

15.99.03.E1.03 Conducting an Investigation

Approved: June 28, 2002

This Standard Administrative Procedure is provided as a guide to implement TEES Rule 15.99.03.E1

1. CONDUCT OF AN INVESTIGATION

After the Agency Director, in consultation with the designated officer, has determined that an investigation is warranted, the investigation will be conducted as described in the general procedures outlined in sections 5.2 and 6 of the System Regulations and TEES Rule 15.99.03.E1. Detailed guidelines are contained in this standard administrative procedure. TEES Rule 15.99.03.E1 and the associated Standard Administrative Procedures apply to individuals whose primary employer is TEES (see Preface and Definitions in 15.99.03.E1).

2. PURPOSE OF THE INVESTIGATION

The purpose of the investigation is to explore the allegations in detail, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation also shall determine whether there are additional instances of possible misconduct that would justify broadening the scope of the investigation beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if the alleged misconduct affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation shall be set forth in an investigation report.

3. SEQUESTRATION OF THE RESEARCH RECORDS

The designated officer or, if directed, the research standards officer shall immediately sequester any additional pertinent research records that come to light during the course of the investigation. This sequestration should occur at or before the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the Agency'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 (see section 3.4 of the Standard Administrative Procedures for Conducting an Inquiry, 15.99.03.E1.02.)

4. NOTIFICATION TO THE RESPONDENT

The designated officer or, if directed, the research standards officer will notify the respondent within two working days after the determination is made to open an investigation. The notification shall include: a copy of the inquiry report; the specific allegations; the sources of research funding; the definition of misconduct; the procedures to be followed in the investigation, including the appointment of the investigation committee and experts, and the rights of the respondent to be interviewed, to provide information, to be assisted by counsel, to challenge the membership of the committee and experts based on bias or conflict of interest, and to comment on the draft report. The fact that federal funding agencies may perform an oversight review of the report regarding federally funded projects will be included, if applicable.

5. RESPONSIBILITY FOR CONDUCTING AN INVESTIGATION

The designated officer shall have the overall responsibility for the conduct of the investigation, following the procedures set forth in this administrative procedure.

5.1 Appointment of Investigation Committee

5.1.1 Committee Membership

The investigation committee should consist of a minimum of three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the Agency or university. Normally, individuals

appointed to the investigation committee should not have served on the inquiry committee. The research standards officer from the inquiry committee will serve as a non-voting resource for the investigation committee.

5.1.2 Experts

Experts may be appointed or carried over from the inquiry process.

5.1.3 Bias or Conflict of Interest

The designated officer will take reasonable steps to ensure that the members of the committee and the experts have no bias or personal or professional conflicts of interest with the respondent, complainant, or the case in question. Refer to section 5.1.3 (Bias or Conflict of Interest) of Standard Administrative Procedures 15.99.03.E1.02 (Conducting an Inquiry).

5.1.4 Objection to Committee or Experts by Respondent

The designated officer or, if directed, the research standards officer shall notify the respondent of the proposed committee membership within five working days after the committee is appointed. This time limit may be extended for good cause by the designated officer, with approval of the Agency Director; the extension must be documented in the record. If the respondent submits a written objection to any appointed member of the investigation committee or expert, based on bias or conflict of interest, within five working days after receiving notification of committee membership, the designated officer shall immediately determine whether to replace the challenged member or expert with a qualified substitute and will notify the respondent accordingly. This time limit may be extended for good cause by the designated officer with approval of the Agency Director; the extension must be documented in the record.

5.1.5 Confidentiality

Members of the committee and experts shall agree to observe the confidentiality of the proceeding and any information or documents reviewed as part of the inquiry. Outside of the official proceedings of the committee, those involved in the investigation may not discuss the proceedings with the respondent, complainant, witnesses, or anyone not authorized by the designated officer to have knowledge of the investigation.

5.1.6 Provision of Assistance

The designated officer and research standards officer, in consultation with a representative of the Office of General Counsel, shall provide staff assistance and guidance to the committee, and the experts on the procedures for conducting and completing the investigation, including procedures for maintaining confidentiality, conducting interviews, analyzing data, and preparing the investigation report.

5.2 New Information

During the investigation, if additional information becomes available that substantially changes the scope of the investigation or would suggest additional respondents, the committee shall notify the designated officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

6. CHARGE TO THE COMMITTEE

The designated officer shall define the scope of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, define misconduct in research or scholarship, and identify the name of the respondent. The charge shall state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, misconduct in research or scholarship occurred and, if so, to what extent, who was responsible, and its seriousness.

6.1 First Meeting

The designated officer, with the assistance of the Office of General Counsel, shall 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 shall be provided with a copy of TEES Rule 15.99.03.E1 and its related SAPs and, where federal funding is concerned, with copies of appropriate federal regulations.

6.2 Developing an Investigation Plan

At the initial meeting, the committee shall begin to develop an investigative plan. The committee shall complete the plan as soon as reasonably possible. The investigation plan will include an inventory of all previously secured evidence and testimony; a determination of whether additional evidence should be secured; what witnesses should be interviewed, including the complainant, respondent, and other witnesses with knowledge of the research events in question; a proposed schedule of meetings, briefing from experts, and interviews; anticipated analyses of evidence (scientific, forensic, or other); and a plan for the investigation report.

7. GENERAL APPROACHES TO CONDUCTING THE INVESTIGATION

During the investigation, the committee shall take the following steps:

7.1 Avoid Bias or Conflict of Interest

All necessary steps shall be taken to avoid bias or conflict of interest between the committee or the experts and the respondent, complainant, and witnesses.

7.2 Refer Other Issues

The designated officer shall be advised of any necessary interim actions to protect the research funds, human or animal subjects, or other steps required by regulation or policy.

7.3 Consult with Designated Officer and General Counsel
The research standards officer, the designated officer, and an attorney from the Office of the General Counsel shall be consulted throughout the investigation regarding issues relating to compliance with Rule 15.99.03.E1 and Administrative Procedures as well as any appropriate federal regulations, appropriate investigatory and interviewing methods and strategies, legal issues, and the standard of proof. The designated officer and an attorney from the Office of the General Counsel shall be or available throughout the investigation to advise the committee.

7.4 Reviewing the Evidence
The investigation committee shall obtain and review all relevant documentation and perform or cause to be performed necessary analyses of the evidence, including scientific, forensic, statistical, or other analyses as needed.

7.5 Conducting Interviews
The investigation committee will conduct the interviews as described in sections 7.0 through 7.3 and 7.5 through 7.7 of the Standard Administrative Procedure, 15.99.03.E1.02, on Conducting an Inquiry, except that at the investigative stage, interviews shall be in depth and all significant witnesses should be interviewed. Each witness shall have the opportunity to respond to inconsistencies between his/her testimony and the evidence or other testimony, subject to the need to take reasonable steps to maintain the confidentiality of the testimony of the respondent and other witnesses.

7.5.1 Preparing for Interviews

The investigation committee shall prepare carefully for each interview. All relevant documents and research data shall be reviewed in advance and specific questions or issues that the committee wants to cover during the interview shall be identified. The committee shall appoint one individual to lead each interview. If significant questions or issues arise during an interview that requires committee deliberation, the committee

shall take a short recess to discuss the issues. Committee deliberations shall never be held in the presence of the interviewee.

7.5.2 Objectivity

The investigation committee shall conduct all interviews in a professional and objective manner, without implying guilt or innocence on the part of any individual.

7.5.3 Transcribing Interviews

Interviews shall be recorded but normally not transcribed. If requested, the transcript of a witness's interview shall be provided to that witness for review and correction of errors. Witnesses may add comments or additional information, but changes to the transcript may be made only to correct factual errors.

7.5.4 Recording Admissions

If the respondent admits to the misconduct, he/she should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement was voluntary and stating that the respondent was advised of his/her right to seek the advice of counsel. The committee shall consult with a representative of the Office of General Counsel on the specific form and procedure for obtaining this statement. The admission may not be used as a basis for closing the investigation unless the committee has adequately determined the extent and significance of the misconduct and all procedural steps for completion of the investigation have been met. The committee may ask the designated officer or a representative of the Office of General Counsel to consult with federal funding agencies, when appropriate, to decide if an admission has adequately addressed all the relevant issues such that the investigation can be considered complete. The investigation shall not be closed unless the respondent has been appropriately notified and given an

opportunity to comment on the investigative report. If the case is considered complete, it should be forwarded to the deciding official with recommendations for appropriate institutional action and then, if necessary, forwarded to any federal funding agency.

7.6 Deliberations

7.6.1 Burden and Standard of Proof

In reaching a conclusion on whether there was misconduct and who committed it, the burden of proof is on TEES to support its conclusions and findings by a preponderance of the evidence (refer to section 6.7 of System Regulation 15.99.03).

7.6.2 Assessment of Misconduct in Research or Scholarship

The committee shall consider whether fabrication, falsification, plagiarism, or retaliation against good faith whistle blowers occurred in proposing, conducting, or reporting research, or whether and why there was serious deviation from accepted practices within the research community at the time the actions were committed.

7.6.3 Sufficient Evidence

The committee shall consider whether there is sufficient evidence of intent such that TEES can meet its burden of proving misconduct by a preponderance of the evidence. The committee shall also consider whether the respondent has presented substantial evidence of honest error or honest differences in interpretations or judgments of data, such that scientific misconduct cannot be proved by a preponderance of the evidence.

8. THE INVESTIGATION REPORT

The investigation report shall contain or describe the following elements:

8.1 Background

The report shall include sufficient background information to ensure a full understanding of the issues. This section shall

describe the facts leading to TEES investigation, including a chronology of the research at issue, the person(s) involved in the alleged misconduct, the role of the complainant, any associated grant applications or publications, and any public health issues. This section shall summarize TEES's inquiry and investigation processes, including the composition of the committees, the persons interviewed, the evidence secured and reviewed, the rules and procedures used, and any other factors that may have influenced the proceedings. All relevant dates shall be included.

8.2 Allegations

The report shall list all the allegations raised by the complainant and any additional misconduct issues that arose during the inquiry and investigation stages. The source and basis for each allegation or issue shall be cited.

8.3 Funding Source

For each allegation of misconduct, identify the funding source(s).

8.4 Respondent's Claims

The report shall summarize each claim that the respondent raises in his/her defense against the misconduct allegations and cite the source of each claim. Any inconsistencies among the respondent's various claims shall be noted. The report shall not consider claims that do not address the allegations at issue; allegations of personal bias by the complainant, for example, shall not be addressed in the report unless they are relevant to the report's conclusions.

8.5 Analysis

The report shall provide a detailed analysis of the evidence that either supports or does not support a finding of misconduct. This analysis shall take into account all the relevant statements, claims, rebuttals, documents, and other evidence related to the case. The use of an expert analyst shall be noted.

8.5.1 Burden and Standard of Proof

The analysis shall be consistent with TEES's definition of misconduct as stated in Rule 15.99.03.E1 and its accompanying standard administrative procedures as well as the definition of misconduct that is part of any applicable federal regulation. The analysis shall describe the relative weight given to the various witnesses and pieces of evidence, noting inconsistencies, credibility, and persuasiveness. It shall demonstrate how a consideration of the evidence as a whole led to the report's findings.

- 8.5.2 The report shall summarize or quote relevant statements and rebuttals made by the complainant, respondent, and/or other witnesses pertinent to the report's analysis and findings. The report shall provide references to the appropriate sources.
- 8.5.3 The committee conducting the investigation shall determine if the respondent committed fabrication, falsification, or plagiarism, and the report shall indicate the extent and seriousness of the fabrication, falsification, or plagiarism, including its effect on previous research findings, research subjects, and the laboratory or project in which the misconduct occurred. If the research standards officer and the committee conducting the investigation determine that the respondent committed misconduct by seriously deviating from "other commonly accepted practices," the report shall thoroughly document the commonly accepted practice of the relevant scientific community at the time the misconduct occurred and indicate the extent of the respondent's deviation from that standard. Publications, standards of TEES or relevant professional societies, state and federal regulations, expert opinion, and other sources shall be described and cited as the basis for the commonly accepted practice. The serious deviation there from shall be described in detail, including an analysis of why it is a serious deviation.

8.5.4 In determining the seriousness of the misconduct, the committee shall consider the following four levels of misconduct: (a) unintentional; (b) negligent; (c) reckless; and (d) knowing and purposeful. The committee shall also consider whether this was an isolated event or part of a pattern.

8.5.5 Misconduct does not include honest error or honest differences in interpretations or judgments of data. If the committee conducting the investigation concludes that misconduct occurred, they must then determine the level of intent of the misconduct as described in 8.5.4 and the report shall describe the evidence that indicates the level of intent. If the committee conducting the investigation concludes that honest error or difference of scientific opinion occurred with respect to any issue, the report shall describe the evidence supporting that finding.

8.5.6 All significant pieces of evidence shall be referenced in the analysis and copies of the significant evidence shall be appended to the report.

8.6 Findings

The investigation report will concisely state the findings of the committee conducting the investigation for each issue identified. The final investigation report shall make separate findings regarding whether or not each issue constitutes misconduct using TEES's definition of misconduct and a federal-funding agency definition of misconduct, if appropriate. If the committee finds misconduct on one or more issues, the report shall identify the type of misconduct (i.e., fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community) for each issue. If the investigation committee determines that an issue constitutes misconduct only under TEES's definition, the report shall identify the issue as such. The committee will recommend sanctions commensurate with the misconduct, level of intent and whether it was an isolated event or part of

a pattern. Sanctions may include, but not limited to: reprimands, training in ethics, reduction in pay, reduction in academic rank, loss of research equipment and/or space or termination of employment.

8.7 Summary

The final investigation report shall conclude with a detailed and specific summary of the findings of the investigation committee for each issue, an overall finding of whether scientific misconduct occurred, the seriousness of that misconduct if it occurred, and as appropriate, documentation to support a finding of misconduct under the regulations of a federal funding agency.

9. TIME LIMIT FOR COMPLETING THE INVESTIGATION REPORT

An investigation shall be completed within 120 calendar days after the first meeting of the designated officer, the research standards officer, the investigation committee and the attorney from the Office of the General Counsel. This period includes conducting the investigation, preparing the report of findings, making that report available for comment by the respondent, the imposition of any recommended sanctions, and submitting the report to any funding agency. The 120 calendar days do not include the appeals period. When federal funding is involved, the designated officer may request an extension of any limitations by submitting a written request to the funding agency. The request shall include an explanation for the delay, an interim progress report, an outline of what remains to be done, and an estimated date of completion. If no funding agency is involved the designated officer may extend the time period by written notice delivered to the respondent. The respondent may request an extension by a written request to the designated officer.

10. TRANSMITTAL TO THE DESIGNATED OFFICER

The draft investigation report shall be forwarded to the designated officer.

11. COMMENTS ON THE DRAFT REPORT

11.1 General Counsel

The draft investigation report will be transmitted to the Office of the General Counsel for a review of its legal sufficiency. The Office of the General Counsel will be requested to transmit comments to the designated officer within 10 working days. This time limit may be extended for good cause by the designated officer with approval of the Agency Director; the extension must be documented in the record. Comments should be incorporated into the report as appropriate. Any changes will be reported to the respondent for comment.

11.2 Respondent

Following the incorporation of the comments from the Office of the General Counsel, the designated officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed ten working days to review and comment on the draft report. This time limit may be extended for good cause by the designated officer with approval of the Agency Director; the extension must be documented in the record. The respondent's comments will be attached to the final report.

12. DOCUMENTING THE INVESTIGATIVE FILE

12.1 Index of Evidence

The research standards officer shall maintain an index of all the relevant evidence secured or examined in conducting the investigation, including any evidence that may support or contradict the report's conclusions. Evidence includes, but is not limited to, research records, transcripts or recordings of interviews, committee correspondence, administrative records, grant applications and awards, manuscripts, publications, and expert analyses.

12.2 Purpose of Documentation

The purpose of the documentation is to substantiate the investigation's findings.

12.3 Record Retention

Refer to section 11.0 of TEES Rule 15.99.03.E1.

13. Transmittal of the Final Investigation Report to the Deciding Official and to Federal Funding Agencies

After comments have been received and the necessary changes have been made to the draft report, the research standards officer and the committee shall transmit the final report with attachments, including the respondent's comments, to the deciding official, through the designated officer, if applicable. The designated officer shall submit a copy of the final report, as necessary, to the appropriate federal funding agency.

OFFICE OF RESPONSIBILITY: Office of Policy Administration

HISTORY: New Standard Administrative Procedure