portion of the research funded by the PHS or NSF;
- (5) divestiture of significant financial interests; or
- (6) severance of relationships that create actual or potential conflicts

In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, RISD may require the management of other conflicting financial interests, as RISD deems appropriate.

NSF exception on managing conflicts

If the Associate Provost determines that imposing conditions or restrictions would either be ineffective or inequitable, and that the potential negative impacts that may arise from a Significant Financial Interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Associate Provost may allow the research to go forward without imposing such conditions or restrictions. (as stated in Chapter V Grantee Standards, Section 510d, NSF 02-151 July 2002)

5. Record Keeping

RISD will retain records of all financial disclosures and all actions taken with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations. In the case of NSF grants, records will be retained for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

6. Definitions

Investigator: means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research or educational activity funded by PHS or NSF, or proposed for such funding. For purposes of the requirements of this policy relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

PHS: means the Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated.

Significant Financial Interest: means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights)

The term does not include:

- (1) salary, royalties, or other remuneration from RISD;
- (2) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- (3) income from service on advisory committees or review panels for public or nonprofit entities;

(4) an equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed ten thousand dollars \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or

(5) salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed ten thousand dollars (\$10,000).

Research: means a systematic investigation designed to develop or contribute to generalizable knowledge, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in the implementing regulations, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Small Business Innovation Research (SBIR) Program: means the extramural research program for small business that is established by the Awarding Components of the PHS and certain other Federal agencies under Pub. L. 97-219, the SBIR Development Act, as amended. For purposes of the implementing regulations, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

7. PHS Certification

RISD will certify the following with each application for funding to PHS which the implementing regulations apply:

- (1) There is in effect a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which federal funding is sought;
- (2) Prior to RISD's expenditure of any funds under the award, RISD will report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by RISD and assure that the interest has been managed, reduced or eliminated in accordance with the implementing regulations; and, for any interest that RISD identifies as conflicting subsequent to RISD's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty (60) days of that identification;
- (3) RISD agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by and how those interests have been managed, reduced, or eliminated to protect the research from bias; and
- (4) RISD will otherwise comply with the implementing regulations.

8. HHS remedies for policy violation

If the failure of an Investigator to comply with the conflict of interest policy of RISD has biased the design, conduct, or reporting of the federally funded research, RISD is required by the regulations to promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to RISD for further action, which may include directions to RISD on how to maintain appropriate objectivity in the funded project. The HHS may at any time inquire into RISD's procedures and actions regarding conflicting financial interests in federally funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with the implementing regulations. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS may decide that a particular conflict of interest will bias the objectivity of the federally funded research to such an extent that further corrective action is needed or that RISD has not managed, reduced, or eliminated the conflict of interest in accordance with the implementing regulations. The PHS may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.

In any case in which the HHS determines that a federally funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by the implementing regulations, RISD will require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

9. NSF required reporting

Whenever RISD determines that it is unable to satisfactorily manage a conflict of interest, it is required by NSF to inform the NSF Office of the General Counsel electronically via the NSF FastLane system.