

Procedures for Addressing Allegations of Research Misconduct

Assessment

An assessment's purpose is to determine whether an allegation warrants an inquiry. An assessment is intended to be a review of readily accessible information relevant to the allegation.

Upon receiving an allegation of research misconduct, the RIO or another designated institutional official will promptly determine whether the allegation (a) falls within the definition of research misconduct, (b) is within the applicability criteria of 42 CFR Part 93 § 93.102, and (c) is credible and specific enough to identify and sequester potential evidence.

If the RIO or another institutional official determines that the allegation meets these three criteria, they will promptly: (a) document the assessment and (b) initiate an inquiry and sequester all research records and other evidence. The RIO or other institutional official must document the assessment and retain the assessment documentation securely for at least seven years after completion of the misconduct proceedings. If the RIO or another institutional official determines that the alleged misconduct does not meet the criteria to proceed to an inquiry, they will write sufficiently detailed documentation to permit a later review by ORI of why UNI did not proceed to an inquiry, and securely retain this documentation for at least seven years.

Inquiry

An inquiry is warranted if the allegation (a) falls within the definition of research misconduct under 42 CFR Part 93, (b) is within the applicability criteria of § 93.102, and (c) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. An inquiry's purpose is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation. An inquiry does not require a full review of all related evidence. UNI will complete the inquiry within 90 days of initiating it

unless circumstances warrant a longer period, in which case it will sufficiently document the reasons for exceeding the time limit in the inquiry report.

Sequestering Evidence and Notifying the Respondent

Before or at the time of notifying the respondent(s), UNI will obtain the original or substantially equivalent copies of all research records and other evidence that are pertinent to the proceeding, inventory these materials, sequester the materials in a secure manner, and retain them for seven years. The institution has a duty to obtain, inventory, and securely sequester evidence that extends to whenever additional items become known or relevant to the inquiry or investigation.

At the time of or before beginning the inquiry, UNI will make a good-faith effort to notify the presumed respondent(s), in writing, that an allegation(s) of research misconduct has been raised against them, the relevant research records have been sequestered, and an inquiry will be conducted to decide whether to proceed with an investigation. If additional allegations are raised, the institution will notify the respondent(s) in writing. When appropriate, the institution will give the respondent(s) copies of, or reasonable supervised access to, the sequestered materials.

If additional respondents are identified, UNI will provide written notification to the new respondent(s). All additional respondents will be given the same rights and opportunities as the initial respondent. Only allegations specific to a particular respondent will be included in the notification to that respondent.

Convening the Committee and Ensuring Neutrality

UNI will ensure that all inquiry committee members understand their commission, keep the identities of respondents, complainants, and witnesses confidential, and conduct the research misconduct proceedings in compliance with the PHS regulation. In lieu of a committee, the institution may task the RIO or another designated institutional official to conduct the inquiry, provided this person utilizes subject matter experts as needed to assist in the inquiry.

Determining Whether an Investigation Is Warranted

The inquiry committee, RIO, or other designated institutional official will conduct a preliminary review of the evidence. In the process of fact-finding, the inquiry committee may interview the respondent and/or witnesses. An investigation is warranted if (a) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under 42 CFR Part 93; and (b) preliminary information- gathering and fact-finding from the inquiry indicates that the allegation may have substance.

The inquiry committee will not determine if research misconduct occurred, nor assess whether the alleged misconduct was intentional, knowing, or reckless; such a determination is not made until the case proceeds to an investigation.

Documenting the Inquiry

At the conclusion of the inquiry, regardless of whether an investigation is warranted, the inquiry committee, RIO, or other designated institutional official will prepare a written inquiry report. The contents of a complete inquiry report will include:

1. The names, professional aliases, and positions of the respondent and complainant(s).
2. A description of the allegation(s) of research misconduct.
3. Details about any funding, including any grant numbers, grant applications, contracts, and publications.
4. The composition of the inquiry committee, if used, including name(s), position(s), and subject matter expertise.
5. An inventory of sequestered research records and other evidence and description of how sequestration was conducted.
6. Transcripts of interviews, if transcribed.
7. Inquiry timeline and procedural history.
8. Any scientific or forensic analyses conducted.
9. The basis for recommending that the allegation(s) warrant an investigation.
10. The basis on which any allegation(s) do not merit further investigation.
11. Any comments on the inquiry report by the respondent or the complainant(s).
12. Any institutional actions implemented, including internal communications or external communications with journals or funding agencies.
13. Documentation of potential evidence of honest error or difference of opinion.

Completing the Inquiry

UNI will give the respondent a copy of the draft inquiry report for review and comment. The institution may, but is not required to, provide relevant portions of the report to a complainant for comment.

UNI will notify the respondent of the inquiry's final outcome and provide the respondent with copies of the final inquiry report, and these policies and procedures. The institution may, but is not required to, notify a complainant whether the inquiry found that an investigation is warranted. If the institution provides notice to one complainant in a case, it must provide notice, to the extent possible, to all complainants in the case.

If an Investigation Is Not Warranted:

If the inquiry committee, RIO, or other designated institutional official determines that an investigation is not warranted, UNI will keep sufficiently detailed documentation to permit a later review by ORI of why the institution did not proceed to an investigation, store these records in a secure manner for at least seven years after the termination of the inquiry, and provide them to ORI upon request.

If an Investigation is Warranted:

If the inquiry committee, RIO, or other designated institutional official determines that an investigation is warranted, UNI must: (a) within a reasonable amount of time after this decision, provide written notice to the respondent(s) of the decision to conduct an investigation of the alleged misconduct, including any allegations of research misconduct not addressed during the inquiry; and (b) within 30 days of determining that an investigation is warranted, provide ORI with a copy of the inquiry report.

On a case-by-case basis, UNI may choose to notify the complainant that there will be an investigation of the alleged misconduct but is required to take the same notification action for all complainants in cases where there is more than one complainant.

Investigation

The purpose of an investigation is to formally develop a factual record, pursue leads, examine the record, and recommend finding(s) to the IDO, who will make the final decision, based on a preponderance of evidence, on each allegation and any institutional actions. As part of its investigation, the institution will pursue diligently all significant issues and relevant leads, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion. Within 30 days after deciding an investigation is warranted, UNI will notify ORI of the decision to investigate and begin the investigation.

Notifying the Respondent and Sequestering Evidence

UNI will notify the respondent(s) of the allegation(s) within 30 days of determining that an investigation is warranted and before the investigation begins. If any additional

respondent(s) are identified during the investigation, the institution will notify them of the allegation(s) and provide them an opportunity to respond. If the institution identifies additional respondents during the investigation, it may choose to either conduct a separate inquiry or add the new respondent(s) to the ongoing investigation. The institution will obtain the original or substantially equivalent copies of all research records and other evidence, inventory these materials, sequester them in a secure manner, and retain them for seven years after its proceeding or any HHS proceeding, whichever is later.

Convening an Investigation Committee

After vetting investigation committee members for conflicts of interest and appropriate scientific expertise, UNI will convene the committee and ensure that the members understand their responsibility to conduct the research misconduct proceedings in compliance with the Research Misconduct Policy. The investigation committee will conduct interviews, pursue leads, and examine all research records and other evidence relevant to reaching a decision on the merits of the allegation(s). The institution will use diligent efforts to ensure that the investigation is thorough, sufficiently documented, and impartial and unbiased to the maximum extent practicable. The institution will notify the respondent in writing of any additional allegations raised against them during the investigation.

Conducting Interviews

UNI will interview each respondent, complainant(s), and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent. The institution will number all relevant exhibits and refer to any exhibits shown to the interviewee during the interview by that number. The institution will record and transcribe interviews during the investigation and make the transcripts available to the interviewee for correction. The institution will include the transcript(s) with any corrections and exhibits in the institutional record of the investigation. The respondent will not be present during the witnesses' interviews, but the institution will provide the respondent with a transcript of each interview, with redactions as appropriate to maintain confidentiality.

Documenting the Investigation

UNI will complete all aspects of the investigation within 180 days. The institution will conduct the investigation, prepare the draft investigation report for each respondent, and provide the opportunity for respondents to comment. The institution will document the IDO's final decision and transmit the institutional record (including the final investigation report and IDO's decision) to ORI. If the investigation takes more than 180 days to

complete, the institution will ask ORI in writing for an extension and document the reasons for exceeding the 180-day period in the investigation report.

The investigation report for each respondent will include:

1. Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.
2. Description and documentation of any funder's support, including any grant numbers, grant applications, contracts, and publications listing such support. This documentation includes known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.
3. Description of the specific allegation(s) of research misconduct for consideration in the investigation of the respondent.
4. Composition of investigation committee, including name(s), position(s), and subject matter expertise.
5. Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on. This inventory will include manuscripts and funding proposals that were considered or relied on during the investigation. The inventory will also include a description of how any sequestration was conducted during the investigation.
6. Transcripts of all interviews conducted.
7. Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that contain the allegedly falsified, fabricated, or plagiarized material.
8. Any scientific or forensic analyses conducted.
9. A copy of these policies and procedures.
10. Any comments made by the respondent and complainant(s) on the draft investigation report and the committee's consideration of those comments.
11. A statement for each separate allegation of whether the committee recommends a finding of research misconduct.

If the committee recommends a finding of research misconduct for an allegation, the investigation report will present a finding for each allegation. These findings will (a) identify the individual(s) who committed the research misconduct; (b) indicate whether the

misconduct was falsification, fabrication, and/or plagiarism; (c) indicate whether the misconduct was committed intentionally, knowingly, or recklessly; (d) identify any significant departure from the accepted practices of the relevant research community and that the allegation was proven by a preponderance of the evidence; (e) summarize the facts and analysis supporting the conclusion and consider the merits of any explanation by the respondent; (f) identify the specific funders' and their support; and (g) state whether any publications need correction or retraction.

If the investigation committee does not recommend a finding of research misconduct for an allegation, the investigation report will provide a detailed rationale for its conclusion.

The investigation committee should also provide a list of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.

Completing the Investigation

UNI will give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the research records and other evidence that the investigation committee considered or relied on. The respondent will submit any comments on the draft report to the institution within 30 days of receiving the draft investigation report. If UNI chooses to share a copy of the draft investigation report or relevant portions of it with the complainant(s) for comment, the complainant's comments will be submitted within 30 days of the date on which they received the report. The institution will add any comments received to the investigation report.

IDO Review of the Investigation Report

The IDO will review the investigation report and make a final written determination of whether the institution found research misconduct and, if so, who committed the misconduct. In this statement, the IDO will include a description of relevant institutional actions taken or to be taken.

Creating and Transmitting the Institutional Record

After the IDO has made a final determination of research misconduct findings, UNI will add the IDO's written decision to the investigation report and organize the institutional record in a logical manner.

The institutional record consists of the records that were compiled or generated during the research misconduct proceeding, except records the institution did not rely on. These records include documentation of the assessment, a single index listing all research records and evidence, the inquiry report and investigation report, and all records considered or relied on during the investigation. The institutional record also includes the

IDO's final decision and any information the respondent provided to the institution. The institutional record must also include a general description of the records that were sequestered but not considered or relied on.

If the respondent filed an appeal, the complete record of any institutional appeal also becomes part of the institutional record. UNI will wait until the appeal is concluded to transmit the institutional record to ORI. After the IDO has made a final written determination, and any institutional appeal is complete, the institution must transmit the institutional record to ORI.

Other Procedures and Special Circumstances

Multiple Institutions and Multiple Respondents

If the alleged research misconduct involves multiple institutions, UNI may work closely with the other affected institutions to determine whether a joint research misconduct proceeding will be conducted. If so, the cooperating institutions will choose an institution to serve as the lead institution. In a joint research misconduct proceeding, the lead institution will obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.

If the alleged research misconduct involves multiple respondents, UNI may either conduct a separate inquiry for each new respondent or add them to the ongoing proceedings. The institution must give additional respondent(s) notice of and an opportunity to respond to the allegations.

Respondent Admissions

UNI will promptly notify ORI in advance if at any point during the proceedings (including the assessment, inquiry, investigation, or appeal stage) it plans to close a research misconduct case because the respondent has admitted to committing research misconduct or a settlement with the respondent has been reached. If the respondent admits to research misconduct, the institution will not close the case until providing ORI with the respondent's signed, written admission. The admission must state the specific fabrication, falsification, or plagiarism that occurred, which research records were affected, and that it constituted a significant departure from accepted practices of the relevant research community. The

institution must not close the case until giving ORI a written statement confirming the respondent's culpability and explaining how the institution determined that the respondent's admission fully addresses the scope of the misconduct.

Other Special Circumstances

At any time during the misconduct proceedings, UNI will immediately notify ORI if any of the following circumstances arise:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
2. Federal, state, or institutional resources or interests are threatened.
3. Research activities should be suspended.
4. There is reasonable indication of possible violations of civil or criminal law.
5. Federal action is required to protect the interests of those involved in the research misconduct proceeding.
6. HHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved.

Records Retention

UNI will maintain the institutional record and all sequestered evidence, including physical objects (regardless of whether the evidence is part of the institutional record), in a secure manner for seven years after the completion of the proceeding or the completion of any HHS proceeding, whichever is later, unless custody has been transferred to HHS.