

15.03.03 Research Misconduct

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Regulation Summary

This regulation outlines the process for reviewing allegations of research misconduct at The Texas A&M University System (system) and its members. Each member must adopt its own rule for handling allegations of scientific or scholarly misconduct consistent with the terms of this regulation. This regulation is applicable to all faculty, staff and students, as described in the definitions.

Definitions

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Regulation

1. GENERAL

- 1.1 Research must be conducted under the highest standards of honesty and integrity. All data, primary sources, procedures, and findings must be properly and thoroughly documented. The credibility and long-term reputation of the system and faculty and staff at each member depend on the encouragement, enforcement and reward of superior ethical standards and good stewardship of research funds. Achieving high standards of research integrity should transcend considerations of finance, personal gain and short-term individual and institutional recognition. For purposes of this regulation, research also includes contract testing conducted by members.
 - 1.1.1 This regulation is applicable to research misconduct occurring within six years of the date that a funding agency, the system, or member receives an allegation of research misconduct, with exceptions noted for Health and Human Services (HHS) funded research in section 7.
- 1.2 In general, the system has adopted review procedures for allegations of research misconduct and standards of research integrity consistent with the HHS Office of Research Integrity's (HHS ORI) requirements, including all time limitations and subsequent use exceptions found in §93.104 of 42 CFR Part 93. Additionally, research misconduct proceedings involving sponsored research must follow the sponsor's research misconduct requirements, as applicable, with additional requirements for research

sponsored by HHS, National Science Foundation (NSF), and the federal government (Office of Science and Technology Policy or OSTP) detailed in sections 7-9, below.

1.2.1 When HHS ORI and other sponsor requirements conflict, the sponsor requirements take precedence when the research is not sponsored by HHS. When research projects have multiple sponsors, all sponsors must be notified of the allegations and a determination will be made as to whether or not which sponsor, if any, will take the lead.

- (a) Members must cooperate with sponsors and oversight agencies during any research misconduct proceeding, including
 - (i) addressing deficiencies or additional allegations as directed by sponsors and oversight agencies,
 - (ii) assisting in administering and enforcing any administrative actions imposed by the sponsor and oversight agencies, and
 - (iii) transferring custody or providing copies of the institutional record or any component of it, and any sequestered evidence to the sponsor or oversight agencies, regardless of whether the evidence is included in the institutional record.
- (b) Members must take all reasonable and practical steps to ensure the cooperation of respondents and other individuals within the institution during research misconduct proceedings, including, but not limited to, the provision of information, research records, and other evidence.

1.2.2 Research misconduct proceedings that do not involve sponsored research default to this regulation and HHS ORI guidance as applicable.

1.3 Confidentiality is an important component of research misconduct proceedings. Disclosure of the identity of respondents, complainants, witnesses, and research subjects that may be identifiable from research records during research misconduct proceedings is limited, to the extent possible, to those who need to know, as determined by the system and the member, consistent with a thorough, competent, objective, and fair proceeding. Those who need to know may include:

- 1.3.1 Institutional Review Boards (IRBs) and other research compliance committees
- 1.3.2 Journals, editors, publishers and co-authors
- 1.3.3 Other institutions of higher education
- 1.3.4 Sponsors of research that are part of the proceedings

1.4 System and the members are responsible for coordinating with sponsors when the research involved includes multiple sources of funding, according to those sponsor requirements.

- 1.4.1 Each member is responsible for responding to each allegation of research misconduct in a thorough, competent, objective, and fair manner.
- 1.4.2 Individuals responsible for any component of a research misconduct proceeding, including the Deciding Official (DO), Research Integrity Officer (RIO), and committee members, cannot have unresolved conflicts of interest with the complainant, respondent, or witnesses. Members must address any potential,

perceived, or actual personal, professional, or financial conflicts of interest between members of any committee or other people involved with the research misconduct proceedings and the complainant, respondent, and witnesses.

- 1.4.3 Throughout research misconduct proceedings, all reasonable and practical steps must be taken to protect the positions and reputations of complainants, witnesses, and committee members, and to protect those individuals from retaliation by respondents and/or individuals associated with the institution.
- 1.4.4 At any point during a research misconduct proceeding, respondents may admit to committing research misconduct, or a settlement with the respondent may be reached.
 - (a) A respondent's admission of research misconduct must be made in writing and signed by the respondent. The admission must be specific to the falsification, fabrication, and/or plagiarism that occurred, which research records were affected, and that it constituted a significant departure from accepted practices of the relevant research community. The statement must meet all elements required for a research misconduct finding according to this regulation and all relevant federal sponsor requirements (see sections 7-9).
 - (b) With a respondent's admission, the institution may decide to terminate an ongoing research misconduct proceeding, or they may continue the proceedings if the admission statement is insufficient or there is a concern that additional allegations may arise. The decision to continue should be consistent with sponsor requirements, made by the RIO and DO, and the inquiry or investigation committee if the proceedings have progressed to the inquiry or investigation stage.
- 1.5 Members are responsible for maintaining the institutional record and all sequestered evidence, including physical objects, even if the evidence is not a part of the institutional record, in a secure manner for seven years after the completion of the research misconduct proceedings or the completion of any sponsor proceedings, whichever is later.
 - 1.5.1 Members must give the respondent copies of, or reasonable supervised access to, sequestered research records and evidence during research misconduct proceedings.
 - 1.5.2 When multiple institutions, whether within or outside of the system, receive allegations of research misconduct, one institution will be designated as the lead institution if a joint research misconduct proceeding is conducted. Members participating in joint research misconduct proceedings must agree to the process, including any deferral to another institution's research misconduct policy as described in a member's rule, through a memorandum of understanding (MOU) or other agreement with the other institution(s) involved.
 - 1.5.3 If the respondent is employed by more than one member, or changes employment during the course of the proceedings, the DO at the member receiving the allegations of misconduct first shall notify the DO(s) of the other member(s), and they will determine which member(s) will be responsible for taking the lead on

the research misconduct proceedings through execution of an MOU including the scope of administrative actions the DOs of the involved members may take.

1.5.3.1 In the event that the members are unable to determine who will handle the proceedings, they will request that the Chief Research Compliance Officer make the determination. The member(s) that do not lead the proceedings must be included in the proceedings or kept informed of the progress of the proceedings as described in the MOU.

2 DUTIES OF THE RESEARCH INTEGRITY OFFICER (RIO), DECIDING OFFICIAL (DO), AND INSTITUTIONAL CERTIFYING OFFICIAL (ICO)

2.1 Deciding Official (DO)

2.1.1 The DO is appointed by the member Chief Executive Officer (CEO). Typically, the member Chief Research Officer (CRO) serves as the DO unless otherwise noted in the member's rule and needs to hold a sufficient rank within the institution to carry out the duties and responsibilities of the DO. The DO has the following responsibilities:

- (a) Takes interim administrative actions, as appropriate, to protect research participants and funds during the research misconduct proceeding.
- (b) Makes final determinations on allegations of research misconduct and any institutional actions after the completion of an investigation. Determinations must be made in writing and become a part of the institutional record.
- (c) Appoints the RIO, unless otherwise stated in the member's Rule (the DO cannot also serve as the RIO).
 - (i) Appoints a Deputy RIO who may assist the RIO, if necessary, unless otherwise stated in the member's Rule (the DO cannot also serve as a Deputy RIO).
 - (ii) Assists the RIO with identifying committee members to serve on inquiry and investigation committees.

2.2 Research Integrity Officer (RIO)

- 2.2.1 Serves as the primary individual responsible for managing a research misconduct proceeding.
- 2.2.2 Conducts the assessment of an allegation of research misconduct.
- 2.2.3 Works with requisite institutional departments to sequester research data at the initiation of an inquiry.
- 2.2.4 Prepares and maintains all documentation gathered or generated during the research misconduct proceeding (the institutional record).
- 2.2.5 Reports research misconduct proceedings to the system Office of General Counsel (OGC) and the Chief Research Compliance Officer (CRCO):
 - (a) Immediately, at any time during the research misconduct proceedings, if there is reason to believe any of the following conditions exist:

- (i) The health or safety of the public is at risk, which includes the immediate need to protect human research participants or animal subjects.
 - (ii) Research activities need to be suspended.
 - (iii) There is a reasonable indication of possible violations of civil or criminal law.
 - (iv) Immediate reporting is required to HHS ORI, NSF, or other sponsor.
 - (b) When a previously reported proceeding ends at inquiry with no finding of research misconduct.
 - (c) When a research misconduct proceeding progresses to the investigation phase.
- 2.2.6 Reports to sponsors and regulatory oversight agencies, as applicable.
- 2.2.7 Manages inquiry and investigation committees.
- (a) Assists with identifying committee members.
- 2.2.8 Ensures that committee members and others involved with research misconduct proceedings do not have unresolved conflicts of interest as per 1.4.2 in this regulation.
- (a) Provide committee members with training and their responsibilities.
 - (b) Manage committee deliberations to ensure adherence to this regulation and all applicable sponsor and regulatory oversight requirements.
- 2.2.9 Manages the work conducted by Deputy RIOs, as applicable.
- 2.3 Institutional Certifying Official (ICO)
- 2.3.1 The ICO ensures that the institution has written policies and procedures for addressing allegations of research misconduct and that the institution complies with its policies and procedures.
 - 2.3.2 The DO, RIO, or another official within the institution may serve as the ICO, although it is preferred that either the DO or RIO serve in this role.
- 2.4 If allegations of research misconduct are made against the RIO or DO, or if the RIO or DO have conflicts of interest with the complainants, respondents, witnesses, or other individuals involved in the research misconduct proceedings, as described in section 2.4.2, members can utilize another individual to serve in that role on an interim basis upon consultation with the OGC.

3 ASSESSMENTS OF ALLEGATIONS OF RESEARCH MISCONDUCT

- 3.1 Allegations may be received through any means of communication and brought to the attention of a system official, member official, or sponsor official.
- 3.2 The assessment of an allegation of research misconduct conducted by the RIO, or another designated official (e.g., Deputy RIO), as applicable, is the process whereby the institution determines whether or not an allegation warrants an inquiry.

- 3.2.1 If the RIO is unavailable or has a conflict with the topic(s) included in the allegation, the institution may appoint another appropriately qualified individual, other than the DO, to conduct the assessment.
- 3.3 Upon receiving an allegation of research misconduct, the RIO must promptly assess the allegation to determine whether the allegation meets the requirements for an inquiry:
 - 3.3.1 Falls within the definition of research misconduct according to this regulation and/or sponsor requirements; and
 - 3.3.2 Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.
- 3.4 When multiple allegations are received, the RIO is responsible for identifying the specific allegations and assessing each.
- 3.5 During the assessment, the funding sources for the research must be identified.
- 3.6 Assessments must be documented to have one of the following two outcomes:
 - 3.6.1 An inquiry must be conducted if the allegation meets the requirements for an inquiry. If it is determined that an inquiry must be conducted after the assessment:
 - (a) The inquiry must start promptly after the conclusion of the assessment; and
 - (b) All research records and other evidence must be sequestered; and
 - (c) The individual conducting the assessment must identify the specific allegations of research misconduct to be reviewed during the inquiry.
 - 3.6.2 An inquiry does not need to be conducted because the requirements for the inquiry have not been met.

4 INQUIRIES OF ALLEGATIONS OF RESEARCH MISCONDUCT

- 4.1 Inquiries are conducted as an initial review of the evidence to determine whether an allegation of research misconduct warrants an investigation. Full reviews of evidence related to the allegation are not needed at this stage of the research misconduct proceeding. It is not the charge of the inquiry committee to make a finding of research misconduct.
 - 4.1.1 Inquiries are to be completed within 90 days, unless circumstances warrant a longer period. If a longer period is warranted, then the RIO must document the reason(s) for exceeding the 90-day period and include that with the inquiry report.
- 4.2 The institution must make a good faith effort to provide written notification of the inquiry to the respondent(s) prior to or at the initiation of the inquiry.
 - 4.2.1 In the case of inquiries with multiple respondents, respondents can only be provided with the allegations of research misconduct specific to that respondent.

- 4.2.2 If additional allegations are raised during the course of the inquiry, the respondent(s) must be promptly notified.
- 4.3 Before or at the time of the institutional notification to the respondent(s) of the allegation(s), the member must promptly take all reasonable and practical steps to:
 - 4.3.1 Obtain all research records and other evidence needed to conduct the research misconduct proceeding, which may include copies of the data or other evidence so long as those copies are substantially equivalent in evidentiary value.
 - (a) When the research records or other evidence are located on or encompass scientific instruments shared by multiple users, members may obtain copies of the data or other evidence from those instruments so long as those copies are substantially equivalent in evidentiary value to the instruments.
 - (b) Where appropriate, during the research misconduct proceedings, the respondent(s) must be given copies of, or reasonable supervised access to, the research records secured by the institution.
 - 4.3.2 Inventory the research records and other evidence, and
 - 4.3.3 Sequester the records and evidence in a secure manner. This includes examining devices and cloud storage platforms, either member owned or not.
- 4.4 The inquiry is conducted by an inquiry committee, appointed by the DO, unless otherwise described in the member rule, and must consist of no less than three individuals, with at least one individual having appropriate scientific expertise relevant to the allegation. The member will ensure that all inquiry committee members understand their charge, keep the identities of respondents, complainants, and witnesses confidential, and conduct their business in compliance with relevant regulations and oversight agency requirements, as applicable.
- 4.5 It is expected that the inquiry committee will:
 - 4.5.1 Review the allegations and available evidence.
 - 4.5.2 Interview the complainant, witnesses, and respondent(s) during the inquiry (interviews with the complainant and witnesses must not be done with the respondent present, and only one respondent at a time may be interviewed).
 - 4.5.3 Sequester additional evidence or items from the research record when they become known or relevant to the inquiry, and
 - 4.5.4 Provide notice of allegations to any newly identified respondents.
 - (a) Members are not required to conduct separate inquiries for each newly identified respondent and may choose to conduct one inquiry and investigation, if needed, for all respondents.

4.6 An investigation is warranted when:

- 4.6.1 There is a reasonable basis for concluding that the allegation continues to fall within the definition of research misconduct; and
 - 4.6.2 Preliminary information gathering and fact-finding from the inquiry indicates that the allegation may have substance and needs to be further investigated.
 - 4.6.3 If an honest error is found as the reason for the allegation of research misconduct, the inquiry may be discontinued early but a report is still required.
- 4.7 The inquiry committee will not determine if research misconduct occurred, nor assess whether the alleged misconduct was intentional, knowing, or reckless; such a determination can only be made within an investigation.
- 4.8 The member must notify the respondent whether the inquiry found that an investigation is warranted or not. The notice must include a copy of the inquiry report, along with references to any federal research misconduct regulations (e.g., 42 CFR Part 93), a copy of this regulation and the member rule. The respondent(s) must be provided with an opportunity to review and comment on the inquiry report. Their comments are to be attached to the inquiry report before providing it to the DO.
- 4.9 At the conclusion of the inquiry, a written report must be prepared and provided to the DO. The report must address whether or not the inquiry committee felt that there is the potential for honest error and differences of opinion that could be further reviewed during an investigation. The inquiry report must follow all applicable sponsor guidelines and formatting requirements, and include:
- 4.9.1 The names and positions of the respondents and complainants.
 - 4.9.2 The allegation of research misconduct reviewed.
 - 4.9.3 Details about any funding (grant numbers, grant applications, contracts, and manuscripts).
 - 4.9.4 Inquiry committee member names, positions, and subject matter expertise.
 - 4.9.5 An inventory of sequestered research records and other evidence and a description of how sequestration was conducted.
 - 4.9.6 Transcripts of interviews, as applicable.
 - 4.9.7 Timeline and procedural history.
 - 4.9.8 Any scientific or forensic analyses conducted.
 - 4.9.9 Basis for whether or not the allegations warrant further investigation, including documentation of potential evidence of honest error or difference of opinion.
 - 4.9.10 Any institutional actions implemented, including internal communications or external communications with journals or funding agencies.
 - 4.9.11 Any comments on the inquiry report by the respondent as an appendix.
 - 4.9.12 If the allegation(s) does not have substance and does not need to be further investigated, the institutional record, research record, and report are to be retained according to system Records Retention Schedule.
 - 4.9.13 If the inquiry report states that the allegation(s) has substance and needs to be further investigated, research sponsors need to be contacted according to their requirements.

5 INVESTIGATIONS OF ALLEGATIONS OF RESEARCH MISCONDUCT

- 5.1 Investigations must begin within 30 days after deciding an investigation is warranted, but not until the respondent has been notified, as marked by the date of the inquiry report, along with the attached respondent's comments, if any, and provided to the DO.
 - 5.1.1 The DO will appoint the investigation committee unless otherwise described within the member's rule. Members of the inquiry committee can serve on the investigation committee.
 - 5.1.2 Investigation committees must consist of no less than three individuals in total, inclusive of multiple people with appropriate scientific expertise relevant to the allegation.
- 5.2 Before the investigation begins:
 - 5.2.1 The RIO or DO must notify the CRCO and the OGC.
 - 5.2.2 The respondent(s) must be notified in writing of the allegations and, if applicable, any additional allegations that, due to timing, were not addressed during the inquiry.
- 5.3 If needed, additional research records and evidence may be requested in order to conduct the investigation.
- 5.4 Investigations must be thoroughly and efficiently documented and conducted in an impartial and unbiased manner. The following must be included as part of an investigation:
 - 5.4.1 All research records and evidence must be examined, although not all records or evidence may be considered relevant to reach a decision on each allegation of research misconduct.
 - 5.4.2 Each respondent, complainant, and any other available person who has been reasonably identified as having information regarding relevant aspects of the investigation, including witnesses identified by the respondent, should be interviewed. Interviews with the complainant and witnesses must not be conducted with the respondent present, and only one respondent at a time may be interviewed.
 - 5.4.3 Additional evidence or items from the research record must be sequestered when they become known or are relevant to the inquiry.
 - 5.4.4 Provide written notice and an opportunity for response to the allegations from any newly identified respondents.
 - (a) Members are not required to conduct a separate inquiry and investigation for each newly identified respondent and may choose to conduct one investigation for all respondents.

- 5.5 All significant issues and leads discovered during the course of the investigation that are determined to be relevant, including any evidence of additional instances of possible research misconduct, must be pursued. If additional allegations of research misconduct are raised during the investigation, the respondent(s) must be notified in writing of the additional allegations raised against them, including additional respondents who may be identified during the investigation.
- 5.6 Investigations are to be completed within 180 days unless circumstances warrant a longer period. If a longer period is needed, then the RIO must document the reasons for exceeding the 180-day period and include that with the investigation report.
- 5.6.1 This time period is inclusive of preparing the draft investigation report for each respondent, providing the draft report to each respondent for comment, which must be done within 150 days of initiating the investigation (see 5.7.3), if the investigation is not otherwise expected to exceed 180 days, and providing the final investigation report and decision by the DO to any research sponsors.
- 5.7 At the conclusion of the investigation, a written report must be prepared, provided to the DO, and address whether or not the investigation committee made a finding of research misconduct. If honest error is determined to be the reason for the allegation of research misconduct, the investigation may be discontinued early, but an investigation report is still required. If the investigation involved multiple respondents, separate investigation reports and research misconduct determinations are required for each respondent.
- 5.7.1 A finding of research misconduct requires that:
- (a) There was a significant departure from accepted practices of the relevant research community, and
 - (b) The misconduct was committed intentionally, knowingly, or recklessly (representing the respondent(s) state of mind when committing the act of research misconduct), and
 - (c) The allegation(s) was proven by a preponderance of the evidence.
- 5.7.2 Members have the burden of proof for making a finding of research misconduct. The destruction of research records relating to and documenting the questioned research is evidence of research misconduct, where the institution establishes by a preponderance of evidence that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegation(s). The failure of respondents to provide research records relating to and documenting the questioned research is evidence of research misconduct when the respondent claims to possess the records but refuses to provide them upon request by the RIO, investigation committee, or other institutional official.
- 5.7.3 The institution must give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the research records and other evidence that the investigation committee considered or relied on. The respondent must submit any comments on the draft report to the institution within 30 days of receiving the draft investigation report.

- (a) The investigation report must follow all applicable sponsor guidelines and formatting requirements and must include:
 - a. The specific allegation(s) of research misconduct and any additional allegation(s) addressed during the research misconduct proceedings.
 - b. Description and documentation of research support, including any grant numbers, grant applications, contracts, and publications listing research support. This documentation includes known applications or proposals for support that the respondent has pending with federal and state agencies.
 - c. Investigation committee member names, positions and subject matter expertise.
 - d. Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on. This inventory will include manuscripts and funding proposals that were considered or relied on during the investigation. The inventory will also include a description of how any sequestration was conducted during the investigation.
 - e. Transcripts of all interviews conducted.
 - f. Identification of all published papers, manuscripts submitted but not accepted for publication (including online publication), funding applications, progress reports, presentations, posters, or other research records that contain the allegedly falsified, fabricated, or plagiarized material.
 - g. Any scientific or forensic analyses conducted.
 - h. A statement for each separate allegation of whether the committee recommends a finding of research misconduct.
 - i. A copy of this regulation and member rule.
 - j. Any comments made by the respondent and complainant(s) on the draft investigation report and the committee's consideration of those comments, as an appendix.
- (b) If the committee recommends one or more findings of research misconduct, the report must include:
 - a. The identity of the individual(s) who committed the research misconduct;
 - b. Indicate whether the misconduct was falsification, fabrication, and/or plagiarism;
 - c. Indicate whether the misconduct was committed intentionally, knowingly, or recklessly;
 - d. Identify any significant departure from the accepted practices of the relevant research community, and that the allegation was proven by a preponderance of the evidence;
 - e. Summarize the facts and analysis supporting the conclusion and consider the merits of any explanation by the respondent;
 - f. Identify the specific research support; and
 - g. State whether any publications need correction or retraction.

6 DECISIONS ON ALLEGATIONS OF RESEARCH MISCONDUCT BY THE DECIDING OFFICIAL

6.1 The DO is responsible for making a final determination of whether or not there were findings of research misconduct. The decision must be in writing and include:

- 6.1.1 Based on a preponderance of the evidence, the member DO's final determination is whether to accept the investigation report, its findings, and the recommended institutional actions.
 - 6.1.1.1 If the DO's determination varies from that of the investigation committee, the DO needs to maintain documentation of a detailed explanation for the basis for rendering a decision different from that of the investigation committee. The explanation should be consistent with the PHS definition of research misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee.
 - 6.1.1.2 The DO also has the ability to return the report to the investigation committee with a request for further fact-finding or analysis.
- 6.1.2 Whether the institution found research misconduct and, if so, who committed the misconduct; and
- 6.1.3 A description of the relevant institutional actions taken or to be taken.
 - (a) In deciding what sanctions are appropriate for respondents being found to have committed research misconduct, the DO should consider the seriousness of the misconduct including, but not limited to, the degree to which the misconduct was intentional, knowing, or reckless; was an isolated event or part of a larger issue or pattern; and the impact on the research record, research subjects, or public health and welfare.
 - (b) If the actions taken by the DO are less than termination or expulsion (or recommendation of termination or expulsion, as applicable), the decision of the DO will be final unless the member has specifically provided for an appeal in its rule relating to research misconduct.
 - (c) If there is a decision to terminate the employment of the respondent, respondents who are faculty may request further review in accordance with System Policy *12.01, Academic Freedom, Responsibility, and Tenure*. Respondents who are nonfaculty employees may pursue available means of appeal as provided by *12.01* and System Regulation *32.01.02, Complaint and Appeal Process for Nonfaculty Employees*.
 - a. For the purposes of this regulation, any action regarding the respondent(s)'s employment will apply with equal force to the respondent(s)'s employment status with any other member(s).
 - (d) If there is a decision to expel a respondent who is a student, the student may request further review in accordance with the member's applicable student disciplinary rule.

7 HEALTH AND HUMAN SERVICES (HHS) OFFICE OF RESEARCH INTEGRITY (ORI) REQUIREMENTS

- 7.1 When an allegation of research misconduct is received involving research funded by an agency within the HHS, members are expected to follow research misconduct proceedings according to this regulation and 42 CFR Part 93, along with all relevant HHS ORI guidance.
- 7.2 Members must maintain an active research integrity assurance with HHS ORI, which requires annual renewal.
- 7.2.1 Maintaining an active research integrity assurance means that the member:
- (a) has written policies and procedures for addressing allegations of research misconduct that comply with 42 CFR Part 93. Written policies and procedures include this regulation, along with applicable member rules and processes, and
 - (b) complies with its policies and procedures for addressing allegations of research misconduct.
- 7.2.2 Complies with 42 CFR Part 93.
- 7.2.3 Members maintaining an active research integrity assurance are responsible for the following notifications:
- (a) Members must notify HHS ORI in advance if the institution plans to close a research misconduct proceeding at the assessment, inquiry, investigation, or appeal stage on the basis that the respondent has admitted committing research misconduct or if a settlement with the respondent has been reached. This notification must also include a statement to ORI describing how the institution determined that the scope of the misconduct was fully addressed by the admission and confirmed the respondent's culpability.
 - (b) Members must notify HHS ORI immediately if the conditions in 2.2.5 exist and if any of the following conditions exist:
 - a. HHS resources or interests are threatened.
 - b. Federal action is required to protect the interests of those involved in the research misconduct proceedings.
 - c. HHS may need to take appropriate steps to safeguard the evidence and protect the rights of those involved.
 - d. A respondent appeals a member's finding(s) of research misconduct or institutional actions imposed by the member.
- 7.2.4 On request, members must transfer custody, or provide copies, to HHS ORI of the institutional record or any component of the institutional record and any sequestered evidence so that HHS ORI may conduct its oversight review, develop the administrative record, or present the administrative record in any proceeding in 42 CFR Part 93.
- 7.2.5 The six-year time limitation described in Section 1.1.1 of this regulation does not apply if the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year period through the use of,

republication of, or citation to the portion(s) of the research record alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent (subsequent use exception).

- 7.2.6 For alleged research misconduct that appears subject to this subsequent use exception, but the member determines is not subject to the exception, the institution will document its determination that the subsequent use exception does not apply and will retain this documentation for the later of seven years after completion of the institutional proceeding or the completion of any HHS proceeding.
- 7.2.7 The six-year time limitation also does not apply if HHS ORI or the member, following consultation with HHS ORI, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.
- 7.2.8 If HHS-funded, a member cannot close the proceedings until HHS ORI is provided with the respondent's signed, written admission and a statement from the member confirming the respondent's culpability and explaining how the institution determined that the respondent's admission fully addresses the scope of misconduct.

7.3 Investigations

- 7.3.1 Members must notify HHS ORI of the decision to begin an investigation on or before the date the investigation begins and provide the inquiry report that meets the requirements of this regulation and 42 CFR Part 93.
- 7.3.2 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, should be interviewed.
 - (a) Interviews during the investigation must be recorded and transcribed (please contact OGC for further guidance regarding transcription).
 - (b) All exhibits shown to interviewees during the interview must be numbered and referred to by that number in the interview.
 - (c) The transcript of the interview must be made available to the relevant interviewee for correction.
 - (d) The transcript(s) with any corrections and numbered exhibits must be included in the institutional record of the investigation.
 - (e) The respondent must not be present during the witness interviews, but must be provided a transcript of the interview.
- 7.3.3 Members must request from HHS ORI, in writing, an extension if the investigation is unable to be completed in 180 days. Investigation reports must include the reasons for exceeding the 180-day period.

- 7.3.4 A final investigation report is required for each respondent and includes items specified in §93.313 of 42 CFR Part 93.

7.4 Decisions on Allegations of Research Misconduct by the Deciding Official

- 7.4.1 If the DO makes a decision contrary to the investigation committee's decision and recommendations, a detailed explanation of that decision needs to be included in the documentation provided to HHS ORI.
- 7.4.2 The DO's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of HHS ORI review.

8 NATIONAL SCIENCE FOUNDATION (NSF) REQUIREMENTS

- 8.1 When an allegation of research misconduct is received involving research funded by the NSF, members are expected to follow research misconduct proceedings according to this regulation and 45 CFR Part 689, along with all relevant NSF guidance.
- 8.2 NSF has the following requirements for assessments, inquiries, and allegations.
 - 8.2.1 When a member receives an allegation of research misconduct and determines through an assessment that the allegation has substance and relates to an NSF-funded activity, the subsequent inquiry must be completed within 90 days. Findings from the inquiry must be provided to NSF unless it is determined that the allegation is without substance or has no relationship to NSF.
 - 8.2.2 If an ongoing inquiry finds that at least one allegation of research misconduct warrants an investigation, the inquiry should conclude and an investigation into all of the allegations started.
 - 8.2.3 If a member receives credible evidence supporting an allegation from NSF or other reputable source such as a journal, an investigation (rather than an inquiry) should be initiated.
 - 8.2.4 When an investigation is conducted, the evidence and conclusion need to be provided to NSF.
 - 8.2.5 The NSF reserves the right to conduct its own assessment, inquiry, and investigation, rather than having the institution conduct it.

9 FEDERAL RESEARCH MISCONDUCT REQUIREMENTS

The Office of Science and Technology Policy (OSTP) published the *Federal Research Misconduct Policy* in December 2000, which is used by several federal research sponsors. This regulation and member rules are consistent with OSTP's Policy.

Related Statutes, Policies, or Requirements

[42 CFR, Part 93](#)

[45 CFR, Part 689](#)

[Federal Research Misconduct Policy \(OSTP\)](#)

Member Rule Requirements

A rule is required to supplement this regulation. See **Regulation Summary** section.

Contact Office

Research
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