

NIH Policy Manual

6003-1 - NIH Intramural Scientists As Principal Investigators On Grant Applications And Contract Proposals

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Transmittal Notice

A. Purpose

This chapter sets forth conditions and procedures under which an NIH intramural research scientist, while still employed by NIH, may develop and submit grant applications and contract proposals to NIH or other agencies of the Federal government, naming that research scientist as the Principal Investigator (PI) for proposed research or related projects which would commence after (s)he terminates Federal employment. These requirements apply specifically to NIH intramural research scientists who have no official duties or responsibilities with respect to review, evaluation, advice, or recommendations on grant applications or contract proposals submitted to NIH, and who are not otherwise involved in NIH grant or contract award or administration. These procedures do not supersede corresponding statutes or regulations, nor do they encompass other conflict-of-interest provisions.

B. Background

Among other things, and especially relevant to this chapter, the Conflict of Interest statutes impose criminal penalties on a Federal employee who:

1. directly or indirectly receives or agrees to receive, or asks, demands, solicits, or seeks any compensation for services rendered or to be rendered either by the employee or another in relation to any proceeding, application, or other determination or particular matter in which the United States is a party or has a direct and substantial interest, or which is before a department or agency; or
2. acts as agent or attorney for anyone before a department or agency in connection with any proceeding, application, or other determination or particular matter; or
3. participates personally and substantially through decision, approval, disapproval, recommendation, rendering of advice, investigation, or otherwise, in a proceeding, application, or other determination or particular matter in which to his/her knowledge, the employee, his/her spouse, minor child, partner, organization in which (s)he is

serving as officer, director, trustee, partner, or employee, or any person or organization with whom (s)he is negotiating or has any arrangement concerning prospective employment, has a financial interest.

C. References

1. Title 18, United States Code, Chapter 11, Bribery, Graft, and Conflicts of Interest, Sections 203, 205, and 208.
2. Title 5, Code of Federal Regulations, Part 735, Employee Responsibilities and Conduct.
3. 45 CFR, Part 73, Standards of Conduct for HHS Employees.

D. Definitions

The following definitions apply to terms as used in this chapter:

1. Grant - a generic term which encompasses all extramural assistance awards, e.g., grants, cooperative agreements, career awards.
2. NIH Intramural Research Scientist - an NIH scientist engaged in or responsible for research activities conducted in NIH facilities.
3. NIH Extramural Staff - NIH personnel engaged in or responsible for initiating projects, reviewing of applications or proposals, or otherwise developing or administering programs or projects, conducted under extramural awards.

E. Policy

While still an NIH employee, an intramural research scientist may develop plans for research and related projects and prepare grant applications and contract proposals to be submitted by non-Federal organizations to NIH and/or other Federal agencies, proposing that employee as the PI. (S)he, the non-Federal applicant/offeror organization, and NIH or other Federal agency must take precautions, however, to preclude the possibility that the employee's actions could be interpreted as violating Federal conflict of interest statutes and/or HHS Standards of Conduct regulations.

F. Implementation

1. Intramural Research Scientists When an NIH intramural research scientist develops and submits grant application(s) and/or contract proposal(s) from a non-Federal organization to NIH and/or other Federal agencies, (s)he must observe certain restrictions:
 - a. The NIH employee may not use any information regarding Federal programs that is not freely available to all applicants; and
 - b. The employee may develop the project plans and prepare the applications/proposals only in his/her private and personal capacity while (s)he is in an off-duty status, and not in the discharge of the individual's official Federal duties; and

- c. That development and preparation may involve no use of any Federal facility or resource of any nature whatsoever, other than routine and general information and materials normally supplied to persons outside the agency, and
- d. The employee may not sign the grant application or contract proposal in any capacity; and
- e. Neither before nor after the application or proposal is submitted to the NIH or other Federal agency for consideration, may the employee act in any way as agent or attorney or intercede, lobby, negotiate, or discuss on behalf of the institution with the concerned agency regarding the grant application or contract proposal.

2. Applicant Organizations If an organization submits a grant application or contract proposal to NIH or other Federal agency proposing as the PI an intramural research scientist currently employed by the NIH, the application or proposal must be accompanied by a letter signed by an appropriate official of the institution stating that:

- a. The named PI is an NIH employee at the time the application or proposal is submitted, and the organization understands that, should the application or proposal obtain funding, no award will be made until the proposed PI has terminated his/her Federal employment.
- b. Should additional information concerning the application or proposal be needed by the NIH or other Federal agency, the organization will provide that information without communication with the proposed PI.
- c. Should the NIH or other Federal agency require additional information which only the proposed PI could provide, the review of the application or proposal will be deferred until the PI is no longer a Federal employee.
- d. At the time any award is made following termination of the proposed PI's Federal employment (s)he will then be identified as responsible for the scientific conduct of the project.

3. NIH Review Process - In addition to the regular processes for reviewing and evaluating all applications and proposals, NIH extramural staff will observe special requirements in reviewing applications and proposals from current NIH intramural research scientists:

- a. NIH extramural staff shall not communicate in any way with an NIH intramural research scientist concerning an application or proposal on which (s)he is the proposed PI, and shall ensure that similar restraints are practiced by all persons involved in the review- award processes. Additional information required in the application or proposal review process shall be obtained only through communication directly with appropriate employees of the applicant/offeror organization.
- b. If the review of the application or proposal necessitates a project site visit, it must be conducted in the absence of the Federal employee who is the proposed PI. If the site visit is of such nature that adequate findings or recommendations can be made only after inputs from the proposed PI, the review of the application or

- proposal will be deferred until (s)he is no longer a Federal employee.
- c. No award of NIH funds may be made for a project resulting from an application or proposal prepared by an NIH intramural research scientist and on which (s)he is proposed as principal investigator, until that individual has terminated his/her Federal employment.
 - d. Prior to each award resulting from an application or proposal developed by an NIH intramural research scientist, the awarding component will provide to the NIH Legal Advisor, OGC, through the Associate Director for Extramural Affairs, NIH all files, including technical and advisory council review groups' records, concerning each application or proposal, to ensure on a case-by-case basis that the requirements and restrictions in this chapter have been followed.

G. Additional Information

For further information on this manual chapter, contact the Extramural Programs Management Office, OERT, Shannon Building, Room 314, telephone 496-2241.

H. Additional Copies of the NIH Manual Chapter

For extra copies of this chapter, send a Form NIH 414-5 "Request for Manual Chapter," to the Printing and Reproduction Branch, DAS, in Bldg. 31, Room B3BE07.