

Assessment, Inquiry and Investigation Procedures

Assessment of Allegations

Upon receiving an allegation of research misconduct, the SIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b) or other applicable law, and whether the allegation falls within the definition of research misconduct. An inquiry must be conducted if these criteria are met.

Ordinarily, an allegation of plagiarism or other misconduct by a student in an educational class setting would not be within the jurisdiction of 42 CFR § 93.102(b), and would be handled by the school according to the appropriate academic or disciplinary policy. Acknowledging this, the SIO and the appropriate student affairs dean will confer regarding the allegations of research misconduct for a student, and determine whether the student Respondent's activity at issue was supported by PHS or other third party sponsors. If the alleged misconduct was supported by PHS or other third party sponsors, the matter will be handled in accordance with this policy. If not, it will be administratively handled by the student affairs deans in accordance with school policy.

In conducting the assessment, the SIO need not interview the Complainant, Respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The SIO shall, on or before the date on which the Respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in this section.

Initiation and Purpose of the Inquiry

If the SIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the SIO must make a good faith effort to notify the Respondent in writing, if the Respondent is known. If the inquiry subsequently identifies additional Respondents, they must be notified in writing. On or before the date on which the Respondent is notified, or the inquiry begins, whichever is earlier, the SIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

Appointment of the Inquiry Committee

The standing UTMB Scientific Integrity Committee shall function as the inquiry committee. The chair of the SIC shall be the chair of the inquiry proceeding. The committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include some individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. If appropriate, the Scientific Integrity Committee or the SIO will consult with scientists with expertise in the fields at issue in the Complaint.

The SIO will notify the Respondent in writing of the committee membership and give the Respondent five (5) business days to object to the SIO in writing regarding any member of the Scientific Integrity Committee based upon a personal, professional, or financial conflict of interest. The SIO will make the final determination of whether a conflict exists

Charge to the Committee

The SIO will prepare a charge for the Scientific Integrity Committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial
- review of the evidence, including the testimony of the Respondent, Complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible; States that an investigation would be warranted if the committee determines:
 - there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and
 - the allegation may have substance, based on the committee's review during the inquiry; and
 - Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

The SIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The SIO will be present or available throughout the inquiry to advise the committee as needed.

Inquiry Process

The inquiry committee will normally receive a report from the SIO regarding his or her interviews and review of the relevant data or materials. The committee may also, at its discretion, interview the Complainant, the Respondent, and key witnesses, review the transcripts or recordings of those interviews conducted by the SIO, or examine relevant research records and materials. After consultation with the SIO, the committee members will decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d) or other applicable law. The scope of the

inquiry is not required to and does not normally include deciding whether misconduct definitely occurred. Nor does it normally involve determining definitively who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the Respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved to the satisfaction of the committee. In that case, and if the misconduct (as described in § I.B. above) involves the U.S. Public Health Service, the SIO shall promptly consult with ORI to determine the next steps that should be taken.

Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the President on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the SIO determines that circumstances clearly warrant a longer period. If the SIO approves an extension, the inquiry record must include written documentation of the reasons for the extension.

Retention of Records from the Assessment and Inquiry

All records will be retained for a period of seven years from the date of the completion of the proceedings.

Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information:

- 1) the name and position of the Respondent;
- 2) the names and titles of the committee members;
- 3) the names and titles of any experts consulted;
- 4) a description of the allegations of research misconduct;
the intramural or extramural support for the underlying activity (for example, for PHS supported research the identifying information should include grant numbers, grant applications, contracts and publications listing PHS support);
- 5) a summary of the inquiry process used;
- 6) a list of the research records reviewed;
- 7) the basis for recommending or not recommending that the allegations warrant an investigation;
and any comments on the draft report by the Respondent or Complainant

Documentation of Decision Not to Investigate

If the President decides that an investigation is not warranted, the SIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI or other regulatory entity of the reasons why an investigation was not conducted. For misconduct involving PHS, these documents must be provided to ORI or other authorized U.S. Department of Health and Human Services personnel upon request.

misconduct that would justify broadening the scope beyond the initial allegations. This is particularly

important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. Federal law requires the findings of the investigation be set forth in an investigation report.

Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the SIO must notify the Respondent in writing of the allegations to be investigated.

If the misconduct involves the PHS, on or before the date on which the investigation begins, the SIO must also notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report.

The SIO must also give the Respondent written notice of any *new* allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

The SIO will, prior to notifying Respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. The need for additional sequestration of records for the investigation may occur for any number of reasons, including UTMB's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

Appointment of the Investigation Committee

The President, in consultation with the SIO and other misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. Federal law requires the findings of the investigation be set forth in an investigation report.

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The SIO will, prior to notifying Respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. The need for additional sequestration of records for the investigation may occur for any number of reasons, including UTMB's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

Appointment of the Investigation Committee

The President, in consultation with the SIO and other institutional officials as appropriate, will appoint an investigation committee of at least 3 members and committee chair as soon after the beginning of the investigation as is practical. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the Respondent and Complainant, and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee. When necessary to secure the necessary expertise or to avoid conflicts of interest, the President may select committee members from outside the institution.

- The President will notify the Respondent of the proposed committee membership to give the Respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The Respondent will have five (5) calendar days to object in writing to any of the members identified for the Investigation Committee, based upon personal, professional, or financial conflicts of interest. The President will make the final determination of whether a conflict exists.

Charge to the Committee and the First Meeting

1. Charge to the Committee

The SIO will define the subject matter of the investigation in a written charge to the committee that:

- Describes the allegations and related issues identified during the inquiry;
- Identifies the Respondent;
- Informs the committee that it must conduct the investigation as prescribed in paragraph E. of this section;
- Defines research misconduct;
Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the committee that in order to determine that the Respondent committed research misconduct it must find that a preponderance of the evidence establishes that:
 1. research misconduct, as defined in this policy, occurred (Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including

- honest error or a difference of opinion);
- 2. the research misconduct is a significant departure from accepted practices of the relevant research community; and
- 3. the Respondent committed the research misconduct intentionally, knowingly, or recklessly; and
- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313 or other applicable law.

First Meeting

The SIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of this statement of policy and procedures and, where appropriate, 42 CFR Part 93. The SIO will be present or available throughout the investigation to advise the committee as needed.

Investigation Process

The investigation committee and the SIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
- Interview each Respondent, Complainant, 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, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation; and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

Time for Completion

The investigation should be completed within 120 calendar days from the date it is initiated. This deadline includes conducting the investigation, preparing the report of findings, providing the draft report for comment, and issuing a final report. For any misconduct proceeding other than one involving the PHS, the SIO has the discretion to extend for good cause the 120 day deadline.

If the misconduct involves the PHS, if the SIO determines that the investigation will not be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth

the reasons for the delay. The SIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports. The deadline for completion of the investigation includes sending the final investigative report to ORI.

A. Elements of the Investigation Report

The investigation committee and the SIO are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the Respondent (which may include the Respondent's CV);
Describes and documents the intramural or extramural support (including for PHS, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support);
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the institutional policies and procedures under which the investigation was conducted;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must:
 - 1) identify whether the research misconduct was falsification, fabrication, plagiarism, or other practices that materially deviate from those that are commonly accepted within the academic community for proposing, conducting, or reporting research, and whether it was committed intentionally, knowingly, or recklessly;
 - 2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the Respondent, including any effort by Respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion;
 - identify the specific intramural or extramural support (*e.g.*, PHS);
 - identify whether any publications need correction or retraction;
 - 3) identify the person(s) responsible for the misconduct; and
 - 4) list any current support or known applications or proposals for support that the Respondent has pending.

Comments on the Draft Report and Access to Evidence

Respondent

The SIO must give the Respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The Respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the SIO. The Respondent's comments must be included and considered in the final report.

Complainant

The SIO will provide the Complainant a copy of the draft investigation report, or relevant portions of it, for comment. The Complainant's comments must be submitted in writing within 30 days of the date

on which he/she received the draft report, and the comments must be included and considered in the final report.

Confidentiality

In distributing the draft report, or portions thereof, to the Respondent and Complainant, the SIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the SIO may require that the recipient sign a confidentiality agreement.