

NIH Policy Manual

6309-1 - Reporting of Proposals Received–Principal Investigators Under Formal Investigation

Issuing Office: OD/OM/OALM/OAMP/DAPE **Phone:** [\(301\) 496-6014](tel:3014966014)

Approving Official(s): DDM

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Transmittal Notice

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 e-mail, mail or fax.

2. Filing Instructions:

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

Insert: NIH Manual Chapter 6309-1, dated 06/01/09.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- NIH Manual System, contact the Division of Management Support, Office of Management Assessment, OM, on 301-496-2832.
- On-line information, enter this URL: <http://www1.od.nih.gov/oma/manualchapters/>

A. Purpose

This chapter provides the policies and procedures that allow 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The DMSR, NIH, was then superseded by the Office of Scientific Integrity (OSI), NIH, as the focal point.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 OAMP/OALM 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 59 FR 36776

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.
3. Technical evaluation panel members (i.e., the Scientific Review Group [SRG] or Source Selection Panel [SSP]) 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 ORI'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, Subpart 315.3, Source Selection
3. HHSAR, Subpart 309.4, Debarment, Suspension, and Ineligibility
4. 45 CFR Part 46, Protection of Human Subjects
5. 59 FR 36776, 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>
7. [NIH Manual Chapter 1743](#) - Keeping and Destroying Records

E. Procedures

1. Contracting Officers are required to provide the ORI "ALERT System Manager" a list of principal investigator names for all research (42 CFR 52h) proposals (new, renewal) received (see Appendix 1). It is not necessary to provide a notice for contract novations, changes in the principal investigator, funding actions, etc.
2. Contracting Officers will provide the following information to the ORI for each proposal as soon as possible after receipt:
 - a. The name of the proposed principal investigator.
 - b. The institution/organization proposing.
 - c. The identifying number (RFP/Contract Number, etc.).
 - d. The contracting office (and sub-component, if applicable), which received the proposal.
 - e. The date the proposal was received.

Notification will be submitted via e-mail, fax (301-594-0043) or mail to:

ALERT System Manager
Office of Research Integrity, OS/OPHS
Tower Oaks, Suite 750
1101 Wootton Parkway
Rockville, MD 20852

Subject: Notification under "ALERT--Contract Proposal Identification System"

(Sample Memorandum is attached)

3. The ORI will notify the appropriate IC Research Integrity Officer (RIO) as soon as possible if any specific action is required on any identified proposal. The RIO will coordinate any such action with the relevant contracting officer. ORI will not send a notice unless there is a problem. Without specific notification, the contracting officer will continue with normal pre-award 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 the [NIH Manual Chapter 1743](#), "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, Section **4000 Grants and Awards, E. Appeals and Litigations – All items that apply** and Section **1100 - General Administration, A. Legislation and Regulations Files – All items that apply**.

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

E-mail messages must also be provided to the 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 chapter is to provide guidance to contracting officers and program officials on the DHHS ALERT System.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** The Division of Acquisition Policy and Evaluation (DAPE), Office of Acquisition Management and Policy (OAMP), Office of Acquisition, Logistics and Management (OALM) is accountable for the method used to ensure that internal controls are implemented and working.
2. **Frequency of Reviews:** Ongoing
3. **Method of Review:** The DAPE/OAMP/OALM will maintain appropriate oversight through reviews of the IC pre-solicitation and pre-award 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. Included in the review is a check of the documentation to ascertain that the "ALERT" notice has been sent to ORI. When repetitive issues are identified, such as the lack of documentation of "ALERT notices" these are brought to the attention of the Acquisition Management Committee, which is responsible for addressing and resolving common acquisition issues. In addition, the Head of the Contracting Activity (HCA) is routinely apprised of any difficulties in the IC implementation of policy. Depending on the nature and extent of the problem, the HCA may recommend additional policy guidance or training of contract staff.
4. **Review Reports:** The HCA receives a summary report of issues identified through reviews conducted by the NIH Board of Contract Awards. In addition, the HCA is routinely notified of problems and takes necessary action to resolve them.

Appendix 1 – Sample ALERT Notification Memorandum

DATE:

TO: ALERT System Manager

Office of Research Integrity, OS/OPHS
Tower Oaks, Suite 750
1101 Wootton Parkway
Rockville, MD 20852

FROM: Contracting Officer _____

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)

Source Selection Information, See FAR 3.104