

Procedure P7-001A: Research Misconduct Reporting Requirements for Federally Funded Research.

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I. Purpose and Scope**A. Purpose.**

1. The Office of Science and Technology Policy (OSTP) requires all federal agencies or departments that support extramural research to implement policies and/or regulations for addressing Research Misconduct. The University is committed to adhering to the policies and regulations of

applicable federal entities when Research Misconduct Allegations arise in federally supported research.

2. Policy 7-001 has been established to provide definitions, processes, and procedures for addressing Research Misconduct that are consistent with all federal entities, insofar as the policies of federal entities are in harmony. However, where variability exists between the policies and regulations of federal entities, the university will implement separate procedures to support identification and compliance with requirements specific to individual federal entities. This procedure addresses the unique reporting requirements of several different federal agencies relative to Research Misconduct Proceedings.

B. Scope.

1. This procedure applies wherever Policy 7-001 applies and federal funding is implicated.
2. If the Research described in an Allegation is funded by a federal agency other than those included in this procedure, the RIO shall follow the reporting and notification processes required by the federal funder.

II. Definitions

The definitions provided in Policy 7-001: Research Misconduct apply for this procedure. In addition, the terms below apply for the limited purpose of this procedure.

- A. “DoD Components” means the Office of the Secretary of Defense, the Combatant Commands, the Defense Agencies, the DoD Field Activities, and all other organization entities in the Department of Defense.

III. Procedure

- A. Reporting and Consulting Requirements for Public Health Services (PHS) Funded Research

1. Allegations of Research Misconduct that fall outside the Six-Year Limitation established under Policy 7-001 shall be considered by the RIO to determine whether, if true, the misconduct could have a substantial adverse effect on public health or safety. If the alleged conduct presents such a risk, the RIO shall consult with the federal Office of Research Integrity (ORI) before invoking the time limitation exception under Policy 7-001.
2. If the Research described in an Allegation is funded by the PHS, the RIO shall, within 30 Days of the determination that an Investigation is warranted, but before the Investigation begins, notify both the director of ORI and the applicable funding entity within the department of Health and Human Services (e.g., NIH Office of Extramural Research - Research Integrity) that the Investigation will begin. The notification shall include the final and complete Inquiry report, including any Respondent/Complainant comment, and documentation of Inquiry committee (or RIO) consideration and response.
3. For all Investigations involving PHS funding, within 180 Days of the Investigation committee seating and charge, the RIO shall provide the ORI and the applicable funding agency with the complete and logically organized Institutional Record.
 - a. If the Investigation cannot be completed in 180 Days, the RIO must ask ORI for an extension. The request must be in writing and include the circumstances or issues warranting additional time.
4. If a Respondent appeals the Institutional Administrative Action(s) imposed by the university, the RIO must promptly notify ORI regarding the appeal.
 - a. If the Institutional Record has already been sent to ORI, the RIO shall provide ORI with initial notification of appeal, and then once the appeal is concluded, the complete record of appeal.
 - b. If the appeal is initiated before the Institutional Record is sent to ORI, the RIO shall provide ORI with initial notification and hold the institutional

record until it can be transmitted with full documentation of the appeal conclusion.

5. The university shall notify ORI immediately, at any stage of the Research Misconduct Proceeding, if it has reason to believe that any of the following conditions exist:
 - a. health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
 - b. to protect HHS resources or interests;
 - c. research activities should be suspended;
 - d. there is a reasonable indication of possible violation(s) of civil or criminal law;
 - e. federal action is needed to protect the interests of those involved in a Research Misconduct Proceeding; or
 - f. HHS may need to take action to safeguard Evidence and/or protect the rights of those involved.
6. If the RIO plans to close a Research Misconduct Proceeding early because the Respondent has admitted to committing Research Misconduct or a settlement with the Respondent has been reached, the RIO should consult with ORI before accepting the admission.
7. The RIO must notify ORI before closing the Institution's Research Misconduct Proceeding and provide both the Respondent's written and signed admission and written statement confirming the respondent's culpability and explaining how the scope of the Respondent's Misconduct was fully addressed.
 - a. Admissions of Research Misconduct must be consistent with Policy 7-001. The RIO must comply with any subsequent instruction or conclusion from ORI regarding the admission.

B. Reporting Requirements for National Science Foundation (NSF) Funded Research

1. If the Research described in an Allegation is funded by the NSF, the RIO shall, within 90 Days of commencing Inquiry, determine if an Investigation is warranted.
 - a. If the Inquiry cannot be completed within 90 Days, but the University desires that NSF deferral continue, NSF may require periodic updates.
2. If an Investigation is warranted, the RIO shall immediately inform the NSF Office of the Inspector General (OIG) that the Inquiry supports Investigation and provide the final Inquiry report.
3. The RIO shall keep the OIG informed during the investigation.
4. The Investigation must be completed within 180 calendar days of Investigation commencement.
 - a. If the Investigation cannot be completed within 180 Days, but the university desires that NSF deferral continue, the RIO shall notify the NSF OIG, who may require periodic updates.
5. The RIO shall provide the OIG with a copy of the final Investigation report.
6. The university shall promptly notify the NSF OIG if, at any stage of a Research Misconduct Proceeding involving Research funded by the NSF, any of the following conditions exist:
 - a. public health or safety is at risk;
 - b. NSF's resources, reputation, or other interests need protecting;
 - c. there is a reasonable indication of possible violations of civil or criminal law;
 - d. research activities should be suspended;

- e. federal action may be needed to protect the interests of a Respondent or of others potentially affected; or
- f. The scientific community or the public should be informed.

C. Reporting Requirements for Department of Energy (DOE) Funded Research

- 1. If Research described in an Allegation funded by the DOE moves to Investigation, the RIO shall immediately inform the DOE Contracting Officer.
- 2. If requested by the Contracting Officer, the RIO shall keep the Contracting Officer informed during the Investigation.
- 3. The Investigation must be completed within 120 Days, with adjudication (i.e., VPR determination of administrative action, sanctions, etc.) completed in 60 Days.
 - a. The VPR (or designee) must coordinate remedial actions with the Contracting Officer.
- 4. The RIO shall provide the Contracting Officer with a copy of the Institutional Record, once complete.

D. Reporting Requirements for Department of Defense (DoD) Funded Research

- 1. The DoD does not provide a comprehensive policy for research misconduct. Instead, DoD Information Document (DODI) 3210.7 authorizes individual DoD Components to develop their own procedures.
 - a. The RIO is responsible for identifying and following the reporting requirements of applicable DoD Components when DoD funded research is implicated in a Research Misconduct case.
- 2. DODI 3210.7, Enclosure 4 requires the university take the following actions for all Research Misconduct proceedings involving DoD funding.
 - a. If the Research Misconduct proceeding moves to Investigation, the RIO shall notify the DoD official specified in the applicable award.

- b. The RIO shall provide a copy of the Institutional Record to the designated DoD official.
- c. The University shall immediately notify the applicable DoD Component if, at any stage of the Inquiry or Investigation of Research funded by the DoD, any of the following conditions exist:
 - i. public health or safety is at risk;
 - ii. the University's resources or other interests are threatened or at risk;
 - iii. research activities are to be suspended because of the Research Misconduct Proceeding;
 - iv. there is a possible violation of civil or criminal law;
 - v. action from the DoD Component is required to protect the interests of those involved in the Misconduct Proceeding;
 - vi. premature public disclosure of the Misconduct proceeding may compromise the Proceeding; or
 - vii. The broader research community or public should be informed.

Sections IV- VII are for user information and are not subject to the approval of the Academic Senate or the Board of Trustees. The Institutional Policy Committee, the Policy Owner, or the Policy Officer may update these sections at any time.

IV. Policies/ Rules, Procedures, Guidelines, Forms and other Related Resources

A. Policies/ Rules.

- 1. Policy 7-001: Policy for Research Misconduct

B. Procedures, Guidelines, and Forms.

C. Other Related Resources. [reserved]

V. References

- A. The references provided in Policy 7-001 apply for this rule.
- B. 45 CFR Part 689 - NSF Policy
- C. 2 CFR Part 910.132 - DOE Policy
- D. Information Document (DODI) 3210.7 - DoD Instruction

VI. Contacts

The designated contact officials for this regulation are:

- A. Policy Owner(s) (primary contact person for questions and advice): Associate Vice President for Research Integrity & Compliance
- B. Policy Officer(s): Vice President for Research

See Rule 1-001 for information about the roles and authority of policy owners and policy officers.

VII. History

Revision History.

- A. Current version. Revision 0.
- B. Previous versions. [*reserved*]
- C. Renumbering
 - 1. Not Applicable.