

SIMMONS UNIVERSITY
Policy and Procedures
for Responding to Allegations
of Research Misconduct

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I. Introduction

A. General Policy

It is the policy of Simmons University (hereinafter “the institution”) to require the highest ethical standards in research; to inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged research misconduct; and to comply in a timely manner with agency requirements for reporting on cases of possible research misconduct when sponsored project funds are involved.

This policy provides and sets forth the procedures for dealing with instances of alleged research misconduct. This policy applies to all persons affiliated with Simmons University, whether the research is funded or not, and is applicable to faculty, staff, and students. Cases of research misconduct involving students are also subject to the normal disciplinary rules governing students.

B. Scope and Applicability

As stated above, this statement of policy and procedures applies to all Simmons faculty, students, and staff involved in the performance of research, without regard to whether the research is funded or not. It is intended to apply to allegations of research misconduct, (i.e. fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) relating to research conducted at or under the auspices of Simmons by such individuals.

This policy is also adopted by Simmons in order to meet its regulatory compliance obligations under federal law, which requires institutional recipients of federal research funding to maintain a research misconduct policy meeting federal requirements. In keeping with that legal obligation, this statement of policy and procedures is intended to carry out this institution’s responsibilities under the “Public Health Service (PHS) Policies on Research Misconduct”, 42 CFR Part 93 (the “PHS Regulations”). As required, the provisions of this policy closely track and implement the specific requirements of the PHS Regulations, and in many cases specifically incorporate or cite to those PHS requirements. For a more detailed listing of the various research related activities to which the PHS Regulations apply (including prior research cited in PHS grant applications, and PHS funded research training), see 42 CFR § 93.102.

At Simmons, student research misconduct is handled according to the type and context of the work. Classroom and course assignments are considered pedagogical exercises, and accordingly, allegations of plagiarism, data fabrication, or data falsification in these assignments will generally be evaluated and adjudicated under the standards and procedures described in the University’s academic integrity policies. However, if the assignment includes intended or actual external dissemination of results, then any misconduct issues should be evaluated and adjudicated under this policy. Student theses, dissertations, and independent research projects should also be evaluated under this policy.

This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date the

institution or PHS received the allegation, **subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.104.** In case of any conflict between this policy and 42 CFR Part 93, the regulation shall prevail.

While the provisions of this policy must always be followed in the case of federally funded research (including PHS funded research), they should also be followed when the research is not federally funded, or has no external support.

II. Definitions

Terms used herein have the same meaning as given them in the Public Health Service Policies on Research Misconduct, 42 CFR Part 93. For ease of reference, the following terms are defined herein:

Complainant means a person who in good faith makes an allegation of research misconduct. See 42 CFR § 93.206.

Deciding Official (DO) means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. A DO's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement. At Simmons University, the DO is the Provost.

Fabrication means making up data or results and recording or reporting them. See 42 CFR 93.211

Falsification means 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. See 42 CFR 93.212

Good faith as applied to a complainant or witness, means 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. Good faith as applied to a committee member means 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. See 42 CFR § 93.214.

Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of § 93.307–93.309. See 42 CFR § 93.215.

Institutional member or members means a person who is employed by, is an agent of, or is affiliated by contract or agreement with Simmons University. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees. See 42 CFR § 93.219.

Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions. See 42 CFR § 93.222.

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.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. (a) Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology. Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge. See 42 CFR § 93.232.

Research Misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion, See 42 CFR 93.234. A finding of research misconduct requires that (a) there be a significant departure from accepted practices of the relevant research community; and (b) the misconduct be committed intentionally, knowingly, or recklessly; and (c) the allegation be proven by a preponderance of the evidence. See 42 CFR 93.103. Intentionally" means "to act with the aim of carrying out the act." 42 CFR 93.221. "Knowingly" means "to act with awareness of the act." 42 CFR 93.223. "Recklessly" means "to act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism." 42 CFR 93.231

Research Integrity Officer (RIO) means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research

misconduct may be identified; (2) overseeing inquires and investigations; and (3) performing the other responsibilities of the RIO, as described in this policy. At Simmons University, the RIO is appointed by the Provost and should have the requisite knowledge and training to carry out the responsibilities of the role.

Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding. See 42 CFR § 93.237.

III. Rights and Responsibilities

The obligations of institutional officials (e.g. Research Integrity Officer, Deciding Official) charged with various administrative and institutional responsibilities under this policy, and the rights and obligations of certain parties and stakeholders (Complainant, Respondent, witnesses) involved in research misconduct proceedings under this policy, are specified in several provisions of the policy appearing below. Without limiting those provisions, and for illustrative purposes only, those rights and responsibilities include the following:

A. Research Integrity Officer (“RIO”)

The responsibilities of the RIO include but are not limited to the following:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct in accordance with Section V.A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;
- In appropriate cases, conduct an “inquiry” into the research misconduct allegations in accordance with Section V below
- When an investigation is required, appoint the chair and members of the investigation committee, ensure that it is properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- 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 requiring recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other institutional 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 institutional members;
- Notify and make reports to ORI as required by 42 CFR Part 93;
- Maintain records of the research misconduct proceeding and make them available

to ORI in accordance with Section VIII.F. of this policy.

B. Complainant

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

C. Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry [42 CFR § 93.307(c) and 42 CFR § 93.310(c)];
- An opportunity to comment on the inquiry report and have his/her comments attached to the report [42 CFR § 93.307(g)],
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report [42 CFR § 93.308(a)];
- 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 [42 CFR § 93.310(c)];
- 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 [42 CFR § 93.310(g)];
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, [42 CFR § 93.310(g)]; and
- 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 have an opportunity to provide written comments on them [42 CFR § 93.312(a)].
- Appeal the final decision of the DO, as provided in Section VIII.D.

The respondent should also be given 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 institutional officials, the Deciding Official may terminate the institution's review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI [42 CFR § 93.317].

D. Deciding Official

The DO will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307.

The DO will, at the conclusion of any investigation, receive the investigation report and, after consulting with the RIO and/or other institutional officials, decide the extent to which

this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members will 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 to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. 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, as needed or appropriate.

Any allegations of research misconduct by or against the RIO should be reported to the DO. In such cases, the DO will serve as the RIO and the President of the University will serve as the DO.

In the event allegations of research misconduct are brought by or against the DO, the President of the University will serve in the capacity of the DO in connection with the investigation.

At any time, an institutional 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.

It is important for all parties to keep in mind that, in order for the RIO or DO or the institution to make a final and definitive “finding” of research misconduct, it must be found not only that an instance of “research misconduct” (as defined in 42 CFR 93.234) actually occurred, but that (a) there [was] a significant departure from accepted practices of the relevant research community; and (b) the misconduct [was] committed intentionally, knowingly, or recklessly; and (c) the allegation [has been] proven by a preponderance of the evidence. See 42 CFR 93.103.

B. Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations, including by providing relevant evidence relevant to an investigation.

C. Confidentiality

The RIO shall, to the maximum extent possible, as allowed by law, and in keeping with the requirements 42 CFR § 93.106: (1) limit disclosure of the identities of respondents, complainants and witnesses (a) to those individuals and entities who have a need need to

know them, as determined by the University, consistent with a thorough, competent, objective and fair research misconduct proceeding, and (b) to ORI in connection with an ORI review of the matter; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those individuals and entities who need to know about or receive such records or evidence in order to carry out a research misconduct proceeding.

With respect to the limitation described in subsection (1) of this section above, the following policies also apply: (i) The limitations of subsection (1) shall no longer apply if and when the University has issued a final determination finding that research misconduct had indeed occurred; and (ii) The RIO shall, in consultation with the DO and legal counsel, determine on behalf of the University which individuals or entities (such as IRB officials, journal editors or publishers, co-authors, collaborating institutions) may have a “need to know” the identities of respondents, complainants or witnesses (together with certain other information related to the research or the research misconduct allegations).

The RIO and the institution shall comply with the provisions of 42 CFR § 93.106, and be guided by the applicable ORI Guidance (including its “Confidentiality Guidance” published on March 5, 2026), on issues related to confidentiality in the context of research misconduct proceedings.

D. Protecting complainants, witnesses, and committee members

Institutional members may not retaliate in any way against complainants, witnesses, or committee members. Institutional 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

As requested and as appropriate, the RIO and other institutional 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. [42 CFR § 93.304(c)].

F. Interim Administrative Actions and Notifying ORI 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 supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and ORI, take appropriate interim action to protect against any such threat. [42 CFR § 93.309(d)].

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 immediately if he/she has reason to believe that any of the following conditions exist [42 CFR § 93.305(g)]: Health or safety of the public is at risk, including an immediate need to protect human or animal subjects; HHS resources or interests are threatened; Research activities should be suspended; There is a reasonable indication of possible violations of civil or criminal law; Federal action is required to protect the interests of those involved in the research misconduct proceeding; or 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.

G. Cases Involving Multiple Respondents.

If the University identifies additional respondents during the inquiry or investigation stages, it shall in all cases provide the additional respondent(s) with notice of the allegations pertaining to them, and an opportunity to respond to them. It shall also comply with the applicable PHS Regulations pertaining to the inquiry and investigation proceedings as specified in 42 CFR 93.305(d) and 42 CFR 93.310(c).

H. Cases Involving Multiple Institutions.

A research misconduct proceeding involving multiple institutions must be conducted consistent with the requirements of 42 CFR § 93.305(e).

V. **Conducting the Assessment and Inquiry**

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine if it (1) Falls within the federal regulatory definition of research misconduct, (2) Is within the applicability criteria of 42 CFR § 93.102; and (3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified. [42 CFR § 93.306(b) and 42 CFR 93.307(a)]. An inquiry must be conducted if these criteria are met.

If the RIO determines that requirements for an inquiry are met, they must: (i) Document the assessment; and (ii) Promptly sequester all research records and other evidence, consistent with § 42 CFR 93.305(a), and promptly initiate the inquiry.

If the RIO or another designated institutional official determines that requirements for an inquiry are not met, they must keep sufficiently detailed documentation of the assessment to permit a later review by ORI of the reasons why the institution did not conduct an inquiry. 42 CFR 93.306(c). Such documentation must be retained in accordance with 42 CFR § 93.318..

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. [42 CFR § 93.307(b)].

C. Notice to Respondent; Sequestration of Research Records

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. If the inquiry subsequently identifies additional respondents, they must be notified in writing. At the time of notification, the RIO shall provide the respondent with a copy of this policy. The RIO must also notify the departmental chair of the Respondent's department.

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. [42 CFR § 93.305 and 42 CFR § 93.307(d)]. The RIO may consult with ORI for advice and assistance in this regard.

D. Conduct of the Inquiry by the RIO.

The RIO shall evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. [42 CFR § 93.307].

E. Considerations for the RIO in Conducting the Inquiry

The RIO will: Establish the time for completion of the inquiry; Describe in writing the allegations and any related issues identified during the allegation assessment; Understand and communicate as needed to appropriate parties that the purpose of the inquiry is to conduct an initial review of the evidence, to determine whether an investigation is warranted,

F. Inquiry Process

The RIO will normally interview the complainant, the respondent, and key witnesses as well as identifying, collecting and examining relevant research records and materials. Then the RIO will evaluate the evidence, including the testimony obtained during the inquiry. The RIO will then decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(f).

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 90 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 respondent must be notified of the same and the inquiry record must include documentation of the reasons for exceeding the 90-day period. [42 CFR § 93.307(h)].

VI. The Inquiry Report

A. 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) a description of the allegations of research misconduct; (3) the funding of the research at issue, if any, including, for example, grant numbers, grant applications, contracts and publications listing PHS support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant; and (6) other specific information required to be included, as specified in 42 CFR 93.309(a)(1) through (12). [42 CFR § 93.309(a)].

B. Notification to the Respondent and Opportunity to Comment

Once the RIO has prepared the investigation report, the RIO shall provide the respondent with a draft copy of it and give the respondent a reasonable opportunity (not exceeding 10 days) to provide comments about it, and the RIO shall attach those comments to the report. 42 CFR 93.307(g). The RIO shall then notify the respondent whether the inquiry found an investigation to be warranted, and provide the respondent with copy of the final inquiry report and include a copy of (or a citation to) 42 CFR Part 93 and the institution's policies and procedures on research misconduct. [42 CFR § 93.308(a)].

The institution is not required to, but may, notify a complainant whether the inquiry found that an investigation is warranted. The institution may, but is not required to, provide relevant portions of the draft inquiry report to a complainant for comment.

The respondent, complainant, and any other recipients of the draft or final report (or parts of the report) must agree to keep all versions of the report confidential as a condition of access to the report (although the Respondent may share them with their attorney).

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

C. 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 institutional officials who need to know of the DO's decision. The RIO must provide the following information to ORI upon request: (1) the institutional policies and procedures under which the inquiry was conducted; and (2) the research records and other evidence reviewed, and copies of all relevant documents. [42 CFR § 93.309(b)].

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. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted. [42 CFR § 93.310(a)]. 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. Under 42 CFR § 93.313 the findings of the investigation must be set forth in an investigation report.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry

report; and (2) 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. [42 CFR § 93.310(b) and (c)].

The RIO 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 investigation that were not previously sequestered during the inquiry. When original research records cannot be obtained, copies of records that are “substantially equivalent in evidentiary value” will fulfill the sequestration requirement. Institutions may also sequester research records and evidence whenever additional items become known or relevant to the inquiry or investigation. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry. [42 CFR § 93.310(d)].

C. Appointment of the Investigation Committee

The RIO, in consultation with the DO as appropriate, will appoint an investigation committee of three members, and shall designate a committee chair, as soon after the beginning of the investigation as is practical. At least half of the members of the committee shall be members of the University’s faculty who have appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. One member of the committee may be external to the University. The investigation committee members must not have any unresolved personal, professional, or financial conflicts of interest with those involved with the investigation.

D. 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:

- 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 (with the assistance of staff to the committee as needed) 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 statement of policy and procedures and a copy of the PHS Regulations. The RIO will be present at committee meetings and available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee and the RIO 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 [42 CFR § 93.310(e)];
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical [42 CFR § 93.310(f)],
- 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 [42 CFR § 93.310(g)];

- Provide the respondent with access to all transcripts, 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. [42 CFR § 93.310(j)].

F. Time for Completion

The investigation is to be completed within 180 days of beginning it, 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 180-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. [42 CFR § 93.311].

VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the RIO 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;
- Describes and documents the funding of the research at issue, if any, including, 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;
- Composition of investigation committee;
- Inventory of sequestered records, how sequestration was conducted, and other information required by 42 CFR 93.313;
- Transcripts of all interviews;
- Specific published papers, manuscripts, posters, presentations, funding applications and/or other documents or materials allegedly containing falsified, fabricated or plagiarized material;
- Any scientific or forensic analyses conducted;
- Any comments made by the respondent and complainant on the draft investigation report and the investigation committee's consideration of those comments
- Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;
- Includes a statement of findings for each allegation of research misconduct

identified during the investigation. [42 CFR § 93.313]. Each statement of findings must satisfy the content requirements of 42 CFR 93.313, and the substantive requirements for “findings” of research misconduct under 42 CFR 93.103, which includes requirements that the statement (and the “findings” it contains): (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) state whether there was a significant departure from accepted practices of the relevant research community; (3) state whether the allegation has been proven by a preponderance of the evidence; (4) 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; (5) identify the specific PHS support if any; (6) identify whether any publications need correction or retraction; (7) identify the person(s) responsible for the misconduct; and (8) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies. [42 CFR § 93.103 and 42 CFR § 93.313].

B. Comments on the Draft Report and Access to Evidence

1. Respondent

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. The respondent's comments must be included and considered in the final report. [42 CFR § 93.312 and 42 CFR § 93.313].

2. Complainant

The RIO may provide the complainant a copy of the draft investigation report, or relevant parts of it, for comment. The complainant will be allowed 30 days from the date he/she received the draft report (or relevant parts of it) to submit comments to the RIO. The complainant's comments (if any) must be included and considered in the final report.

3. Confidentiality

The respondent, complainant, and any other recipients of the draft or final report (or parts of the report) must agree to keep, and must keep, all versions of the report confidential as a condition of access to the report (although the Respondent may share them with their attorney), provided this limitation may be in some cases be waived or removed in whole or in part by the RIO in his or her discretion for compelling reasons.

C. Decision by Deciding Official

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's and complainant's comments are included and considered, and transmit the final investigation report to the DO, who will determine and set forth in a written decision: (a) Whether the institution found research misconduct and, if so, who committed the misconduct; and (b) A description of relevant institutional actions taken or to be taken.

If this determination by the DO varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain 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.

When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing. The DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies, as well as ORI.

D. Appeals

The respondent may appeal the final decision by the DO to the President of the University. Such an appeal must be made by written notice to the President within 30 days from the respondent's receipt of the final decision.

The President must render a decision on an appeal promptly. The President has the sole discretion to render a decision on any appeal from the final decision by the DO.

The PHS Regulations contain specific requirements related to institution-level appeals, relating primarily to inclusion of the "complete record of the appeal" in the "institutional record" of the research misconduct proceeding required to be submitted to ORI. See specifically 42 CFR §§ 93.315, .316, and .220.

E. Notice to ORI of Institutional Findings and Actions

After the Institutional Deciding Official has made a final determination of research misconduct findings in accordance with 42 CFR § 93.314, the institution must transmit the institutional record to ORI. The institutional record must be consistent with § 93.220 and logically organized. [42 CFR § 93.316].

F. Retention and Custody of Institutional Record and Sequestered Evidence

The University must 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 completion of the latter of institutional proceeding or an HHS proceeding (if any) involving the research misconduct allegation, unless custody has been transferred to HHS or ORI advises otherwise in writing. The provisions of 42 CFR 93.318 shall govern such required record retention and transfers of custody to HHS.

IX. Completion of Cases; Reporting Premature Closures to ORI

Generally, 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, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315. [42 CFR § 316(a)].

X. Institutional Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- 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;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the research misconduct.

XI. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional 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 the institution's responsibilities under 42 CFR Part 93.

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 42 CFR Part 93, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. [42 CFR § 304(k)]. Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional 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 determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, and 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. [42 CFR § 93.304(l)]. 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. The RIO and/or other institutional officials, are responsible for implementing any steps the DO approves.

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.

Simmons is very grateful to Connecticut College, whose "Connecticut College Policy and Procedures for Responding to Allegations of Research Misconduct" served as a guide for this policy.