SOUTHERN CONNECTICUT STATE UNIVERSITY
OFFICE OF RESEARCH INTEGRITY (SCSU ORI)

POLICIES AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

Revised April 2020

These Policies and Procedures have been developed using the Federal ORI *Sample Policies and Procedures for Responding to Allegations of Research Misconduct* as a template. "The sample… is intended to assist… institutions… to develop research misconduct policies and procedures consistent with 42 CFR Part 93." (1)

(1) U.S. Office of Research Integrity, *Sample Policy and Procedures for Responding to Allegations of Research Misconduct*, https://ori.hhs.gov/sites/default/files/SamplePolicyandProcedures-5-07.pdf (2007)

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I. Introduction

A. SCSU Research Protection Program

Through its Research Protection Program ("Program"), Southern Connecticut State University Office of Research Integrity ("SCSU ORI") seeks to support a culture of research integrity within Southern Connecticut State University ("SCSU" or "University"), in which all participants in the University research activities internalize and pursue the goal of self-directed responsible conduct in scholarship and research. Allegations of misconduct in research must be treated with seriousness and examined carefully and responsibly.

The SCSU Office of Research Integrity is part of the University's Research Protection Program. The Program's components include:

1. SCSU Office of Research Integrity (SCSU ORI);
2. Institutional Review Board (IRB);
3. Institutional Animal Care and Use Committee (IACUC);
4. Institutional Biosafety Committee (IBC); and
5. Educational Resources Collection.

The Program, through its five components, encourages those engaged in research and in research education to adopt established moral, ethical, and legal principles of responsible scholarship and research conduct and to apply those principles in research activities and in research teaching according to accepted institutional policies and procedures in the following ways:

- Promote and monitor responsible conduct in all human and non-human research, and to act on substantive allegations of research misconduct;
- Safeguard the rights and welfare of human research participants in accordance with ethical principles delineated in The Belmont Report, federal codes, state statutes, and institutional requirements;

- Assure humane and sensitive care and use of vertebrate research animals through compliance with federal, state, and institutional requirements;
- Disseminate information regarding research protection;
- Provide and oversee training and educational requirements of investigators and research protection personnel.

B. Scope

This statement of Policies and Procedures ("Policies and Procedures") is intended to carry out SCSU's responsibilities under the Public Health Service ("PHS") Policies on Research Misconduct, 42 CFR Part 93. Other government agencies publish their own research misconduct regulations. To the extent those regulations apply to an allegation of research misconduct and are inconsistent with these Policies and Procedures, SCSU ORI will comply with the applicable regulatory requirements. As permitted by 42 CFR § 93.319, this document also applies to research that is not government-funded, although such cases need not be reported to government agencies. These Policies and Procedures apply to allegations of research misconduct involving:

> Any person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with SCSU, including without limitation officials, tenured and non-tenured faculty, teaching and support staff, researchers, research coordinators, technicians, post-doctoral and other fellows, students employed by SCSU, research assistants, visiting scholars and agents. These Policies and Procedures may be applied to any individual no longer affiliated with SCSU if the alleged misconduct occurred while the person was employed by, an agent of, or affiliated with the University. This includes any research proposed, performed, reviewed, or reported by any research record generated from that research, whether external, internal, funded, or non-funded. [42 CFR § 93.102].

These Policies and Procedures do not apply to authorship or collaboration disputes and apply only to allegations of research misconduct that occurred within six (6) years of the date the SCSU Office of Research Integrity, or the U.S. Department of Health and Human Services ("HHS") received the allegation [42 CFR § 93.105(a)], subject to the subsequent use, health or safety of the public, and "grandfather" exceptions provided in 42 CFR 93.105(b).

II. Definitions

The terms used in these Policies and Procedures have the same meaning as defined in the Public Health Service Policies on Research Misconduct, 42 CFR Part 93. This section includes definitions that do not appear in 42 CFR Part 93.

Allegation: a disclosure of possible research misconduct through any means of communication.

Inquiry Committee member: an individual appointed by the RIO in consultation with other

institutional officials, as appropriate, to conduct all or a portion of the research misconduct process under these Policies and Procedures. Appointed individuals must not have any unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and have appropriate scientific expertise to evaluate the evidence and issues related to the research misconduct allegation(s), interview the principals and key witnesses, and conduct the inquiry.

Complainant: a person who in good faith makes an allegation of research misconduct.

Conflict of interest: financial, personal, or professional relationships that may compromise, orappear to compromise a person's decisions.

Deciding Official ("DO") means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. At SCSU, the DO is the University Provost. 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.

Evidence: any document or other record, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Good faith:

- *As applied to a complainant or witness*: having a belief in the truth of one's allegation or testimony that a reasonable person in the same position could have, based on the information known to the person 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 applied to a committee member*: cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping the institution meet its responsibilities under the Policies and Procedures. A committee member does not act in good faith if the committee member's 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.

Inquiry: preliminary information-gathering and preliminary fact-finding in accordance with these Policies and Procedures to determine whether an allegation of research misconduct warrants investigation.

Investigation: the formal development of a factual record and the examination of that record leading to a decision about whether to recommend a finding of research misconduct, which may include a recommendation for other appropriate actions, including institutional

actions.

Federal ORI: the Office of Research Integrity in the U.S. Department of Health and Human Services (DHHS). Federal ORI is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service (PHS).

Preponderance of the evidence: proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Research: a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge or specific knowledge by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to the matters to be studied.

Research Integrity Officer ("RIO") means the institutional official appointed by the University Provost and responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct covered by applicable federal regulations or institutional requirements, 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) fulfilling any other responsibilities described in these Policies and Procedures.

Research Misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.
(b) 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.
(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
(d) Research misconduct does not include honest error or differences of opinion.

Research record: the record of data or results that embody the facts resulting from scientific inquiry or other scholarly endeavors, including but not limited to research proposals, laboratory records (physical and electronic), progress reports, abstracts, theses, oral presentations, internal reports, journal articles, correspondence, and any documents and materials provided to an institutional official in the course of a research misconduct proceeding.

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

Retaliation: an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to a good faith allegation of research misconduct or good faith cooperation with a research misconduct proceeding.

III. Rights and Responsibilities

A. Research Integrity Officer

The University Provost will appoint the Research Integrity Officer ("RIO") who will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. The RIO must recuse him/herself when he/she is respondent of a research misconduct complaint, and University Provost will appoint an interim RIO for the purpose of such investigation. The SCSU ORI website will contain the name of the current RIO. A detailed listing of the responsibilities of the RIO is set forth in **Appendix A**.

These responsibilities include the following duties related to research misconduct proceedings:

- 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 (including institutional standards) to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify the Federal ORI or relevant government agencies of special circumstances, in accordance with Section IV.G. of this policy;
- 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;
- Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;
- Notify the respondent and provide opportunities for him/her to review/ comment/respond to allegations, evidence, and committee reports in accordance with Section III.C. of this policy;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- With the Provost, appoint the chair and members of the inquiry and investigation committees, ensure that the committees are 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 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;

- Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to Federal ORI or applicable government agencies as required by 42 CFR Part 93; other applicable law, and institutional policy;
- Ensure that administrative actions taken by the institution and applicable government agencies 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
- Maintain records of the research misconduct proceeding and make them available to appropriate institutional officials and to Federal ORI or relevant government agencies in accordance with Section VIII.F. of this policy.

B. Complainant

Inquiry Phase: The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. The complainant may be interviewed at the inquiry stage and, on the basis of case-by-case determinations, may be given relevant portions of the draft inquiry report for comment and correction (within a timeframe that permits the inquiry to be completed within sixty (60) days of its initiation). [42 CFR § 93.307(g). SCSU ORI may notify the complainant(s) who made the allegation(s) whether the inquiry found that an investigation is warranted. [42 CFR § 93.308(b)]

Investigation Phase: The complainant will be interviewed during an investigation, and be given the transcript or recording of the interview for correction. The transcript or recording of the interview is required to be included in the record of the investigation. [42 CFR § 93.310(g)] As a matter of policy and on the basis of case-by-case determinations, SCSU may provide to the complainant for comment portions of the inquiry report and the draft investigation report or relevant portions of it within a timeframe that permits the investigation to be completed within 120 days of its initiation. [42 CFR § 93.311(a)]. The comments of the complainant, if any, on the draft investigation report must be submitted within thirty (30) days of the date on which the complainant received the draft investigation report or relevant portions of it. [42 CFR § 93.312(b)]. The investigation committee must consider any comments made by the complainant on the draft investigation report and include those comments as part of, or as an attachment to, the final investigation report. [42 CFR § 93.313(g)].

C. Respondent

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

Inquiry Phase:

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry [42 CFR §§ 93.304(c), 93.307(b)];

- Respondents may choose up to two (2) support individuals during the process, and may consult with legal counsel or a non-lawyer personal adviser (personal advisor must be an institutional member of the University who is not a principal or witness in the research misconduct inquiry or investigation) to seek advice and may bring the legal counsel or the personal adviser to interviews or meetings throughout the process. Legal counsel or personal adviser may be present at any proceedings or interviews that the respondent attends but may not question witnesses or otherwise take part in the research misconduct proceedings.
- An opportunity to review and comment on the inquiry report and have respondent's written comments attached to the report [42 CFR §§ 93.304(e), 93.307(f)]; and
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to the applicable federal regulations and SCSU's Policies and Procedures on research misconduct [42 CFR 93.308(a)].

Investigation Phase:

- 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 thirty (30) days after the institution decides to begin an investigation), and 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 [42 CFR § 93.310(c)];
- Be interviewed during the investigation, receive a copy of the recording or transcript, 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, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of 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 be notified that any written comments must be submitted within thirty (30) days of the date on which the copy was received and that the written comments will be considered by the institution and addressed in the final report [42 CFR §§ 93.304(f), 93.312(a)].

The respondent will be given an opportunity to admit that research misconduct occurred and that respondent committed the research misconduct. With the advice of the RIO or other institutional officials, the Deciding Official may terminate the institution's review of an allegation that has been admitted, provided that, for government-funded research, the institution's acceptance of the admission and any proposed settlement is approved by the relevant government agency.

The respondent may appeal in writing a finding of research misconduct in the investigation report that could result in a reversal or modification of the finding(s). [42 CFR § 93.314(a)] (See Section VIII.D Appeals)

D. Deciding Official

The DO will receive the inquiry report and after consulting with the RIO or other institutional officials, and decide whether an investigation is warranted under the applicable criteria in 42 CFR § 93.307(d) or other government agency pursuant to these Policies and Procedures. Any finding that an investigation is warranted must be made in writing by the DO and must be provided to the relevant government agency in cases of federally funded research, and to SCSU ORI only for non-government funded research, together with a copy of the inquiry report meeting the applicable federal requirements, within thirty (30) days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least seven (7) years after termination of the inquiry, so that the relevant government agency may assess the reasons why the institution decided not to conduct an investigation.

The DO will receive the investigation report and, after consulting with the RIO 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. 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 the relevant government agency as required by 42 CFR § 93.315 or other applicable government regulations.

When the Deciding Official is the respondent of a research misconduct complaint, the Deciding Official must recuse him/herself. The University President will appoint an interim Deciding Official during such inquiry or investigation.

IV. General Policies and Principles

A. Research Misconduct Prohibited; Evidentiary Standards

SCSU prohibits research misconduct, investigates and responds to allegations of research misconduct in accordance with these Procedures.

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community;
- The respondent committed the research misconduct intentionally, knowingly, or recklessly; and
- The finding(s) must be established by a preponderance of the evidence.

The destruction of research records, absence of research records, or respondent's failure to provide research records adequately documenting the questioned research is evidence of

research misconduct where it is established by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

The University bears the burden of proof for making a finding of research misconduct. A respondent has the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised, such as honest error or differences of opinion, and proving any mitigating factors. [42 CFR § 93.106].

B. Responsibility to Report Misconduct

All institutional members who in good faith suspect that an individual(s) subject to these Policies and Procedures is committing or has committed research misconduct must immediately report the 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, the individual may meet with or contact the RIO to discuss the suspected research misconduct informally, which may include discussing it anonymously or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or the allegation to other offices or officials with responsibility for resolving the issue(s).

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.

RIO contact information:
Voice: 203-392-5243
Email: ori@southernct.edu
Address: Research Protection Program Office, Engleman Hall, Wing D, Room D220
501 Crescent Street, New Haven, CT 06515

Also available for consultation:
Executive Director of Research and Innovation
Voice: 203-392-6461
Email: dri@southernct.edu
Address: SCSU, Academic Science Building, 108D
501 Crescent Street, New Haven, CT 06515

C. Cooperation with Research Misconduct Proceedings

Institutional members shall cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. All individuals subject to these Policies and Procedures, including respondents, have an obligation to

provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

D. Confidentiality

The potential damage to the reputation and rights of a respondent may be significant. The RIO and all others at the institution who may be involved in the research misconduct proceedings shall to the extent possible: (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; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research participants might be identified to those who need to know in order to carry out a research misconduct proceeding. Inappropriate dissemination of information may result in sanctions or disciplinary action, subject to the procedures applicable to the employee's classification of employment. The RIO will use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information. To the extent possible, the institution will provide confidentiality for witnesses when circumstances indicate that witnesses may be harassed or otherwise need protection. Notwithstanding the above, when government agencies have jurisdiction and SCSU ORI is required to disclose the identity of respondents and complainants to the relevant government agency, SCSU ORI will comply with the applicable regulatory requirements.

E. Retaliation Prohibited: 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.

F. Protecting the Restoration of the Respondent's Reputation

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(k)].

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the institution.

G. Interim Administrative Actions and Notifying Government Agencies 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 federally supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and the applicable government agency, take appropriate interim action to protect against any such threat [42 CFR § 93.304(h)]. 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 the government agency immediately if the RIO has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- Federal 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;
- The research misconduct proceeding may be made public prematurely and government agency action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed [42 CFR § 93.318].

V. Conducting the Assessment and Inquiry

A. Preliminary Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO, in consultation with other institutional officials and without notice to any of the parties involved, will immediately assess the allegation to determine whether an inquiry is warranted, that is, whether the allegation: (1) is sufficiently credible and specific so that potential evidence of research misconduct may be identified, and, if applicable, is within the jurisdictional criteria of a government agency; and (2) whether the allegation falls within the definition of research misconduct as defined by these Policies and Procedures. An inquiry must be conducted if these criteria are met.

The assessment period should be brief, preferably concluded within a week. Where it is not feasible to conclude the assessment within a week, the process should proceed expeditiously. 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. The preliminary assessment shall be documented and all records pertaining to the review of allegations will be retained by the RIO for seven (7) years following the completion of the proceeding.

B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, the RIO will immediately initiate the inquiry process and secure the relevant research records. 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(c)].

C. Sequestration of Research Records

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 to prevent the loss, alteration, or fraudulent creation of records. Except 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 §93.307(b)]. In some cases, the respondent may have supervised access to their research materials. [42 CFR §93.305(b)].-In cases of federally funded research, the RIO may consult with the applicable government agency for advice and assistance.

D. Notice to Respondent

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. The written charge letter will include a description of the charge, possible sanctions and outcomes, and a reference to these Policies and Procedures. If the inquiry subsequently identifies additional respondents, they must be notified in writing in accordance with these Policies and Procedures.

E. Appointment of the Inquiry Committee

Federal regulations do not require that the inquiry be conducted by an inquiry committee. The RIO will determine if an inquiry committee will be used based on the complexity of the allegation(s) and the available evidence. If a committee is required, the RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical. The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry [42 CFR § 93.304(b)] 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. When necessary to secure the appropriate expertise or to avoid conflicts of interest, the RIO in consultation with other institutional officials, may select committee members from outside the institution.

The institution will notify the respondent of the proposed committee membership and give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The institution limits the period for submitting objections to no more than ten (10) calendar days. The RIO makes the final determination of whether a conflict exists.

F. Charge to the Inquiry Committee and First Meeting

The RIO will prepare a charge for the inquiry committee that:

- Sets forth the expected timeframe for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, and to determine whether an investigation is warranted;
- 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 and, if applicable, is within the jurisdictional criteria of a government agency; and, (2) the allegation may have substance, based on the committee's preliminary review during the inquiry;
- 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 these Procedures and, if applicable, the relevant government agency requirements.

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.

G. Inquiry Process

The inquiry committee will ordinarily interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials. Any interviews will be recorded or transcribed, with recordings or transcripts provided to the interviewee for correction. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, the committee members will decide whether an investigation is warranted based on the criteria in these Policies and Procedures and, if applicable, the relevant government agency requirements. 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, if federal funding is involved, the institution shall promptly report to the applicable government

agency and consult with the government agency to determine the next steps. See Section X.

In cases where government funding is not involved, and the RIO alone will determine the need for an investigation, the interview process will be the same as above except:

If a legally sufficient admission (a written, witnessed, and signed admission by the respondent) of research misconduct is made by the respondent, the RIO will convene an inquiry committee to review the signed admission and any other relevant data. If the committee agrees, misconduct may be indicated at the inquiry stage providing all relevant issues are resolved. The RIO will prepare a written report of the inquiry that meets the requirements of these Policies and Procedures (see Section VIII) and will submit it to the DO. An investigation may not be warranted.

The RIO will interview the complainant, the respondent, and key witnesses as well as examine relevant research records and materials. The RIO will evaluate the evidence, including the testimony obtained during the inquiry. The RIO, will decide whether an investigation is warranted based on the criteria in 42 CFR § 93.307(d) or other applicable government criteria, and these Policies and Procedures. 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.

H. 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 sixty (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 [42 CFR § 93.307(g)]. The respondent will be notified of the extension.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information [42 CFR § 93.309(a)]:

- The name and position of the respondent;
- A description of the allegations of research misconduct;
- The funding support, including, for example, grant numbers, grant applications, contracts and publications listing all support;
- The basis for recommending or not recommending that the allegations warrant an investigation;
- Any comments on the draft report by the respondent or complainant;

- A summary of the inquiry process used;
- A list of the research records reviewed;
- Summaries of any interviews;
- If any other actions should be taken if an investigation is not recommended;
- If a committee is convened, the names and titles of the committee members and experts who conducted the inquiry.

The CSCU Systems Office Legal Affairs shall be available to advise the RIO and the inquiry committee with respect to the legal sufficiency of the inquiry report. Modifications should be made, as appropriate, in consultation with the RIO and the inquiry committee.

B. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent in writing whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within ten (10) calendar days, and include a copy of or refer to 42 CFR Part 93, or other government regulation if applicable, and these Policies and Procedures. The RIO will notify the complainant whether the inquiry found an investigation is warranted. [42 CFR § 93.308(a)].

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

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 Government Agencies When Appropriate

When applicable, within thirty (30) calendar days of the DO's decision that an investigation is warranted, the RIO will provide the Federal ORI or the relevant government agency with the DO's written decision and a copy of the inquiry report. The RIO will notify those institutional officials who need to know of the DO's decision. The RIO must provide the following information to the Federal ORI or relevant government agency upon request: (1) the institutional 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. [42 CFR § 93.309(a) and (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 seven (7) years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by the Federal ORI or other government agencies of the reasons why an investigation was not conducted. These documents must be provided to Federal ORI or other authorized government personnel upon request.

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation ordinarily should begin after completion of the inquiry, and in the case of federal funding must begin within thirty (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. 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. In the case of federal funding, the findings of the investigation must be set forth in an investigation report. [42 CFR § 93.313]

B. Notifying Relevant Government Agency and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must: (1) if applicable, notify the relevant government agency Director of the decision to begin the investigation and provide the relevant agency a copy of the inquiry report (or comply with any other notice obligation to a government agency); 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 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 the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry [42 CFR § 93.310(d)].

C. Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair as soon after the beginning of the investigation as is practical. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee.

When necessary to secure expertise or to avoid conflicts of interest, the RIO in consultation with other institutional officials will select committee members from outside the institution. The respondent will be notified of the proposed committee membership and be given the opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The respondent has ten (10) calendar days to submit any objections regarding the proposed committee members. The RIO will make the final determination of whether a conflict exists.

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 by these Policies and Procedures;
- Defines research misconduct;
- Instructs the committee on the burden of proof (See Section V. A); the charge must state that the committee must evaluate the evidence and testimony of the respondent, complainant, and key witnesses 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 whether the respondent committed research misconduct, it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly; and,

- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of these Policies and Procedures and, if applicable, government agency requirements. [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 these Policies and Procedures and any applicable government agency regulations. The RIO will be present or 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, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation [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)]; 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(h)].

F. Time for Completion

The investigation is to be completed within one hundred and twenty (120) days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment, finalizing the report and, if applicable, sending the necessary notification to regulatory agencies. However, if the RIO determines that the investigation will not be completed within the 120-day period, the RIO will, if applicable, notify the relevant federal agency(ies) as required and in accordance with federal regulations, setting forth the reasons for the delay. If the Federal ORI or other government agency grants the request for an extension and directs the filing of such reports, the RIO will ensure that periodic progress reports are filed with the applicable government agency in accordance with applicable regulations. [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. If considered appropriate by the committee, the respondent's C.V. or resume may be included as part of the identification.
- Describes and documents the financial support for the research subject to the allegations, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing the financial support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes these Policies and Procedures under which the investigation was conducted, unless the Policies and Procedures were provided to the Federal ORI or other applicable government agency previously;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and,
- Includes a statement of findings for each allegation of research misconduct identified during the investigation [42 CFR § 93.313]. Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific financial support (if any); (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with other federal agencies or external funders. [42 CFR § 93.313(f)]

Where the investigation committee simultaneously is considering allegations of research misconduct and allegations of other professional conduct violations, the investigation committee and the RIO may separate the findings into two reports: one report concerning research misconduct findings that must be reported to federal agencies and a second report concerning findings that need not be reported to federal agencies, including allegations concerning non-federally funded research or other professional conduct violations. The CSCU Systems Office Legal Affairs shall be available to advise the investigation committee and the RIO with respect to the report(s). Modifications should be made as appropriate in consultation with the RIO and the investigation committee.

B. Comments on the Draft Investigation 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 thirty (30) days from receipt of 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(a), 93.313(g)]

2. Complainant

On a case-by-case basis, the institution may provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. The complainant's comments must be submitted within thirty (30) days from receipt of the draft report. The complainant's comments must be included and considered in the final report. See 42 CFR §§ 93.312(b) and 93.313(g).]

3. Confidentiality

In distributing the draft report, or portions thereof, to the parties for comment, the RIO will inform the recipient(s) of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. The RIO will require that the recipient sign a confidentiality agreement. Please see **Appendix B**.

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 if required, the complainant's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the investigation committee, the DO will explain in detail in writing 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 RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. In consultation with institutional officials, 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.

D. Appeals

The respondent may appeal in writing a finding of research misconduct that could result in a reversal or modification of the institution's findings in the investigation report. The appeal must be completed within one-hundred and twenty (120) days of its filing. In cases of federally funded research, the federal agency will determine whether good cause exists for an extension, based upon the institution's written request for an extension that explains the need for the extension. If the Federal ORI or other government agency grants an extension, it may direct the filing of periodic progress reports [42 CFR § 93.314(c)]. In cases of non-federally funded research, the institution may grant an appeal. With the exception of government agency involvement, the institutional appeal process is the same as that under [42 CFR § 93.314].

E. Notice to Federal Agencies of Institutional Findings and Actions

When the DO reaches a final decision on the case, the investigation is complete. Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation, or the 120-day period for completion of any appeal, submit the following to the relevant government agency: (1) a copy of the final investigation report with all attachments and any appeal; (2) a statement of whether the institution accepts the findings of the investigation report or the outcome of the appeal; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent [42 CFR § 93.315].

F. Maintaining Records for Review by Federal Agencies

The RIO must maintain and provide to the Federal ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to the applicable government agency or the appropriate HHS component, Federal ORI or other relevant government agency 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 seven (7) years after completion of the proceeding or the completion of any government agency oversight proceeding involving the research misconduct allegation, or as required by any applicable record retention provision, whichever is later. [42 CFR § 93.317(b)]. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification [42 CFR § 93.300(g)] requested by the Federal ORI to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation [42 CFR §93.403].

IX. Completion of Cases; Reporting Premature Closures to Government Agencies or Other Funders

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify the applicable government agency 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 the applicable government agency, as prescribed in these Policies and Procedures. [42 CFR § 93.316(a)]. All reports will be signed by the institutional official and submitted to the relevant government agency. For allegations that include non-PHS funded research, the RIO must comply with any other notice obligation to a government agency or other funder.

X. Institutional Administrative Actions

After a determination of research misconduct is made, the DO may decide on appropriate actions to be taken, after consultation with the RIO and other institutional members as appropriate. Sanctions for research misconduct shall be based on the seriousness of the misconduct, including but not limited to, the degree to which the misconduct: a) was intentional, knowing or reckless; b) was an isolated event or part of a pattern; and c) had significant impact on the research record, research subjects, other researchers, institutions, or the public welfare. The range of administrative actions includes, but is not limited to:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal, letter of reprimand, special monitoring of future work, probation, suspension of the responsible person from the particular project;
- Leave without pay, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment subject to the procedures applicable to the employee's classification of employment;
- Restitution of funds to the grantor agency as appropriate; suspension or termination of an active award, letters of reprimand; 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 to pursue allegations.

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 Federal ORI concurrence where required by 42 CFR Part 93 (or, for non-PHS funded research, other applicable government agency requirements), the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation [42 CFR § 93.304(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 a government agency 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. [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 is 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, the DO will determine whether any administrative action should be taken against the person who failed to act in good faith.

Appendix A

Research Integrity Officer Responsibilities

I. General

The Research Integrity Officer (RIO) has lead responsibility for ensuring that the institution:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct;
- Has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to the relevant funding agency, as required by applicable federal regulations;
- Complies with its written policies and procedures and the requirements of applicable federal regulations, including 42 CFR Part 93;
- Informs its institutional members who are subject to federal regulations or other funding sources about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures;
- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the financially supported research process.

II. Notice and Reporting to and Cooperation with Federal ORI and Other Government Agencies

The RIO has lead responsibility for ensuring that the institution:

- Files an annual report with the Federal ORI or any other government agency containing the information prescribed by the relevant agency;
- Sends to the government agency with the annual report such other aggregated information as the agency may prescribe on the institution's research misconduct proceedings and the institution's compliance with federal regulations;
- Notifies the Federal ORI or the relevant government agency immediately if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, HHS or other government resources or interests are threatened, research activities should be suspended, there is reasonable indication of possible violations of civil or criminal law, government action is required to protect the interests of those involved in the research misconduct proceeding, the institution believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed;
- Provides the Federal ORI or the relevant government agency with the written finding by the responsible institutional official that an investigation is warranted

and a copy of the inquiry report, within thirty (30) days of the date on which the finding is made;
- Notifies the Federal ORI or the relevant government agency of the decision to begin an investigation on or before the date the investigation begins;
- Within one hundred and twenty (120) days of beginning an investigation, or such additional days as may be granted by Federal ORI or the relevant government agency, (or upon completion of any appeal made available by the institution) provides the Federal ORI or the relevant government agency with the investigation report, a statement of whether the institution accepts the investigation's findings, a statement of whether the institution found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the respondent;
- Seeks advance Federal ORI or relevant government agency approval if the institution plans to close a case at the inquiry, investigation, or appeal stage on the\\ basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the 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;
- Cooperates fully with the Federal ORI or relevant government agency during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

III. Research Misconduct Proceeding

A. General

The RIO is responsible for:

- Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner;
- Taking all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to their providing information, research records and evidence;
- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;
- Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding;

- Recusing him/herself when he/she is the respondent of a research misconduct complaint, and the University Provost will appoint an interim RIO for the purpose of such investigation;
- Keeping the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- In cooperation with other institutional officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other institutional members;
- Making all reasonable and practical efforts, if requested and as appropriate, 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;
- Assisting the DO in implementing the DO's decision to take administrative action against any complainant, witness, or committee member determined by the DO not to have acted in good faith;
- Maintaining records of the research misconduct proceeding, as defined in 42 CFR § 93.317, in a secure manner for seven (7) years after completion of the proceeding, or the completion of any government agency proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to the government agency or the government agency has advised that the records no longer need to be retained;
- Ensuring that administrative actions taken by the institution and federal government agencies are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

B. Allegation Receipt and Assessment

The RIO is responsible for:

- Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receiving allegations of research misconduct;
- Assessing each allegation of research misconduct to determine if an inquiry is warranted because the allegation falls within the definition of research misconduct, and if applicable, is within the jurisdictional criteria of 42 CFR § 93.102(b), or other government agency, and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

C. Inquiry

The RIO is responsible for:

- Initiating the inquiry process if it is determined that an inquiry is warranted;
- At the time of, or before beginning the inquiry, making a good faith effort to notify the respondent in writing, if the respondent is known;

- On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventorying the records and evidence and sequestering 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 the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments;
- Appointing an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical;
- Preparing a charge for the inquiry committee in accordance with the institution's policies and procedures and any relevant government agency requirements;
- Convening the first meeting of the inquiry committee and at that meeting briefing the committee on the allegations, the charge to the committee, and the appropriate procedures for conducting the inquiry, including the need for confidentiality and for developing a plan for the inquiry, and assisting the committee with organizational and other issues that may arise;
- Providing the inquiry committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews;
- Being available or present throughout the inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an investigation is warranted on the basis of the criteria in the institution's policies and procedures and any relevant government agency requirements;
- Determining whether circumstances clearly warrant a period longer than sixty (60) days to complete the inquiry (including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the 60-day period in the record of the research misconduct proceeding;
- Assisting the inquiry committee in preparing a draft inquiry report, sending the respondent a copy of the draft report for comment (and the complainant when) within a time period that permits the inquiry to be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and the complainant as determined on a case-by-case basis), and ensuring that the comments are attached to the final inquiry report;
- Receiving the final inquiry report from the inquiry committee and forwarding it, together with any comments the RIO may wish to make, to the DO who will determine in writing whether an investigation is warranted;
- Within thirty (30) days of a DO decision that an investigation is warranted, in cases of federally-funded research, providing the Federal ORI or the applicable government agency, with the written finding and a copy of the inquiry report and notifying those institutional officials who need to know of the decision;
- Notifying the respondent (and the complainant as determined on a case-by-case basis) whether the inquiry found an investigation to be warranted and including in

the notice copies of or a reference to 42 CFR Part 93 or other applicable government regulations, and the institution's research misconduct policies and procedures;
- Providing to Federal ORI or the relevant government agency, upon request, the institutional policies and procedures under which the inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the allegations to be considered in the investigation;
- If the DO decides that an investigation is not warranted, securing and maintaining for seven (7) years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by the Federal ORI or the relevant government agency of the reasons why an investigation was not conducted.

D. Investigation

The RIO is responsible for:

- Initiating the investigation within thirty (30) calendar days after the determination by the DO that an investigation is warranted;
- On or before the date on which the investigation begins: (1) in cases of federally-funded research notifying the Federal ORI or the relevant government agency of the decision to begin the investigation and providing the Federal ORI or the applicable government agency a copy of the inquiry report; and (2) notifying the respondent in writing of the allegations to be investigated;
- Prior to notifying respondent of the allegations, taking 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;
- In consultation with other institutional officials as appropriate, appointing an investigation committee and committee chair as soon after the initiation of the investigation as is practical;
- Preparing a charge for the investigation committee in accordance with the institution's policies and procedures;
- Convening the first meeting of the investigation committee and at that meeting: (1) briefing the committee on the charge, the inquiry report and the procedures and standards for the conduct of the investigation, including the need for confidentiality and developing a specific plan for the investigation; and (2) providing committee members a copy of the institution's policies and procedures and applicable government regulations;
- Providing the investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews;
- Being available or present throughout the investigation to advise the committee as needed;

- On behalf of the institution, the RIO is responsible for each of the following steps and for ensuring that the investigation committee: (1) uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented; (2) takes reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical; (3) interviews 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 records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the research misconduct proceeding; and (4) pursues 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 continues the investigation to completion;
- Upon determining that the investigation cannot be completed within one hundred and twenty (120) days of its initiation (including providing the draft report for comment and sending the final report with any comments to the Federal ORI or the relevant government agency), submitting a request to the Federal ORI or the relevant government agency for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with the Federal ORI or the applicable government agency;
- Assisting the investigation committee in preparing a draft investigation report that meets the applicable federal regulatory requirements and the institution's policies and procedures, sending the respondent (and complainant as determined on a case-by-case basis) a copy of the draft report for comment within thirty (30) days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and complainant as determined on a case-by-case basis) and ensuring that the comments are included and considered in the final investigation report;
- Transmitting the draft investigation report to institutional counsel for a review of its legal sufficiency;
- Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee;
- Transmitting the final investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (2) if the DO determines whether or not to accept the report, its findings and the recommended institutional actions, transmitting to the Federal ORI or the relevant government agency within the time period for completing the investigation, a copy of the final investigation report with all attachments, a statement of whether the institution accepts the findings of the report, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent; or (3) if the institution provides for an appeal by the respondent that could result in a modification or reversal of the

DO's finding of research misconduct, ensuring that the appeal is completed within one hundred and twenty (120) days of its filing, or seeking an extension from the Federal ORI or the relevant government agency in writing (with an explanation of the need for the extension) and, upon completion of the appeal, transmitting to the government agency a copy of the investigation report with all attachments, a copy of the appeal proceedings, a statement of whether the institution accepts the findings of the appeal proceeding, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent;

- When a final decision on the case is reached, the RIO will normally notify both the respondent and the complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case;
- Maintaining and providing to Federal ORI or applicable government agencies upon request all relevant research records and records of the institution's research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.

This Appendix was composed using the Office of Research Integrity's *Appendix A: Research Integrity Officer Responsibilities,* found at: https://ori.hhs.gov/sites/default/files/SamplePolicyandProcedures-AppendixA-5-07.pdf

Appendix B

SOUTHERN CONNECTICUT STATE UNIVERSITY
OFFICE OF RESEARCH INTEGRITY
(SCSU ORI)

Confidentiality Agreement

I _____ have received the following documents from the SCSU Office of Research Integrity:

I agree to hold these documents in the strictest confidence and to share this information with only those individuals listed below. I further agree to protect these documents when not in use by appropriately sequestering them under lock and key.

I agree to return these documents undamaged to the SCSU Office of Research Integrity

on or before _____by_____o'clock.

Document Release

Government agency or SCSU institutional official permitting release of the documents:

Print name	Signature	Date

Person receiving documents:

Print name	Signature	Date

Document Return

Government agency or SCSU institutional official receiving returned documents:

Print name	Signature	Date	Time

Person returning documents:

Print name	Signature	Date	Time