Scripps Research

Policy 308

Responding to Allegations of Research Misconduct

Responsible Office / Department: Compliance and Legal Operations

A. PURPOSE

The Scripps Research Institute (TSRI) expects the highest ethical standards of professional conduct by its members in performing scholarly and scientific activities with honesty and integrity. The enterprise of scientific research relies upon the trust and confidence of both the scientific community and the public at large in the integrity of the scientific process. Research misconduct undermines the integrity of the scientific process. Unethical behavior represents a breach of trust among scientists that undermines the advancement of knowledge and public confidence in the reliability of science.

Members of TSRI are expected to adhere to the ethical standards set forth by TSRI and to maintain the intellectual integrity of research conducted at TSRI. TSRI faculty are responsible for establishing and maintaining an ethical environment and for assuring the integrity of the research conducted in their laboratory. TSRI faculty are also responsible for assuring adequate supervision of research personnel and trainees, for auditing primary research data, and for reviewing critically any proposed publication of research results.

This policy was established to prevent, detect, and respond to possible research misconduct at TSRI. This policy is designed to maintain openness and creativity in the scientific enterprise and to enable TSRI to respond promptly, firmly, and effectively to allegations of possible misconduct while respecting the legitimate concerns and reputation of good faith complainants.

B. POLICY

a. Roles and Responsibilities

i. President of TSRI

The President of TSRI is responsible for developing mechanisms to make this Policy known to all faculty, staff, students, and collaborators, and to carry out the procedures contained in this Policy.

The President of TSRI will receive the inquiry report and, after consulting with the Research Integrity Officer, decide whether an investigation is warranted. Within 30 days of the President's finding that an investigation is warranted, or when required by regulation, (in cases involving NSF jurisdiction, the NSF Office of Inspector General must be notified immediately) the Research Integrity Officer shall provide any applicable federal agency with the written findings of the President and a copy of the inquiry report meeting the requirements of Section B(d) of this Policy.

The President of TSRI will receive the investigation report and, after consulting with the Research Integrity Officer and other appropriate TSRI officials, decide the extent to which TSRI accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. In this role the President serves as TSRI's Institutional Deciding Official, who makes final determinations on allegations of research misconduct and

any institutional actions. The same individual may not serve as both the Institutional Deciding Official and the Research Integrity Officer.

ii. Research Integrity Officer

The President of TSRI will appoint the Research Integrity Officer who will have primary responsibility for implementation of this Policy. The Research Integrity Officer will be an institutional official who is well qualified to administer the research misconduct proceeding. The Research Integrity Officer may delegate, to the extent consistent with applicable law and regulation, any of the Research Integrity Officer's responsibilities in this Policy. The Research Integrity Officer or the Research Integrity Officer's designee may consult with legal counsel, or such other advisors as deemed useful and appropriate, in carrying out the Research Integrity Officer's responsibilities under this Policy. The Research Integrity Officer may not serve as the Institutional Deciding Official.

Among other responsibilities, the Research Integrity Officer will appoint the inquiry and investigation committees and ensure that necessary and appropriate resources and expertise are secured to carry out a thorough and authoritative evaluation of the relevant evidence during the inquiry and investigation.

iii. Complainant

The Complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. The Research Integrity Officer may provide the complainant with relevant portions of the inquiry report for comment.

The complainant shall have an opportunity to be interviewed during an investigation, and if interviewed shall be given the transcript of the interview for correction. The Research Integrity Officer may provide the complainant with the draft investigation report or relevant portions of the report for comment. Any comments must be in writing and submitted within 30 days of the complainant's receipt of the draft investigation report or relevant portions of the report. Timely comments shall be considered by TSRI and included with the final investigation report.

iv. Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the inquiry and investigation. The Research Integrity Officer shall make a good faith effort to notify the respondent in writing at the time of or before beginning an inquiry. The respondent shall be notified of the outcome of the inquiry and receive a copy of the draft inquiry report that includes a copy of or refers to pertinent regulations and this Policy. The respondent shall be given an opportunity to provide written comments on the draft inquiry report, within 10 days of receiving the report, and have his/her comments attached to the final report.

If TSRI conducts a research misconduct investigation, a good faith effort shall be made to notify the respondent 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. If a decision is made to pursue allegations of research misconduct that were not addressed in the initial notice of investigation, the respondent shall be given timely notice of such new allegations against him/her.

The respondent shall have an opportunity to be interviewed during the investigation and an opportunity to correct, in writing, the transcript of the interview. The recording

and transcript shall be included in the record of the investigation. The respondent will be provided with access to all transcripts but will not be present during the interviews of other witnesses. The respondent may identify people who have information on relevant aspects of the investigation.

The respondent shall be provided with a copy of the draft investigation report and, concurrently, a copy of or supervised access to the evidence on which the report is based. The respondent may submit written comments on the draft investigation report within 30 days of the date on which the draft was received. Timely comments shall be considered by TSRI and included in the final report.

The respondent will have an opportunity to appeal the findings of the President of TSRI regarding research misconduct by submitting a Notice of Appeal to the Governance Committee of the Board of Directors, or relevant Board Committee, within 15 days of receiving notice of the President's decision. The committee will complete its review of any such appeal as promptly as practicable.

b. General Policies and Principles

i. Policy Applies to Institutional Members

This policy applies to institutional members, as defined in Section D (definition of "Institutional Member"). It applies throughout TSRI, including the California and Florida campuses. Institutional members are responsible for establishing, implementing, and maintaining appropriate procedures consistent with TSRI's Policy to prevent and detect possible research misconduct.

ii. Responsibility to Report Misconduct

Any faculty member, student, or staff member who believes in good faith that an act of research misconduct is taking place or has taken place at TSRI has an obligation to report his/her concerns to a TSRI official or directly to the Research Integrity Officer. TSRI officials who become aware of situations of possible research misconduct, either by their own observations or because of reports from others, have a responsibility to report them to the Research Integrity Officer to assure that the proper procedure is followed. If the circumstances described do not meet the definition of research misconduct, the Research Integrity Officer may refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

Institutional members may discuss with the Research Integrity Officer and other appropriate TSRI officials concerns about possible research misconduct and appropriate procedures for reporting allegations. The Research Integrity Officer and other officials shall keep such discussions confidential to the extent feasible consistent with this Policy and applicable law.

iii. Duty to Promote the Best Interests and Integrity of TSRI

TSRI encourages intellectual honesty of all institutional members in all scientific endeavors by maintaining open communication, submitting work for peer review, avoiding conflicts of interest (pursuant to TSRI's policies on conflict of interest), and committing to self-regulation.

iv. Education

TSRI educates and informs faculty and other individuals employed by TSRI about standards for proposing, conducting, and reporting research, as well as this Policy and the importance of complying with it.

v. Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the Research Integrity Officer and other TSRI officials in the review of allegations of research misconduct and in conducting inquiries and investigations. Institutional members, including respondents, have an obligation to provide evidence relevant to research misconduct proceedings to the Research Integrity Officer or other appropriate TSRI officials.

A respondent has a duty to preserve all research records. Failure to maintain adequate records is not sufficient to provide evidence of research misconduct. A respondent's destruction of research records documenting the research questioned is evidence of research misconduct where TSRI establishes by a preponderance of the evidence that the respondent intentionally or knowingly destroyed the records after being informed of the research misconduct allegations. A respondent's failure to provide research records documenting the research questioned is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request.

vi. Confidentiality

The Research Integrity Officer shall endeavor to protect the confidentiality of respondents, complainants, witnesses, and research subjects identifiable from research records or evidence by limiting disclosure to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding or as required by law.

Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. The limitation on disclosure of the identity of respondents, complainants, and witnesses no longer applies once an institution has made a final determination of research misconduct findings. TSRI must disclose the identity of respondents, complainants, or other relevant persons to ORI pursuant to an ORI review of research misconduct proceedings. This Policy does not prohibit TSRI from managing published data or acknowledging that data may be unreliable.

vii. Disclosure Obligation

As a condition of employment, institutional members shall confirm in writing that they have been informed of and agree to comply with TSRI's research standards and this Policy.

viii. Administrative Review of Policies

TSRI periodically evaluates and, if appropriate, will revise this Policy. TSRI will keep this Policy in compliance with 42 C.F.R. Part 93, make it publicly available, and provide it to ORI and other HHS components on request.

ix. Interim Administrative Actions and Notifying Federal Agencies of Special Circumstances

Throughout the research misconduct proceeding, the Research Integrity Officer 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 Research Integrity Officer will, in consultation with other TSRI officials and appropriate federal agencies, take appropriate interim action to protect against any such threat. Interim action may

include: additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of responsibility for handling federal funds and equipment, additional review of research data and results, or delaying publication.

The Research Integrity Officer shall, at any time during a research misconduct proceeding notify appropriate federal officials of any facts that may be relevant to protect public health, federal funds and equipment, and the integrity of the federally supported research process, and immediately notify the appropriate federal agencies if he/she has reason to believe that any of the following conditions exist: (1) health or safety of the public is at risk, including an immediate need to protect human or animal subjects; (2) federal resources or interests are threatened; (3) research activities should be suspended; (4) there is a reasonable indication of possible violations of civil or criminal law; (5) federal action may be needed to protect the interests of those involved in the research misconduct proceeding; or (6) TSRI believes the research misconduct proceeding may be made public prematurely so that the agency may take appropriate steps to safeguard evidence and protect the rights of those involved.

In any case, the Research Integrity Officer may order interim measures to protect federal or other funding sponsors and to insure that the purposes of the research activity and the financial assistance are carried out.

x. Multiple Respondents

If additional respondents are identified during an inquiry or investigation, a separate inquiry for each new respondent is not required, the newly identified respondent may be added to the ongoing inquiry or investigation. Each additional respondent must be given written notice of, and an opportunity to respond to, the allegations against him or her consistent with this Policy. An investigation of multiple respondents may proceed with the same investigation committee, but a separate investigation report and a separate research misconduct determination are required for each respondent.

xi. Multiple Institutions

When allegations involve research conducted at multiple institutions and a joint research misconduct proceeding is conducted, one institution must be designated as the “lead institution.” The lead institution should obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, a joint proceeding may include committee members from the institutions involved, and the determinations of whether further inquiry or investigation is warranted, whether research misconduct occurred, and what institutional actions will be taken may be made by the institutions jointly or tasked to the lead institution.

xii. Subsequent Use Rule

This policy applies to allegations of research misconduct occurring within six years of the date that Scripps Research or the funder received the allegation, subject to the following exceptions. The six-year time limitation does not apply if:

1. The respondent continues or renews an incident of alleged research misconduct that occurred before the six-year time limitation and does so through the use of, republication of or citation to the portion(s) of the research record (e.g., processed data, journal articles, funding proposals, data repositories) alleged to have been fabricated, falsified, or plagiarized, for potential benefit of the respondent.

a. When the respondent uses, republishes, or cites to the portion(s) of the research record that is alleged to have been fabricated, falsified, or plagiarized, in submitted or published manuscripts, submitted PHS grant applications, progress reports submitted to PHS funding components, posters, presentations, or other research records within six years of when the allegations were received by the U.S. Department of Health and Human Services (HHS) or Scripps Research, this exception applies.
b. For research misconduct that appears subject to the subsequent use exception, a determination that the subsequent use exception does not apply must be documented. For PHS-supported activities, such documentation must be retained in accordance with 42 CFR §93.318.

2. ORI or other applicable federal agency, or Scripps Research following consultation with ORI or the applicable federal agency, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

c. Conducting the Inquiry

i. Assessment of Allegations

Promptly after receiving an allegation of research misconduct, the Research Integrity Officer will assess the allegation to determine whether it (1) falls within the definition of research misconduct in this Policy and applicable federal regulations (including, for PHS-supported research, 42 C.F.R. § 93.234), (2) for PHS-supported research, is within the applicability criteria of 42 C.F.R. § 93.102, and (3) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. If all applicable criteria are met, an inquiry will be conducted.

In conducting the assessment, the Research Integrity Officer 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.

If the Research Integrity Officer determines that the criteria for an inquiry are met, the Research Integrity Officer will document the assessment, promptly sequester all research records and other evidence in accordance with Section B(c)(iii), and promptly initiate the inquiry. If the Research Integrity Officer determines that the criteria for an inquiry are not met, the Research Integrity Officer will keep sufficiently detailed documentation of the assessment to permit a later review by ORI or other applicable federal agency of the reasons why an inquiry was not conducted and will retain that documentation in accordance with Section B(f)(vi).

ii. Notice to Respondent

At the time of or before beginning an inquiry, the Research Integrity Officer shall make a good faith effort to notify the respondent in writing of TSRI's decision to conduct an inquiry. If the inquiry subsequently identifies additional respondents, they shall also be notified in writing. Only allegations specific to a particular respondent will be included in the notice to that respondent. If additional allegations are raised during the inquiry, the Research Integrity Officer will notify the respondent in writing of the additional allegations raised against him or her.

iii. Sequestration of the Research Records

On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the Research Integrity Officer shall 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. 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 have evidentiary value substantially equivalent to that of the instruments. In appropriate cases, the Research Integrity Officer may consult with ORI, NSF, or other appropriate federal agencies for advice and assistance in connection with sequestration. Where appropriate, the Research Integrity Officer shall give the respondent copies of, or reasonable supervised access to, the sequestered research records.

iv. Appointment of the Inquiry Committee

The Research Integrity Officer is responsible for conducting, or designating others to conduct, the inquiry. In cases where the allegations and apparent evidence are straightforward, the Research Integrity Officer may choose to conduct the inquiry directly or designate another qualified individual, referred to as the inquiry official, to do so. The inquiry official shall not have unresolved personal, professional, or financial conflicts of interest in relation to the inquiry and should have appropriate scientific expertise to evaluate the evidence and issues related to the allegation and conduct the inquiry.

In complex cases, the Research Integrity Officer, in consultation with other TSRI officials, as appropriate, will normally appoint a committee of three or more persons, including a committee chair, to conduct the inquiry. Where warranted, the Research Integrity Officer may determine that a smaller or larger committee is appropriate. The members of the inquiry committee shall consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest in relation to the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation and conduct the inquiry. When necessary to secure expertise or to avoid conflicts of interest, the Research Integrity Officer may select committee members from outside TSRI. Neither the Research Integrity Officer nor TSRI's legal counsel will serve as a member of the inquiry committee.

The Research Integrity Officer, in consultation with the inquiry committee, will determine whether additional experts are needed to provide special expertise to the inquiry committee regarding the analysis of specific evidence. If experts are utilized, their role will be strictly advisory to the inquiry committee.

The respondent shall have an opportunity to object to the inquiry official or a proposed member of the inquiry committee based upon a personal, professional, or financial conflict of interest, by submitting written objections to the Research Integrity Officer no more than 10 days following notification of the proposed inquiry official or committee membership. The Research Integrity Officer makes the final determination as to whether a conflict exists.

If TSRI uses a committee, consortium, or other person to conduct any part of a research misconduct proceeding on its behalf, TSRI will address any potential, perceived, or actual personal, professional, or financial conflicts of interest between the committee members, consortium, or other person and the complainant, respondent, or witnesses, and will ensure that the proceeding is conducted in compliance with 42 C.F.R. Part 93.

v. Charge to the Inquiry Committee

The Research Integrity Officer will prepare a charge to the inquiry official or inquiry committee that: (1) sets forth the time for completion of the inquiry; (2) describes the allegations and any related issues identified during the allegation assessment; (3) states that the purpose of the inquiry is to conduct an initial review of the evidence to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible; (4) states the criteria for determining that an investigation is warranted; and (5) informs the inquiry official or inquiry committee that it is responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of Section B(d) of this Policy.

The Research Integrity Officer may choose to meet with the inquiry official or inquiry committee to review the charge, discuss the allegations, discuss the appropriate procedures for conducting the inquiry, assist the inquiry official or committee with organizing plans for the inquiry, and answer any questions raised by the inquiry official or committee. The Research Integrity Officer or his or her designee will be available throughout the inquiry to advise the inquiry official, or inquiry committee as needed.

vi. Inquiry Process

The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. The purpose of the inquiry is not to decide whether misconduct definitely occurred, determine who committed the research misconduct or conduct exhaustive interviews and analysis.

After evaluation of the evidence, the inquiry official or inquiry committee will consult with the Research Integrity Officer and decide whether to recommend that an investigation is warranted. An investigation is warranted if: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct in this Policy and, for PHS-supported research, involves PHS-supported biomedical or behavioral research, research training, or related activities as provided in 42 C.F.R. § 93.102, and (2) preliminary information-gathering and preliminary fact-finding from the inquiry indicate that the allegation may have substance. Findings of research misconduct, including a determination that the alleged misconduct was intentional, knowing, or reckless, cannot be made at the inquiry stage.

If the respondent offers an admission of research misconduct, the admission must be in writing and signed by the respondent, must specify the falsification, fabrication, and/or plagiarism that occurred and the research records affected, and must meet all elements required for a finding of research misconduct under 42 C.F.R. § 93.103. TSRI will not close a proceeding on the basis of an admission until it has provided the signed admission to ORI, together with a statement describing how TSRI determined that the admission fully addressed the scope of the misconduct and confirmed the respondent's culpability. The Research Integrity Officer, in consultation with the President of TSRI and other appropriate TSRI officials, shall promptly consult with any appropriate federal agencies to determine the next steps that should be taken**.**

vii. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the President of TSRI on whether an investigation is warranted, must be completed within 90 days of its initiation unless the Research Integrity Officer determines that circumstances clearly warrant a longer period. If the inquiry takes longer than 90 days, and the Research Integrity Officer approves an extension, the inquiry report shall document the reasons for exceeding the 90-day period.

d. The Inquiry Report

i. Elements of the Inquiry Report

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

1) the names, professional aliases, and positions of the respondent and complainant;
2) a description of the allegations of research misconduct;
3) the PHS, NSF, or other federal agency support, including, for example, grant numbers, grant applications, contracts and publications listing such support;
4) the composition of the inquiry committee, if one was used, including the name, position, and subject matter expertise of each member;
5) a description of analyses conducted;
6) transcripts of any interviews that were transcribed;
7) a timeline and procedural history;
8) an inventory of sequestered research records and other evidence, and a description of how sequestration was conducted;
9) the basis for recommending or not recommending that the allegations warrant an investigation (including the basis on which any allegation does not merit an investigation);
10) any written comments on the draft report by the respondent or the complainant; and
11) any institutional actions implemented, including communications with journals or funding agencies.

The inquiry report should also include: the names and titles of the inquiry official or committee members and experts who conducted the inquiry; a summary of the inquiry process used; a list of the research records reviewed; and whether any other actions should be taken if an investigation is not recommended. The inquiry report must also note any potential evidence of honest error or difference of opinion.

ii. Opportunity to Comment on the Inquiry Report

The Research Integrity Officer shall provide the respondent with a copy of the draft inquiry report and, concurrently, with a copy of 42 C.F.R. Part 93 or other applicable federal research misconduct policy. The respondent shall be provided with an opportunity to review and comment on the inquiry report. Any comments from the respondent must be in writing and received within 10 days of his/her receipt of the inquiry report and will be attached to the report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The Research Integrity Officer will deliver the final report to the President of TSRI.

The Research Integrity Officer may provide the complainant with relevant portions of the inquiry report for comment. Any comments from the complainant must be in writing and received within 10 days of his/her receipt of the inquiry report. A confidentiality agreement should be a condition for access to the report.

iii. Institutional Decision and Notification

1. Decision by the President of TSRI

The Research Integrity Officer will transmit the final inquiry report and any written comments to the President of TSRI, who will determine in writing whether an investigation is warranted. The inquiry is complete when the President makes this determination.

2. Notification to Respondent and Complainant

The Research Integrity Officer shall notify the respondent whether the inquiry found that an investigation is warranted. The notice shall include a

copy of the inquiry report and include a copy of or refer to this Policy and 42 C.F.R. Part 93 or other applicable federal research misconduct policy.
The Research Integrity Officer may also notify the complainant whether the inquiry found that an investigation is warranted. If TSRI provides notice to one complainant in a case, it will provide notice, to the extent possible, to all complainants in the case.

3. **Notification to Applicable Federal Agency**
Within 30 days of the President's decision that an investigation is warranted, the Research Integrity Officer shall provide ORI or other applicable federal agency with the President's written decision and a copy of the inquiry report. (In cases involving NSF jurisdiction, the NSF Office of Inspector General must be notified immediately.) The Research Integrity Officer will also notify TSRI officials who need to know of the President's decision.

4. **Documentation of Decision Not to Investigate**
If the President of TSRI decides that an investigation is not warranted, the Research Integrity Officer shall secure and maintain, for seven years after the termination of the inquiry, sufficiently detailed documentation of the inquiry to permit a later assessment by supporting federal agencies of the reasons why an investigation was not conducted. These documents shall be provided to ORI or other authorized federal personnel upon request**.**

e. Conducting the Investigation

i. Initiation and Purpose

The investigation shall begin within 30 days after the President's determination that an investigation is warranted. 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 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. The findings of the investigation shall be set forth in an investigation report.

ii. Notifying Federal Officials and Respondent

On or before the date on which the investigation begins, but no more than 30 days after the President of TSRI determines that an investigation is warranted, the Research Integrity Officer shall notify the ORI Director or other appropriate federal officials of the decision to begin the investigation and provide such officials with a copy of the inquiry report. Within a reasonable time after determining that an investigation is warranted, but before the investigation begins, the Research Integrity Officer shall notify the respondent in writing of the allegations to be investigated, unless such notification has already been made. If allegations not addressed during the inquiry or in the initial notice of the investigation are pursued, the Research Integrity Officer shall give the respondent reasonably timely written notice of any such new allegations.

iii. Sequestration of the Research Records

Before or at the time TSRI notifies the respondent of the investigation, the Research Integrity Officer shall 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. 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, in evidentiary value, to the instruments.

When original research records cannot be obtained, copies of records that are "substantially equivalent in evidentiary value" will fulfill the sequestration requirement. TSRI will also, whenever possible, obtain and sequester research records and other evidence whenever additional items become known or relevant to the inquiry or investigation.

iv. Appointment of the Investigation Committee

As soon as practicable after beginning the investigation, the Research Integrity Officer, in consultation with other TSRI officials, as appropriate, will appoint an investigation committee and committee chair, which will conduct the investigation.

The investigation committee shall consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest in relation to the investigation. Members of the inquiry committee may also serve on the investigation committee. Investigation committee members should have appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant, and conduct the investigation. When necessary to secure expertise or to avoid conflicts of interest, the Research Integrity Officer may select committee members from outside TSRI. Neither the Research Integrity Officer nor TSRI's legal counsel will serve as members of the investigation committee.

The respondent shall have an opportunity to object to proposed members of the investigation committee based upon a personal, professional, or financial conflict of interest, by submitting written objections to the Research Integrity Officer no more than 10 days following notification regarding the committee membership. The Research Integrity Officer makes the final determination as to whether a conflict exists.

v. Charge to the Investigation Committee

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

(1) describes the allegations and related issues identified during the inquiry;
(2) identifies the respondent;
(3) informs the investigation committee that it must conduct the investigation as prescribed in this Policy;
(4) defines research misconduct;
(5) informs the investigation committee that it must evaluate the evidence and testimony to determine and recommend whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent and who was responsible; and
(6) informs the investigation committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of Section B(f).

The Research Integrity Officer may choose to meet with the investigation committee to review the charge, the inquiry report, and prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan.

The investigation committee shall be provided with a copy of this Policy and, if applicable, 42 C.F.R. Part 93, or other applicable federal research misconduct policy. The Research Integrity Officer or designee will ordinarily be available throughout the investigation to advise the investigation committee as needed.

vi. Investigation Process

The investigation committee and the Research Integrity Officer shall:

(1) Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;

(2) Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical, 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 inquiry or investigation;

(3) Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record and transcribe each interview, number any exhibits shown to the interviewee and refer to them by number during the interview, provide the transcript to the interviewee for correction, and include the recording, the transcript with any written corrections, and the numbered exhibits in the record of the investigation (the respondent must not be present during the interviews of other witnesses but must be provided a transcript of each such interview); and

(4) Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

vii. Standard for Making a Finding of Research Misconduct

In order to make a finding of research misconduct, the investigation committee must recommend, and the Institutional Deciding Official must determine, by a preponderance of the evidence, that: (1) research misconduct occurred, as defined in this Policy or applicable federal agency policy; (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.

TSRI has the burden of proof for making a finding of research misconduct. The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses he/she raises during the investigation. In determining whether TSRI has carried its burden of proof, TSRI will give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

viii. Time for Completion

The investigation must be completed within 180 days of its initiation, including conducting the investigation, preparing the draft investigation report for each respondent, providing the draft report for comment, and transmitting the institutional record, including the final investigation report and the decision of the Institutional Deciding Official, to ORI, NSF, or other federal agency, if applicable. However, if the Research Integrity Officer determines

that the investigation will not be completed within the 180 day period, or as requested by the applicable agency, he/she shall submit to the applicable agency a written request for an extension setting forth the reasons for the delay. If the investigation takes longer than 180 days to complete, the investigation report must include the reasons for exceeding the 180-day period.

f. The Investigation Report

i. Elements of the Investigation Report

1. The Investigation committee and the Research Integrity Officer are responsible for preparing a written investigation report for each respondent which shall:

(1) describe the nature of the allegation of research misconduct;
(2) describe and document any PHS support or other federal or private funding, including, for example, any grant numbers, grant applications, contracts, and publications listing any such support;
(3) describe the specific allegations of research misconduct considered in the investigation;
(4) include the composition of the investigation committee, including the name, position, and subject matter expertise of each member;
(5) include an inventory of sequestered research records and other evidence and how sequestration was conducted, including any manuscripts and funding proposals considered or relied on during the investigation;
(6) include interview transcripts;
(7) include any scientific or forensic analyses conducted;
(8) identify the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that allegedly contained falsified, fabricated, or plagiarized material;
(9) include any comments made by the respondent and the complainant on the draft investigation report and the investigation committee's consideration of those comments;
(10) include a copy of this Policy; and
(11) identify and summarize the research records and evidence reviewed and identify any evidence taken into custody but not reviewed.

2. The report must also include a statement of findings for each separate allegation of research misconduct identified during the investigation. The statement of findings must state whether the investigation committee recommends a finding of research misconduct for the allegation and, if so:

(1) Identify whether the research misconduct was: falsification, fabrication, or plagiarism; a significant departure from accepted practices of the relevant research community; and committed intentionally, knowingly, or recklessly, and state whether the other requirements for a finding of research misconduct under 42 C.F.R. § 93.103 have been met;
(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 the 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 specifically any PHS support or other federal funding;
(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 PHS or non-PHS federal agencies.

If the investigation committee does not recommend a finding of research misconduct for an allegation, the investigation report must provide a detailed rationale for that conclusion.

ii. Comments on the Draft Investigation Report and Access to Evidence

1. Respondent

The Research Integrity Officer shall provide the respondent with a copy of the draft investigation report for comment and rebuttal, and shall provide the respondent, concurrently, with a copy of, or supervised access to, the evidence on which the report is based. The respondent will be provided with access to all interview transcripts. The respondent shall be allowed 30 days to review the draft report and submit written comments to the Research Integrity Officer. The respondent's comments shall be taken into consideration when preparing the final investigation report and shall be attached to the final report.

2. Complainant

The Research Integrity Officer may provide the complainant with a copy of the draft investigation report, or relevant portions of it, for comment. If provided with a copy of the report, the complainant's comments must be in writing and submitted within 30 days of the date on which he/she received the draft report. Comments received from the complainant shall be taken into consideration in preparing the final investigation report and shall be attached to the final report.

3. Confidentiality

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

iii. Decision by the President of TSRI

The Research Integrity Officer will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's and, in appropriate cases, the complainant's written comments are included and considered. The Research Integrity Officer will transmit the final investigation report to the President of TSRI, who, as the Institutional Deciding Official, will make the final determination in writing of: (1) whether TSRI accepts the findings recommended by the investigation committee and whether TSRI finds that research misconduct occurred and, if so, who committed it; and (2) the appropriate institutional actions taken in response to the accepted findings of research misconduct. If the President's determination varies from the findings recommended by the investigation committee, the President will as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the President 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 Research Integrity Officer will normally notify both the respondent and the complainant in writing. The Research Integrity Officer is also responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. The President of TSRI 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.

iv. Appeals

The respondent has the right to appeal the findings of TSRI's President regarding research misconduct by submitting a Notice of Appeal to the Governance Committee of the Board of Directors, or relevant Board Committee, within 15 days of receiving notice of the President's decision. The reason for requesting a review must be stated in the Notice of Appeal and must be based on either the discovery of new evidence of such significance that it would change the outcome of the investigation, or procedural infirmities, such as bias or conflict of interest by one or more committee members or refusal to accept probative evidence.

Appeals will be completed as promptly as practicable. If an appeal will prevent TSRI from transmitting the institutional record to ORI within the 180-day period described in Section B(e)(viii), the Research Integrity Officer shall make a written request to ORI for an extension that explains the need for the extension.

v. Notice to Applicable Federal Agencies of Institutional Findings and Actions

Unless an extension has been granted, within 180 days of beginning the investigation, the Research Integrity Officer shall submit to ORI, or other applicable agency, the institutional record with all attachments and any appeal; a statement of whether TSRI accepts the findings of the investigation report or the outcome of the appeal; a statement of whether TSRI found misconduct and, if so, who committed the misconduct; and a description of any pending or completed administrative actions against the respondent.

The entire institutional record will be submitted to ORI upon the conclusion of the investigation including:

a. documentation of the assessment;
b. the inquiry report and all records considered or relied on during the inquiry;
c. the investigation report and all records considered or relied on during the investigation;
d. all transcripts;
e. decisions by President of TSRI;
f. records of any appeals; an index listing all the research records and evidence that the institution compiled during the research misconduct proceeding; and
g. a general description of the records that were sequestered but not considered or relied on.

The Research Integrity Officer shall promptly notify ORI if a respondent appeals TSRI's findings of research misconduct or institutional actions. If the respondent appeals before the institutional record has been transmitted to ORI, TSRI will wait until the appeal concludes to transmit the institutional record, will include the complete record of the appeal, and, if more than 180 days will be required, the

Research Integrity Officer will request an extension from ORI in writing. If the institutional record was transmitted before the appeal, TSRI will provide ORI the complete record of the appeal once the appeal concludes. The institutional record must be logically organized.

vi. Maintaining Records for Review by Federal Agencies

The Research Integrity Officer shall maintain, and upon request, provide to ORI, or other applicable federal agencies, records of the research misconduct proceedings, including:

(1) records secured by TSRI for the inquiry and investigation;
(2) documentation of the determination of irrelevant or duplicate records;
(3) the inquiry report and final documents produced in the course of preparing that report, including the documentation of any decision not to investigate;
(4) the investigation report and all records in support of that report, including the recordings and transcriptions of each interview conducted pursuant to this Policy;
(5) the complete record of any institutional appeal;
(6) documentation of each allegation assessment, including documentation sufficient to permit a later review by ORI of the reasons why an inquiry was not conducted;
(7) documentation of any determination that the subsequent use exception to the six-year limitation does not apply; and
(8) all sequestered evidence, including physical objects, whether or not the evidence is part of the institutional record.

Unless custody has been transferred to the applicable federal agency or the agency has advised TSRI, in writing, that the records no longer need to be retained, these records shall be maintained in a secure manner for seven years after completion of the proceeding or the completion of any federal agency proceeding involving the research misconduct allegation, whichever is later.

The Research Integrity Officer is also responsible for providing any information, documentation, research records, evidence, or clarification requested by ORI or other applicable federal agency to carry out its review of an allegation of research misconduct or of TSRI's handling of such an allegation. TSRI will also address any deficiencies or additional allegations in the institutional record if directed by ORI, and will give the respondent an opportunity to respond to any information or allegations ORI adds to the institutional record. TSRI will assist in administering and enforcing any HHS administrative actions imposed on its institutional members.

g. Completion of Cases and Reporting Premature Closures to Applicable Federal Agencies

i. Generally, all inquiries and investigations will be carried through to completion, and all significant issues will be pursued diligently. The Research Integrity Officer shall notify ORI or any other applicable federal agency in advance if there are plans to close a case at the assessment, inquiry, investigation, or appeal stage on the basis that the respondent has admitted to committing research misconduct (in a written, signed admission that meets the requirements of Section B(c)(vi)), a settlement with the respondent has been reached, or for any other reason except that: (1) no notification to federal agencies need be provided when a case is closed after an assessment that finds an inquiry is not warranted, or after an inquiry that finds pursuant to Section B(d)(iii) that an investigation is not warranted; and (2) if an

investigation is completed, the institution's findings must be reported as specified under Section B(f)(v) of this policy.

h. Institutional Administrative Actions

i. If the President of TSRI determines that a finding of research misconduct is substantiated, TSRI may adopt sanctions, which may include, for example:

(1) A letter of reprimand or admonishment to be included in respondent's file;
(2) Supervision or monitoring of future work;
(3) Probation or suspension;
(4) Removal from the research project in question;
(5) Salary reduction or the initiation of steps leading to possible rank reduction or termination of employment;
(6) Formal notification of sponsoring agencies, funding sources, co-authors, co-investigators, collaborators, campus and university publications, editors of journals in which fraudulent research was published, state professional licensing boards, professional societies, and other institutions with which the respondent has been affiliated;
(7) Withdrawal or correction of all pending abstracts and papers emanating from the research where research misconduct was found;
(8) Formal withdrawal of pending applications for research support;
(9) Public announcements; and/or
(10) Restitution of funds.

None of these sanctions limits the authority of the funding sponsor to impose its own sanctions.

i. Other Considerations

i. Termination or Resignation Prior to Completing the 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.

If the respondent, without admitting to the misconduct, elects to resign his or her position after TSRI 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 or termination, the Research Integrity Officer and any inquiry official or committee 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 proceeding.

j. Protecting the Respondent

Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice. The respondent may be accompanied by counsel or a personal adviser at the respondent's own interviews and at meetings on the case, but the lawyer or personal advisor's role will be limited to counseling the respondent and the respondent will be responsible for answering all questions.

As requested, and as appropriate, the Research Integrity Officer and other TSRI 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. Depending on the particular circumstances and the views of the

respondent, the Research Integrity Officer should consider whether to notify those individuals aware of or involved in the investigation of the final outcome, publicize the final outcome in any forum in which the allegation of research misconduct was previously publicized, and/or expunge references 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 President of TSRI.

k. Protecting the Complainant, 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 Research Integrity Officer.

During the research misconduct proceeding and upon its completion, regardless of whether or not TSRI or a federal agency determines that research misconduct occurred, the Research Integrity Officer shall 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.

l. Allegations Not Made in Good Faith

If relevant, the President of TSRI 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 President of TSRI determines that there was an absence of good faith, the President will determine whether any administrative action should be taken against the person who failed to act in good faith.

m. Finality of Institutional Decision

An institutional decision regarding findings of research misconduct does not require findings of research misconduct by ORI to be considered final and to warrant remediation under this policy.

C. SCOPE

a. This policy applies to all persons who are employed by, is an agent of, or is affiliated by contract or agreement with TSRI. Institutional members may include, but are not limited to, TSRI officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, subject matter experts, consultants, attorneys, and agents; and contractors, subcontractors, and subawardees, and their employees or agents in the course and scope of their performance of a contract, subcontract or subaward with TSRI.

b. This policy addresses research misconduct as defined in Section D (definition of "Research Misconduct") below, and no other types of misconduct. This Policy applies to all research regardless of the source of financial support. Regarding PHS funded activities, the Policy is intended to meet the requirements of the PHS regulations at 42 C.F.R. Part 93, which apply to any research, research-training or research-related grant or cooperative agreement with PHS. When this Policy is applied to research that is sponsored by a federal entity whose policy differs from the provisions within this Policy, then that federal entity's policy governs.

c. This Policy, as revised to conform to 42 C.F.R. Part 93 as published at 89 Fed. Reg. 76280 (Sept. 17, 2024), applies to allegations of research misconduct received by TSRI on or after January 1, 2026. For allegations involving PHS support that TSRI received before January

1, 2026, TSRI will follow 42 C.F.R. Part 93 as published in the 2005 edition of the Code of Federal Regulations unless TSRI and the respondent both elect in writing to follow the current rule.

D. DEFINITIONS

a. **Accepted practices of the relevant research community:** This term means those practices established by 42 CFR Part 93 and by PHS funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS awards.

b. **Administrative record.** The administrative record comprises: the institutional record; any information provided by the respondent to ORI, including but not limited to the transcript of any virtual or in-person meetings under § 93.403(b) between the respondent and ORI, and correspondence between the respondent and ORI; any additional information provided to ORI while the case is pending before ORI; and any analysis or additional information generated or obtained by ORI. Any analysis or additional information generated or obtained by ORI will also be made available to the respondent.

c. **Allegation:** A disclosure of possible research misconduct through any means of communication and brought directly to the attention of an institutional or federal official. The disclosure may be by written or oral statement or other communication to an institutional or federal official.

d. **Applicable Agencies:** ORI if PHS support is involved, NSF if it has jurisdiction, and other agencies whose policies require specific actions and reporting of research misconduct.

e. **Assessment.** Assessment means a consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct; appears to involve PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training; and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The assessment only involves the review of readily accessible information relevant to the allegation.

f. **Committee Member:** Any individual serving on the inquiry committee or the investigation committee.

g. **Complainant:** A person who in good faith makes an allegation of research misconduct.

h. **Day:** Day means calendar day unless otherwise specified. If a deadline falls on a Saturday, Sunday, or federal holiday, the deadline is extended to the next day that is not a Saturday, Sunday, or federal holiday.

i. **Evidence:** Anything offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact, including documents (in hard copy or electronic form), information, tangible items, and testimony.

j. **Falsification:** 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.

k. **Fabrication:** Making up data or results and recording or reporting them.

l. **Good Faith:** As applied to a complainant or witness means having a reasonable belief in the truth of one's allegation or testimony, 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 knowledge of or reckless disregard for information that would negate the allegation or testimony.

Good faith as applied to an institutional or committee member means cooperating with the research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities under 42 CFR Part 93. An institutional or committee member does not act in good faith if their acts or omissions during the research misconduct proceedings are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

m. **Inquiry:** Preliminary information-gathering and preliminary initial fact-finding that meets the criteria and follows the procedures set forth in Section B(c) and B(d) of this Policy and applicable federal regulations.

n. **Institutional Deciding Official:** Institutional Deciding Official means the institutional official who makes final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as the Institutional Deciding Official and the Research Integrity Officer.

o. **Institutional Member:** A person who is employed by, is an agent of, or is affiliated by contract or agreement with TSRI. Institutional members may include, but are not limited to, TSRI officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, subject matter experts, consultants, attorneys, and agents; and contractors, subcontractors, and subawardees, and their employees or agents in the course and scope of their performance of a contract, subcontract or subaward with TSRI.

p. **Institutional record.** The institutional record is comprised of: (a) The records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. These records include but are not limited to (1) documentation of the assessment as required by § 93.306(c); (2) if an inquiry is conducted, the inquiry report and all records (other than drafts of the report) considered or relied on during the inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate as required by § 93.309(c); (3) if an investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to § 93.310(g), and information the respondent provided to the institution; (4) decision(s) by the President of TSRI, such as the written decision from the President of TSRI under § 93.314; (5) the complete record of any institutional appeal consistent with § 93.315; (b) a single index listing all the research records and evidence that the institution compiled during the research misconduct proceeding, except records the institution did not consider or rely on; and (c) a general description of the records that were sequestered but not considered or relied on.

q. **Intentionally.** To act intentionally means to act with the aim of carrying out the act.

r. **Investigation:** The formal development and examination of a factual record leading to (1) a decision not to make a finding of research misconduct or (2) a recommendation for a finding of research misconduct, which may include a recommendation for administrative or other appropriate action.

s. **Knowingly.** To act knowingly means to act with awareness of the act.

t. **Notice:** Notice means a written or electronic communication served in person or sent by mail or its equivalent to the last known street address, facsimile number, or email address of the addressee.

u. **Plagiarism:** The appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Plagiarism also 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. Plagiarism 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.

v. **PHS Support:** PHS funding, or applications or proposals for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: Funding for PHS intramural research, PHS grants, cooperative agreements, contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

w. **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.

x. **Recklessly.** 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.

y. **Research:** Research means a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating, or confirming information or underlying mechanisms related to biological causes, functions, or effects; diseases; treatments; or related matters to be studied.

z. **Research Integrity Officer(s):** The institutional official(s) who is responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. The Research Integrity Officer is designated by the President of TSRI and has responsibility for research misconduct throughout TSRI, including both the Florida and California campuses.

aa. **Research Misconduct:** 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.

bb. Research Misconduct Proceeding: Any action related to alleged research misconduct, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, and appeals.

cc. Research Record: The record of data or results that embody the facts resulting from scientific inquiry, in physical or electronic form, including but not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, internal reports, journal articles, and any documents and materials provided to a federal or institutional official by a respondent in the course of the research misconduct proceeding.

dd. Respondent: The person(s) against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

ee. Retaliation: An adverse action taken against a complainant, witness, or committee member by TSRI or one of its institutional members in response to: (1) a good faith allegation of research misconduct; (2) good faith cooperation with a research misconduct proceeding; or (3) a complaint of inadequate institutional response to an allegation of research misconduct.

E. REFERENCES AND RELATED DOCUMENTS

a. ORI - The Office of Research Integrity
b. Public Health Service Policies on Research Misconduct – 42 CFR Part 93 (September 2024)
c. Public Health Service (PHS) Policies on Research Misconduct – 42 CFR Part 93 (June 2005)
d. National Science Foundation Scientific Integrity Policy
e. Federal Research Misconduct Policy - OSTP
f. National Aeronautics Space Administration- Investigation of Research Misconduct

Last Updated: to reflect 2024 Final Rule updates; 10.27.2026