I. POLICY

In accordance with the EVMS Code of Conduct, all members of the EVMS community engaged in research are expected to conduct their research with integrity and intellectual honesty at all times. In addition, EVMS must have policies and procedures for addressing allegations of research misconduct when US Public Health Service (PHS), the National Science Foundation (NSF), and other agency funds are involved.

This Policy and Procedure for Responding to Allegations of Research Misconduct (the "Policy") establishes the process by which EVMS shall address allegations of research misconduct, as defined below, to ensure the integrity of research conducted by members of the EVMS community, regardless of funding source, and to comply with PHS Regulations on Research Misconduct as outlined under 42 C.F.R. Part 93 (the "PHS Regulations") and National Science Foundation Regulations on Research Misconduct under 42 C.F. R. Part 689 (the "NSF Regulations").

II. APPLICABILITY

A. This Policy applies to allegations of research misconduct involving:

1. A person who, at the time of the alleged research misconduct, was an institutional member as defined below; and

2. The conduct of internally or externally funded research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information; applications or proposals for external support for research, research training or activities related to that research or research training, and/or plagiarism of research records produced in the course of funded research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for funds resulted in a grant, contract, cooperative agreement, or other forms of external support.

B. This Policy does not apply to authorship or collaboration disputes and does not apply to allegations of research misconduct that occurred more than six years from the date EVMS received the allegation, subject to exceptions outlined in the PHS Regulations.

C. EVMS has other internal policies related to the conduct of research, including but not limited to the EVMS Code of Conduct, and policies or procedures that govern animal or human subjects' research. EVMS may find conduct reported under this policy as actionable under any such policy even if the conduct does not meet the definition of research misconduct as outlined in this Policy. Any process or finding under such policies will not be a finding of research misconduct under this Policy and will not be reportable under PHS Regulations or NSF Regulations.

III. Definitions

"Complainant" means a person who makes a good faith allegation of research misconduct.

"Deciding Official" or "DO" means the EVMS official who makes final determinations on allegations of research misconduct and any EVMS administrative actions. The Deciding Official will not be the same individual as the Research Integrity Officer.

"Good faith" means:
As it relates to a complainant or witness, having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony.
As it relates to a committee member, cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

"Institutional member" means a person who is employed by, is an agent of, or is affiliated by contract or agreement with EVMS. Institutional members may include, but are not limited to, faculty, support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, subawardees, and their employees.

"NSF" means the National Science Foundation.

"OIG" means the NSF Office of Inspector General which has the authority for addressing research integrity for NSF-supported activities.

"Office of Research Integrity" or "ORI" means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS-supported activities.

"Preponderance of the evidence" means proof by information that evidence in support of an allegation or fact, compared with evidence opposing it, leads to the conclusion that the allegation or fact at issue is more probably true than not.

"Public Health Service" or "PHS" means the unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating

Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

"PHS support" means funding (grants, cooperative agreements, contracts, sub-grants or subcontracts), and applications or proposals for biomedical or behavioral research, biomedical or behavioral research training, or activities, that are funded by PHS.

"Research" means a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

"Research Integrity Officer" or "RIO" means the EVMS official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, under the PHS Regulations or NSF Regulations or other granting agency regulations, and if the allegations are sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquires and investigations; and (3) the other responsibilities described in this Policy.

"Research misconduct" means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results where (1) "fabrication" is making up data or results and recording or reporting them; (2) "falsification" is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record; and (3) "plagiarism" is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

"Research misconduct proceeding" means any actions related to alleged research misconduct taken under this Policy, including but not limited to, allegation assessments, inquiries, investigations, and associated administrative acts such as issuance of notices and reports.

"Respondent" means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

IV. RIGHTS AND RESPONSIBILITIES

A. Research Integrity Officer.

1. The Associate Dean for Research Administration will serve as the RIO who will have primary responsibility for the implementation of EVMS policies and procedures on research misconduct.

2. RIO responsibilities include the following general duties related to research misconduct proceedings:

a. Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;

b. Receive allegations of research misconduct;

c. Assess each allegation of research misconduct in accordance with Section VI(A) of this Policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;

d. As necessary, take interim action and notify ORI of special circumstances, in accordance with this Policy;

e. Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with this Policy and maintain it securely in accordance with this Policy and applicable law and regulation;

f. Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and EVMS policy;

g. Notify the respondent and provide opportunities for him/her to review/ comment/respond to allegations, evidence, and committee reports in accordance this Policy;

h. Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;

i. Appoint the chair and members of inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;

j. Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take

appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;

k. In cooperation with other EVMS officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other EVMS members;

l. Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;

m. Notify and make reports to ORI as required by 42 CFR Part 93;

n. Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and

o. Maintain records of the research misconduct proceeding and make them available to ORI in accordance with this Policy.

B. Deciding Official .

1. The Vice Dean for Research, or designee, will serve as the DO.

2. The DO will have the following responsibilities:

a. At the inquiry stage, the DO will receive the inquiry report and after consulting with the RIO and/or other EVMS officials, and provide a decision, in writing, whether an investigation is warranted.

b. At the investigation stage, the DO will receive the investigation report and, after consulting with the RIO and/or other EVMS officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, EVMS administrative actions are appropriate.

c. The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to ORI, as required by 42 CFR § 93.315.

C. Complainant.

1. The Complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation.

2. The Complainant may be interviewed at the inquiry stage and given the transcript or recording of the interview for correction.

3. The Complainant shall be interviewed during an investigation, and be given the transcript of their interview for correction as outlined in Section IX(D).

D. Respondent.

1. The Respondent is responsible for maintaining confidentiality and cooperating with the inquiry and investigation.

2. The Respondent has the following rights:

a. A good faith effort by the RIO to notify the respondent in writing at the time of or before beginning an inquiry;

b. An opportunity to comment on the inquiry report and have their comments attached to the report;

c. Be notified of the outcome of the inquiry, and receive a copy of the inquiry report and, in the case of PHS support that includes a copy of, or reference to the PHS Regulations and this Policy;

d. Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the institution decides to begin an investigation), and to be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;

e. Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;

f. Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation; and

g. Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.

h. The opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other EVMS officials, the Deciding Official may terminate EVMS review of an allegation that has been admitted. In the case of PHS support, EVMS acceptance of the admission and any proposed settlement is approved by ORI.

V. GENERAL PRINCIPLES

A. Responsibility to Report Misconduct.

1. All EVMS members must report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, they may meet with or contact the RIO at 757-446-8448 or mud@evms.edu to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically.

2. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem. Reports received via the EVMS Ethics and Compliance Hotline that will first be referred to the RIO for review in accordance with this section.

3. At any time, an EVMS member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings. EVMS members will cooperate with the RIO and other EVMS officials in the review of allegations and the conduct of inquiries and investigations. EVMS members, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other EVMS officials.

C. Confidentiality. The RIO shall:

1. Limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective, and fair research misconduct proceeding.

2. Except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding.

3. The RIO shall, when necessary, use written confidentiality agreements or other mechanisms to ensure that recipients of information do not make any further disclosure of

identifying information, including referring the matter for disciplinary action if an individual violates confidentiality.

D. Protecting Complainants, Witnesses, and Committee Members from Retaliation. EVMS members may not retaliate in any way against complainants, witnesses, or committee members. EVMS members should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

1. As requested, and as appropriate, the RIO and other EVMS officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

2. During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in this Policy and any that might be required under PHS Regulations or NSF Regulations.

3. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the personal adviser to interviews or meetings on the case. The personal adviser may consult with the Respondent as necessary, but may not address the panel or otherwise directly participate in the inquiry or investigation. Legal counsel may not attend interviews or meetings on the case.

F. Interim Administrative Actions and Notifying ORI or OIG of Special Circumstances. Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS or NSF supported research process. In the event of such a threat, the RIO will, in consultation with other EVMS officials and ORI or OIG, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI or OIG immediately if he/she has reason to believe that any of the following conditions exist:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;

2. HHS or NSF resources or interests are threatened;

3. Research activities should be suspended;

4. There is a 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. The research misconduct proceeding may be made public prematurely, and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or

7. The research community or public should be informed.

VI. ASSESSMENT AND INQUIRY

A. Assessment of Allegations.

1. Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation(s) to determine whether:

a. They are sufficiently credible;

b. They are sufficiently specific so that potential evidence of research misconduct may be identified;

c. Whether the research is within the jurisdictional criteria of PHS support, NSF support or other granting agency; and

d. Whether the allegation falls within the definition of research misconduct as defined in the PHS Regulations or the NSF Regulations, as applicable.

2. The assessment period shall conclude within 5 business days. An inquiry must be conducted if all of the above criteria are met.

3. In conducting the assessment, the RIO 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.

B. Initiation and Purpose of the Inquiry. If the RIO 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.

C. Notice to Respondent; Sequestration of Research Records

1. At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known.

2. If the inquiry subsequently identifies additional respondents, they must be notified in writing.

3. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO 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. The RIO may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Committee. As soon as practical, the RIO, in consultation with other EVMS officials as appropriate, will appoint a 3-person inquiry committee. The RIO shall designate one member as the committee chair. The inquiry committee shall consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include 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.

E. Charge to the Committee and First Meeting. The RIO will prepare a charge for the inquiry committee that:

1. Sets forth the time for completion of the inquiry;

2. Describes the allegations and any related issues identified during the allegation assessment;

3. 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;

4. States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct as set forth in PHS Regulation or NSF Regulation and (2) the allegation may have substance, based on the committee's review during the inquiry.

5. 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 the PHS Regulations as applicable.

6. At the committee's first meeting, the RIO 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 RIO will be present or available throughout the inquiry to advise the committee as needed.

F. Inquiry Process

1. The inquiry committee will interview the complainant, the respondent, and key witnesses and examine relevant research records and materials.

Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, the committee members will make a recommendation to the DO as to whether an investigation is warranted. The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely 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. In that case, the institution shall promptly consult with ORI to determine the next steps that should be taken. See Section IX.

G. Time for Completion. The inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period and the respondent will be notified of the extension.

H. Inquiry Report.

1. *Draft Report.* A written draft inquiry report will be prepared that contains the following:

a. The name and position of the respondent;

b. A description of the allegations of research misconduct;

c. The grant support, including, for example, grant numbers, grant applications, contracts and publications listing grant support or a statement that the research was not grant funded;

d. Whether an investigation is warranted and the basis for recommending or not recommending an investigation;

e. Any comments on the draft report by the respondent or complainant.

f. Other actions that are recommended if an investigation is not recommended (e.g., referral to another EVMS process).

2. *Legal Review*. EVMS Office of the General Counsel shall also review the draft inquiry report for legal sufficiency and any modifications shall be made as appropriate in consultation with the RIO and the inquiry committee.

3. *Notification to the Respondent and Opportunity to Comment*.

a. The RIO shall notify the respondent whether the inquiry found that an investigation is warranted. The notice shall include a copy of the draft inquiry report, a copy of reference to 42 CFR Part 93 and EVMS policies and procedures on research misconduct.

b. The respondent shall have 10 days to provide any comments on the draft inquiry report to the RIO.

4. *Complainant Comments.*

a. On a case-by-case basis and where deemed necessary in the sole discretion of the RIO, the Complainant may be provided with relevant portions of the draft inquiry report for comment.

b. The respondent shall have 10 days to provide any comments on the draft inquiry report to the RIO.

5. *Final Inquiry Report.* Any comments that are submitted by the respondent or complainant will be attached to the final inquiry report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final inquiry report to the RIO.

I. Institutional Decision and Notification.

1. *Decision by Deciding Official*. The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

2. *Notification to ORI.* Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI with the DO's written decision and a copy of the inquiry report. The RIO will also notify those EVMS officials who need to know of the DO's

decision. The RIO must provide the following information to ORI upon request: (1) the EVMS policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.

3. *Documentation of Decision Not to Investigate.* If the DO decides that an investigation is not warranted, the RIO 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 of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

VII. INVESTIGATION

A. Initiation and Purpose.

1. The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted (the conclusion of the inquiry).

2. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research 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.

3. On or before the date on which the investigation begins, the RIO must:

a. Notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and

b. Notify the respondent in writing of the allegations to be investigated. The RIO 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.

4. Prior to notifying respondent of the allegations, and to the extent the RIO has not already done so at the inquiry stage, the RIO will, 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 EVMS 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.

B. Appointment of the Investigation Committee. The RIO, in consultation with other EVMS officials as appropriate, will appoint a 5-person investigation committee. The RIO shall designate one member as the committee chair. 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 avoid conflicts of interest or to provide additional expertise, the RIO may select committee members from outside EVMS.

C. Charge to the Committee and the First Meeting

1. *Charge to the Committee*. The RIO will define the subject matter of the investigation in a written charge to the committee that:

a. Describes the allegations and related issues identified during the inquiry;

b. Identifies the respondent;

c. Informs the committee that it must conduct the investigation as prescribed in Section D, Investigation Process, below;

d. Defines research misconduct;

e. 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;

f. 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:

(i) 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);

(ii) the research misconduct is a significant departure from accepted practices of the relevant research community; and

(iii) the respondent committed the research misconduct intentionally, knowingly, or recklessly.

g. 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.

2. *First Meeting*. The RIO 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 Policy and the PHS Regulations or NSF Regulations (as applicable). The RIO will be present or available throughout the investigation to advise the committee as needed.

D. Investigation Process. The investigation committee and the RIO must:

1. 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;

2. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;

3. 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

4. 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.

E. Time for Completion. The investigation is to be completed within 120 days of initiation, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI. However, if the RIO 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 RIO 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.

F. Investigative Report.

1. *Draft Report*. The RIO and investigation committee shall prepare a written draft report of the investigation that:

a. Describes the nature of the allegation of research misconduct, including identification of the respondent;

b. Describes and documents the grant support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing grant support or a statement that the research was not grant funded;

c. Describes the specific allegations of research misconduct considered in the investigation;

d. Includes the EVMS policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;

e. Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and

f. Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must:

(i) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;

(ii) 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;

(iii) identify the specific PHS or NSF support;

(iv) identify whether any publications need correction or retraction;

(v) identify the person(s) responsible for the misconduct; and

(vi) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.

2. *Legal Review*. EVMS Office of the General Counsel shall also review the draft report for legal sufficiency and any modifications shall be made as appropriate in consultation with the RIO and the investigation committee.

3. *Comments on the Draft Report.*

a. The RIO 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 RIO.

b. On a case-by-case basis and where deemed necessary in the sole discretion of the RIO, the Complainant may be provided with relevant portions of the draft inquiry report for comment. The respondent shall have thirty days to provide any comments on the draft report to the RIO.

c. In distributing the draft report, or portions thereof the RIO 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 RIO may require that the recipient sign a confidentiality agreement.

4. *Final Investigative Report.* The RIO will assist the investigation committee in finalizing the investigation report, including ensuring that the respondent's and complainants' comments are attached and considered. The committee will deliver the final inquiry report to the RIO.

G. Investigation Decision. The RIO will transmit the final investigation report and any comments to the DO, who will determine in writing:

1. Whether the institution accepts the investigation report, its findings, and the recommended EVMS actions; and

2. The appropriate EVMS actions in response to the accepted findings of research misconduct.

3. If the DO does not accept the findings and recommendations of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

4. The RIO shall notify the respondent, the complainant, and ORI or OIG, as applicable, in writing of the DO's decision. The decision of the DO is final and may not be appealed or grieved.

5. Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation, submit the following to ORI or OIG as applicable:

a. A copy of the final investigation report with all attachments;

b. A statement of whether the institution accepts the findings of the investigation report;

c. A statement of whether the institution found misconduct and, if so, who committed the misconduct; and

d. A description of any pending or completed administrative actions against the respondent.

6. After informing ORI/OIG, the DO will determine any administrative actions that shall be taken, including but not limited to:

a. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;

b. Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;

c. Restitution of funds to the grantor agency as appropriate;

d. Notification of law enforcement agencies, professional societies, professional licensing boards, etc.; and

e. Other action appropriate to the research misconduct.

f. Ensuring compliance with all notification requirements of funding or sponsoring agencies.

H. Records.

1. The RIO must maintain and provide to ORI upon request:

a. The records that the institution secures for the proceeding pursuant to the PHS Regulations, except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;

b. The documentation of the determination of irrelevant or duplicate records;

c. The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate; and

d. The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted.

2. Unless custody has been transferred to HHS/ORI, or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS or NSF proceeding involving a research misconduct allegation.

3. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of EVMS handling of such an allegation.

VIII. COMPLETION OF THE RESEARCH MISCONDUCT PROCESS

All inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI in advance if there are plans to close a case at the inquiry or investigation stage if the respondent has admitted guilt, a settlement with the respondent has been reached; or for any other reason, except closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage, which must be reported to ORI, as outlined in Section VII(G)(5) above.

IX. OTHER CONSIDERATIONS

A. Termination or Resignation Prior to Completing Inquiry or Investigation. The termination of the respondent's EVMS employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of EVMS responsibilities under the PHS Regulations. If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation. Following a final finding of no research misconduct, including ORI concurrence where required by PHS Regulations, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Any EVMS actions to restore the respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses and Committee Members. During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI/OIG

determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them, including referral for disciplinary action in accordance with EVMS policies. The RIO is responsible for ensuring that any steps the DO approves are implemented.

D. Allegations Not Made in Good Faith. If relevant, the DO will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith, he/she will determine whether any administrative action should be taken against the person who failed to act in good faith, including referral for disciplinary action in accordance with EVMS policies.