SAMPLE POLICIES AND PROCEDURES FOR ADDRESSING ALLEGATIONS OF RESEARCH MISCONDUCT

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
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This guidance document is an example provided by the Department of Health and Human Services (HHS) Office of Research Integrity (ORI) to assist research institutions in developing policies and procedures as required under the 2024 Public Health Service (PHS) Policies on Research Misconduct regulation at 42 CFR Part 93. This guidance document does not create or confer rights for or on any person and does not operate to bind ORI, HHS, or the public. It also does not guarantee that ORI will find an institution compliant when addressing allegations of research misconduct. In case of any conflict between this document and 42 CFR Part 93, the regulation will prevail.

You may use an alternative approach or provide more detailed policies, procedures, or explanations if the approach satisfies the requirements of the applicable statutes and regulations. For further information, see ORI's library of guidance documents on topics related to conducting research misconduct proceedings and fostering research integrity.

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General Policies and Principles

[Institution Name] is committed to upholding the highest standards of scientific rigor in research.[1] This institution is committed to fostering an environment that promotes research integrity and the responsible conduct of research, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.[2]

All institutional members are expected to conduct research with honesty, rigor, and transparency. Each institutional member is responsible for contributing to an organizational culture that establishes, maintains, and promotes research integrity and the responsible conduct of research.

[Institution Name] strives to reduce the risk of research misconduct, support all good-faith efforts to report suspected misconduct, promptly and thoroughly address all allegations of research misconduct, and seek to rectify the scientific record and/or restore researchers' reputations, as appropriate.

Research misconduct is contrary to the interests of [Institution Name], the health and safety of the public, the integrity of research, and the conservation of public funds. Both the institution and its institutional members have an affirmative duty to protect those funds from misuse by ensuring the integrity of all research conducted on behalf of [Institution Name].[3]

[Institution Name] is responsible for ensuring that these policies and procedures for addressing allegations of research misconduct meet the requirements of the PHS Policies on Research Misconduct (42 CFR Part 93, "the PHS regulation"). The institution will establish and maintain these policies and procedures, inform all institutional members about these policies and procedures, and make these policies and procedures publicly available. [Institution Name] is committed to following these policies and procedures when responding to allegations of research misconduct.[4]

For definitions of terms used in this section and elsewhere, see the Definitions section.

Scope and Applicability

These policies and procedures apply to allegations of research misconduct involving:

1. Applications or proposals for PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training.[5]
2. PHS-supported biomedical or behavioral research.[6]
3. PHS-supported biomedical or behavioral research training programs.[7]
4. PHS-supported activities that are related to biomedical or behavorial research or research training, such as, but not limited to, the operation of tissue and data banks or the dissemination of research information.[8]
5. Research records produced during PHS-supported research, research training, or activities related to that research or research training.[9]
6. Research proposed, performed, reviewed, or reported, as well as any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in an awarded grant, contract, cooperative agreement, subaward, or other form of PHS support.[10]

These policies and procedures apply only to research misconduct occurring within six years of the date[11]HHS or [Institution Name] receives an allegation of research misconduct, subject to the following exceptions:

- The six-year time limitation 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").[12] For alleged research misconduct that appears subject to this subsequent use exception, but [Institution Name] 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.[13]
- The six-year time limitation also does not apply if ORI or [Institution Name], following consultation with 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.[14]

These policies and procedures do not supersede or establish an alternative to the PHS regulation or any existing regulations for handling research misconduct involving non-PHS supported research.[15] They do not replace the PHS regulation, and in case of any conflict between this document and 42 CFR Part 93, the PHS regulation will prevail. They are intended to enable [Institution Name] to comply with the requirements of the PHS regulation.

Definitions

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.[16]

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.[17]

Allegation. This term is a disclosure of possible research misconduct through any means of communication and brought directly to the attention of an institutional or HHS official.[18]

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.[19]

Complainant. Complainant means an individual who in good faith makes an allegation of research misconduct.[20]

Evidence. Evidence means anything offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony.[21]

Fabrication. Fabrication means making up data or results and recording or reporting them.[22]

Falsification. Falsification means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.[23]

Good faith. (a) 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. (b) 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.[24]

Inquiry. Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of § 93.307 through § 93.309.[25]

Institution. Institution means any person who applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to, colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, research institutions, and independent researchers.[26]

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.[27]

Institutional member. Institutional member and members means an individual (or individuals) who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, technicians, postdoctoral and other fellows, students, volunteers, subject matter experts, consultants, or attorneys, or employees or agents of contractors, subcontractors, or sub-awardees.[28]

Institutional record. The institutional record comprises: (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 Institutional Deciding Official, such as the written decision from the Institutional Deciding Official 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.[29]

Intentionally. To act intentionally means to act with the aim of carrying out the act.[30]

Investigation. Investigation means the formal development of a factual record and the examination of that record that meets the criteria and follows the procedures of §§ 93.310 through 93.317.[31]

Knowingly. To act knowingly means to act with awareness of the act.[32]

Plagiarism. Plagiarism means the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit. (a) Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology. (b) 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.[33]

Preponderance of the evidence. Preponderance of the evidence means proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.[34]

PHS support. PHS support means PHS funding, or applications or proposals for PHS funding, 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, or contracts; subawards, contracts, or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements, or contracts.[35]

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.[36]

Research Integrity Officer. The Research Integrity Officer (RIO) refers to the institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with 42 CFR Part 93.[37]

Research misconduct. Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.[38]

Research misconduct proceeding. Research misconduct proceeding means any actions related to alleged research misconduct taken under 42 CFR Part 93, including allegation assessments, inquiries, investigations, ORI oversight reviews, and appeals under subpart E of 42 CFR Part 93.[39]

Research record. Research record means the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are 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, and journal articles.[40]

Respondent. Respondent means the individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.[41]

Retaliation. Retaliation means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to (a) a good faith allegation of research misconduct or (b) good faith cooperation with a research misconduct proceeding.[42]

Small institution. Small institution means an institution that may be too small to conduct an inquiry or investigation into an allegation of research misconduct as required by 42 CFR Part 93 without actual or apparent conflicts of interest.[43]

Suspension and Debarment Official. Suspension and Debarment Official or SDO means the HHS official authorized to impose suspension and debarment, which are the actions that Federal agencies take to disqualify persons deemed not presently responsible from doing business with the Federal Government.[44]

Roles, Rights, and Responsibilities

Institution

[Institution Name]'s General Responsibilities

To the extent possible, the institution will limit disclosure of the identity of respondents, complainants, and witnesses while conducting the research misconduct proceedings to those who need to know, inform all institutional members about these policies and procedures, and make these policies and procedures publicly available.[45] This limitation on disclosure no longer applies once the institution has made a final determination of research misconduct findings.[46] The institution will respond to each

allegation of research misconduct under 42 CFR Part 93 in a thorough, competent, objective, and fair manner.[47] The institution will take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and other evidence.[48] The institution agrees to cooperate with ORI during any research misconduct proceeding or compliance review, including addressing deficiencies or additional allegations in the institutional record if directed by ORI and to assist in administering and enforcing any HHS administrative actions imposed on institutional members.[49] The institution may also take steps to manage published data or acknowledge that data may be unreliable.[50]

[Institution Name]'s Responsibilities During and After a Research Misconduct Proceeding

Except as may otherwise be prescribed by applicable law, the institution will maintain confidentiality for any records or evidence from which research subjects might be identified and will limit disclosure to those who need to know to carry out a research misconduct proceeding.[51] Before or at the time of notifying the respondent of the allegation(s) and whenever additional items become known or relevant, the institution will promptly take all reasonable and practical steps to obtain all research records and other evidence and sequester them securely.[52] The institution will ensure that the institutional record contains all required elements, i.e., research records that were compiled and considered during the proceedings, assessment documentation, and inquiry and/or investigation reports. Upon completion of the inquiry, the institution will provide ORI with the complete inquiry report and add it to the institutional record.[53] The institution will maintain the institutional record and all sequestered research records and other evidence in a secure manner for seven years after completion of the institutional and/or HHS proceeding.[54]

The institution will provide information related to the alleged research misconduct and proceedings to ORI upon request and transfer custody or provide copies of the institutional record or any component of it and any sequestered evidence to HHS, regardless of whether the evidence is included in the institutional record.[55] Additionally, the institution will promptly notify ORI of any special circumstances that may arise.[56]

Disclosure of the identity of respondents, complainants, and witnesses while the institution is conducting the research misconduct proceedings is limited to those who need to know, which the institution will determine consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions.[57]

[Institution Name]'s Responsibilities to the Complainant(s)

The institution will provide confidentiality consistent with 42 CFR Part 93 for all complainants in a research misconduct proceeding. The institution will also take precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have potential, perceived, or actual personal, professional, or financial conflicts of interest with the complainant(s).[58] The institution agrees to take all reasonable and practical steps to protect the positions and reputations of complainants and to protect these individuals from retaliation by respondents and/or other institutional members.[59] If [Institution Name] chooses to notify one complainant of the inquiry results in a case, all complainants will be notified by the institution, to the extent possible.[60]

[Institution Name]'s Responsibilities to the Respondent(s)

As with complainants, the institution will provide confidentiality consistent with 42 CFR Part 93 to all respondents in a research misconduct proceeding. The institution will make a good-faith effort to notify the respondent(s) in writing of the allegations being made against them. [61] The institution will take precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the respondent.[62] The institution is responsible for giving the respondent(s) copies of or supervised access to the sequestered research records.[63] The institution will notify the respondent whether the inquiry found that an investigation is warranted, provide the respondent an opportunity to review and comment on the inquiry report, and attach their comments to the inquiry report.[64] If an investigation is commenced, the institution must notify the respondent, give written notice of any additional allegations raised against them not previously addressed by the inquiry report, and allow the respondent(s) an opportunity to review the witness transcripts. [65] The institution will give the respondent(s) an opportunity to read and comment on the draft investigation report and any information or allegations added to the institutional record.[66] The institution will give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.[67]

The institution will bear the burden of proof, by a preponderance of the evidence, for making a finding of research misconduct.[68] The institution will make all reasonable, practical efforts, if requested and as appropriate, to protect or restore the reputation of respondents against whom no finding of research misconduct is made.[69]

[Institution Name]'s Responsibilities to Committee Members

The institution will ensure that a committee, consortium, or person acting on the institution's behalf conducts research misconduct proceedings in compliance with the PHS regulation. The institution will take all reasonable and practical steps to protect the positions and reputations of good-faith committee members and to protect these individuals from retaliation.[70]

[Institution Name]'s Responsibilities to the Witness[es]

The institution will provide confidentiality consistent with 42 CFR Part 93 for all witnesses. The institutions will take precautions to ensure that individuals responsible for carrying out any part of the proceedings do not have unresolved personal, professional, or financial conflicts of interest with the witnesses.[71] The institutions will also take all reasonable and practical steps to protect the positions and reputations of witnesses and to protect these individuals from retaliation.[72]

Research Integrity Officer

The Research Integrity Officer (RIO) is the institutional official responsible for administering [Institution Name]'s written policies and procedures for addressing allegations of research misconduct in compliance with the PHS regulation.[73] The same individual will not serve as both the Institutional Deciding Official and the RIO.[74] The institution may choose to have the RIO or another designated institutional official conduct the inquiry in lieu of a committee, and, if needed, this individual may utilize one or more subject matter experts to assist them in the inquiry.[75]

Upon receiving an allegation of research misconduct, the RIO or another designated institutional official will promptly assess the allegation to determine whether the allegation (a) is within the definition of research misconduct under the PHS regulation, (b) is within the applicability criteria of the regulation at § 93.102, and (c) is sufficiently credible and specific so that potential evidence of research misconduct may be identified.[76] If the RIO or another designated institutional official determines that the requirements for an inquiry are met, they shall document the assessment, promptly sequester all research records and other evidence per the PHS regulation, and promptly initiate the inquiry.[77] If the RIO or another designated institutional official determines that requirements for an inquiry are not met, they will keep sufficiently detailed documentation of the assessment to permit a later review by ORI of the reasons why [Institution Name] did not conduct an inquiry.[78] The institution will keep this documentation and related records in a secure manner for seven years and provide them to ORI upon request.[79]

Complainant

The complainant is the person who in good faith makes an allegation of research misconduct.[80] The complainant brings research misconduct allegations directly to the attention of an institutional or HHS official through any means of communication.

The complainant will make allegations in good faith, as it is defined in the PHS regulation, as having a reasonable belief in the truth of one's allegation or testimony, based on the information known to the complainant at the time.[81]

Respondent

The respondent is the individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.[82] The respondent has the burden of going forward with and proving, by a preponderance of evidence, affirmative defenses raised.[83] The respondent's destruction of research records documenting the questioned research is evidence of research misconduct where a preponderance of evidence establishes that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations.[84] The respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request.[85]

The respondent will not be present during the witnesses' interviews but will be provided a transcript of the interview after it takes place.[86] The respondent will have opportunities to (a) view and comment on the inquiry report, (b) view and comment on the investigation report, and (c) submit any comments on the draft investigation report to [Institution Name] within 30 days of receiving it.[87]

If admitting to research misconduct, the respondent will sign a written statement specifying the affected research records and confirming the misconduct was falsification, fabrication, and/or plagiarism; committed intentionally, knowingly, or recklessly; and a significant departure from accepted practices of the relevant research community.[88]

Committee and Consortium Members

Committee members (and consortium members where applicable) are experts who act in good faith to cooperate with the research misconduct proceedings by impartially carrying out their assigned duties for the purpose of helping [Institution Name] meet its responsibilities under 42 CFR Part 93.[89] Committee and consortium members will have relevant scientific expertise and be free of real or perceived conflicts of interest with any of the involved parties.[90]

Committee or consortium members or anyone acting on behalf of [Institution Name] will conduct research misconduct proceedings consistent with the PHS regulation. They will determine whether an investigation is warranted, documenting the decision in an inquiry report.[91] During an investigation, committee or consortium members participate in recorded interviews of 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(s).[92] They will also determine whether or not the respondent(s) engaged in research misconduct and document the decision in the investigation report.[93] They consider respondent and/or complainant comments on the inquiry/investigation report(s) and document that consideration in the investigation report.[94]

An investigation into multiple respondents may convene with the same investigation committee or consortium members or anyone acting on behalf of [Institution Name], but there will be separate investigation reports and separate research misconduct determinations for each respondent.[95] Committee or consortium members may serve for more than one investigation, in cases with multiple respondents.[96] Committee members may also serve for both the inquiry and the investigation.

Witnesses

Witnesses are people whom [Institution Name] has reasonably identified as having information regarding any relevant aspects of the investigation. Witnesses provide information for review during research misconduct proceedings. Witnesses will cooperate with the research misconduct proceedings in good faith and have a reasonable belief in the truth of their testimony, based on the information known to them at the time.[97]

Institutional Deciding Official

The Institutional Deciding Official (IDO) makes the final determination of research misconduct findings.[98] The IDO cannot serve as the RIO.[99] The IDO documents their determination in a written decision that includes whether research misconduct occurred, and if so, what kind and who committed it, and a description of the relevant actions [Institution Name] has taken or will take.[100] The IDO's written decision becomes part of the institutional record.[101]

Procedures for Addressing Allegations of Research Misconduct

Assessment

An assessment's purpose is to determine whether an allegation warrants an inquiry.[102] An assessment is intended to be a review of readily accessible information relevant to the allegation.[103]

Upon receiving an allegation of research misconduct, the RIO or another designated institutional official will promptly determine whether the allegation (a) falls within the definition of research misconduct, (b) is within the applicability criteria of 42 CFR Part 93 § 93.102, and (c) is credible and specific enough to identify and sequester potential evidence.[104]

If the RIO or another institutional official determines that the allegation meets these three criteria, they will promptly: (a) document the assessment and (b) initiate an inquiry and sequester all research records and other evidence.[105] The RIO or other institutional official must document the assessment and retain the assessment documentation securely for seven years after completion of the misconduct proceedings.[106] If the RIO or another institutional official determines that the alleged misconduct does not meet the criteria to proceed to an inquiry, they will write sufficiently detailed documentation to permit a later review by ORI of why [Institution Name] did not proceed to an inquiry and securely retain this documentation for seven years.[107]

Inquiry

An inquiry is warranted if the allegation (a) falls within the definition of research misconduct under 42 CFR Part 93, (b) is within the applicability criteria of § 93.102, and (c) is sufficiently credible and specific so that potential evidence of research misconduct may be identified.[108] An inquiry's purpose is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation.[109] An inquiry does not require a full review of all related evidence.[110] [Institution Name] will complete the inquiry within 90 days of initiating it unless circumstances warrant a longer period, in which it will sufficiently document the reasons for exceeding the time limit in the inquiry report.[111]

Sequestering Evidence and Notifying the Respondent

Before or at the time of notifying the respondent(s), [Institution Name] will obtain the original or substantially equivalent copies of all research records and other evidence that are pertinent to the proceeding, inventory these materials, sequester the materials in a secure manner, and retain them for seven years.[112] The institution has a duty to obtain, inventory, and securely sequester evidence that extends to whenever additional items become known or relevant to the inquiry or investigation.[113]

At the time of or before beginning the inquiry, [Institution Name] will make a good-faith effort to notify the presumed respondent(s), in writing, that an allegation(s) of research misconduct has been raised against them, the relevant research records have been sequestered, and an inquiry will be conducted to decide whether to proceed with an investigation.[114] If additional allegations are raised, the institution

will notify the respondent(s) in writing.[115] When appropriate, the institution will give the respondent(s) copies of, or reasonable supervised access to, the sequestered materials.[116]

If additional respondents are identified, [Institution Name] will provide written notification to the new respondent(s).[117] All additional respondents will be given the same rights and opportunities as the initial respondent.[118] Only allegations specific to a particular respondent will be included in the notification to that respondent.[119]

Convening the Committee and Ensuring Neutrality

[Institution Name] will ensure that all inquiry committee members understand their commission, keep the identities of respondents, complainants, and witnesses confidential, and conduct the research misconduct proceedings in compliance with the PHS regulation. In lieu of a committee, the institution may task the RIO or another designated institutional official to conduct the inquiry, provided this person utilizes subject matter experts as needed to assist in the inquiry.[120]

Determining Whether an Investigation Is Warranted

The inquiry committee, RIO, or other designated institutional official will conduct a preliminary review of the evidence.[121] In the process of fact-finding, the inquiry committee may interview the respondent and/or witnesses.[122] An investigation is warranted if (a) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under 42 CFR Part 93 and involves PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, as provided in § 93.102; and (b) preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance.[123]

The inquiry committee will not determine if research misconduct occurred, nor assess whether the alleged misconduct was intentional, knowing, or reckless; such a determination is not made until the case proceeds to an investigation.[124]

Documenting the Inquiry

At the conclusion of the inquiry, regardless of whether an investigation is warranted, the inquiry committee, RIO, or other designated institutional official will prepare a written inquiry report. The contents of a complete inquiry report will include:

1. The names, professional aliases, and positions of the respondent and complainant(s).
2. A description of the allegation(s) of research misconduct.
3. Details about the PHS funding, including any grant numbers, grant applications, contracts, and publications listing PHS support.
4. The composition of the inquiry committee, if used, including name(s), position(s), and subject matter expertise.
5. An inventory of sequestered research records and other evidence and description of how sequestration was conducted.
6. Transcripts of interviews, if transcribed.
7. Inquiry timeline and procedural history.
8. Any scientific or forensic analyses conducted.

9. The basis for recommending that the allegation(s) warrant an investigation.
10. The basis on which any allegation(s) do not merit further investigation.
11. Any comments on the inquiry report by the respondent or the complainant(s).
12. Any institutional actions implemented, including internal communications or external communications with journals or funding agencies.[125]
13. Documentation of potential evidence of honest error or difference of opinion.[126]

Completing the Inquiry

[Institution Name] will give the respondent a copy of the draft inquiry report for review and comment.[127] The institution may, but is not required to, provide relevant portions of the report to a complainant for comment.[128]

[Institution Name] will notify the respondent of the inquiry's final outcome and provide the respondent with copies of the final inquiry report, the PHS regulation, and these policies and procedures.[129] The institution may, but is not required to, notify a complainant whether the inquiry found that an investigation is warranted.[130] If the institution provides notice to one complainant in a case, it must provide notice, to the extent possible, to all complainants in the case.[131]

If an Investigation Is Not Warranted:

If the inquiry committee, RIO, or other designated institutional official determines that an investigation is not warranted, [Institution Name] will keep sufficiently detailed documentation to permit a later review by ORI of why the institution did not proceed to an investigation, store these records in a secure manner for at least seven years after the termination of the inquiry, and provide them to ORI upon request. [132]

If an Investigation is Warranted:

If the inquiry committee, RIO, or other designated institutional official determines that an investigation is warranted, [Institution Name] must: (a) within a reasonable amount of time after this decision, provide written notice to the respondent(s) of the decision to conduct an investigation of the alleged misconduct, including any allegations of research misconduct not addressed during the inquiry;[133] and (b) within 30 days of determining that an investigation is warranted, provide ORI with a copy of the inquiry report.[134]

On a case-by-case basis, [Institution Name] may choose to notify the complainant that there will be an investigation of the alleged misconduct but is required to take the same notification action for all complainants in cases where there is more than one complainant.[135]

Investigation

The purpose of an investigation is to formally develop a factual record, pursue leads, examine the record, and recommend finding(s) to the IDO, who will make the final decision, based on a preponderance of evidence, on each allegation and any institutional actions.[136] As part of its investigation, the institution will pursue diligently all significant issues and relevant leads, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.[137] Within 30

days after deciding an investigation is warranted, [Institution Name] will notify ORI of the decision to investigate and begin the investigation.[138]

Notifying the Respondent and Sequestering Evidence

[Institution Name] will notify the respondent(s) of the allegation(s) within 30 days of determining that an investigation is warranted and before the investigation begins.[139] If any additional respondent(s) are identified during the investigation, the institution will notify them of the allegation(s) and provide them an opportunity to respond consistent with the PHS regulation.[140] If the institution identifies additional respondents during the investigation, it may choose to either conduct a separate inquiry or add the new respondent(s) to the ongoing investigation.[141] The institution will obtain the original or substantially equivalent copies of all research records and other evidence, inventory these materials, sequester them in a secure manner, and retain them for seven years after its proceeding or any HHS proceeding, whichever is later.[142]

Convening an Investigation Committee

After vetting investigation committee members for conflicts of interest and appropriate scientific expertise, the [Institution Name] will convene the committee and ensure that the members understand their responsibility to conduct the research misconduct proceedings in compliance with the PHS regulation.[143] The investigation committee will conduct interviews, pursue leads, and examine all research records and other evidence relevant to reaching a decision on the merits of the allegation(s).[144] The institution will use diligent efforts to ensure that the investigation is thorough, sufficiently documented, and impartial and unbiased to the maximum extent practicable.[145] The institution will notify the respondent in writing of any additional allegations raised against them during the investigation.[146]

Conducting Interviews

[Institution Name] will interview each respondent, complainant(s), 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.[147] The institution will number all relevant exhibits and refer to any exhibits shown to the interviewee during the interview by that number.[148] The institution will record and transcribe interviews during the investigation and make the transcripts available to the interviewee for correction.[149] The institution will include the transcript(s) with any corrections and exhibits in the institutional record of the investigation.[150] The respondent will not be present during the witnesses' interviews, but the institution will provide the respondent with a transcript of each interview, with redactions as appropriate to maintain confidentiality.[151]

Documenting the Investigation

[Institution Name] will complete all aspects of the investigation within 180 days.[152] The institution will conduct the investigation, prepare the draft investigation report for each respondent, and provide the opportunity for respondents to comment.[153] The institution will document the IDO's final decision and transmit the institutional record (including the final investigation report and IDO's decision) to ORI.[154] If the investigation takes more than 180 days to complete, the institution will ask ORI in writing for an extension and document the reasons for exceeding the 180-day period in the investigation report.[155]

The investigation report for each respondent will include:

1. Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.
2. Description and documentation of the PHS support, including any grant numbers, grant applications, contracts, and publications listing PHS support. This documentation includes known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.
3. Description of the specific allegation(s) of research misconduct for consideration in the investigation of the respondent.
4. Composition of investigation committee, including name(s), position(s), and subject matter expertise.
5. Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on.[156] 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.
6. Transcripts of all interviews conducted.
7. Identification of 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 contain the allegedly falsified, fabricated, or plagiarized material.
8. Any scientific or forensic analyses conducted.
9. A copy of these policies and procedures.
10. Any comments made by the respondent and complainant(s) on the draft investigation report and the committee's consideration of those comments.
11. A statement for each separate allegation of whether the committee recommends a finding of research misconduct.[157]

If the committee recommends a finding of research misconduct for an allegation, the investigation report will present a finding for each allegation. These findings will (a) identify 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 PHS support; and (g) state whether any publications need correction or retraction.[158]

If the investigation committee does *not* recommend a finding of research misconduct for an allegation, the investigation report will provide a detailed rationale for its conclusion.[159]

The investigation committee should also provide a list of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.[160]

Completing the Investigation

[Institution Name] will 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.[161] The respondent will submit any comments on the draft report to the institution within 30 days of receiving the draft investigation report.[162] If [Institution Name] chooses to share a copy of the draft investigation report or relevant portions of it with the complainant(s) for comment, the complainant's comments will be submitted within 30 days of the date on which they received the report.[163] The institution will add any comments received to the investigation report.[164]

IDO Review of the Investigation Report

The IDO will review the investigation report and make a final written determination of whether the institution found research misconduct and, if so, who committed the misconduct.[165] In this statement, the IDO will include a description of relevant institutional actions taken or to be taken.[166]

Creating and Transmitting the Institutional Record

After the IDO has made a final determination of research misconduct findings, [Institution Name] will add the IDO's written decision to the investigation report and organize the institutional record in a logical manner.[167]

The institutional record consists of the records that were compiled or generated during the research misconduct proceeding, except records the institution did not rely on.[168] These records include documentation of the assessment, a single index listing all research records and evidence, the inquiry report and investigation report, and all records considered or relied on during the investigation.[169] The institutional record also includes the IDO's final decision and any information the respondent provided to the institution.[170] The institutional record must also include a general description of the records that were sequestered but not considered or relied on.[171]

If the respondent filed an appeal, the complete record of any institutional appeal also becomes part of the institutional record.[172] For institutions with an internal appeals process, the [Institution Name] will wait until the appeal is concluded to transmit the institutional record to ORI.[173] After the IDO has made a final written determination, and any institutional appeal is complete, the institution must transmit the institutional record to ORI.[174]

Other Procedures and Special Circumstances

Multiple Institutions and Multiple Respondents

If the alleged research misconduct involves multiple institutions, [Institution Name] may work closely with the other affected institutions to determine whether a joint research misconduct proceeding will be conducted.[175] If so, the cooperating institutions will choose an institution to serve as the lead institution. In a joint research misconduct proceeding, the lead institution will obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions.[176] By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved.[177] The determination of whether further inquiry and/or

investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.[178]

If the alleged research misconduct involves multiple respondents, [Institution Name] may either conduct a separate inquiry for each new respondent or add them to the ongoing proceedings.[179] The institution must give additional respondent(s) notice of and an opportunity to respond to the allegations.[180]

Respondent Admissions

[Institution Name] will promptly notify ORI in advance if at any point during the proceedings (including the assessment, inquiry, investigation, or appeal stage) it plans to close a research misconduct case because the respondent has admitted to committing research misconduct or a settlement with the respondent has been reached.[181] If the respondent admits to research misconduct, the institution will not close the case until providing ORI with the respondent's signed, written admission. [182] The admission must state the specific fabrication, falsification, or plagiarism that occurred, which research records were affected, and that it constituted a significant departure from accepted practices of the relevant research community.[183] The institution must not close the case until giving ORI a written statement confirming the respondent's culpability and explaining how the institution determined that the respondent's admission fully addresses the scope of the misconduct.[184]

Other Special Circumstances

At any time during the misconduct proceedings, [Institution Name] will immediately notify ORI if any of the following circumstances arise:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
2. HHS resources or interests are threatened.
3. Research activities should be suspended.
4. There is reasonable indication of possible violations of civil or criminal law.
5. Federal action is required to protect the interests of those involved in the research misconduct proceeding.
6. HHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved.[185]

Records Retention

[Institution Name] will maintain the institutional record and all sequestered evidence, including physical objects (regardless of whether the evidence is part of the institutional record), in a secure manner for seven years after the completion of the proceeding or the completion of any HHS proceeding, whichever is later, unless custody has been transferred to HHS.[186]

[1] Throughout these sample Policies and Procedures, ORI has made use of extensive endnotes citing to the regulations at 42 CFR Part 93 in order to serve as a reference to Institutions, and to enable them to see the

regulatory language behind this sample document. Institutions may choose, but are not required, to replicate this approach in their own documents.

[2] 42 CFR Part 93 § 93.300(c).
[3] § 93.100.
[4] § 93.300(a).
[5] § 93.102(b)(1).
[6] § 93.102(b)(2).
[7] § 93.102(b)(3).
[8] § 93.102(b)(4).
[9] § 93.102(b)(5).
[10] § 93.102(b)(6).
[11] § 93.104(a).
[12] § 93.104(b)(1).
[13] §§ 93.104(b)(1) and 93.318.
[14] § 93.104(b)(2).
[15] § 93.102(c).
[16] § 93.200.
[17] § 93.202.
[18] § 93.203.
[19] § 93.204.
[20] § 93.206.
[21] § 93.210.
[22] § 93.211.
[23] § 93.212.
[24] § 93.214.
[25] § 93.215.
[26] § 93.216.
[27] § 93.218.
[28] § 93.219.
[29] § 93.220.
[30] § 93.221.
[31] § 93.222.
[32] § 93.223.
[33] § 93.227.
[34] § 93.228.
[35] § 93.230.
[36] § 93.231.
[37] § 93.233.
[38] § 93.234.
[39] § 93.235.
[40] § 93.236.
[41] § 93.237.
[42] § 93.238.
[43] § 93.240.
[44] § 93.241.
[45] §§ 93.106(a) and 93.302(a)(4)(ii).
[46] § 93.106(a)
[47] § 93.241.
[48] § 93.300(f).

[49] § 93.300(g-h).
[50] § 93.106(c).
[51] § 93.106(b). Applicable to all confidentiality requirements in this section.
[52] § 93.305.
[53] §§ 93.317 and 93.220.
[54] § 93.318.
[55] § 93.318(b).
[56] § 93.305(g).
[57] § 93.106(a).
[58] §§ 93.300(b) and 93.305(f)(1).
[59] § 93.300(d).
[60] § 93.308(b).
[61] § 93.307(c).
[62] § 93.300(b).
[63] § 93.305(b).
[64] §§ 93.308(a) and 93.307(g).
[65] §§ 93.310(c) and 93.310(g)(5).
[66] § 93.312.
[67] § 93.105(b).
[68] §§ 93.105 and 93.103(c).
[69] §§ 93.105 and 93.304(c).
[70] §§ 93.305(f) and 93.300(d).
[71] § 93.300(b).
[72] § 93.300(d).
[73] § 93.233.
[74] § 93.218.
[75] § 93.307(e)(2).
[76] § 93.306(b).
[77] § 93.306(c).
[78] § 93.306(c)(3).
[79] § 93.318.
[80] § 93.206.
[81] § 93.214.
[82] § 93.237.
[83] §§ 93.105(b)(2) and 93.105(b)(3).
[84] § 93.105(b)(1).
[85] § 93.105(b).
[86] § 93.310(g)(5).
[87] §§ 93.307(g)(3) and 93.312.
[88] §§ 93.103 and 93.317(b).
[89] § 93.214(b).
[90] § 93.305(f).
[91] § 93.307.
[92] § 93.310(g).
[93] § 93.313.
[94] § 93.313(j).
[95] § 93.310(c)(3).
[96] § 93.305(d).
[97] § 93.214(a).

[98] § 93.218.
[99] § 93.218.
[100] § 93.314.
[101] § 93.220(a)(4).
[102] § 93.306(a).
[103] § 93.204.
[104] § 93.306(b-c).
[105] §§ 93.306(b) and 93.306(c).
[106] §§ 93.306(c)(2) and 93.318.
[107] §§ 93.306(c)(3) and 93.318.
[108] § 93.307(a)(1-3).
[109] § 93.307(b).
[110] Id.
[111] § 93.307(h).
[112] §§ 93.305(a) and 93.318.
[113] §§ 93.305(a)(2) and 93.318.
[114] § 93.307(c).
[115] § 93.307(c).
[116] § 93.305(b).
[117] § 93.305(d).
[118] Id.
[119] § 93.307(c).
[120] § 93.307(e)(2).
[121] § 93.307(b).
[122] § 93.307(e)(3).
[123] § 93.307(f)(i-ii).
[124] § 93.307(f)(ii)(2).
[125] § 93.309(a)(1-12).
[126] § 93.307(g)(2).
[127] § 93.307g(3).
[128] § 93.308(b).
[129] § 93.308(a).
[130] § 93.308(b).
[131] Id.
[132] § 93.309(c).
[133] § 93.308(a).
[134] § 93.309(a).
[135] § 93.308(b).
[136] §§ 93.310 and 93.314.
[137] § 93.310(j).
[138] § 93.310(a-b).
[139] § 93.310(a-c).
[140] § 93.310(c)(2).
[141] §§ 93.310(c)(2) and 93.310(c)(3).
[142] § 93.318.
[143] § 93.310(f).
[144] § 93.310.
[145] § 93.310(f).
[146] § 93.310(c)(1).

[147] § 93.310(g).
[148] § 93.310(g)(2).
[149] §§ 93.310(g)(1) and 93.310(g)(3).
[150] § 93.310(g)(4).
[151] §§ 93.106, 93.300(d), and 93.310(g)(5). Institutions must, to the extent possible, provide confidentiality to respondents, complainants, and witnesses and protect complainants, witnesses, and committee members from retaliation. It is up to institutions to determine how to do so in practical terms (e.g., by redacting transcripts).
[152] § 93.311(a).
[153] § 93.312.
[154] § 93.316.
[155] § 93.311(b).
[156] § 93.313(e).
[157] § 93.313(a-k).
[158] § 93.313(k)(1)(i-vii).
[159] § 93.313(k)(2).
[160] § 93.313(k)(3).
[161] § 93.312(a).
[162] Id.
[163] § 93.312(b).
[164] § 93.313(j).
[165] § 93.314(a).
[166] § 93.314(b).
[167] §§ 93.220(a)(4) and 93.316.
[168] § 93.220.
[169] §§ 93.220(a)(1-3) and 93.220(b).
[170] § 93.220(a)(3-4).
[171] § 93.220(c).
[172] § 93.220(5).
[173] § 93.315(b).
[174] § 93.316.
[175] § 93.305(e).
[176] Id.
[177] Id.
[178] Id.
[179] § 93.305(d).
[180] Id.
[181] § 93.317(a).
[182] § 93.317(b).
[183] §§ 93.103 and 93.317(b).
[184] § 93.317(b).
[185] § 93.305(g)(1-6).
[186] § 93.318.