

NATIONAL SCIENCE FOUNDATION**Investigator Financial Disclosure Policy**

AGENCY: National Science Foundation.

ACTION: Notice of technical changes to investigator financial disclosure policy.

SUMMARY: The National Science Foundation (NSF) is making certain technical changes and clarifications to its Investigator Financial Disclosure Policy in order to make the Policy more consistent with the provisions of the final Department of Health and Human Services (HHS) rule on this subject.

EFFECTIVE DATE: The effective date of the Investigator Financial Disclosure Policy and these technical changes is October 1, 1995. Proposals submitted on or after October 1, 1995 must contain the new certifications set forth in the Policy.

EFFECTIVE DATES: Christopher L. Ashley, Assistant General Counsel, National Science Foundation, 4201 Wilson Boulevard, Room 1265, Arlington, VA 22230, (703) 306-1060.

SUPPLEMENTARY INFORMATION:**Paperwork Reduction Act Control Number 3145-0149**

On June 28, 1994 NSF published in the **Federal Register** a final Policy announcing revised award conditions relating to investigator financial disclosure. Those revised conditions require grantee institutions to maintain written and enforced policies on investigator conflict of interest. 59 FR 33308 (June 28, 1994).

NSF has been coordinating its Investigator Financial Disclosure Policy with the Public Health Service and the Office of the Secretary of the Department of Health and Human Services (HHS). At the same time NSF published its final policy, HHS published a notice of proposed rulemaking also dealing with investigator conflicts. HHS received and reviewed public comments on that proposed rule, and is issuing in this **Federal Register** its final rule regarding investigator conflicts that will be effective on October 1, 1995. In cooperation with HHS, NSF is now making certain corresponding technical changes and clarifications to its Investigator Financial Disclosure Policy in order to maintain consistency with the final HHS rule. In addition, NSF and HHS will be working together to develop common guidance, including a set of questions and answers, to help institutions implement conflict of interest policies that comply with both HHS and NSF requirements.

The following summarizes the changes and clarifications to NSF's Investigator Financial Disclosure Policy: *Grant Policy Manual References:* All references to GPM 310 will be changed to GPM 510.

Disclosures by Investigators: Subparagraph b of GPM 510 will be revised to require disclosure to the institution's representative of significant financial interests that "would reasonably appear to be affected" by the activities funded or proposed for funding by NSF. Previously, the provision had required disclosure of interests that "reasonably appear to be directly and significantly affected" by such activities. This change will result in a slightly broader disclosure by the investigator. As explained below, the institutional representative(s) will be responsible for reviewing the disclosures to determine which disclosed interests could directly and significantly affect the design, conduct or reporting of the research.

Definition of "Significant Financial Interest"—Exclusions: For greater clarity, the exclusion set out in subparagraph b.5 of GPM 510 will be split into two separate exclusions—one for equity interests and one for other types of payments. Also, the dollar threshold increased from \$5,000 to \$10,000. To be excluded from the definition of "significant financial interest," an equity interest, when aggregated for the Investigator and his or her spouse and dependent children, must be under both the \$10,000 and five percent ownership thresholds. For example, an investigator who owns an equity interest which is worth \$20,000 (with reference to public prices or other reasonable measures of fair market value), but which represents only one percent ownership in the entity, would nevertheless be required to disclose that interest if it would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF.

Conflicts of Interest: In subparagraph d of GPM 510, the definition of a conflict of interest will be revised. As revised, a conflict of interest exists if the reviewer(s) of disclosures determines that a significant financial interest "could directly and significantly affect the design, conduct, or reporting of" NSF-funded activities. Thus, contrary to the previous definition, the reviewer(s) rather than the investigator determines whether a significant financial interest directly and significantly affects the design, conduct or reporting of NSF-funded activities.

Timing of Conflict of Interest Review and Resolution: In order to conform

with the HHS final rule, the Certification for Authorized Institutional Representative or Individual Applicant (in the Section WHAT WOULD BE REQUIRED IN PROPOSALS) will be changed to require the institutional representative to certify that any identified conflicts of interests will be managed, reduced or eliminated "prior to the institution's expenditure of any funds under the award." The certification previously required resolution of conflicts "prior to funding the award." This technical change will enable institutions to refrain from reviewing and resolving identified conflicts until after the award is funded, thereby eliminating the need to review and resolve conflicts in proposals that do not get funded. Also, the last sentence of the certification has been separated into two sentences to clarify that conflicts of interest that cannot be satisfactorily managed, reduced or eliminated must be reported to NSF. Accordingly, the certification will now read as follows:

In addition, if the applicant institution employs more than fifty persons, the authorized official of the applicant institution is certifying that the institution has implemented a written and enforced conflict of interest policy that is consistent with the provisions of Grant Policy Manual Section 510; that to the best of his/her knowledge, all financial disclosures required by that conflict of interest policy have been made; and that all identified conflicts of interest will have been satisfactorily managed, reduced or eliminated prior to the institution's expenditure of any funds under the award, in accordance with the institution's conflict of interest policy. Conflicts which cannot be satisfactorily managed, reduced or eliminated must be disclosed to NSF.

Deletion of Additional Certification for Principal Investigators and Co-Principal Investigators: In order to conform with the HHS final rule, NSF's policy will be revised to delete the additional Certification for Principal Investigators and Co-Principal Investigators that was previously to be included in Section C-1 of Part II of the Grant Proposal Guide and on Page 2 of the NSF Form 1207, Cover Sheet for Proposal to NSF. Although submission of the additional certification to NSF is no longer required, NSF believes that most institutions' policies will have principal and co-principal investigators certify to the institution that the investigator has read and understands the institution's policy, that all required disclosures were made and that the investigator will comply with any conditions or restrictions imposed by the institution to manage, reduce or eliminate conflicts of interest.

Other Clarifications

1. *Application of Policy to Increments of Major Awards:* In addition to new NSF proposals, the Policy will apply to certain large ongoing projects such as centers and other activities that are currently being funded by NSF on an incremental basis through cooperative agreements or other agreements for which new proposals may not be submitted for several years. NSF will require that institutions and investigators involved in such projects, at the time of their first funding increment which occurs after October 1, 1995, provide the certifications required by the Policy for all cooperative agreements and for all continuing grant increments exceeding \$1,000,000. Such awardees will be advised in advance in writing by the Grants Officer that they will be required to have a policy in place and submit the required certifications as a condition of future funding increments.

2. In addition to the technical changes and clarifications announced above, NSF has made a small number of word

changes to resolve minor inconsistencies between its policy and the final HHS rule. These changes are not intended to alter the meaning of any provision of NSF's final policy. The changes are as follows:

a. In subparagraph b.1 of GPM 510, the word "applicant" will be added before the word "institution." The exclusion from the definition of "significant financial interest" will now read "salary, royalties or other remuneration from the applicant institution."

b. In subparagraph c of GPM 510, the word "pendency" will be replaced with the word "period". An institutional policy must require financial disclosures to be updated during the period the award is in effect.

c. In subparagraph d of GPM 510, immediately before the list of examples of conditions or restrictions to manage, reduce or limit conflicts of interest, the words "but are not limited to" will be added after "include."

d. In the second sentence of subparagraph d of GPM 510, the phrase "research or educational activities

funded or proposed for funding by NSF" will be replaced with the phrase "NSF-funded research or educational activities."

e. Subparagraph g of GPM 510 will be revised to require institutions to maintain records "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."

f. The words "actual or potential" will be deleted in all places where they are used to modify "conflict of interest."

3. *Paperwork and Recordkeeping Burden:* In cooperation with HHS, NSF has revised its estimate of the paperwork burden associated with the Policy in order to make its estimate consistent with HHS' and to conform to certain changes in the law since NSF issued the final Policy. NSF and HHS have used the same methodology in estimating respective paperwork burdens for their rules.

NSF's revised estimates are as follows:

REPORTING AND RECORDKEEPING

	Number of respondents	Hours per response	Total
Files *	2,300	4	9,200
Reports of conflict to NSF **	50	80	4,000
Subsequent reports of conflict of interest	7	2	14

* Consistent with HHS methodology, NSF is now using the number of files expected to be necessary as a basis for estimating the Policy's recordkeeping burden. NSF estimates that the Policy will apply to approximately 10,000 awards annually and that 23% of all investigators will have disclosures which will require the creation of a file. NSF estimates that 77% of investigators will not have disclosures requiring the creation of a file. NSF estimates that it will require four hours for the establishment and maintenance of a file.

** HHS has estimated that it will receive 200 reports of conflicts of interest. NSF believes that it will receive significantly fewer reports of conflicts because NSF makes fewer awards annually than HHS and because, on average, activities funded by NSF are less likely to affect the financial interests of investigators.

DISCLOSURE BY INVESTIGATORS

	Number of respondents	Hours per response	Total
38,000		1.0	38,000

INSTITUTIONAL DISCLOSURE OF POLICY TO INVESTIGATORS ***

	Number of Institutions	Hours per response	Total
2,000		20	40,000

*** NSF did not initially include an estimate for this aspect of the paperwork burden. However, in light of revisions to the Paperwork Reduction Act, effective October 1, 1995, which will require this element to be estimated, NSF is including such an estimate. NSF's estimate is consistent with that of HHS.

Total hours for reporting, recordkeeping and disclosure: 91,214.

In accordance with the requirements of the Paperwork Reduction Act of 1980, the National Science Foundation has submitted the information collection requirements cited above to OMB for

review and approval. Organizations and individuals desiring to submit comments on the information collection requirements and the estimated burden should direct such comments to the information address cited above and to: NSF Desk Officer, Office of Information

and Regulatory Affairs, OMB, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Accordingly, NSF's Investigator Financial Disclosure Policy now reads as follows:

The Investigator Financial Disclosure Policy

NSF's Investigator Financial Disclosure Policy has the following primary features:

A. A requirement that any NSF grantee employing more than fifty persons maintain "an appropriate written and enforced policy on conflict of interest."

B. Minimum requirements for what must be in an institution's policy. These include (a) limited and targeted financial disclosure, (b) designation of a person(s) to review the disclosures and resolve actual or potential problems revealed, (c) enforcement mechanisms, and (d) arrangements for informing NSF of conflicts issues that are not resolved to the satisfaction of the institution.

Changes made to NSF issuances to establish and communicate the Policy are described below. Copies of the NSF Grant General Conditions and the NSF Grant Proposal Guide referenced in the Policy may be obtained from the National Science Foundation, Forms and Publications Unit, 4201 Wilson Blvd., Rm. P-15, Arlington, Virginia 22230, (703) 306-1130, Internet: pubs@nsf.gov. Copies of the NSF Grant Policy Manual may be obtained from the Government Printing Office.

What Would be Required in Institutional Policies

Grant General Conditions

Insert a new subparagraph b. to Article 23:

Records of investigator financial disclosures and of actions taken to manage conflicts of interest (see Grant Policy Manual Section 510), shall be retained until 3 years after the later of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

Renumber subsequent subparagraphs accordingly.

Insert a new Article 33:

For proposals submitted on or after October 1, 1995, if the grantee employs more than fifty persons, the grantee shall maintain an appropriate written and enforced policy on conflict of interest consistent with the provisions of *Grant Policy Manual* Section 510.

Renumber subsequent articles accordingly.

Grant Policy Manual

Add a new GPM 510 "Conflict of Interest Policies":

a. NSF requires each grantee institution employing more than fifty persons to maintain an appropriate written and enforced policy on conflict

of interest. Guidance for such policies has been issued by university associations and scientific societies.¹

b. An institutional conflict of interest policy should require that each investigator disclose to a responsible representative of the institution all significant financial interests of the investigator (including those of the investigator's spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

The term *investigator* means the principal investigator, co-principal investigators, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

The term *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 the applicant institution;
2. Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
3. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
4. Income from service on advisory committees or review panels for public or nonprofit entities;
5. 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 \$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 5% ownership interest in any single entity; or

6. Salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the next twelve month period.

c. An institutional policy must ensure that investigators have provided all required financial disclosures at the time the proposal is submitted to NSF. It must also require that those financial disclosures are updated during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained.

d. An institutional policy must designate one or more persons to review financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the reviewer(s) reasonably determine that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate 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 the portion of the NSF-funded research that would be affected by the significant financial interests;
5. Divestiture of significant financial interests; or
6. Severance of relationships that create conflicts.

If the reviewer(s) determines that imposing conditions or restrictions would be either 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 reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.

e. The institutional policy must include adequate enforcement mechanisms, and provide for sanctions where appropriate.

f. The institutional policy must include arrangements for keeping NSF's Office of General Counsel appropriately

¹ See On Preventing Conflicts of Interests in Government-Sponsored Research at Universities, a Joint Statement of the Council of the American Association of University Professors and the American Council on Education (1964); Managing Externally Funded Programs at Colleges and Universities, especially "Principle X. Research Ethics and Conflicts", issued by the Council on Government Relations (1989); Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research, issued by the Association of American Medical Colleges (1990); and Framework Document for Managing Financial Conflicts of Interest, issued by the Association of American Universities (1993).

informed if the institution finds that it is unable to satisfactorily manage a conflict of interest.

g. Institutions must maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest 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.

What Would Be Required in Proposals

Grant Proposal Guide

Section II.C.1, INSTRUCTIONS FOR PROPOSAL PREPARATION, at the end of the *Certification for Authorized Institutional Representative or Individual Applicant*, will be revised to add:

A new certification will be added that requires an institutional representative to certify that the institution has implemented a written and enforced

policy on conflicts of interest consistent with the provisions of *Grant Policy Manual* Section 510; that to the best of his/her knowledge, all financial disclosures required by that conflict of interest policy have been made; and that all identified conflicts of interests will have been satisfactorily managed, reduced or eliminated prior to the institution's expenditure of any funds under the award, in accordance with the institution's conflict of interest policy. Conflicts which cannot be satisfactorily managed, reduced or eliminated must be disclosed to NSF.

Page 2 of the NSF Form 1207, *Cover Sheet for Proposal to the NSF*, will be revised to add the following to the end of the section on Certification for Authorized Institutional Representative or Individual Applicant:

In addition, if the applicant institution employs more than fifty persons, the authorized official of the

applicant institution is certifying that the institution has implemented a written and enforced conflict of interest policy that is consistent with the provisions of *Grant Policy Manual* Section 510; that to the best of his/her knowledge, all financial disclosures required by that conflict of interest policy have been made; and that all identified conflicts of interest will have been satisfactorily managed, reduced or eliminated prior to the institution's expenditure of any funds under the award, in accordance with the institution's conflict of interest policy. Conflicts which cannot be satisfactorily managed, reduced or eliminated must be disclosed to NSF.

Dated: May 17, 1995.

Lawrence Rudolph,

General Counsel.

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