

NIH POLICY MANUAL
6309-1 - REPORTING OF PROPOSALS RECEIVED --
PRINCIPAL INVESTIGATORS UNDER FORMAL INVESTIGATION

Issuing Office: OA/OCM/DAPE 496-6014

Release Date: **09/01/99**

1. Explanation of Material Transmitted: This chapter provides the policy and procedures for the NIH management of the DHHS Alert System which is now located in the Office of Research Integrity (ORI), Office of Public Health and Science (OPHS), Office of the Secretary(OS), DHHS. This revision makes minor technical corrections and provides for submission of the notice by mail or fax.

2. Filing Instructions:

Remove: NIH Manual 6309-1, dated 03/05/93

Insert: NIH Manual 6309-1, dated 09/01/99

3. Distribution: NIH Mailing Keys F-401 and F-407

PLEASE NOTE: For information on:

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<http://www3.od.nih.gov/oma/manualchapters/>

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A. PURPOSE:

This chapter provides the policies and procedures, which allows the NIH to identify research contract proposals that include a principal investigator who is under formal investigation.

B. BACKGROUND:

The NIH policy concerning procedures and information involving formal investigations of fraud and abuse was initially established by I&I Memorandum OERT 81-1. The I&I Memorandum DCG 84-11 (Rev. 2) established: (1) The Division of Management Survey and Review (DMSR) as a focal point for the dissemination of specific information on institutions, organizations or principal investigators under ongoing investigation of fraud or abuse; (2) a procedure that allowed Bureaus, Institutes, and Divisions (now, Institutes and Centers (ICs) to alert DMSR to specific principal investigators identified in proposals; (3) a requirement that the IC report selected information on each proposal received; and (4) notification procedures.

The DMSR, NIH, was then superseded by the Office of Scientific Integrity (OSI), NIH, as the focal point. The OSI was abolished in June 1992 and its functions were transferred to the Office of Research Integrity, (ORI), OASH, PHS. This action was taken to restructure and strengthen the PHS research integrity program. The program was subsequently transferred to the DHHS/OS/OPHS. The OCM has been assigned coordination responsibilities for the identification of all pending contract proposals from the institution, organization, or principal investigator under formal investigation. The HHS is actively participating in supplying information for contracting officer usage as described in the 94 FR 12033.

C. POLICY:

1. The NIH policy is to make appropriate officials aware, on a need to know basis, that an offeror's principal investigator for an NIH contract is under investigation.
2. Technical evaluation of pending contract proposals normally will not be delayed because of any ongoing investigation for possible fraud or abuse.

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3. Technical evaluation group members normally will not be made aware of allegations or charges (regardless of the source) or the existence of a pending investigation; the intent is to avoid influencing the review of the proposal(s). Factual information resulting from ORS's investigations on which formal actions have been completed may be shared with the evaluation group members only if the information bears directly on the scientific merit of a proposal under review, and if the sharing of such information is acceptable to the IC director.
4. When appropriate, the National Advisory Council or Board Members, because of their broader advisory responsibilities, may be made aware of the existence and current status of investigations bearing on proposals brought to the Council or Board while the investigations are under way. Normally, however, questions relating to the fitness of the offeror's principal investigator will have been resolved before Council review takes place.

D. REFERENCES:

1. I&I Memorandum OERT 81-1 (expired)
2. HHSAR, Part 315.3, Source Selection
3. HHSAR, Subpart 309.4, Debarment, Suspension, and Ineligibility
4. 45 CFR Part 46, Protection of Human Subjects
5. 94 FR 12033, Office of the Assistant Secretary for Health; Privacy Act of 1974; Altered System of Records
6. Office of Research Integrity Web site <http://ori.dhhs.gov>

E. PROCEDURES:

1. The Chief Contracting Officers are required to provide the ORI "ALERT System Manager" a list of principal investigator names for all research (42CFR52h) proposals (new, renewal) received in the IC (see Appendix 1). It is not necessary to provide a notice for contract novations, changes in the principal investigator, funding actions, etc.
2. The Chief Contracting Officers will provide the following information to the ORI for each proposal as soon as possible after receipt in the IC:
 - a. The name of the proposed principal investigator.

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- b. The institution/organization proposing.
- c. The identifying number (RFP/Contract Number, etc.).
- d. The IC (and sub-component, if applicable), which received the proposal.
- e. The date the proposal was received in the IC.

Notification will be submitted via mail or fax (301-443-5351) to:

ALERT System Manager
Office of Research Integrity, OPHS/OS
ROCKWALL II Suite 700

Subject: Notification under "ALERT--Contract Proposal Identification System"
(Sample Memorandum is attached)

- 3. The ORI will notify the IC Director as soon as possible if any specific action is required on any identified proposal. You will not receive a notice from ORI unless there is a problem. Without specific notification, the IC will continue with normal preaward and award activities.

F. RECORDS RETENTION AND DISPOSAL:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, *NIH Records Control Schedule*, Item 2600-A-4, Routine Procurement Files."

NIH e-mail messages. The NIH e-mail messages (messages, including attachments, that are created on the NIH computer systems or transmitted over the NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. *These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.*

All e-mail messages are considered Government property, and if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff

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conducting official reviews or investigations, and the Office of the Inspector General may request access to or copies of the e-mail messages.

E-mail messages must also be provided to Congressional Oversight Committees, if requested, and are subject to the Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

G. MANAGEMENT CONTROLS:

The purpose of this manual issuance is to provide guidance to contracting officers and program officials on the DHHS ALERT System.

1. **Office Responsible for Reviewing Management Controls Relative to this Chapter:** The Division of Acquisition Policy and Evaluation (DAPE), Office of Contracts Management (OCM), is accountable for the method used to ensure that management controls are implemented and working.
2. **Frequency of Reviews:** Ongoing
3. **Method of Review:** The DAPE/OCM will maintain appropriate oversight through reviews of the IC presolicitation and preaward contract files conducted by the NIH Board of Contract Awards. The NIH Board of Contract Awards reviews a percentage of contract actions from each IC. Issues identified by the Board are provided to the IC for corrective action. When repetitive issues are identified, these are brought to the attention of the Acquisition Management Committee, which is responsible for addressing and resolving common acquisition issues. In addition, the Principal Official Responsible for Acquisition (PORA) is routinely apprised of any difficulties in the IC implementation of policy. Depending on the nature and extent of the problem, the PORA may recommend additional policy guidance or training of contract staff.
4. **Review Reports:** The PORA is routinely notified of problems and takes necessary action to resolve them.

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Sample ALERT Notification Memorandum

Appendix 1

DATE:

TO: ALERT System Manager
Office of Research Integrity, OPHS/OS
ROCKWALL II Suite 700

FROM: IC _____

SUBJECT: Notification under "ALERT - Contract Proposal Identification System" as Required by
NIH Manual Issuance 6309-1

RFP/Contract # _____

Closing Date of RFP _____

Institution/Organization Proposed Principal Investigator

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

(Signature)

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Source Selection Information, See FAR 3.104