NIH Policy Manual

6309-1 - Reporting of Research Contract Proposals Received–Principal Investigators Under Formal Investigation for Research Misconduct

Issuing Office: OD/OM/OALM/OAMP/DAPE **Phone:** (301) 496-6014

Approving Official(s): DDM

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Transmittal Notice

1. **Explanation of Material Transmitted:** This manual chapter provides the policy and procedures for the NIH management of the HHS PHS Alert System which records concerning individuals found to have committee Scientific Misconduct in Sponsored Research (SORN) (09-37-0151) that tracks individuals found to have engaged in research misconduct (falsification, fabrication, or plagiarism) in research funded by the PHS. The system allows PHS agencies to discharge effectively their responsibilities in the award and administration of research and training grants, cooperative agreements and contracts, while protecting the privacy and other rights of individuals. The system is managed by HHS/OS/OASH/ORI Office of Research Integrity (ORI), Office of the Assistant Secretary for Health (OASH), Office of the Secretary (OS), DHHS. This revision updates the content by adding required sections, removing sections that are no longer required, ensuring all policy information is current, and providing a link for submission of the required notice by e-mail. This is necessary to adhere to the 5-year requirement for review as outlined in Manual Chapter 1710 – Publishing and Maintaining Policies in the NIH Policy Manual.

2. **Filing Instructions:**

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

   Insert: NIH Manual Chapter 6309-1, dated 06/02/2025.

3. **PLEASE NOTE:** For information on:

    - Content of this manual chapter, contact the issuing office listed above.
    - NIH Policy Manual, contact the Division of Compliance Management, OMA, on 301-496-4606 or: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx.

A. Purpose

This manual 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 for research misconduct, as defined under 42 C.F.R. Part 93. "Research misconduct" means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. "Investigation" means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

B. Scope

This manual chapter applies to all domestic and foreign NIH Research and Development contract proposals that will undergo scientific peer review in accordance with 42 C.F.R. Part 52h, for purposes of screening proposed Principal Investigators (PI) to determine if the PI is under investigation for research misconduct, 42 U.S.C. § 289b Personnel involved in this process include the Contracting Officer, OS/OASH/ORI HHS PHS Alert System Manager, and cognizant ICO Research Integrity Officer.

C. Background

The NIH policy concerning procedures and information involving formal investigations of research misconduct 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 research misconduct; (2) a procedure that allowed Bureaus, Institutes, and Divisions (now, Institutes, Centers and Offices(ICOs)) to alert DMSR to specific principal investigators identified in proposals; (3) a requirement that the ICO 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), Office of the Assistant Secretary for Health, (OASH), Public Health Service, (PHS.) This action was taken to restructure and strengthen the PHS research integrity program. The program was subsequently reorganized under the HHS/OS/OPHS, which was later named back to HHS/OS/OASH. The Office of Acquisition Management and Policy (OAMP), Office of Acquisition, Logistics and Management (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.

D. 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 for research misconduct.
2. Technical evaluation of pending contract proposals normally will not be delayed because of any ongoing investigation for possible research misconduct.
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 ICO 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.

E. Roles and Responsibilities

1. Institutes, Centers, and Offices

    a. Role: Serves as the sponsor of the research project, providing technical direction and funding for the proposed research contract.

2. ICO Directors: Ensure adherence within their organizations to established NIH policies, and maintain adequate communication between program, contracting, and review staff. Division of Acquisition Policy and Evaluation (DAPE), Office of Acquisition Management and Policy (OAMP), Office of Acquisition, Logistics and Management (OALM)

    a. Role: Responsible to communicating awareness of the Alert Notification policy to the acquisitions community and to provide procedural instructions for its compliance.

3. Principal Investigator

a. Role: The Principal Investigator (PI) serves as the lead member of the team proposed to conduct research as outlined in the offeror's proposal. Upon award of a contract, the PI has primary responsibility for ensuring compliance with the scientific conduct of the research and following the technical requirements of the contract.

4. Office of Research Integrity, (ORI)

    a. Role: The Office of Research Integrity (ORI) oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of Health and Human Services with the exception of the regulatory research integrity activities of the Food and Drug Administration. ORI receives the Alert Notification and reviews the identified Principal Investigators to determine if any are under investigation for research fraud or abuse.

5. Head of the Contracting Activity (HCA)

    a. Role: Establishes NIH policies and procedures for business reviews, evaluations, and awards for R&D contracts under requirements established in the FAR and HHSAR and determines the adequacy of procedures implementing those principles.

6. Contracting Officer: The Contracting Officer (CO) is responsible for preparing and publicly posting the solicitation in accordance with all federal laws and regulations. Upon receipt of proposals in response to the solicitation, the CO prepares and submits the required Alert Notification to the HHS PHS Alert System Manager, OS/OASH/ORI. If the CO receives notice from the Research Integrity Officer (RIO) that the PI is under investigation, the CO is to proceed with the acquisition as usual unless subsequently notified by RIO associated with the allegation(s). The CO will share the reported allegation(s) with the program office. Upon such subsequent notification from the RIO, the CO will raise the matter to OALM and OGC for guidance on what remedies are appropriate for the CO to take with respect to the situation. Actions taken by the CO may include, but are not limited to, termination of the contract if an award has been made and recommending debarment of the PI.
7. Scientific Review Officers (SRO): Establish and supervise equitable scientific reviews and evaluations for R&D contract proposals. The SRO ensures that SRG members have no real or apparent conflicts of interest precluding their participation in proposal reviews in a given competition, unless a waiver is obtained under 42 C.F.R. Part 52(h) to allow a member's participation under

defined circumstances. The SRO ensures reviewers sign and submit Conflict of Interest, Confidentiality and Non-Disclosure of Information Certifications. SROs interact with program staff and COs as necessary to understand the review requirements of the acquisition, including providing advice on evaluation criteria during solicitation development. SROs document the SRG reviews to the CO and program office. In the event the IC RIO reports that a PI associated with one of the proposals received is under investigation, neither a suspicion or allegation of research misconduct nor a pending inquiry or investigation will normally delay review of proposals. To avoid influencing the peer review process, peer reviewers are generally not informed of the pending investigation.

8. ICO Research Integrity Officer (RIO): Each ICO has a designated RIO who handles allegations of misconduct in research. If the ORI identifies concerns related to any PI identified in the Alert Notification, ORI will notify the sponsoring ICO RIO who in turn notifies the cognizant CO of the nature of the allegation(s). The RIO will subsequently inform the CO if findings of the investigation support the alleged research misconduct.

F. References

1. I&I Memorandum OERT 81-1 (expired)
2. I&I Memorandum 84-14 DCG (expired)
3. HHSAR, Subpart 315.3, Source Selection
4. HHSAR, Subpart 309.4, Debarment, Suspension, and Ineligibility
5. 45 C.F.R. Part 46, Protection of Human Subjects
6. 59 FR 36776, Office of the Assistant Secretary for Health; Privacy Act of 1974; Altered System of Records
7. Office of Research Integrity Web site https://ori.hhs.gov
8. NIH Manual Chapter 1743 – Managing Federal Records
9. NIH Manual Chapter 1710 – Publishing and Maintaining Policies in the NIH Policy Manual
10. 42 C.F.R. Part 52(h) – Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects

G. Procedures

Upon receipt of Research and Development proposals and prior to scientific peer review, the Contracting Officer shall take steps outlined in Appendix 1 to ensure the necessary screening of proposed PIs is accomplished, in coordination with the OS/OASH/ORI HHS PHS Alert System Manager.

Appendix 1 – Procedures for initiating notification to the HHS PHS Alert System Manager

1. Contracting Officers are required to provide the ORI "HHS PHS ALERT System Manager" a list of principal investigator names for all research proposals (new, renewal) received (see Appendix 2).
2. Contracting Officers will provide the following information to the ORI for each proposal as soon as possible after receipt:
    - The name of the proposed principal investigator.
    - The institution/organization proposing.
    - The identifying number (RFP/Contract Number, etc.).
    - The contracting office (and sub-component, if applicable), which received the proposal.
    - The date the proposal was received.

Notification will be submitted via e-mail (askORI@hhs.gov) or mail to:

HHS PHS ALERT System Manager

Office of Research Integrity, OS/OASH

Tower Oaks, Suite 750

1101 Wootton Parkway

Rockville, MD 20852

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

(Sample Memorandum is include below as Appendix 2.)

The ORI will notify the appropriate ICO 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.

Appendix 2 - Sample ALERT Notification Memorandum

DATE:

TO: HHS PHS ALERT System Manager

Office of Research Integrity, OS/OASH

Tower Oaks, Suite 750

1101 Wootton Parkway

Rockville, MD 20852

The ALERT notification may be sent electronically to askORI@hhs.gov

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