

**Hennepin Healthcare Research Institute
Administrative Policies and Procedures
for Dealing with Misconduct in
Research**

Approved May 23, 1990

Revised May 6, 2015

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Revised December 22, 2025

INTRODUCTION

Fraud in research and other scholarly activities undermines the research enterprise in ways that go far beyond the waste of public funds. Although a rare event relative to the large research literature, occasional violations inevitably appear in this as in all human pursuits. As a leading research institution, the Hennepin Healthcare Research Institute (HHRI or Institute) has a major responsibility, not only to provide an environment that promotes integrity, but also to establish and enforce policies and procedures that deal effectively with allegations or evidence of fraud. This policy contains elements designed to support HHRI's general compliance responsibilities as outlined in the Department of Health and Human Services (DHHS) Research Integrity's 2024 Final Rule on Research Misconduct (42 CFR Part 93) attached hereto for reference as Appendix I.

HHRI expects the utmost professionalism from its employees in all circumstances. HHRI researchers may not engage in actions which constitute fraud in research or other scholarly activities. The scholarly and research community are totally committed to the principles of this policy. This policy addresses research misconduct as defined by the Final Rule mentioned above and is not intended to address all potential behavior and performance issues related to the work conducted by HHRI researchers. Other institutional policies addressing compliance requirements and codes of conduct also govern the conduct of research at HHRI and questions raised through this policy may have other applicable consequences and/or remedies.

In dealing with this problem, it is important not to create an atmosphere that might discourage openness and creativity. Good and innovative science cannot flourish in an atmosphere of heavy regulation. Moreover, it is particularly important to distinguish fraud from honest error and the ambiguities of interpretation that are inherent in the research process and are normally corrected by further research.

If an allegation is raised, HHRI has the following procedures: (I) to conduct an assessment to determine whether the allegation is sufficiently credible and specific to warrant an inquiry; (II) when warranted by the initial assessment, to initiate an inquiry to determine whether the allegation or related issues warrant further formal investigation; (III) when warranted by the initial inquiry, to initiate a formal investigation to collect and thoroughly examine evidence; (IV) to provide a formal written report detailing the findings of the inquiry/investigation; and (V) to recommend appropriate disposition of the matter. Throughout these five stages, the process shall be guided by the following principles:

- ☐ HHRI shall take care that the process pursued to resolve allegations of fraud does not damage science itself.
- ☐ HHRI shall provide rigorous leadership in the pursuit and resolution of all charges.

- HHRI shall strive to treat all parties with justice and fairness and shall be sensitive to their positions, reputations and vulnerabilities. This includes providing all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.
- HHRI procedures shall strive to preserve the highest attainable degree of confidentiality, consistent with thorough, competent, objective and fair proceedings. To the extent possible, disclosure of information about proceedings will be limited to only those who have a need to know to carry out their responsibilities.
- The integrity of HHRI processes shall be maintained by taking precautions to ensure no individuals involved in the proceedings have any unresolved personal, professional, or financial conflicts of interest.
- HHRI procedures shall be as expeditious as possible, and the resolution of charges shall be completed in a timely manner and take all reasonable and practical steps to ensure cooperation of respondents and other institutional members
- HHRI shall document the pertinent facts and actions at each stage, and use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and other evidence relevant to reaching a decision on the merits of the allegation(s)
- HHRI shall recognize and discharge its responsibilities after resolving allegations of research misconduct internally, to individuals involved; and externally, to the public, sponsors of research, the research literature, and the research community, to the extent that is appropriate and allowable. This includes cooperating with the DHHS, as applicable, in addressing any identified deficiencies and administering and/or enforcing any DHHS administrative actions.
- HHRI shall also: (1) provide education about research misconduct; (2) interpret the HHRI policy on research misconduct; (3) counsel faculty and staff; and (4) disseminate the policy.
- HHRI shall take all reasonable and practical steps necessary to collect, inventory, and securely sequester and maintain all research records and other evidence needed to conduct the research misconduct proceeding. If requested and appropriate, respondent will be granted reasonable supervised access to the research records that are sequestered in the proceeding and copies will be provided to DHHS if DHHS has purview and determines that an independent investigation is warranted. Records related to misconduct proceedings will be retained in a secure manner for a minimum of seven years following the completion of a proceeding, or seven years from the completion of any related DHHS proceeding if one is initiated.
- HHRI has the burden of proof for making a finding of research misconduct, which must be proved by a preponderance of the evidence. The respondent has the burden of going forward with and proving, by a preponderance of the evidence, all affirmative defenses raised and any mitigating factors relevant to a decision to impose administrative actions after a research misconduct proceeding.

APPLICABILITY

The policy and procedures set forth herein shall apply to all HHRI employees and researchers engaged in research and other scholarly activities under the aegis of HHRI. Copies of this policy and procedures will be provided to all HHRI researchers and HHRI employees as part of their employment information. All investigators conducting research under the auspices of HHRI and their staff will receive written notification and be required to sign to the effect that they have read and understood the policy and procedures.

DEFINITION OF RESEARCH MISCONDUCT

Research misconduct is an act of deception. It means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. It does not include honest error or differences of opinion. It is different from those factors intrinsic to the process of science, conflicting data, or differences in interpretation or judgments about data. The term research misconduct is used here to include a broad range of deceptive practices, including the following:

1. Falsification of Data -- 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.
2. Fabrication of Data -- Fabrication means making up data or results and recording or reporting them.
3. Plagiarism -- the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit.
4. Other practices that intentionally, knowingly, or recklessly represent a significant departure from those that are commonly accepted within the relevant research community for proposing, conducting or reporting research including, for example, the misappropriation of others' ideas -- unauthorized use of privileged information (such as violation of confidentiality in peer review), however obtained.

PROCESS FOR HANDLING ALLEGATIONS OF RESEARCH MISCONDUCT

GENERAL PRINCIPLES

The responsibility to pursue an allegation of research misconduct belongs to HHRI and shall be carried out fully to resolve questions regarding integrity of the research. Even in the absence of a specific complaint, HHRI shall be alert to questionable academic conduct that might raise legitimate suspicion of fraudulent research. In an assessment, inquiry and any investigation which may follow, HHRI shall focus on the substance of the issues and shall be vigilant not to permit any personal conflicts between colleagues to obscure the facts.

In order to address all allegations of research misconduct expeditiously, HHRI shall designate a committee of senior administrators to whom allegations shall be reported; ordinarily, the

President of HHRI and the Chair of the investigator's primary department will be included.

The President will counsel confidentially any individual who comes forward with an allegation of research misconduct and will perform an assessment to determine whether the allegation falls within the scope of the misconduct policies and procedures. Regardless of the nature of the concern, the President will seek to assist in the resolution of the allegation through whatever institutional processes are appropriate. If the President determines that the concern is properly addressed by the policies and procedures set forth herein, specific policies and procedures relating to the inquiry and investigation will be discussed with the individual who has questions about the integrity of a research project. Once these discussions are completed, the committee of senior administrators as outlined above will be convened. If the individual chooses not to make a formal allegation, but the President believes there is sufficient cause to warrant an inquiry, the matter shall be pursued by the President in consultation with the committee members outlined above. Even if the respondent leaves the Institute before the case is resolved, HHRI has a responsibility to continue the examination of the allegations and reach a conclusion. Further, HHRI shall cooperate with another institution's process to resolve such questions if an allegation involves multiple institutions.

The Institute will secure the necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any assessment, inquiry or investigation. As appropriate, the Institute will take interim administrative actions to protect both Federal and non-Federal funds and to ensure that the purposes of the Federal financial assistance are carried out.

The Institute will strive to carry out its investigations through to completion and to pursue diligently all significant issues. If it plans to terminate an inquiry or investigation involving any Public Health Service (PHS) related research for any reason without completing all the requirements identified in Title 42, Subchapter D of the Code of Federal Regulations, Section 50.103 (d), it shall make a report of such planned termination, including a description of the reasons for such termination, to the ORI, which will then decide whether further investigation should be undertaken.

The Institute will notify the ORI if it ascertains at any stage of an assessment, inquiry or investigation involving PHS-related research that any of the following conditions exist:

1. There is an immediate health hazard involved, including an immediate need to protect human or animal subjects;
2. There is an immediate need to protect Federal resources or interests;
3. There is an immediate need to protect the interests of person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
4. It is probable that the alleged incident is going to be reported publicly; and
5. There is a reasonable indication of possible criminal violation. In this instance, the Institute will inform the ORI within 24 hours of obtaining such information.
6. There is a need to suspend PHS-related research.

Additionally, the Institute recognizes the right of the DHHS to perform its own investigation at any time prior to, during, or following the Institute's investigation.

I. INSTITUTIONAL ASSESSMENT

The purpose of an assessment is to determine whether an allegation warrants an inquiry. Upon receiving an allegation of research misconduct, the matter will be referred to the HHRI President who will promptly assess the allegation to determine whether the allegation falls within the definition of research misconduct and is sufficiently credible and specific to permit potential evidence of research misconduct to be identified. The assessment will be documented with sufficient detail to permit a later review by the ORI if requested, and if the allegation is substantiated, the President will promptly initiate an inquiry.

II. INSTITUTIONAL INQUIRY

A. Purpose

Whenever an assessment determines an inquiry is warranted, the President of HHRI in consultation with the Chief of the relevant Department shall initiate an inquiry. In the inquiry stage, factual information and evidence is gathered and expeditiously reviewed to determine if any investigation of the charge is warranted. The purpose of an inquiry is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation. An inquiry is not a formal hearing and does not require a full review of the evidence related to the allegation; it is designed to separate allegations deserving of further investigation from frivolous, unjustified, or clearly mistaken allegations.

B. Structure

The inquiry will be handled by a formal committee. Ordinarily, this committee will be led by the President of HHRI. In addition, the investigator's primary department Chair will function as an ex officio and non-voting member. In the situation that any of these individuals has a conflict of interest with the case, that individual will designate the next administratively responsible individual from that organization to membership on this committee. It is the responsibility of the committee to ensure that the inquiry is conducted in a fair and just manner. Additional individuals may be chosen to assist in the inquiry process, but they shall have no conflicts of interest with the case in question, be unbiased, and have appropriate backgrounds for judging the issues being raised. The President of HHRI shall be responsible for coordinating the activities of this committee.

HHRI's Legal Counsel shall be consulted to minimize the risk of liability for actions taken in the conduct of the inquiry and investigation.

C. Process

Upon initiation of an inquiry, the committee is responsible for notifying the respondent within a reasonable time of the charges and the process that will follow. If a larger committee is to be used the committee members shall be appointed and convened promptly.

Whether a case can be reviewed effectively without the involvement of a complainant depends upon the nature of the allegation and the evidence available. Cases that depend specifically upon the observations or statements of a complainant cannot proceed without the open involvement of that individual; other cases that can rely on documentary evidence may permit a complainant to remain anonymous. While it may be desirable to keep the identity of a complainant confidential during an inquiry, the Minnesota Data Practices Act and amendments may make such confidentiality impossible. During an inquiry, confidentiality is desirable in order to protect the rights of all parties involved.

The President shall assume responsibility for disseminating the information to the appropriate individuals. Notification normally shall be made in writing, and copies shall be filed in the Office of the President. The safety and security of all documents shall be assured.

When an inquiry is initiated, the respondent shall be reminded of the obligation to cooperate in providing the material necessary to conduct the inquiry. Uncooperative behavior is unacceptable and may result in immediate implementation of a formal investigation and appropriate HHRI sanctions.

Due to the sensitive and serious nature of an allegation of research misconduct or fraud, each case shall be resolved expeditiously. Reasonable deadlines shall be established for each case to facilitate the process. An inquiry normally shall be completed and a written report of the findings shall be filed within 90 days of initiation of the inquiry. If the committee cannot meet the established deadlines, a report, citing the reasons for the delay and progress to date, shall be submitted for the record and the respondent, and appropriately involved other individuals shall be informed.

D. Findings of the Inquiry

The completion of an inquiry is marked by a determination of whether or not a formal investigation is warranted. There shall be written documentation to summarize the process, including the evidence reviewed and relevant interviews, and conclusion of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of the inquiry. If they comment on the report, their comments may be part of the record. The complainant also shall be informed by the President whether or not the complainant's allegations will be subject to further investigation.

If the initial inquiry of the committee finds that the allegations are of substance and require a Formal Investigation (Section II), the agency sponsoring the research shall be notified within 30 days of the determination. In the case of research, research-training, or research-related grant or cooperative agreement funding obtained through any Public Health Service agency, the Director of the Office of Research Integrity (ORI)

shall be informed in writing that an investigation is warranted and will be provided a copy of the inquiry report which will include:

1. The names, professional aliases, and positions of the respondent and complainant;
2. A description of the allegation(s) of research misconduct;
3. The PHS support, including, for example, 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. Inventory of sequestered research records and other evidence and description of how sequestration was conducted;
6. Transcripts of any transcribed interviews;
7. 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 an investigation;
11. Any comments on the inquiry report by the respondent or the complainant;
12. Any institutional actions implemented, including communications with journals or funding agencies.

HHRI will also notify ORI of any special circumstances that may exist, and provide the following information to ORI whenever requested:

1. The institutional policies and procedures under which the inquiry was conducted; and
2. The research records and other evidence reviewed, and copies of all relevant documents.

If an allegation is found to be unsupported but has been submitted in good faith, no further formal action, other than informing all parties involved, shall be taken. The proceedings of an inquiry, including the identity of the respondent, shall be held in strict confidence to protect the parties involved. However, sufficiently detailed documentation of this inquiry shall be maintained in a secure manner for a period of at least seven years after termination of the inquiry and shall, upon request, be provided to authorized Department of Health and Human Services personnel. If confidentiality is breached, HHRI shall take reasonable steps to minimize the damage to reputations that may result from inaccurate reports. Allegations that have not been brought in good faith may lead to appropriate disciplinary action. Complainants shall be made aware from the outset that their confidentiality will not be maintained if a complaint is maliciously motivated and false.

Where a complaint has been brought in good faith, even if mistakenly, HHRI shall seek to protect the complainant against retaliation.

III. FORMAL INVESTIGATION

A. Purpose

A formal investigation shall be initiated only after an Inquiry Committee issues a finding that an investigation is warranted. An investigation's purpose is to explore further the allegations and determine whether fraud has been committed. In the course

of an investigation, additional information may emerge that justifies broadening the scope of the investigation beyond the initial allegations. The respondent shall be informed when significant new directions of investigation are undertaken. The investigation shall focus on accusations of fraud as defined above and shall examine the factual materials of each case. The investigation shall look carefully at the substance of the charges and examine all relevant evidence.

B. Structure

The investigation will be undertaken by an ad hoc committee which will be formed to evaluate the specific case. Members of the Investigative Committee may be chosen from within or outside HHRI. Members will be selected by the Inquiry Committee. It is important that the committee have appropriate scientific and scholarly expertise to assure a sound knowledge base from which to work.

Conflicts of interest by committee members toward the individual(s) accused shall be avoided. Those investigating the allegations shall be selected taking into consideration the closeness of their professional or personal affiliation with the complainant or the respondent. Any member of the Investigative Committee who has a conflict of interest in a given case shall not be permitted to be involved in any aspect of the committee's handling of that case.

C. Process

If an investigation is warranted, the President of HHRI shall initiate an investigation within 30 days of the completion of the inquiry and HHRI will notify ORI of the decision to begin an investigation on or before the date the investigation begins if applicable.

An investigational process shall be established for each formal investigation, and the complainant and respondent shall be notified of the investigation in writing before it is initiated. All parties involved are obligated to cooperate with the proceedings in providing information relating to the case. The Investigative Committee will secure necessary and appropriate expertise to carry out an impartial, thorough and authoritative evaluation of relevant evidence in an investigation. The investigation normally will include examination of all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Interviews shall be conducted of all individuals involved either in making the allegation or against whom the allegation is made as well as other individuals who might have information regarding key aspects of the allegations, including witnesses identified by the respondent. The respondent will not be permitted to be present during any witnesses interviews but will be provided a transcript of any witness interviews.

Interviews during the investigation will be recorded and transcribed and the transcript of the interview made available to the relevant interviewee for correction. Any exhibits shown to the interviewee during the interview will be numbered and referred to by that number in the interview. Interview transcript(s) with any corrections and numbered exhibits will be included in the institutional record of the investigation.

All necessary information shall be provided in writing to the respondent in a timely manner to facilitate the preparation of a response. The respondent shall have the opportunity to address the charges and evidence in detail.

If warranted, the Institute shall take interim administrative actions to protect Federal funds, the health and safety of research subjects and patients, or the interests of students and colleagues. Such actions may range from slight restrictions to suspension of the activities of the respondent. Interim administrative actions shall be taken in full awareness of how they might affect the respondent and HHRI's ongoing research.

Significant developments during the investigation, as well as the final findings of the Committee, shall be reported to the sponsor. In the case of PHS-supported research, the ORI shall be kept apprised of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest. When the investigation is concluded, all entities initially notified of the formal investigation shall be informed of its final outcome.

An investigation shall be conducted as expeditiously as possible and generally shall be completed within 180 days. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation and submitting the report to the ORI. If they can be identified, the person(s) who raised the allegation shall be provided with those portions of the report that address their role and opinions in the investigation.

The nature of some investigations may render the 180-day time period difficult to meet. If, after thoughtful consideration of the need for a thorough and rigorous examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter, the 180-day deadline cannot be met, an interim report shall be submitted by the Investigative Committee to the President, accompanied by a request for an extension. The Institute will then submit to the ORI a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion. If the request for an extension is approved by the ORI, the Institute shall file any periodic progress reports that are requested by the ORI. The Institute recognizes that if satisfactory progress is not made in its investigation, the ORI may undertake an investigation of its own.

D. Findings of the Investigation

The Investigative Committee shall provide a draft report to the respondent for comment before a final report is filed. The respondent shall have 30 days to submit any comments. The findings of the Investigative Committee shall be submitted in writing to the President who is responsible for making the final determination as the Institutional Deciding Official. The President's final determination will be submitted in writing for the institutional record and will outline whether the institution found research misconduct was committed and a description of the relevant actions taken or to be taken. The respondent shall also receive the final, full report of the investigation. When there is more than one respondent, each shall receive those parts of the draft and final reports that are pertinent to his/her role.

The final report shall describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings. The final report shall also include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions taken by the institution.

When applicable the final report along with documentation to substantiate the investigation's findings and the final determination by the HHRI President will be submitted to the ORI. The report to ORI shall specifically include the following information:

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, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.
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; and a description of how any sequestration was conducted during the investigation. This inventory will include manuscripts and funding proposals that were considered or relied on 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 allegedly contained the falsified, fabricated, or plagiarized material.
8. Any scientific or forensic analyses conducted.
9. If not already provided to ORI, the institutional policies and procedures under which the investigation was conducted.
10. Any comments made by the respondent and complainant on the draft investigation report and the investigation committee's consideration of those comments.
11. A statement for each separate allegation of whether the investigation committee recommends a finding of research misconduct.
12. If the investigation committee recommends a finding of research misconduct for an allegation, the investigation report will, for that allegation:
 - a. Identify the individual(s) who committed the research misconduct.
 - b. Indicate whether the research misconduct was falsification, fabrication, and/or plagiarism.
 - c. Indicate whether the research misconduct was committed intentionally, knowingly, or recklessly.
 - d. Explain whether the other requirements for a finding of research misconduct have been met.
 - e. Summarize the facts and the analysis which support the conclusion and consider the merits of any explanation by the respondent.

- f. Identify the specific PHS support.
 - g. Identify whether any publications need correction or retraction.
- 13. If the investigation committee does not recommend a finding of research misconduct for an allegation, the investigation report must provide a detailed rationale.
- 14. List of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.

The Institute recognizes that upon receipt of the final report of the investigation and supporting materials, the ORI will review the information in order to determine whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness and competence. The Institute shall respond promptly to any requests from the ORI for clarification or additional information. The Institute understands that the ORI, if necessary, will perform its own investigation.

IV. RESOLUTION

The investigation into allegations of research misconduct may have any number of outcomes, including: that fraud was committed; that research or scholarly misconduct short of fraud was established; there was no culpable conduct, but serious research, scholarly, or artistic errors were discovered in the course of the investigation; errors that were less than serious were discovered; that no fraud, misconduct or scholarly error was committed.

Thus, an investigation of research misconduct may disclose evidence that requires further action, even in those cases in which no fraud is found.

A. No Finding of Fraud

When the investigation finds no support for allegations of fraud, all entities, initially informed of the investigation shall be notified promptly as outlined above. HHRI shall retain the findings of the investigation and accompanying documentation in a confidential and secure file for a period of at least seven years.

If the Investigative Committee determines that the allegations of research misconduct were maliciously motivated, this information will be reported to the individual's Department Chair for appropriate disciplinary action. If the allegations, however incorrect, are found to have been made in good faith, no disciplinary measures shall be taken and efforts shall be made to prevent retaliatory actions.

B. Serious Research Error if Found

Even when no culpable misconduct has occurred, HHRI shall consider means to correct the research record.

C. Findings of Fraud

All entities initially informed of the investigation shall be notified promptly of the findings of fraud.

If an individual is found guilty of fraud, the President, in conjunction with the

individual's Department Chair shall determine the disciplinary action to be taken. (See examples of possible disciplinary action under V.B. below.)

The Institute recognizes that in addition to sanctions it may decide to impose, the Department of Health and Human Services also may impose sanctions of its own upon investigators or institutions based upon authorities it possesses or may possess, if such action seems appropriate.

- D. If applicable, HHRI will notify 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 to committing research misconduct or a settlement with the respondent has been reached. A respondent's admission of research misconduct must be made in writing and be signed by the respondent. An admission must specify the falsification, fabrication, and/or plagiarism that occurred and which research records were affected. The admission statement must meet all elements required for a research misconduct finding under this policy and must be provided to ORI before the institution closes its research misconduct proceeding. HHRI will also provide a statement to ORI describing how it determined that the scope of the misconduct was fully addressed by the admission and confirmed the respondent's culpability.

V. APPEAL/FINAL REVIEW

The respondent may file a written appeal of the Investigative Committee's decision. Appeals shall be restricted to the body of evidence already presented, and the grounds for appeal shall be limited to failure to follow appropriate procedures in the investigation or arbitrary and capricious decision making. The appeal shall be filed within 30 days of the issuance of the report of findings and presented to the original Inquiry Committee for review of the appeal. If applicable, an appeal will be promptly reported to ORI. The report of the appeal process shall be concluded within 30 days. The decision of the Appeals Committee is final. New evidence, however, may warrant a new investigation.

VI. DISPOSITION

A. Notification

The complainant and other concerned parties, as set forth in the following illustrative, but not exhaustive, list, shall be notified of the disposition of the investigation:

- ☐ Sponsoring agencies, funding sources
- ☐ Co-authors, co-investigators, collaborators
- ☐ Editors of journals in which fraudulent research was published with appropriate retraction or correction

Under appropriate circumstances any of the following bodies may be informed of the outcome of these deliberations:

- ☐ Professional licensing boards
- ☐ Editors of journals or other publications, other institutions, sponsoring agencies, and funding sources with which the individual has been affiliated
- ☐ Professional societies
- ☐ Where appropriate, criminal authorities

B. Institutional Disciplinary Action

The HHRI may take disciplinary action for its employees and recommend such action for non-employees and members as warranted by the circumstances of each case.

Action may include:

- ☐ Removal from a particular project
- ☐ Letter of reprimand
- ☐ Special monitoring of future work

HHRI employees:

- ☐ Probation and/or Suspension
- ☐ Salary reduction
- ☐ Rank reduction
- ☐ Termination of employment

Non-Institute employees may be banned from use of HHRI facilities and participation in HHRI research activities.

VII. POLICY REVIEW

The President will be responsible for reviewing these policies and procedures on an annual basis.

VIII. ANNUAL SUBMISSION OF ASSURANCES TO PHS

The President will be responsible for updating the Institute's assurance on an annual basis on a date specified by the ORI.

IX. APPENDIX I - 42 CFR PART 93

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 93

RIN 0937-AA12

Public Health Service Policies on Research Misconduct

AGENCY: U.S. Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule revises the regulations governing Public Health Service Policies on Research Misconduct. The final rule reflects both substantive and non-substantive revisions in response to public comments and to improve clarity. The purpose of the final rule is to implement policy changes and respond to technological changes that occurred over the past several years applicable to research misconduct.

DATES: *Effective Date:* This final rule is effective January 1, 2025.

Applicability Date: All regulatory requirements are applicable beginning on or after January 1, 2026.

ADDRESSES: Address any comments or questions regarding the final rule to Sheila R. Garrity, JD, MPH, MBA, Director, Office of Research Integrity (ORI), 1101 Wootton Parkway, Suite 240, Rockville, MD 20852. Some commonly asked questions and answers will be posted on the ORI website prior to the effective date of the final rule. The URL for the ORI website is <https://ori.hhs.gov>.

FOR FURTHER INFORMATION CONTACT: Justina Lawrence, (240) 453-8200.

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Research Integrity (ORI) within the Department of Health and Human Services (HHS) oversees and directs Public Health Service (PHS) research integrity activities on behalf of the HHS Secretary, with the exception of the regulatory research integrity activities of the Food and Drug Administration.

ORI was established in 1993 by amendment to section 493 of the Public Health Service Act (42 U.S.C. 289b). The HHS Secretary has authority under section 493 to promulgate a regulation that provides an administrative process for entities that apply for or receive PHS funding for biomedical or behavioral research to respond to research misconduct allegations in connection with such research and to provide assurances to the Department that the entities have an administrative process

in place to respond to research misconduct allegations, investigate research misconduct allegations, and comply with the Department's regulation. Section 493 also authorizes the HHS Secretary to promulgate a regulation addressing ORI's actions, including appropriate remedies, with respect to research misconduct.

In 2005, HHS updated regulations implementing section 493 that predated ORI's establishment. Specifically, HHS removed 42 Code of Federal Regulations (CFR) part 50, subpart A and added 42 CFR part 93, Public Health Service Policies on Research Misconduct. Since 2005, ORI and regulated entities experienced policy developments and technological changes applicable to research misconduct, such as the 2008 NIH Public Access policy; the 2023 NIH Data Management and Sharing policy; the shift to saving data on the cloud; and the ability to use artificial intelligence to detect image falsification, among many other developments.

Therefore, ORI decided to revise part 93.

On October 6, 2023, ORI issued a Notice of Proposed Rulemaking (NPRM) that proposed revisions to 42 CFR part 93 based on the experience ORI and institutions gained with the regulation since it was promulgated in 2005 (88 FR 69583). In addition, the NPRM was issued in response to increasing public concerns about research integrity in science and institutional questions about research misconduct review proceedings. The NPRM proposed several changes to provide clarity, transparency, and a better streamlined process.

The NPRM proposed changes to subpart A. These changes included requiring grant recipients to take responsibility for the research integrity assurances of their subrecipients; adding ORI oversight of and increasing reporting requirements for subsequent use exception determinations; reducing disclosure limitations; and expanding institutional reporting obligations.

Proposed changes to subpart B in the NPRM included adding or revising definitions of commonly used terms such as institutional record, administrative record, honest error, intentionally, knowingly, recklessly, and accepted practices of the relevant research community.

Proposed changes to subpart C in the NPRM included clarification for maintaining active institutional research integrity assurances and addressing apparent or actual conflicts of interest. The NPRM also proposed changes to the institutional research misconduct review process, including assessments, sequestration of research records,

inquiries, investigations, and the maintenance of institutional records.

Proposed changes to subpart D in the NPRM included clarification of institutional assembly of administrative records and potential ORI actions for institutional noncompliance. In addition, ORI proposed clarifying that the lack of an ORI finding of research misconduct does not overturn an institution's determination of research misconduct. Other proposed changes to subpart D included when and how ORI may disclose information about a research misconduct proceeding.

Proposed changes to subpart E in the NPRM included a streamlined process for contesting ORI findings of research misconduct and HHS administrative actions. The proposed appeals process included Administrative Law Judge (ALJ) review of an administrative record, rather than a *de novo* review of evidence presented at a hearing before an ALJ.

The NPRM sought comments from individuals, institutional officials, organizations, institutions, research funding agencies, and other members of the public on the proposed revisions and how to improve the clarity of the existing regulation.

II. Overview of Comments and Significant Changes in Final Rule

ORI received 269 comments via [Regulations.gov](https://www.regulations.gov). ORI also received comments as part of its interagency review process. ORI received 199 relevant comments representing the views of two main constituent groups: institutions and individuals. In several instances, duplicative comments were posted by the same institution or individual. ORI received 171 unique comments submitted by 123 institutions and 46 individuals. In two cases, an institution submitted two separate sets of comments; since the content of each submission was distinct, ORI counted each submission as a unique comment. In addition, some comments were endorsed by multiple individuals or institutions. For example, one institutional comment was explicitly supported by 70 separate commenters. Another institutional comment was explicitly supported by 83 separate commenters. Ten commenters supported an additional institutional statement, and three commenters supported other representative groups' statements.

Most comments addressed multiple sections of the proposed rule. Many commenters made general statements supporting the more efficient execution and oversight of research misconduct proceedings proposed in the NPRM;

however, most commenters recommended changes to enhance the clarity of the proposed regulation. These comments generally involved maintaining the balance between ensuring a complete review of misconduct allegations and protecting the rights of respondents and recognizing the potential for administrative burden and cost on institutions.

Most commenters anticipated administrative burden resulting from various parts of the NPRM. These comments were divided among five topics: burden related to the assessment phase, burden related to determining honest error, burden related to transcribing interviews, burden related to reporting, and burdens placed on small institutions. Several commenters requested more time to implement the final rule, and the amount of time requested varied widely. A majority requested one year, while others requested different timelines.

Many commenters recommended revisions to or removal of proposed definitions. Commenters also made general comments on the proposed rule, with most commenters recommending additions, revisions, or removal of various sections.

Commenters expressed a variety of concerns about potential conflicts of interest but did not recommend the removal or revision of any particular section of the proposed regulation. Commenters also expressed concerns about harm to respondents' reputation; these concerns included ORI's access to assessment reports and potential breaches of confidentiality when sharing transcripts. Commenters also expressed concerns about the effects of the proposed regulation on whistleblowers. These concerns included fears of retaliation, negative effects on reporting misconduct, and breaches of confidentiality.

The NPRM proposed several substantive changes in which commenters provided feedback that informed the drafting of the final rule. The following paragraphs provide an overview of the feedback received from commenters. More detailed descriptions of comments on specific sections of the proposed regulation are addressed below in section III.

Subpart A Summary of Significant Public Comments and Changes

Proposed § 93.102(a) would require primary PHS grant recipients to take responsibility for the compliance of their subrecipients. A number of commenters recommended removing the proposed requirement making each

PHS funding recipient responsible for the compliance of their subrecipients, because institutional responsibility for regulatory compliance was not clarified. ORI did not intend to impose a new burden on prime funding recipients; in the final rule subrecipients are required to have their own assurances filed with ORI. Proposed § 93.105(b), which involved time limitations for research misconduct proceedings, required more reporting requirements and established that ORI makes the final determination of when a subsequent use exception can be applied. Commenters recommended revising this section to state that institutions should be afforded discretion in applying the subsequent use exceptions. ORI agreed institutions should be able to determine whether the subsequent use exception applies to a given situation. Proposed § 93.106 would require increased institutional reporting obligations to ORI related to institutional confidentiality obligations. Commenters found the language of the proposed regulation in this section overcomplicated institutional confidentiality obligations, added problematic provisions, and contained information more appropriate for guidance. ORI recognized institutions' concerns about implementing the confidentiality requirements in the proposed rule and changed the final rule to provide latitude for institutions to decide confidentiality requirements for themselves. A number of commenters disapproved omitting the 2005 regulation's Evidentiary Standards section from the NPRM, and asked ORI to maintain the burden of proof language from the 2005 regulation. ORI had proposed removing this section because evidentiary standards were discussed in several other parts of the NPRM; however, ORI concurred with commenters, restored and updated aspects of the Evidentiary Standards section, and revised the final rule to clarify specific situations in which an adverse inference can be made but did not address all situations in which an adverse inference can be made. Nothing in the final rule precludes an institution or HHS from drawing an adverse inference under a different set of facts if appropriate.

Subpart B Summary of Significant Public Comments and Changes

Proposed Secs. 93.205, 93.211, 93.217, 93.236 and 93.245 set forth definitions for Appeal, Difference of Opinion, Honest Error, Research Integrity, Suspension and Debarment to provide definitions of commonly used terms. Several commenters recommended removing these

definitions because they did not enhance the clarity of the regulation. ORI agreed and removed these definitions. Proposed Secs. 93.223, 93.217, and 93.234, which set forth definitions for Institutional Record, Recklessly, and Small Institution, were also added to provide definitions for commonly used terms. Commenters recommended revisions to clarify these definitions. ORI concurred and revised these definitions, described in detail in the next section.

Subpart C Summary of Significant Public Comments and Changes

Proposed § 93.304 regarding institutional policies and procedures removed a provision that was in the 2005 regulation requiring institutions to have policies and procedures in place to protect the rights of respondents. Commenters were concerned about protecting these rights and ORI restored the language from the 2005 regulation that institutions provide for all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

Proposed § 93.305 was meant to provide details on institutional responsibilities in the general conduct of misconduct proceedings. Some commenters appreciated the provision that permits an institution to add respondents to an ongoing misconduct case without conducting a separate inquiry for each new respondent. Other commenters were concerned that listing the types of researchers the institutions should consider as potential respondents created a confusing standard and could be detrimental to those individuals. ORI concurred and removed the list of potential co-respondents as well as the parenthetical list of additional research records to examine, because these lists were intended to be exemplary rather than prescriptive. Some commenters found the section on pursuing leads overly prescriptive, while others found it overly broad. Many commenters were concerned that pursuing all leads during an inquiry would be burdensome and costly—as well as cause reputational harm to innocent researchers. ORI concurred and moved the requirement to pursue all leads to § 93.310(j), which details the investigation requirements.

Commenters also objected to the proposed requirement to transcribe all interviews in § 93.305 of the NPRM, especially interviews conducted during the assessment or inquiry phase, because it could discourage reporting of

allegations and contribute to institutional burden. ORI concurred, revised the section, and moved it to § 93.310(g), which details the investigation requirements. The revised section removes the requirement for transcribed interviews during the assessment and inquiry phases. Some commenters noted this section may not provide fair procedures to respondents. Other commenters recommended removing the section entirely, stating that institutions should be allowed to institute best practices without regulatory oversight. A few commenters favored retaining the section as proposed. ORI removed all portions of the proposed subsection that did not specify requirements—that is, sections on the institution's choice to use a committee, consortium, or person to conduct, support, or participate in proceedings; what a consortium might be comprised of; and the institution's choice to allow respondents/complainants to object to committee or consortium member(s). The information was intended to be exemplary, not prescriptive. ORI intends to issue guidance on this topic.

Proposed § 93.306, which describes the institutional assessment of research misconduct allegations, increased reporting requirements, and time limitations were added to ensure prompt institutional response in addressing allegations of misconduct. Commenters were concerned about the burden of increased pre-investigation reporting requirements. ORI concurred and revised this section to simplify the assessment phase and require institutions to document their assessment process rather than write a formal report. The final rule clarifies that, if an institution determines to close a research misconduct proceeding after the assessment, it must retain documentation of its rationale sufficient to permit a later review by ORI.

Proposed § 93.307, which involves the institutional inquiry, increased reporting requirements, and time limitations were added to ensure prompt institutional response in addressing allegations of misconduct. The NPRM proposed to prohibit an institution from determining honest error during the inquiry stage. Some commenters requested clarification because the process for notifying additional respondents of an institutional inquiry appeared unclear. ORI concurred and revised this section to simplify the language. Commenters also recommended removing proposed § 93.307(f)(2) because they conveyed the requirement that institutions determine honest error only at the investigation

stage would unfairly burden both respondents and institutions. ORI agreed and removed § 93.307(f)(2). Several commenters recommended removing proposed § 93.307(h), which set a 60-day timeframe for completing an inquiry, stating that institutions should have more flexibility in the timeframe to thoroughly conduct an inquiry. ORI concurred and lengthened the inquiry timeline from 60 to 90 days. If the inquiry takes longer than 90 days to complete, the inquiry report must document the reasons for exceeding the 90-day period.

The institutional investigation phase described in proposed § 93.310 was meant to provide additional institutional responsibilities in the conduct of an institutional investigation of research misconduct, including additional reporting and proposed rules about sequestration of evidence, multiple respondents, and multiple institutions. A few commenters recommended removal of proposed § 93.310(c)(2) because they conveyed their concern that the regulation infringes on the rights of respondents who are added to an ongoing investigation without an additional inquiry. ORI clarified § 93.310(c)(2) that when a new respondent is added to an ongoing proceeding, institutions may but are not required to conduct a separate inquiry for additional respondents, and additional respondents must be notified of allegation(s) and provided an opportunity to respond.

Proposed § 93.313(k) and (l)(2) describing the institutional investigation report was meant to clarify the requirements for an investigation report. The section included lists of examples of sequestered materials. The section also included a prohibition against split decisions by an investigation committee. Commenters recommended removing proposed § 93.313(k), which included a requirement that institutions identify any research records and other evidence obtained and sequestered but not reviewed, because it was deemed resource-intensive and an unnecessary burden. ORI concurred and removed § 93.313(k) as duplicative of 93.313(e). ORI notes that the inventory requirement described in 93.313(e) does not require identification of specific files or emails but allows for a broader summary of the types of files or emails sequestered. Commenters also recommended removing language in proposed § 93.313(l)(2) prohibiting investigation committees from making a split decision. ORI removed that prohibition and included language that the report must clearly state the

investigation committee's conclusions regarding whether research misconduct occurred.

The institutional appeals process described in proposed § 93.314 would require that institutional appeals be completed within 120 days or apply for an extension. Commenters recommended deleting or significantly revising § 93.314, contending the institutional appeal was within the institution's purview, not ORI's. ORI concurred and removed most of the requirements in § 93.314 and added § 93.315 to acknowledge institutional purview. ORI recognizes the potential inefficiency of starting oversight review while an institutional appeal is ongoing that could reverse or modify the institutional findings of research misconduct. The final rule clarifies that institutions should not transmit their institutional record until the conclusion of any institutional appeals. If an appeal is filed after the institution has transmitted the institutional record, the institution must promptly notify ORI so the agency can postpone oversight review until the institutional appeal is complete.

Subpart D Summary of Significant Public Comments and Changes

Proposed § 93.410(b) would allow ORI to publish notice of institutional research misconduct proceedings that did not result in ORI findings. Many commenters urged ORI to remove § 93.410(b), which proposed that ORI may publish notice of institutional investigations and actions. Commenters cited regulatory overreach, breaches of confidentiality, and inconsistency with other agencies' policies. ORI removed 93.410(b) from the final rule, ensuring institutions have discretion in this area. Proposed § 93.411 would require HHS to provide notification and publish final HHS actions that result in a finding of research misconduct. One commenter objected to replacing "may" with "shall," regarding ORI's publication of findings and settlements. ORI restored the 2005 regulatory language of "may" to retain flexibility.

Subpart E Summary of Significant Public Comments and Changes

Proposed § 93.512 provided for a simpler and more expedient appeals process, which would entail ALJ review of an administrative record to determine whether ORI's findings and HHS's proposed administrative actions (other than suspension or debarment) are reasonable and not based on a material error of law or fact. The proposed appeals process also provided for the possibility of a limited hearing if the

ALJ determines that there is a genuine dispute over material fact. One commenter, in response to the NPRM's request for comments on the scope of and need for limited hearings, suggested the research misconduct process allows for sufficient procedures to make such limited hearings unnecessary. ORI agreed, removed proposed § 93.512 from the final rule, made clarifying edits throughout subpart E, including removing language concerning suspension and debarment and adding the qualifiers "proposed" or "HHS" before the phrase "administrative actions."

ORI made other changes in the final rule to generally provide clarity requested by the commenters. In addition to specific changes discussed below, ORI changed "will" to "may" in places throughout the final rule, as appropriate, to add flexibility. ORI made nonsubstantive edits throughout the final rule in accordance with the Plain Writing Act of 2010. ORI also merged or separated content within sections of the final rule to improve clarity and readability. ORI streamlined language to avoid repeatedly distinguishing research misconduct proceedings subject to part 93 from suspension and debarment actions governed by regulations separate and distinct from part 93. These changes either were nonsubstantive or increased the flexibility accorded to regulated entities.

III. Section-by-Section Description of Changes in the Final Rule

A. Application of Effective Date to Research Misconduct Proceedings, Final Rule § 93.75

Commenters suggested delaying the effective date of the final rule, citing the time required for institutions to update their policies and procedures and train staff, with many commenters recommending an effective date 18 months after the publication date. ORI retained the proposed effective date of January 1, 2025, but clarified that all regulatory requirements are applicable on or after January 1, 2026, in order to provide ample time for institutions to prepare for the final rule. ORI will not require institutions to implement and submit revised policies and procedures that comply with the final rule until the submission of their annual report covering 2025, which is due on or before April 30, 2026. ORI believes that this approach balances the need to promptly implement improvements made by the final rule with the time for institutions to update their policies and procedures. ORI added § 93.75 to clarify the applicability date, specifying that

beginning on January 1, 2026, an institution must follow the final rule for allegations received by the institution on or after January 1, 2026. For allegations received by an institution before January 1, 2026, an institution must follow 42 CFR part 93 as published in the 2005 edition of the Code of Federal Regulations, unless the respondent and institution both elect in writing to follow the new final rule.

B. Applicability, NPRM § 93.102(a)

A number of commenters recommended removing the proposed requirement making each PHS funding recipient responsible for the compliance of their subrecipients, because institutional responsibility for regulatory compliance was not clarified. A few commenters recommended revision for the same reason, adding that subrecipients should have assurances on file with ORI to ensure compliance by all recipients of PHS funding. ORI removed the sentence, "Further, each recipient of such support is responsible for the compliance of their subrecipients with this part," because ORI did not intend to impose a new burden on prime funding recipients; subrecipients are required to have their own assurances filed with ORI.

C. Applicability, NPRM § 93.102(d)

Revisions clarify that suspension and debarment at HHS are governed by regulations separate and distinct from part 93. As noted above, corresponding revisions throughout the final rule streamline language because there is no need to repeatedly distinguish research misconduct proceedings subject to this part from suspension and debarment actions subject to separate and distinct regulations. ORI also revised the language in this section to confirm that the Suspension and Debarment Official (SDO) and ORI may coordinate actions to the extent consistent with the SDO's and ORI's respective authorities. Such coordination includes jointly issuing notices or seeking settlements of actions and proceedings.

D. Research Misconduct, NPRM Secs. 93.103

Commenters recommended deleting this section, because it duplicated information found elsewhere, specifically the definitions of fabrication, falsification, and plagiarism. ORI concurred and deleted this section in its entirety.

E. Requirements for Findings of Research Misconduct, NPRM Secs. 93.104(a), (b), and (c)

Commenters expressed appreciation that the proposed regulation clarified the three requirements for findings of research misconduct and confirmed three elements must be met. ORI made one change for grammatical consistency across all subsections.

F. Time Limitations, NPRM § 93.105(b)

Commenters recommended revising this section to state that institutions should be allowed to determine their own timeframe for applying subsequent use exceptions. ORI agreed institutions should be able to determine whether the subsequent use exception applies to a given case. To have a consistent regulatory standard across all institutions, ORI retained the six-year limitation. Commenters also expressed concern about the potential cost and burdens of the proposed requirement that institutions inform ORI of the relevant facts before concluding the subsequent use exception does not apply. ORI concurred and revised the section to require institutions to document how they determined the exception did or did not apply and to retain that information in the institutional record. ORI may address the application of the subsequent use exception for institutional reporting requirements through future policymaking.

G. Confidentiality, NPRM § 93.106

In response to commenters mentioning circumstances in which institutions may have a legitimate need to inform persons outside the institution about a pending research misconduct proceeding, ORI clarified that institutions may alert journal editors and others who need to know of potentially inaccurate data in a timely manner, and the final rule specifies that institutions are not prohibited from managing published data or acknowledging that data may be unreliable. In addition, to prevent some institutions from keeping research-related information confidential longer than necessary, the final rule now clarifies the length of time an institution is bound by the confidentiality provision. Commenters also stated that the language proposed in this section overcomplicated institutional confidentiality obligations and contained information more appropriate for guidance. ORI recognized institutions' concerns about overly prescriptive language and changed the final rule to provide greater latitude for

institutions to decide how to meet confidentiality requirements. ORI also removed the subsections that discussed what constitutes “those who need to know.”

H. Appeal, NPRM § 93.204

Commenters recommended deleting this definition because it was unnecessary. ORI concurred and removed this definition.

I. Charge Letter, NPRM § 93.206

ORI removed specific language addressing joint charge letters, because § 93.102(d) of the final rule addresses situations in which ORI and the SDO may jointly issue notices. ORI also revised proposed § 93.206 to remove references to the SDO in the definition and avoid redundancy in subpart A.

J. Difference of Opinion, NPRM § 93.211

Several commenters recommended removing this definition because it did not enhance the clarity of the regulation. ORI agreed and removed this definition.

K. Honest Error, NPRM § 93.217

Several commenters requested revision of this definition of honest error. A minority of commenters asked ORI to add a reference to good faith and intent and to provide examples. Most commenters recommended removing the definition because they conveyed that it was unnecessary. ORI concurred and removed this definition.

L. Institutional Record, NPRM § 93.223

Commenters generally supported including this definition but expressed concerns about the institutional burden of sequestering irrelevant records and conveyed that the institutional investigation committee should have autonomy to decide which records to consider. While ORI understands sequestration imposes an institutional burden, ORI has found that records originally not considered by an institution may be relevant to the research misconduct proceeding. ORI balanced these concerns by revising the proposed definition of institutional record and retaining a maintenance requirement in § 93.318 for sequestered evidence that is not part of the institutional record. ORI revised the proposed definition to clarify that the institutional record comprises all records the institution compiled or generated during the research misconduct proceeding, except for the records the institution did not consider or rely on. The institutional record index does not need to include records the institution did not consider or rely on. ORI revised the proposed definition

to include a requirement for a general description of records sequestered but not considered or relied on. Additionally, ORI revised wording to clarify that assessments are to be documented, but an assessment report is not required. ORI intends to issue guidance on this topic.

M. Recklessly, NPRM § 93.234

Many commenters proposed revisions to this definition. Some commenters requested clarification of and distinction between the definitions of “knowingly” and “recklessly,” as well as a definition of “harm.” Several commenters requested guidance with examples to help institutions distinguish between “careless” and “reckless” supervision. One commenter approved of the existing definition. ORI revised the definition in response to these comments to make it easier to apply in the research misconduct context. In particular, ORI revised the definition to make it specific to proposing, performing, or reviewing research, or reporting research results, rather than “acting” more generally, and specific to a risk of fabrication, falsification, or plagiarism.

N. Investigation, NPRM § 93.225

Commenters proposed revising this definition to provide further clarification. ORI agreed and revised the definition by removing unnecessary language for clarity.

O. Research Integrity, NPRM § 93.236

Many commenters recommended removing this definition because they found it narrow, unclear, and inconsistent with the National Academies of Sciences, Engineering, and Medicine (NASEM) definition. One commenter recommended retaining the proposed definition. ORI decided to remove this definition and may provide future guidance on this topic.

P. Research Misconduct Proceedings, NPRM § 93.239

Regarding the appeals process and involvement of an ALJ, ORI added clarifying language, “appeals under subpart E,” to avoid ambiguity and to distinguish this process from institutional appeals.

Q. Research Record, NPRM § 93.240

Commenters requested clarification of this definition. ORI added “records of” before “oral presentations” to exclude from the definition any records of completely internal presentations where problems were potentially identified and corrected before outside reporting. ORI also changed the phrase “internal

reports” to “lab meeting reports” to clarify the meaning of this phrase, which may be part of the research record. Additionally, ORI removed “internet” from “internet and online” content because of the repetitive meaning of the two words. ORI intends to issue guidance on this definition.

R. Small Institution, NPRM § 93.244

Several commenters recommended revisions to the definition because they conveyed that the criteria used to designate a small institution were overly restrictive. ORI agreed and removed the statement that a small institution typically has “a total of 10 or fewer institutional members” and may address this topic through future policymaking.

S. Suspension and Debarment, NPRM § 93.245

ORI removed this proposed definition of “suspension and debarment” and merged significant aspects of the definition with “Suspension and Debarment Official or SDO” to reduce redundancy.

T. Institutional Policies and Procedures, NPRM § 93.304

One commenter commended ORI for requiring all institutions to file an assurance to apply for PHS support. Commenters expressed concern about omitting the 2005 regulation’s requirement to make all reasonable and practical efforts to restore the reputation of respondents not found to have committed research misconduct. Commenters requested restoring proposed § 93.304 to the 2005 wording. ORI concurred and restored the 2005 wording regarding policies and procedures to protect the reputation of respondents when no finding has been made.

U. General Conduct of Research Misconduct Proceedings – Sequestration of Research Records and Other Evidence, NPRM § 93.305(a)

ORI noted the requirement to sequester all research records and other evidence was mentioned more than once in the NPRM. To reduce redundancy, this requirement is explained in full only once in the final rule, under General Conduct of Research Misconduct Proceedings.

V. General Conduct of Research Misconduct Proceedings – Multiple Respondents, NPRM § 93.305(d)

Some commenters appreciated the provision that permits an institution to add respondents to an ongoing research misconduct case without conducting a separate inquiry for each new

respondent. Others expressed the provision could set a precedent that infringes on respondents' rights. To address this concern, the final rule specifies that each additional respondent must be provided notice of the allegations and an opportunity to respond, consistent with subpart C. Some commenters were also concerned that listing the types of researchers the institutions should consider as potential respondents created a confusing standard and could be detrimental to those individuals. ORI concurred and removed the list of potential co-respondents as well as the parenthetical list of additional research records to examine, because these lists were intended to be exemplary rather than prescriptive. Some commenters suggested changing "must consider whether any additional researchers are responsible" to "may consider whether any additional researchers are responsible." ORI revised this section to allow institutions the flexibility to use their own judgment.

W. General Conduct of Research Misconduct Proceedings – Pursue Leads, NPRM § 93.305(f)

Some commenters found this section overly prescriptive while others found it overly broad. Many commenters were concerned that pursuing all leads during an inquiry would be burdensome and costly—as well as cause reputational harm to innocent researchers. ORI concurred and moved the requirement to pursue all leads to § 93.310(j), which details the investigation requirements. ORI also removed the parenthetical list of additional research records to examine, because it was intended to be exemplary, not prescriptive. ORI intends to provide further guidance specifying recommended practices for pursuing leads.

X. General Conduct of Research Misconduct Proceedings – Interviews, NPRM § 93.305(g)

Commenters objected to the proposed requirement to transcribe all interviews, especially interviews conducted during the assessment or inquiry phase, because it could discourage reporting of allegations and contribute to institutional burden. Some commenters expressed that if transcripts are mandatory, they should be required only during the investigation. ORI concurred, revised the proposed section, and moved it to § 93.310(g), which details the investigation requirements. The revised section removes the requirement for transcribed interviews during the assessment and inquiry phases.

Y. Conduct of Research Misconduct Proceedings – Using a Committee, Consortium, or Other Person for Research Misconduct Proceedings, NPRM § 93.305(h)

Some commenters noted a concern that this section may not provide fair procedures to respondents. Other commenters recommended removing the section entirely, stating that institutions should be allowed to institute best practices without regulatory oversight. A few commenters favored retaining the section as proposed. ORI removed all portions of the proposed subsection that did not specify requirements—that is, sections on the institution's choice to use a committee, consortium, or person to conduct, support, or participate in proceedings; what a consortium might be comprised of; and the institution's choice to allow respondents/complainants to object to committee or consortium member(s). The information was intended to be exemplary, not prescriptive.

Z. Institutional Assessment, NPRM § 93.306

A number of commenters were concerned about the burden of increased pre-investigation reporting requirements. ORI concurred and revised this section to simplify the assessment phase and require institutions to document their assessment process rather than write a formal report. Commenters also expressed concern about potential harm to respondents' reputations if ORI is permitted to read an institution's assessment documentation. In response to the concern about reputational harm, ORI notes that any assessment documentation obtained by ORI will be subject to the Privacy Act, 5 U.S.C. 552a. Many commenters asked ORI to remove § 93.306(e), which proposed requiring institutions to complete the assessment within 30 days. Commenters expressed that this timeline was unrealistic, would be burdensome for institutions, and could undermine the rigor and utility of the sequestration process. One commenter was concerned about the impact of this assessment timeframe on respondents' mental health. ORI concurred and removed the 30-day assessment timeline requirement.

AA. Institutional Inquiry, NPRM § 93.307

Some commenters requested clarification because the process for notifying additional respondents of an institutional inquiry appeared unclear.

ORI concurred and revised this section to simplify the language. Commenters also recommended removing proposed § 93.307(f)(2) because they conveyed that the requirement that institutions determine honest error only at the investigation stage would unfairly burden both respondents and institutions. ORI agreed and removed proposed § 93.307(f)(2). Several commenters recommended removing proposed § 93.307(h), which set a 60-day timeframe for completing an inquiry, stating that institutions should have more flexibility in the timeframe to thoroughly conduct an inquiry. ORI concurred and lengthened the inquiry timeline from 60 to 90 days. If the inquiry takes longer than 90 days to complete, the inquiry report must document the reasons for exceeding the 90-day period. ORI also revised references to "research records" throughout the final rule to ensure consistency with § 93.307(d), which describes "research records and other evidence." In addition, ORI removed proposed § 93.307(e)(5) in the final rule to eliminate redundancy, because § 93.310(j) specifically addresses the institutional responsibility to pursue all leads.

BB. Reporting to ORI on the Decision To Initiate an Investigation, NPRM § 93.309

ORI removed the proposed requirement that the Institutional Deciding Official review the inquiry report and provide a written decision to proceed to an investigation, to eliminate potential administrative burden.

CC. Institutional Investigation, NPRM § 93.310

A few commenters recommended removal of § 93.310(c)(2) because they expressed a concern that the regulation infringes on the rights of respondents who are added to an ongoing investigation without an additional inquiry. ORI clarified in § 93.310(c)(2) that when a new respondent is added to an ongoing proceeding, institutions may but are not required to conduct a separate inquiry for additional respondents, and additional respondents must be notified of allegation(s) and provided an opportunity to respond consistent with subpart C. In response to commenters requesting additional clarity for regulated entities, ORI moved proposed § 93.310(h) regarding the institutional responsibility to pursue leads to § 93.310(j) and streamlined the language, including clarifying the respondent notification requirement.

DD. Investigation Report, NPRM § 93.313(k)

Commenters requested clarity on how the investigation report should identify sequestered evidence. Commenters also recommended removing § 93.313(k), which included a requirement that institutions identify any research records and other evidence obtained and sequestered but not reviewed, because it was deemed resource-intensive and an unnecessary burden. ORI revised § 93.313 to replace proposed Secs. 93.313(e) and (k) with a single requirement in § 93.313(e) to include in the investigation report an inventory of sequestered research records and other evidence, except records the institution did not consider or rely on. ORI made a corresponding revision to § 93.220(c) of the final rule requiring that the institutional record include a general description of the records that were sequestered but not considered or relied on. ORI notes that the general description in § 93.220(c) does not require identification of specific files or emails but allows for a broader summary of the types of files or emails sequestered.

EE. Investigation Report, NPRM § 93.313(l)(2)

Commenters recommended removing language in proposed § 93.313(l)(2) prohibiting investigation committees from making a split decision. ORI removed that prohibition and included language that the report must clearly state the investigation committee's conclusions regarding whether research misconduct occurred for each separate allegation.

FF. Institutional Appeals, NPRM § 93.314

Commenters recommended deleting or significantly revising proposed § 93.314, which requires institutions to complete any institutional appeals within 120 days or seek an extension, contending the institutional appeal was within the institution's purview, not ORI's. ORI concurred and removed most of the requirements in § 93.314. ORI recognizes the potential inefficiency of starting oversight review while an institutional appeal is ongoing that could reverse or modify the institutional findings of research misconduct. The final rule clarifies that institutions should not transmit their institutional record until the conclusion of any institutional appeals. If an appeal is filed after the institution has transmitted the institutional record, the institution must promptly notify ORI so the agency

can postpone oversight review until the institutional appeal is complete.

GG. Decision by the Institutional Deciding Official, Final Rule § 93.314

ORI added this section to clearly identify the responsibilities of the Institutional Deciding Official at the conclusion of an investigation and to respond to commenters generally requesting additional clarity.

HH. Completing the Research Misconduct Process, NPRM § 93.316(a)

ORI revised the requirement that institutions notify ORI in advance if an institution plans to close research misconduct proceedings to omit "or for any other reason" to eliminate unnecessary burden.

II. Institutional Standards of Conduct, NPRM § 93.318

This section was intended to indicate that ORI findings of research misconduct or HHS settlements of research misconduct proceedings, or the absence thereof, do not affect institutional findings or actions taken based on an institution's standards of conduct. ORI combined (a) and (b) of this section and clarified language accordingly.

JJ. Interaction With Other Entities and Interim Actions, NPRM § 93.401

ORI added language to clarify the relationship between ORI and the HHS official authorized to impose suspension and debarment.

KK. Final HHS Actions, NPRM § 93.406

ORI removed unnecessary language regarding suspension and debarment.

LL. HHS Administrative Actions, NPRM § 93.407

ORI revised this section to clarify that, for purposes of this regulation, HHS administrative actions do not include suspension and debarment. However, the HHS official authorized to impose suspension and debarment remains free to pursue those actions under applicable regulations, as stated in § 93.407(d).

MM. Mitigating and Aggravating Factors in HHS Administrative Actions, NPRM § 93.408

ORI removed unnecessary language regarding suspension and debarment.

NN. Final HHS Action With No Settlement or Finding of Research Misconduct, NPRM § 93.410(a)

ORI removed the phrase "as it deems necessary" in § 93.410(a) because it does not add further meaning to the section.

OO. Final HHS Action With No Settlement or Finding of Research Misconduct, NPRM § 93.410(b)

Many commenters urged ORI to remove § 93.410(b), which proposed that ORI publish notice of institutional investigations and actions. Commenters cited regulatory overreach, breaches of confidentiality, and inconsistency with other agencies' policies. One commenter noted that ORI's publication of institutional reports and findings would be inconsistent with the confidentiality provisions established in the clinical research context. A minority of commenters recommended revising the section to redact respondents' identifying information to ensure confidentiality. A few commenters recommended retaining the section as proposed. ORI removed proposed § 93.410(b) from the final rule, ensuring institutions have discretion in this area.

PP. Final HHS Action With a Settlement or Finding of Misconduct, NPRM § 93.411

One commenter objected to replacing "may" with "shall," regarding ORI's publication of findings and settlements. ORI restored the 2005 regulatory language of "may" to retain flexibility.

QQ. HHS Compliance Actions, NPRM § 93.413

ORI revised this section to clarify the process for making a discretionary referral to the HHS official authorized to impose suspension and debarment under separate and distinct regulations. In addition, ORI changed the section's name to "ORI compliance actions" for accuracy.

RR. Notice, NPRM § 93.414

One commenter objected to replacing "may" with "shall" regarding ORI's publication of findings and settlements. ORI restored the 2005 regulatory language of "may" to retain flexibility. Commenters were concerned this portion of the proposed regulation weakens respondents' confidentiality protections and runs counter to the remedial purpose of regulations and HHS administrative actions. One commenter requested adding language to protect the institution's confidentiality in subsection (b). Numerous commenters recommended requiring ORI to notify the relevant institution when it closes a case without a settlement or a finding of research misconduct. One commenter expressed that ORI should attempt to restore the reputation of respondents not found to have committed research misconduct; they also expressed that if a complainant is found to have conflicts

of interest with the respondent, ORI should consider taking action against the complainant. Another commenter was concerned about § 93.414(f), which provides that any publications or disclosures pursuant to this section are not considered appealable “administrative actions.” ORI revised this section for clarity and removed proposed subsections 93.414(c)–(f) in response to the comments.

SS. General Policy, NPRM § 93.500

ORI revised this section to clarify that a respondent must exhaust administrative remedies under this part prior to seeking judicial review in Federal court.

TT. Conferences, NPRM § 93.510

ORI revised this section to restore in subsection 93.510(e) the phrase “Whenever possible” from the 2005 regulation to retain flexibility for the ALJ.

UU. Hearing To Resolve Genuine Factual Dispute, NPRM § 93.511

One commenter, in response to the NPRM’s request for comments on the scope of and need for limited hearings, suggested the research misconduct process allows for sufficient procedures to make such limited hearings unnecessary. ORI agreed, removed proposed § 93.511 from the final rule, and made corresponding edits throughout subpart E.

VV. The Administrative Law Judge’s Ruling, NPRM § 93.512

To promote consistency in agency decision making, ORI reinstated and updated from the 2005 regulation an opportunity for the Assistant Secretary for Health (ASH) to review the ALJ’s decision under subpart E. Although § 93.511 in the final rule explicitly provides that the ASH may review the ALJ’s recommended decision before it becomes final, the ASH and the Secretary also have the ability to review ORI findings of research misconduct and/or proposed HHS administrative actions before a charge letter is issued under § 93.405 and to act as final decision maker before a charge letter is issued, if either of them so chooses.

IV. Significant Comments Not Resulting in Changes

A. Accepted Practices of the Relevant Research Community, NPRM § 93.200

Commenters supported retaining this proposed definition but found it overly expansive. Commenters recommended revised language, including practices specific to PHS-funded research. ORI left this definition unchanged to

acknowledge the expanding universe of research disciplines.

B. Allegation, NPRM § 93.203

Commenters supported revising this definition to clarify purposeful disclosure of possible research misconduct. After consideration, ORI left the definition as proposed, to avoid adding another element to the definition that may discourage reporting possible research misconduct.

C. Assessment, NPRM § 93.205

Many commenters recommended deleting this definition because they conveyed that it was unnecessary. Some commenters’ recommended revisions were related to concerns about the proposed description of the assessment phase in subpart C. A minority of commenters supported the inclusion of the definition but sought clarification for what constitutes readily available information. ORI made changes to subpart C and left the definition of “assessment” as proposed because there was no consensus among the comments and because it was satisfied that the proposed definition served the purpose of explaining the term to those who may be unfamiliar with the term in the research misconduct context. ORI may address this topic through future policymaking.

D. Complainant, NPRM § 93.207

Commenters recommended revising this definition to add details about complainant anonymity. ORI agreed on the importance of anonymity and addressed confidentiality elsewhere in subpart A of the final rule. ORI left the definition of complainant unchanged.

E. Contract, NPRM § 93.208

One commenter proposed removing this definition because it is a commonly understood term. ORI opted to leave the definition as proposed, because it is helpful to those who are not familiar with contracts under the Federal Acquisition Regulation.

F. Day, NPRM § 93.209

Some commenters recommended removing or revising this definition to factor in academic calendars. Since academic calendars vary, ORI retained the definition in its proposed form.

G. Departmental Appeals Board, NPRM § 93.210

One commenter recommended removing this definition because it is a commonly understood term. ORI retained the definition in its proposed form because it is helpful to those who are not familiar with that organization.

H. Evidence, NPRM § 93.212

A small number of commenters provided contradictory recommendations about removing or enhancing the definition. ORI retained the definition in its proposed form because there was no consensus among the comments and because it was satisfied that the proposed definition served the purpose of explaining the term to those who may be unfamiliar with the term in the research misconduct context.

I. Falsification, NPRM § 93.214

One commenter recommended revising this definition to include allegations of misconduct and intent. ORI retained the definition in its proposed form because it is consistent with the definition found in the 2000 Office of Science and Technology Policy’s Federal Policy on Research Misconduct, 65 FR 76260 (Dec. 6, 2000).

J. Good Faith, NPRM § 93.216

Some commenters recommended revising this definition to express nuance without fundamentally altering its meaning. ORI retained the definition in its proposed form because commenters were not opposed to the meaning expressed in the definition.

K. Institution, NPRM § 93.219

One commenter recommended revising this definition to clarify that institutions are not persons. ORI retained the definition in its proposed form. While the definition refers to “any person,” the term “person” is defined in § 93.226 of the final rule to include both individuals and other legal entities that are not individuals.

L. Institutional Deciding Official, NPRM § 93.221

Commenters recommended revising this definition to permit the Research Integrity Officer, or RIO, to serve as the Institutional Deciding Official. ORI retained the definition in its proposed form, because requiring a different individual to serve in each role will better ensure a fair and unbiased outcome.

M. Institutional Member, NPRM § 93.222

Commenters recommended revising the definition to remove the inclusion of subcontractors and subrecipients. ORI retained the definition in its proposed form and clarified related wording under “Applicability” in subpart A, because an individual’s duty to protect PHS funds from misuse should not depend on the individual’s employment status with a specific institution.

N. Intentionally, NPRM § 93.224

Commenters suggested revising this definition to provide further clarification. One commenter also suggested better harmonization with definitions used by other Federal agencies. ORI retained the definition in its proposed form to avoid including additional terms that could introduce ambiguity. ORI intends to explore opportunities to harmonize policy across Federal entities.

O. Knowingly, NPRM § 93.226

Many commenters generally supported retaining this proposed definition; however, several commenters requested clarification on distinctions among “knowingly,” “recklessly,” and “intentionally.” ORI retained the definition in its proposed form to avoid including additional terms that could introduce ambiguity.

P. Notice, NPRM § 93.227

One commenter recommended removing this definition. Another commenter recommended revision to remove the word “serve.” ORI retained the definition because it describes an essential part of the process of notifying respondents. ORI retained the word “serve” for clarity and notes that the definition does not require the use of a process server.

Q. Office of Research Integrity or ORI, NPRM § 93.228

One commenter recommended removing this definition because it is a commonly understood term. ORI retained the definition in its proposed form because it is helpful to the public.

R. Plagiarism, NPRM § 93.230

Commenters recommended revising this definition, particularly to clarify “self-plagiarism.” ORI retained the definition in its proposed form. Because “plagiarism” is defined as the appropriation of “another person’s” ideas, processes, results, or words, without giving appropriate credit, the exclusion of a “self-plagiarism” definition was intended to confirm that the appropriation must be of “another person’s” rather than one’s own ideas, processes, results, or words. Thus, ORI does not believe it necessary to further define “self-plagiarism” in its regulation, but ORI may address this topic through future policymaking.

S. Preponderance of Evidence, NPRM § 93.231

One commenter supported the inclusion of the definition. Another commenter recommended revision to clarify the definition. ORI retained the

definition because there was no consensus among the comments and because it was satisfied that the proposed definition served the purpose of explaining the term to those who may be unfamiliar with the term in the research misconduct context.

T. Research Integrity Officer or RIO, NPRM § 93.237

Several commenters provided feedback on this definition. Many commenters supported the inclusion of this definition. A minority of commenters recommended its removal because they conveyed that it was unnecessary or confusing. ORI retained the definition in its proposed form because it is helpful to the public and clarifies the specific responsibilities of this role.

U. Research Misconduct, NPRM § 93.238

Commenters recommended revision of the definition to include questionable research practices. One commenter conveyed that the definition was unnecessary. One commenter requested retention of the proposed definition. ORI decided to retain this definition because it is consistent with the definition found in the 2000 Office of Science and Technology Policy’s Federal Policy on Research Misconduct, 65 FR 76260 (Dec. 6, 2000).

V. Retaliation, NPRM § 93.242

Commenters recommended revision of this definition to make it more expansive. ORI retained the definition in its proposed form as a more limited definition is needed to accommodate HHS components that address retaliation in other contexts.

W. General Responsibilities for Compliance, NPRM § 93.300(g)

Commenters proposed removing the portion of § 93.300(g) that requires institutions to address deficiencies or additional allegations, noting that ORI already has a broad mandate to ensure compliance. One commenter asked ORI to add a requirement that institutions take precautions to ensure that complainants do not have unresolved conflicts of interest with the respondent. Some commenters recommended retaining the section as proposed. Commenters also requested more guidance on fostering an environment of research integrity and developing and evaluating effective training programs; one commenter offered suggestions about how to improve Responsible Conduct of Research training. ORI acknowledges the compliance process can be complex. ORI left this section

unchanged because providing guidance rather than stipulating additional regulatory requirements reduces institutional burden. ORI intends to issue further guidance on these topics.

X. Research Integrity Assurances, NPRM § 93.301

One commenter noted changing the title of this section from “Institutional Assurances” to “Research Integrity Assurances” was confusing and could be misread as materially altering the nature of institutional assurances. One commenter expressed it was inappropriate to require the person who coordinates an institution’s compliance assurances and Responsible Conduct of Research program to also be responsible for fostering an environment that supports research integrity, because that is a leadership-level responsibility. There was a request for more specific guidance on how institutions can foster research integrity, with examples focused not only on research but also the concept of “research integrity” more broadly. ORI acknowledges the compliance process can be complex. ORI left this section unchanged because providing guidance rather than stipulating additional regulatory requirements reduces institutional burden. ORI intends to issue further guidance on these topics.

Y. Maintaining Active Research Integrity Assurances, NPRM § 93.302(a)

One commenter requested greater clarity in proposed § 93.302(a)(4)(ii) on the scope of policies and procedures that institutions are required to make publicly available. ORI intends to issue guidance on this topic.

Z. General Conduct of Research Misconduct Proceedings – Sequestration of Research Records and Other Evidence, NPRM § 93.305(a)

Most commenters approved of proposed § 93.305(a) and expressed appreciation that institutions may sequester copies of records if they are substantially equivalent in evidentiary value. ORI retained the language as proposed.

AA. General Conduct of Research Misconduct Proceedings – Multiple Institutions, NPRM § 93.305(e)

Commenters appreciated ORI’s addition of this subsection because there has been an increase in complex cases involving more than one institution. However, they requested further guidance on how to handle such cases, including how to determine a lead institution. ORI intends to issue further guidance on this topic.

BB. General Conduct of Research Misconduct Proceedings – Interviews, NPRM § 93.305(g)

Some commenters suggested revising NPRM section § 93.305(g)(5) to require institutions to redact all interview transcripts before forwarding them to the respondent, to protect interviewees' identities. ORI left this section unchanged and moved it to § 93.310(g) because policies regarding interview transcriptions prior to the investigation phase should be left to the discretion of institutions.

CC. Institutional Investigation, NPRM § 93.310

Commenters recommended revising § 93.310(a) to extend the time to begin an investigation. ORI retained the proposed language because it is important to proceed promptly after an institution decides an investigation is warranted.

DD. Investigation Time Limits, NPRM § 93.311

Several commenters approved of ORI's increasing the investigation period from 120 to 180 days; however, a significant number of commenters expressed that 180 days is inadequate to conduct a thorough investigation. These commenters requested timeframes ranging up to a year or more. ORI retained the proposed 180-day timeline, because the timeframe balances the needs of institutions and the need of respondents to have investigations conclude within a reasonable amount of time, and institutions have the opportunity to request extensions. ORI will continue to work closely with institutions that request and substantiate the need for an extension.

EE. Interaction With Other Entities and Interim Actions, NPRM § 93.401(b)

Commenters recommended revising § 93.401(b) to require ORI to notify the RIO or the Institutional Deciding Official if ORI makes a determination to refer a case to the Department of Justice or other Federal agencies while the institution's research misconduct proceedings are pending. ORI retained the language of this section because such referrals are nonpublic.

FF. ORI Allegation Assessments, NPRM § 93.402

One commenter was concerned about the removal of language that was in the 2005 regulation specifying the requirements for ORI to conduct an assessment. ORI did not restore the language because it is redundant with § 93.204 of the final rule.

GG. Final HHS Action With No Settlement or Finding of Research Misconduct, NPRM § 93.410(b)

One commenter stated that the institutional investigation report is part of a PHS-supported research process and should be made public; they suggested copies of or links to all institutional investigation reports should be posted on the ORI website. ORI retained the language as proposed because the institutional investigation report is not a public document and is protected by the Privacy Act, 5 U.S.C. 552a.

HH. Rights of the Parties, NPRM § 93.505

One commenter suggested that discovery and *de novo* review are not needed; all that should be required is consideration of all the evidence available to the ALJ, including the institutional record and additional testimony and other evidence provided during the appeal. ORI did not make further changes because ORI already proposed removing the discovery and *de novo* review provisions in the NPRM.

V. Effective Date

The final rule will become effective January 1, 2025, and all regulatory requirements will be applicable on January 1, 2026, which will apply prospectively. The effect of the prospective application to research misconduct proceedings will depend on when allegations are received by institutions. The final rule applies to research misconduct proceedings based on allegations received by institutions on or after January 1, 2026. For allegations received by an institution prior to January 1, 2026, an institution must follow 42 CFR part 93 as published in the 2005 edition of the Code of Federal Regulations, unless a respondent and institution agree in writing to apply the final rule to a particular research misconduct proceeding. Institutions must implement and submit revised policies and procedures that comply with the final rule along with their annual report covering 2025, which must be received by ORI on or before April 30, 2026.

VI. Required Regulatory Analyses

We examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and the Congressional Review Act (5 U.S.C. 801–808).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits,

costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). A “significant regulatory action” under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) includes a “regulatory action likely to result in a rule that may have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.” The analysis below concludes that this final rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1). OIRA has determined that this final rule is a significant regulatory action, but that it does not meet the criteria set forth in 5 U.S.C. 804(2) under the Congressional Review Act.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small institutions. The analysis below concludes that the final rule will not have a significant economic impact on a substantial number of small institutions.

The Unfunded Mandates Reform Act of 1995 (UMRA) generally requires that each agency conduct a cost-benefit analysis, identify and consider a reasonable number of regulatory alternatives, and select the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule before promulgating any proposed or final rule that includes a Federal mandate that may result in expenditures of more than \$100 million (adjusted for inflation) in at least one year by State, local, and tribal governments, or by the private sector. Each agency must also seek input from State, local, and tribal governments. The current threshold after adjustment for inflation using the Implicit Price Deflator for the Gross Domestic Product is \$183 million, reported in 2023 dollars. Per the analysis below, this final rule will not result in an unfunded mandate in any year that meets or exceeds this amount.

Baseline and Summary of Impacts

Under the current regulatory requirements, all recipients of PHS

support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training must comply with certain reporting and record keeping requirements. However, since many of these impacts have not been comprehensively quantified and monetized in a previously published regulatory impact analysis, when considering the potential impacts of this final rule, we adopt an analytic baseline that excludes many ongoing activities associated with the existing requirements. For example, absent any further regulatory action, we anticipate that covered entities would continue to incur costs (inclusive of the opportunity costs of staff time and other resources) associated with filing an annual statement of assurance (research integrity assurance) and an annual report on allegations received; costs associated with submitting reports and evidence to support their results and conclusions of inquiries or investigations of research misconduct; and costs associated with obtaining all research records and other evidence when there is an allegation of research misconduct and engaging persons to handle the process for addressing the allegations of research misconduct.

We anticipate that the final rule will likely reduce the burden of compliance by institutions through reduced confusion and uncertainty. Thus, the benefits of this final rule stem from reduced confusion for research institutions to understand the requirements that apply to them. This final rule will reduce the potential for lengthy back-and-forth discussions between ORI and institutions to ensure that institutions conduct complete and fair investigations of allegations of research misconduct. It will also streamline the process for respondents to appeal ORI findings of research misconduct and proposed HHS administrative actions. We anticipate that these revisions will reduce the burden across the affected research community. This final rule will also help foster an environment of responsible conduct of research.

We anticipate that this final rule will likely result in one-time costs associated with covered institutions updating their policies and procedures for responding to allegations of research misconduct. For institutions that undertake proceedings to address allegations of research misconduct, we identify and monetize additional recurring costs associated with documenting aspects of those proceedings. We quantify and monetize these costs in the next section.

One-Time Costs Associated With Updating Policies and Procedures

In support of the NPRM, we performed an initial threshold analysis to assess the approximate magnitude of the impacts of the proposed rule to determine whether it would result in a significant regulatory action per section 3(f)(1) of Executive Order 12866. We identified the potential costs associated with covered institutions updating their policies and procedures for responding to allegations of research misconduct as the largest impact under the proposed rule. To quantify this impact, we adopted a count of 5,910 institutions holding research integrity assurances that would update their policies and procedures. For the purposes of the initial threshold analysis, we adopted 16 hours as an estimate for the average time across all covered entities for these tasks. Across all covered entities, this was 94,560 total hours spent updating policies and procedures.

To monetize the change in time use associated with these activities, we adopted an hourly value of time based on the cost of labor, including wages and benefits, and also indirect costs, which “reflect resources necessary for the administrative oversight of employees and generally include time spent on administrative personnel issues (e.g., human resources activities such as hiring, performance reviews, personnel transfers, affirmative action programs), writing administrative guidance documents, office expenses (e.g., space rental, utilities, equipment costs), and outreach and general training (e.g., employee development).”¹

For these tasks, we identified a pre-tax hourly wage for Education Administrators, Postsecondary. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for these individuals was \$53.49 per hour.² We assumed that benefits plus indirect costs equal approximately 100 percent of pre-tax wages, and adjusted this hourly rate by multiplying by two, for a fully loaded hourly wage rate of \$106.98. We multiplied this fully loaded hourly wage rate by the 94,560 total

hours across covered entities spent updating policies and procedures and estimated a total cost in the first year of about \$10.1 million.

We received public comments suggesting it will take institutions more than 16 hours to update their policies and procedures,³ with alternative estimates including between 17–26 hours, between 27–40 hours, or more than 40 hours. We appreciate these comments, and in response, we present an additional threshold analysis, following the same approach described above, but adopting several revised assumptions and updated data. This threshold analysis helps to determine whether it will result in a significant regulatory action per section 3(f)(1) of Executive Order 12866 and to determine whether any effects will exceed the UMRA threshold. For this analysis, we adopt a more recent estimate that 6,394 institutions holding research integrity assurances. Consistent with an upper-bound estimate from public comments, we adopt 40 hours as the average hours per covered entity. We updated the pre-tax hourly wage to \$55.38 per hour,⁴ for a fully loaded hourly wage rate of \$110.76. The modified assumptions indicate that, across all covered entities, 255,760 hours would be spent updating policies and procedures. Monetizing this impact using the fully loaded hourly wage rate, this would represent a cost in the first year of about \$28.3 million. Thus, our modified threshold analysis indicates that the largest economic impact of the final rule would not exceed the monetary threshold for significant regulatory actions per section 3(f)(1) of Executive Order 12866 or the UMRA threshold. We emphasize that this estimate corresponds to an upper-bound estimate of the potential impacts based on public comments to the proposed rule.

As discussed in greater detail in the Preamble, this final rule includes several revisions that generally reduce the burden on the institutions covered, compared to the proposed rule. To estimate the costs associated with covered institutions updating their policies and procedures, we adopt 16 hours as an estimate for the average time per covered entity and apply the updated fully loaded hourly wage

¹ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2017. “Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.” <https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework>. Page v. Accessed March 29, 2024.

² U.S. Bureau of Labor Statistics. Occupational Employment and Wages, May 2021. 11–9033 Education Administrators, Postsecondary. Mean hourly wage. <https://www.bls.gov/oes/current/oes119033.htm>. Accessed March 29, 2024.

³ For example, see “Comment from COGR, HHS–OASH–2023–0014, HHS–OASH–2023–0014–0001, 2023–21746.” <https://www.regulations.gov/comment/HHS-OASH-2023-0014-0074>. Accessed March 29, 2024.

⁴ U.S. Bureau of Labor Statistics. Occupational Employment and Wages, May 2022. 11–9033 Education Administrators, Postsecondary. Mean hourly wage. <https://www.bls.gov/oes/current/oes119033.htm>. Accessed March 29, 2024.

estimate (\$110.76) and covered entity count (6,394 institutions). Combining these assumptions results in an estimate of the total cost associated with updating policies and procedures in the first year of about \$11.3 million.

Recurring Costs Attributable to the Final Rule

For institutions that address allegations of research misconduct, we identify additional recurring costs associated with the final rule’s reporting, recordkeeping, and third-party disclosure requirements related to institutions responding to allegations of research misconduct. To quantify these impacts, we adopt an estimate of 230 cases per year, matching the most recent annual count of cases reported to HHS.

Consistent with our estimates in the Paperwork Reduction Act section of this Preamble, we believe that institutions will spend a total of 221,030 hours per year on these requirements, which is about 961 hours per case. To monetize these impacts, we adopt the fully loaded hourly value of time of \$110.76 per hour for postsecondary education administrators. Across all 230 cases, we compute an annual cost associated with these regulatory requirements of \$24,481,283 per year. The Paperwork Reduction Act section of this Preamble contains additional details on the annual burden estimates and total costs associated with each of these requirements.

Summary and Timing of Costs of the Final Rule

Across all covered institutions, we anticipate that the final rule will result in about \$11.3 million in one-time costs associated with institutions updating policies and procedures. We account for timing of these impacts by assuming they will occur in 2025. We also identify incremental costs of about \$24.5 million associated with the final rule’s reporting, recordkeeping, and third-party disclosure requirements related to institutions responding to allegations of research misconduct. Consistent with the implementation schedule of the final rule, we account for timing of these recurring impacts by assuming they will occur in 2026 and in subsequent years. Over a 5-year time horizon, we report a present value of total costs attributable to the final rule of about \$102.5 million, or annualized costs of about \$21.7 million, both calculated using a constant 2% real discount rate.

TABLE 1—COSTS OF THE FINAL RULE
[Constant 2023 dollars, 2% discount rate]

Year	Cost
2025	\$11,331,191
2026	24,481,283
2027	24,481,283
2028	24,481,283
2029	24,481,283
Present Value	102,499,288
Annualized	21,746,084

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to prepare a regulatory flexibility analysis describing the impact of the final rule on small entities (“institutions” for purposes of the final rule) unless they certify that a final rule will not, if promulgated, have a significant economic impact on a substantial number of small institutions. HHS generally considers a rule to have a significant impact on a substantial number of small institutions if it has at least a 3% impact on revenue on at least 5% of small institutions. We considered whether the final rule would result in effects that exceed these thresholds. This analysis below concludes, and the Secretary certifies that this final rule will not have a significant impact on a substantial number of small institutions, as defined by the Regulatory Flexibility Act, based on the following facts.

As of March 1, 2024, approximately 22 percent (1,412) of 6,394 institutions holding research integrity assurances are small institutions. The primary impact of the final rule on covered institutions results from the reporting and record keeping provisions, which are analyzed in detail under the heading “The Paperwork Reduction Act.” Potentially significant annual burdens apply only if an institution learns of possible research misconduct and begins an inquiry, investigation, or both.

Institutions covered by 42 CFR part 93 reported having conducted a total of 124 inquiries and 121 investigations during the 2023 reporting period. In total, one inquiry and three investigations were conducted by small institutions. Small institutions may be able to avoid developing and filing the full policies and procedures for addressing allegations of research misconduct required by § 93.304 by filing a Small Institution Statement. Under the 2005 regulation, this is called a Small Organization Statement. ORI or another appropriate HHS office will work with small institutions to develop and/or advise on a process for handling allegations of research misconduct

consistent with 42 CFR part 93. The burden of filing the Small Institution Statement is 0.5 hour. Thus, the burden of developing and filing the full policies and procedures for addressing allegations of research misconduct required by § 93.304 will not fall on a substantial number of small entities.

A small entity that files the Small Institution Statement must still report allegations of research misconduct to ORI and comply with all provisions of the final rule except as described in § 93.303. The most significant burden that could fall on an entity filing a Small Institution Statement is in addressing allegations of research misconduct, which would include obtaining all research records and other evidence when there is an allegation of research misconduct, engaging persons to handle the process for addressing the allegations of research misconduct, and submitting reports and evidence to support the small institution’s results and conclusions of inquiries or investigations of research misconduct. The average burden per response is estimated at 40 hours. Based on reports of research misconduct over the past five years, fewer than five small institutions will have to incur that burden in any year. Based on this analysis, HHS concludes that the regulations set forth in the final rule will not impose a significant burden on a substantial number of small institutions.

Paperwork Reduction Act

Sections 104, 301–303, 305–313, and 315–318 of this final rule contain information collection requirements that are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521). These provisions involve the following institutional activities in addressing allegations of misconduct involving PHS-funded research:

Title: The title of the section of the Public Health Service Policies on Research Misconduct involving institutional activities.

Description: The relevant passage(s) of the section describing the institutional information collection requirements.

Description of Respondents: The “respondents” for the collection of information described in this regulation are institutions that apply for or receive PHS support through grants, contracts, or cooperative agreements for any project or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to

that research or training (see definition of “Institution” at § 93.216).

Subpart A—General

Section 93.104

(ii) For research misconduct that appears subject to the subsequent use exception, institutions must document their determination that the subsequent use exception does not apply. Such documentation must be retained in accordance with § 93.318.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—40 hours.

Total Annual Burden—9,200 hours.

Subpart C—Responsibilities of Institutions

Compliance and Assurances

Section 93.305

(b) *Access to research records.* Where appropriate, an institution must give the respondent copies of, or reasonable supervised access to, the research records that are sequestered in accordance with paragraph (a) of this section.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—25 hours.

Total Annual Burden—5,750 hours.

(c) *Maintenance of sequestered research records and other evidence.* An institution must maintain the sequestered research records and other evidence as required by § 93.318.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—80 hours.

Total Annual Burden—18,400 hours.

(g) *Notifying ORI of special circumstances.* At any time during a research misconduct proceeding, as defined in § 93.235, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:

(1) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

(2) 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.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—1 hour.

Total Annual Burden—230 hours.

The Institutional Assessment

Section 93.306

(c) *Assessment results.*

(2) If the RIO or another designated institutional official determines that requirements for an inquiry are met, they must: (i) document the assessment;

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—80 hours.

Total Annual Burden—18,400 hours.

(ii) promptly sequester all research records and other evidence, consistent with § 93.305(a), and promptly initiate the inquiry.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—160 hours.

Total Annual Burden—36,800 hours.

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

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—10 hours.

Total Annual Burden—2,300 hours.

The Institutional Inquiry

Section 93.307

(d) *Sequestration of records.* An institution must obtain all research records and other evidence needed to conduct the research misconduct proceeding, consistent with § 93.305(a).

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—80 hours.

Total Annual Burden—18,400 hours.

Section 93.308

(a) *Notice to respondent.* The institution must notify the respondent whether the inquiry found that an

investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to this part and the institution's policies and procedures adopted under its research integrity assurance.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—2 hours.

Total Annual Burden—460 hours.

Section 93.309

(a) Within 30 days of determining that an investigation is warranted, the institution must provide ORI with a copy of the inquiry report, which includes the following information:

(1) The names, professional aliases, and positions of the respondent and complainant;

(2) A description of the allegation(s) of research misconduct;

(3) The PHS support, including, for example, 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) Inventory of sequestered research records and other evidence and description of how sequestration was conducted;

(6) Transcripts of any transcribed interviews;

(7) 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 an investigation;

(11) Any comments on the inquiry report by the respondent or the complainant; and

(12) Any institutional actions implemented, including communications with journals or funding agencies.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—4 hours.

Total Annual Burden—920 hours.

(b) Institutions must keep detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the institution decided not to investigate. Such documentation must be retained in accordance with § 93.318.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—0 hours. Burden accounted for in § 93.316(a)(2).

Total Annual Burden—0 hours.

(c) In accordance with § 93.305(g), institutions must notify ORI of any special circumstances that may exist.

Number of Respondents—230.

Number of Responses per

Respondent—1.

Annual Average Burden per Response—2 hours.

Total Annual Burden—460 hours.

The Institutional Investigation

Section 93.310

Institutions conducting research misconduct investigations must: (b) Notify ORI of the decision to begin an investigation on or before the date the investigation begins and provide an inquiry report that meets the requirements of § 93.307 and § 93.309.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—0 hours. Burden accounted for in § 93.309(a).

Total Annual Burden—0 hours.

(d) *Notice to the respondent.* Notify the respondent in writing of the allegation(s) within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—0 hours. Burden accounted for in § 93.308(a).

Total Annual Burden—0 hours.

(g) *Interviews.* During the investigation, an institution must interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent. (1) Interviews during the investigation must be recorded and transcribed.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—300 hours.

Total Annual Burden—69,000 hours.

(3) The transcript of the interview must be made available to the relevant interviewee for correction.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—4 hours.

Total Annual Burden—920 hours.

(5) The respondent must be provided a transcript of the interview.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—4 hours.

Total Annual Burden—920 hours.

(j) *Pursue leads.* If additional allegations are raised, the respondent(s) must be notified in writing of the additional allegations raised against them.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—2 hours.

Total Annual Burden—460 hours.

Section 93.310

(b) *Extension of time limit.* If unable to complete the investigation in 180 days, the institution must ask ORI for an extension in writing that includes the circumstances or issues warranting additional time.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—1 hour.

Total Annual Burden—230 hours.

(c) *Progress reports.* If ORI grants an extension, it may direct the institution to file periodic progress reports.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—1 hour.

Total Annual Burden—230 hours.

Section 93.312

(a) 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.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—2 hours.

Total Annual Burden—460 hours.

Section 93.313

A final investigation report for each respondent must be in writing and include:

(a) Description of the nature of the allegation(s) of research misconduct,

including any additional allegation(s) addressed during the research misconduct proceeding.

(b) Description and documentation of the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.

(c) Description of the specific allegation(s) of research misconduct for consideration in the investigation of the respondent.

(d) Composition of investigation committee, including name(s), position(s), and subject matter expertise.

(e) Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on; and a description of how any sequestration was conducted during the investigation. This inventory must include manuscripts and funding proposals that were considered or relied on during the investigation.

(f) Transcripts of all interviews conducted, as described in § 93.310(g).

(g) 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 allegedly contained the falsified, fabricated, or plagiarized material.

(h) Any scientific or forensic analyses conducted.

(i) If not already provided to ORI, the institutional policies and procedures under which the investigation was conducted.

(j) Any comments made by the respondent and complainant on the draft investigation report and the investigation committee's consideration of those comments.

(k) A statement for each separate allegation of whether the investigation committee recommends a finding of research misconduct.

(1) If the investigation committee recommends a finding of research misconduct for an allegation, the investigation report must, for that allegation:

(i) Identify the individual(s) who committed the research misconduct.

(ii) Indicate whether the research misconduct was falsification, fabrication, and/or plagiarism.

(iii) Indicate whether the research misconduct was committed intentionally, knowingly, or recklessly.

(iv) State whether the other requirements for a finding of research misconduct, as described in § 93.103, have been met.

(v) Summarize the facts and the analysis which support the conclusion

and consider the merits of any explanation by the respondent.

(vi) Identify the specific PHS support.

(vii) Identify whether any publications need correction or retraction.

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

(l) List of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—160 hours.

Total Annual Burden—36,800 hours.

Section 93.315

(a) If a respondent appeals an institution's finding(s) of research misconduct or institutional actions, the institution must promptly notify ORI.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—1 hour.

Total Annual Burden—230 hours.

(b) If the institution has not transmitted its institutional record to ORI in accordance with § 93.316 prior to the appeal, the institution must wait until the appeal is concluded to transmit its institutional record. The institution must ensure that the complete record of the appeal is included in the institutional record consistent with § 93.220(a)(5).

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—0 hours. Burden accounted for in § 93.316(a).

Total Annual Burden—0 hours.

(c) If the institution has transmitted its institutional record to ORI in accordance with § 93.316 prior to the appeal, the institution must provide ORI a complete record of the appeal once the appeal is concluded.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—2 hours.

Total Annual Burden—460 hours.

Section 93.316

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

Per § 93.220: 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.

(c) A general description of the records that were sequestered but not considered or relied on.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—4 hours.

Total Annual Burden—920 hours.

Section 93.317

(a) Institutions must notify 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 to committing research misconduct or a settlement with the respondent has been reached.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—1 hour.

Total Annual Burden—230 hours.

(b) The [respondent's written] admission statement must meet all elements required for a research misconduct finding under § 93.103 and must be provided to ORI before the institution closes its research misconduct proceeding.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—10 hours.

Total Annual Burden—2,300 hours.

(b—continued): The institution must also provide a statement to ORI describing how it determined that the scope of the misconduct was fully addressed by the admission and confirmed the respondent's culpability.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—10 hours.

Total Annual Burden—2,300 hours.

Section 93.318

(a) Maintenance of institutional record and all sequestered evidence. An institution must maintain the institutional record and all sequestered evidence including physical objects (regardless of whether the evidence is part of the institutional record) in a secure manner for seven years after completion of the proceeding or the completion of any HHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later, unless custody has been transferred to HHS under paragraph (b) of this section or ORI advises otherwise in writing.

Number of Respondents—230.

Number of Responses per Respondent—1.

Annual Average Burden per Response—8 hours.

Total Annual Burden—1,840 hours.

ESTIMATED ANNUALIZED BURDEN HOUR TABLE (9/3/2024)

Forms (If necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden Hours
§ 93.104	Institutions	230	1	40	9,200
§ 93.305.b	Institutions	230	1	25	5,750
§ 93.305.c	Institutions	230	1	80	18,400
§ 93.325	Institutions	230	1	1	230
§ 93.306.c.2.i	Institutions	230	1	80	18,400
§ 93.306.c.2.ii	Institutions	230	1	160	36,800
§ 93.306.c.2.iii	Institutions	230	1	10	2,300
§ 93.307	Institutions	230	1	80	18,400
§ 93.308	Institutions	230	1	2	460
Sec 93.309.a	Institutions	230	1	4	920
Sec 93.309.c	Institutions	230	1	2	460
§ 93.310.g.1	Institutions	230	1	300	69,000
§ 93.310.g.3	Institutions	230	1	4	920
§ 93.310.g.5	Institutions	230	1	4	920
§ 93.310.j	Institutions	230	1	2	460
§ 93.310.b	Institutions	230	1	1	230
§ 93.310.c	Institutions	230	1	1	230
§ 93.312	Institutions	230	1	2	460
§ 93.313	Institutions	230	1	160	36,800
§ 93.315.a	Institutions	230	1	1	230
§ 93.315.c	Institutions	230	1	2	460
Total					221,030

Estimated annualized cost to respondents (9/3/2024) Forms (If necessary)	Type of respondent	Total burden hours	Hourly wage rate	Total respondent cost
§ 93.104	Institutions	9,200	\$111	\$1,018,992
§ 93.305.b	Institutions	5,750	111	636,870
§ 93.305.c	Institutions	18,400	111	2,037,984
§ 93.325	Institutions	230	111	25,475
§ 93.306.c.2.i	Institutions	18,400	111	2,037,984
§ 93.306.c.2.ii	Institutions	36,800	111	4,075,968
§ 93.306.c.2.iii	Institutions	2,300	111	254,748
§ 93.307	Institutions	18,400	111	2,037,984
§ 93.308	Institutions	460	111	50,950
Sec 93.309.a	Institutions	920	111	101,899
Sec 93.309.c	Institutions	460	111	50,950
§ 93.310.g.1	Institutions	69,000	111	7,642,440
§ 93.310.g.3	Institutions	920	111	101,899
§ 93.310.g.5	Institutions	920	111	101,899
§ 93.310.j	Institutions	460	111	50,950
§ 93.310.b	Institutions	230	111	25,475
§ 93.310.c	Institutions	230	111	25,475
§ 93.312	Institutions	460	111	50,950
§ 93.313	Institutions	36,800	111	4,075,968
§ 93.315.a	Institutions	230	111	25,475
§ 93.315.c	Institutions	460	111	50,950
Total				24,481,283

Following publication of the final rule, ORI will publish 60-day and 30-day notices in the **Federal Register** seeking public comment on these information collection requirements and associated burden estimates, and ORI will submit an Information Collection Request (ICR) to OMB seeking approval for these requirements under existing OMB Control Number 0937–0198, which currently covers the assurance and annual reporting requirements of 42 CFR part 93 (the Institutional Assurance and Annual Report on Possible Research

Misconduct, PHS–6349, and the Assurance of Compliance by Sub-Award Recipients, PHS–6315). Before the applicability date of this final rule, ORI anticipates publishing a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove this ICR. This final rule does not make any substantive revisions to the Assurance or Annual Report that would require clearance under the PRA, but ORI anticipates making minor updates to these forms as part of the upcoming revision to 0937–0198.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 42 CFR Part 93

Government contracts, Grant programs, Reporting and recordkeeping requirements, Research, Science and technology.

■ For reasons discussed in the preamble, HHS is revising 42 CFR part 93 to read as follows:

PART 93—PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

Sec.

93.25 Organization of this part.

93.50 Special terms.

93.75 Application of effective date to research misconduct proceedings.

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93.221 Intentionally.

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93.310 Institutional investigation.

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Authority: 42 U.S.C. 216 and 289b

§ 93.25 Organization of this part.

This part is subdivided into five subparts. Each subpart contains information related to a broad topic or specific audience with special responsibilities as shown in the following table.

TABLE 1 TO § 93.25

In subpart	You will find sections related to
...	...
A	General information about this part.
B	Definitions used in this part.
C	Responsibilities of institutions with PHS support.
D	Responsibilities of the U.S. Department of Health and Human Services and the Office of Research Integrity.
E	Information on how to contest ORI research misconduct findings and proposed HHS administrative actions.

§ 93.50 Special terms.

This part uses terms throughout the text that have special meaning. Those terms are defined in subpart B of this part.

§ 93.75 Application of effective date to research misconduct proceedings.

(a) An institution must follow this part for allegations received by the institution on or after January 1, 2026, except for the policies and procedures required under §§ 93.300(a) and 93.302(b), which must be implemented and submitted by due date of the annual report covering the 2025 reporting year, as specified by ORI.

(b) For allegations received by an institution before January 1, 2026, unless the institution and the respondent both elect in writing to follow this part, an institution must follow this part as published in the 2005 edition of the Code of Federal Regulations.

Subpart A—General**§ 93.100 General policy.**

(a) Research misconduct involving Public Health Service (PHS) support is contrary to the interests of the PHS and the Federal Government, to the health and safety of the public, to the integrity of research, and to the conservation of public funds.

(b) The U.S. Department of Health and Human Services (HHS) and institutions that apply for or receive PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training share responsibility for the integrity of the research process. HHS has ultimate oversight authority for PHS-supported research, and for taking other actions as appropriate or necessary, including the right to assess allegations and to perform inquiries or investigations at any time. Institutions and institutional members have an affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS-supported work, and primary responsibility for responding to and reporting allegations of research misconduct, as provided in this part.

§ 93.101 Purpose.

The purpose of this part is to—

(a) Establish the responsibilities of HHS, the Office of Research Integrity (ORI), and institutions in addressing allegations of research misconduct;

(b) Define what constitutes research misconduct in PHS-supported research;

(c) Establish the requirements for a finding of research misconduct;

(d) Define the general types of administrative actions HHS may take in response to research misconduct;

(e) Require institutions to:

(1) Develop and implement policies and procedures for reporting and addressing allegations of research misconduct covered by this part;

(2) Provide HHS with the assurances necessary to permit institutions to participate in PHS-supported research;

(f) Protect the health and safety of the public, promote the integrity of PHS-supported research and the research process, and conserve public funds.

§ 93.102 Applicability.

(a) Every extramural or intramural institution that applies for or receives PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training must comply with this part.

(b) This part applies to allegations of research misconduct involving:

(1) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, biomedical or behavioral research training, or activities related to that research or research training;

(2) PHS-supported biomedical or behavioral extramural or intramural research;

(3) PHS-supported biomedical or behavioral extramural or intramural research training programs;

(4) PHS-supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as, but not limited to, the operation of tissue and data banks or the dissemination of research information;

(5) Research records produced during PHS-supported research, research training, or activities related to that research or research training; and

(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.

(c) This part does not supersede or establish an alternative to any applicable statutes, regulations, policies, or procedures for handling fiscal improprieties, the ethical treatment of human or animal subjects, criminal matters, personnel actions against Federal employees, or addressing whistleblowers and/or retaliation.

(d) This part does not supersede or establish an alternative to the HHS suspension and debarment regulations set forth at 2 CFR part 180, as implemented by HHS at 2 CFR part 376; and 48 CFR part 9, subpart 9.4, as supplemented by HHS at 48 CFR part 309, subpart 309.4. The Suspension and Debarment Official SDO and ORI may coordinate actions to the extent consistent with the SDO's and ORI's respective authorities. Such coordination includes jointly issuing notices or seeking settlements of actions and proceedings.

(e) This part does not prohibit or otherwise limit how institutions handle allegations of misconduct that do not fall within this part's definition of research misconduct or that do not involve PHS support.

§ 93.103 Requirements for findings of research misconduct.

A finding of research misconduct made under this part requires that:

(a) There be a significant departure from accepted practices of the relevant research community; and

(b) The misconduct be committed intentionally, knowingly, or recklessly; and

(c) The allegation be proven by a preponderance of the evidence.

§ 93.104 Time limitations.

(a) *Six-year limitation.* This part applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct.

(b) *Exceptions to the six-year limitation.* Paragraph (a) of this section does not apply in the following instances:

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

(i) When the respondent uses, republishes, or cites to the portion(s) of the research record that is alleged to have been fabricated, falsified, or plagiarized, in submitted or published manuscripts, submitted PHS grant applications, progress reports submitted to PHS funding components, posters, presentations, or other research records within six years of when the allegations were received by HHS or an institution, this exception applies.

(ii) For research misconduct that appears subject to the subsequent use exception, institutions must document their determination that the subsequent use exception does not apply. Such documentation must be retained in accordance with § 93.318.

(2) *Exception for the health or safety of the public.* If ORI or the institution, 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, this exception applies.

§ 93.105 Evidentiary standards.

(a) *Standard of proof.* An institutional or HHS finding of research misconduct must be proved by a preponderance of the evidence.

(b) *Burden of proof.* (1) The institution or HHS has the burden of proof for making a finding of research misconduct. A respondent's destruction of research records documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a

preponderance of the evidence that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. A 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.

(2) The respondent has the burden of going forward with and proving, by a preponderance of the evidence, all affirmative defenses raised. In determining whether HHS or the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

(3) The respondent has the burden of going forward with and proving, by a preponderance of the evidence, any mitigating factors relevant to a decision to impose administrative actions after a research misconduct proceeding.

§ 93.106 Confidentiality.

(a) Disclosure of the identity of respondents, complainants, and witnesses while conducting the research misconduct proceedings is limited, to the extent possible, to those who need to know, as determined by the institution, 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. This limitation on disclosure of the identity of respondents, complainants, and witnesses no longer applies once an institution has made a final determination of research misconduct findings. The institution, however, must disclose the identity of respondents, complainants, or other relevant persons to ORI pursuant to an ORI review of research misconduct proceedings under this part.

(b) Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who need to know to carry out a research misconduct proceeding.

(c) This section does not prohibit institutions from managing published data or acknowledging that data may be unreliable.

§ 93.107 Coordination with other agencies.

(a) When more than one agency of the Federal Government has jurisdiction over a research misconduct allegation, HHS will cooperate with the other agencies in designating a lead agency to coordinate the response of the agencies to the allegation. Where HHS is not the lead agency, it may, in consultation with the lead agency, take appropriate action.

(b) In research misconduct proceedings involving more than one agency, HHS may refer to the other agency's (or agencies') evidence or reports if HHS determines that the evidence or reports will assist in resolving HHS issues. In appropriate cases, HHS may seek to resolve allegations jointly with the other agency or agencies.

Subpart B—Definitions

§ 93.200 Accepted practices of the relevant research community.

Accepted practices of the relevant research community 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.

§ 93.201 Administrative action.

Administrative action means an HHS action, consistent with § 93.407, taken in response to a research misconduct proceeding to protect the health and safety of the public, to promote the integrity of PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, or to conserve public funds.

§ 93.202 Administrative record.

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.

§ 93.203 Allegation.

Allegation means a disclosure of possible research misconduct through

any means of communication and brought directly to the attention of an institutional or HHS official.

§ 93.204 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.

§ 93.205 Charge letter.

Charge letter means the written notice, as well as any amendments to the notice, sent to the respondent stating the findings of research misconduct and any proposed HHS administrative actions.

§ 93.206 Complainant.

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

§ 93.207 Contract.

Contract means an acquisition instrument awarded under the Federal Acquisition Regulation (FAR), 48 CFR chapter 1.

§ 93.208 Day.

Day means calendar day unless otherwise specified. If a deadline falls on a Saturday, Sunday, or Federal holiday, the deadline will be extended to the next day that is not a Saturday, Sunday, or Federal holiday.

§ 93.209 Departmental Appeals Board or DAB.

Departmental Appeals Board or DAB means the organization, within the HHS Office of the Secretary, established to conduct hearings and provide impartial review of disputed decisions made by HHS operating components.

§ 93.210 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.

§ 93.211 Fabrication.

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

§ 93.212 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.

§ 93.213 Funding component.

Funding component means any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity covered by this part involving research or research training; funding components may be agencies, bureaus, centers, institutes, divisions, offices, or other awarding units within the PHS.

§ 93.214 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 this part. 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.

§ 93.215 Inquiry.

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

§ 93.216 Institution.

Institution means any person that 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.

§ 93.217 Institutional Certifying Official.

Institutional Certifying Official means the institutional official responsible for assuring on behalf of an institution that the institution has written policies and procedures for addressing allegations of research misconduct, in compliance with this part; and complies with its own policies and procedures and the requirements of this part. The Institutional Certifying Official is responsible for certifying the content of the institution's annual report, which contains information specified by ORI on the institution's compliance with this part, and ensuring the report is submitted to ORI, as required.

§ 93.218 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.

§ 93.219 Institutional member.

Institutional member or 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.

§ 93.220 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.

(c) A general description of the records that were sequestered but not considered or relied on.

§ 93.221 Intentionally.

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

§ 93.222 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.

§ 93.223 Knowingly.

To act knowingly means to act with awareness of the act.

§ 93.224 Notice.

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

§ 93.225 Office of Research Integrity or ORI.

Office of Research Integrity or ORI means the office established by Public Health Service Act section 493 (42 U.S.C. 289b) and to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS-supported activities.

§ 93.226 Person.

Person means any individual, corporation, partnership, institution, association, unit of government, or other legal entity, however organized.

§ 93.227 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.

§ 93.228 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.

§ 93.229 Public Health Service or PHS.

Public Health Service or PHS consists of the following components within HHS: the Office of the Assistant Secretary for Health, the Office of Global Affairs, the Administration for Strategic Preparedness and Response, the Advanced Research Projects Agency for Health, the Agency for Healthcare Research and Quality, the Agency for Toxic Substances and Disease Registry, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, and any other components of HHS designated or established as components of the Public Health Service.

§ 93.230 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.

§ 93.231 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.

§ 93.232 Research.

Research means a systematic experiment, study, evaluation,

demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating, or confirming information or underlying mechanisms related to biological causes, functions, or effects; diseases; treatments; or related matters to be studied.

§ 93.233 Research Integrity Officer or RIO.

Research Integrity Officer or 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 this part.

§ 93.234 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.

§ 93.235 Research misconduct proceeding.

Research misconduct proceeding means any actions related to alleged research misconduct taken under this part, including allegation assessments, inquiries, investigations, ORI oversight reviews, and appeals under subpart E of this part.

§ 93.236 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.

§ 93.237 Respondent.

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

§ 93.238 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.

§ 93.239 Secretary or HHS.

Secretary or HHS means the Secretary of HHS or any other official or employee of HHS to whom the Secretary delegates authority.

§ 93.240 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 this part without actual or apparent conflicts of interest.

§ 93.241 Suspension and Debarment Official or SDO.

Suspension and Debarment Official (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.

Subpart C—Responsibilities of Institutions

Compliance and Assurances

§ 93.300 General responsibilities for compliance.

Institutions must:

(a) Have written policies and procedures for addressing allegations of research misconduct that meet the requirements of this part;

(b) Respond to each allegation of research misconduct for which the institution is responsible under this part in a thorough, competent, objective, and fair manner, including taking 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 complainant, respondent, or witnesses;

(c) Foster a research 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;

(d) Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses, and committee members and to protect these individuals from retaliation by respondents and/or other institutional members;

(e) Provide confidentiality consistent with § 93.106 to all respondents, complainants, and witnesses in a research misconduct proceeding, and to

research subjects identifiable from research records or other evidence;

(f) 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;

(g) Cooperate with HHS during any research misconduct proceeding or compliance review, including addressing deficiencies or additional allegations in the institutional record if directed by ORI;

(h) Assist in administering and enforcing any HHS administrative actions imposed on its institutional members; and

(i) Have an active research integrity assurance.

§ 93.301 Research integrity assurances.

(a) *General policy.* (1) An institution that applies for or receives PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, must provide HHS with an assurance of compliance with this part by establishing and then maintaining an active research integrity assurance.

(2) PHS funding components may only authorize release of funds for extramural biomedical and behavioral research, biomedical and behavioral research training, or activities related to that research or research training, to institutions with an active research integrity assurance on file with ORI.

(b) *Research integrity assurance.* The Institutional Certifying Official must assure on behalf of the institution, initially and then annually thereafter, that the institution:

(1) Has written policies and procedures for addressing allegations of research misconduct, in compliance with this part.

(2) Complies with its policies and procedures for addressing allegations of research misconduct.

(3) Complies with all provisions of this part.

§ 93.302 Maintaining active research integrity assurances.

(a) *Compliance with this part.* ORI considers an institution in compliance with this part when it:

(1) Has policies and procedures for addressing allegations of research misconduct according to this part, keeps those policies in compliance with this part, and upon request, provides them to ORI and other HHS components.

(2) Complies with its policies and procedures for addressing allegations of research misconduct.

(3) Complies with all provisions of this part.

(4) Takes all reasonable and practical specific steps to foster research integrity consistent with § 93.300, including but not limited to:

(i) Informing the institution's members about its policies and procedures for addressing allegations of research misconduct, and the institution's commitment to compliance with the policies and procedures; and

(ii) Making its policies and procedures for addressing allegations of research misconduct publicly available.

(b) *Annual report.* An institution must file an annual report with ORI, which contains information specified by ORI, on the institution's compliance with this part. The Institutional Certifying Official is responsible for certifying the content of this report and for ensuring the report is submitted as required.

(c) *Additional information.* Along with its annual report, an institution must send ORI such other information as ORI may request on the institution's research misconduct proceedings covered by this part and the institution's compliance with the requirements of this part.

§ 93.303 Research integrity assurances for small institutions.

(a) Small institutions may file a Small Institution Statement with ORI in place of the institutional policies and procedures required by §§ 93.300(a), 93.301, and 93.304, upon approval by ORI.

(b) The Small Institution Statement does not relieve the institution from complying with any other provision of this part.

(c) By submitting a Small Institution Statement, the institution agrees to report all allegations of research misconduct to ORI. ORI or another appropriate HHS office will work with the institution to develop and/or advise on a process for handling allegations of research misconduct consistent with this part.

(d) If a small institution has or believes it has a conflict of interest during any phase of a research misconduct proceeding, the small institution may contact ORI for guidance.

§ 93.304 Institutional policies and procedures.

Institutions seeking an approved research integrity assurance must have written policies and procedures for addressing allegations of research misconduct. Such policies and procedures must:

(a) Address and be consistent with all applicable requirements pertaining to

institutional responsibilities included in this part;

(b) Include and be consistent with applicable definitions in this part; and

(c) Provide for all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

§ 93.305 General conduct of research misconduct proceedings.

(a) *Sequestration of research records and other evidence.* An institution must promptly take all reasonable and practical steps to obtain all research records and other evidence, which may include copies of the data or other evidence so long as those copies are substantially equivalent in evidentiary value, needed to conduct the research misconduct proceeding; inventory the research records and other evidence; and sequester them in a secure manner. Where the research records or other evidence are located on or encompass scientific instruments shared by multiple users, institutions may obtain copies of the data or other evidence from such instruments, so long as those copies are substantially equivalent in evidentiary value to the instruments. Whenever possible, the institution must obtain the research records or other evidence:

(1) Before or at the time the institution notifies the respondent of the allegation(s); and

(2) Whenever additional items become known or relevant to the inquiry or investigation.

(b) *Access to research records.* Where appropriate, an institution must give the respondent copies of, or reasonable supervised access to, the research records that are sequestered in accordance with paragraph (a) of this section.

(c) *Maintenance of sequestered research records and other evidence.* An institution must maintain the sequestered research records and other evidence as required by § 93.318.

(d) *Multiple respondents.* If an institution identifies additional respondents during an inquiry or investigation, the institution is not required to conduct a separate inquiry for each new respondent. However, each additional respondent must be provided notice of and an opportunity to respond to the allegations, consistent with this subpart.

(e) *Multiple institutions.* When allegations involve research conducted at multiple institutions, one institution must be designated as the lead

institution if a joint research misconduct proceeding is conducted. In a joint research misconduct proceeding, the lead institution should obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. 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.

(f) *Using a committee, consortium, or other person for research misconduct proceedings.* (1) An institution must address any potential, perceived, or actual personal, professional, or financial conflicts of interest between members of the committee or consortium, or other person, and the complainant, respondent, or witnesses.

(2) An institution must ensure that a committee, consortium, or person acting on its behalf conducts research misconduct proceedings in compliance with the requirements of this part.

(g) *Notifying ORI of special circumstances.* At any time during a research misconduct proceeding, as defined in § 93.235, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:

(1) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

(2) 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.

The Institutional Assessment

§ 93.306 Institutional assessment.

(a) *Purpose.* An assessment's purpose is to determine whether an allegation warrants an inquiry.

(b) *Conducting the institutional assessment.* Upon receiving an allegation of research misconduct, the RIO or another designated institutional official must promptly assess the allegation to determine whether the allegation:

(1) Falls within the definition of research misconduct under this part;

(2) Is within the applicability criteria of § 93.102; and

(3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

(c) *Assessment results.* (1) An inquiry must be conducted if the allegation meets the three assessment criteria in paragraph (b) of this section.

(2) If the RIO or another designated institutional official determines that requirements for an inquiry are met, they must:

(i) Document the assessment; and

(ii) Promptly sequester all research records and other evidence, consistent with § 93.305(a), and promptly initiate the inquiry.

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

The Institutional Inquiry

§ 93.307 Institutional inquiry.

(a) *Criteria warranting an inquiry.* An inquiry is warranted if the allegation meets the following three criteria:

(1) Falls within the definition of research misconduct under this part;

(2) Is within the applicability criteria of § 93.102; and

(3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

(b) *Purpose.* An inquiry's purpose is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation. An inquiry does not require a full review of the evidence related to the allegation.

(c) *Notice to the respondent.* At the time of or before beginning an inquiry, an institution must make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the institution must notify them. Only allegations specific to a particular respondent are to be included in the notification to that respondent. If additional allegations are raised, the respondent(s) must be notified in writing of the additional allegations raised against them.

(d) *Sequestration of records.* An institution must obtain all research records and other evidence needed to conduct the research misconduct proceeding, consistent with § 93.305(a).

(e) *Conducting the inquiry—(1) Multiple institutions.* A joint research misconduct proceeding must be conducted consistent with § 93.305(e).

(2) *Person conducting the inquiry.* Institutions may convene committees of experts to conduct reviews at the inquiry stage to determine whether an investigation is warranted. The inquiry review may be done by a RIO or another designated institutional official in lieu of a committee, with the caveat that if needed, these individuals may utilize one or more subject matter experts to assist them in the inquiry.

(3) *Interviews.* Institutions may interview witnesses or respondents that would provide additional information for the institution's review.

(f) *Inquiry results—(1) Criteria warranting an investigation.* An investigation is warranted if:

(i) There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part 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

(ii) Preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance.

(2) *Findings of research misconduct.* Findings of research misconduct, including the determination of whether the alleged misconduct is intentional, knowing, or reckless, cannot be made at the inquiry stage.

(g) *Inquiry report.* (1) The institution must prepare a written report that meets the requirements of this section and § 93.309.

(2) If there is potential evidence of honest error or difference of opinion, the institution must note this in the inquiry report.

(3) The institution must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments received to the report.

(h) *Time for completion.* (1) The institution must complete the inquiry within 90 days of its initiation unless circumstances warrant a longer period.

(2) If the inquiry takes longer than 90 days to complete, the inquiry report must document the reasons for exceeding the 90-day period.

§ 93.308 Notice of the results of the inquiry.

(a) *Notice to respondent.* The institution must notify the respondent whether the inquiry found that an

investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to this part and the institution's policies and procedures adopted under its research integrity assurance.

(b) *Notice to complainant.* The institution is not required to notify a complainant whether the inquiry found that an investigation is warranted. The institution may, but is not required to, provide relevant portions of the report to a complainant for comment. If an institution provides notice to one complainant in a case, it must provide notice, to the extent possible, to all complainants in the case.

§ 93.309 Reporting to ORI on the decision to initiate an investigation.

(a) Within 30 days of determining that an investigation is warranted, the institution must provide ORI with a copy of the inquiry report, which includes the following information:

- (1) The names, professional aliases, and positions of the respondent and complainant;
- (2) A description of the allegation(s) of research misconduct;
- (3) The PHS support, including, for example, 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) Inventory of sequestered research records and other evidence and description of how sequestration was conducted;
- (6) Transcripts of any transcribed interviews;
- (7) 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 an investigation;
- (11) Any comments on the inquiry report by the respondent or the complainant; and
- (12) Any institutional actions implemented, including communications with journals or funding agencies.

(b) The institution must provide the following information to ORI whenever requested:

- (1) The institutional policies and procedures under which the inquiry was conducted; and
 - (2) The research records and other evidence reviewed, and copies of all relevant documents.
- (c) Institutions must keep detailed documentation of inquiries to permit a

later assessment by ORI of the reasons why the institution decided not to investigate. Such documentation must be retained in accordance with § 93.318.

(d) In accordance with § 93.305(g), institutions must notify ORI of any special circumstances that may exist.

The Institutional Investigation

§ 93.310 Institutional investigation.

Institutions conducting research misconduct investigations must:

(a) *Time.* Begin the investigation within 30 days after deciding an investigation is warranted.

(b) *Notice to ORI.* Notify ORI of the decision to begin an investigation on or before the date the investigation begins and provide an inquiry report that meets the requirements of §§ 93.307 and § 93.309.

(c) *Notice to the respondent.* Notify the respondent in writing of the allegation(s) within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins.

(1) The institution must give the respondent written notice of any allegation(s) of research misconduct not addressed during the inquiry or in the initial notice of investigation within a reasonable amount of time of deciding to pursue such allegation(s).

(2) If the institution identifies additional respondents during the investigation, the institution may but is not required to conduct a separate inquiry for each new respondent. If any additional respondent(s) are identified during the investigation, the institution must notify them of the allegation(s) and provide them an opportunity to respond consistent with this subpart.

(3) While an investigation into multiple respondents can convene with the same investigation committee members, separate investigation reports and research misconduct determinations are required for each respondent.

(d) *Sequestration of records.* Obtain all research records and other evidence needed to conduct the investigation, consistent with § 93.305(a).

(e) *Documentation.* Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and other evidence relevant to reaching a decision on the merits of the allegation(s).

(f) *Ensuring a fair investigation.* Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do

not have unresolved personal, professional, or financial conflicts of interest relevant to the investigation. An institution may use the same committee members from the inquiry in their subsequent investigation.

(g) *Interviews.* During the investigation, an institution must interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent.

(1) Interviews during the investigation must be recorded and transcribed.

(2) Any exhibits shown to the interviewee during the interview must be numbered and referred to by that number in the interview.

(3) The transcript of the interview must be made available to the relevant interviewee for correction.

(4) The transcript(s) with any corrections and numbered exhibits must be included in the institutional record of the investigation.

(5) The respondent must not be present during the witnesses' interviews but must be provided a transcript of the interview.

(h) *Multiple respondents.* Consider, consistent with § 93.305(d), the prospect of additional researchers being responsible for the alleged research misconduct.

(i) *Multiple institutions.* A research misconduct proceeding involving multiple institutions must be conducted consistent with § 93.305(e).

(j) *Pursue leads.* Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion. If additional allegations are raised, the respondent(s) must be notified in writing of the additional allegations raised against them.

§ 93.311 Investigation time limits.

(a) *Time limit for completing an investigation.* An institution must complete all aspects of an investigation within 180 days of beginning it, including conducting the investigation, preparing the draft investigation report for each respondent, providing the draft report to each respondent for comment in accordance with § 93.312, and transmitting the institutional record including the final investigation report and decision by the Institutional Deciding Official to ORI in accordance with § 93.316.

(b) *Extension of time limit.* If unable to complete the investigation in 180 days, the institution must ask ORI for an extension in writing that includes the circumstances or issues warranting additional time.

(c) *Progress reports.* If ORI grants an extension, it may direct the institution to file periodic progress reports.

(d) *Investigation report.* If the investigation takes longer than 180 days to complete, the investigation report must include the reasons for exceeding the 180-day period.

§ 93.312 Opportunity to comment on the draft investigation report.

(a) 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.

(b) The institution may provide the complainant a copy of the draft investigation report or relevant portions of that report. The comments of the complainant, if any, must be submitted within 30 days of the date on which the complainant received the draft investigation report or relevant portions of it.

§ 93.313 Investigation report.

A final investigation report for each respondent must be in writing and include:

(a) Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.

(b) Description and documentation of the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.

(c) Description of the specific allegation(s) of research misconduct for consideration in the investigation of the respondent.

(d) Composition of investigation committee, including name(s), position(s), and subject matter expertise.

(e) Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on; and a description of how any sequestration was conducted during the investigation. This inventory must include manuscripts and funding proposals that were considered or relied on during the investigation.

(f) Transcripts of all interviews conducted, as described in § 93.310(g).

(g) 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 allegedly contained the falsified, fabricated, or plagiarized material.

(h) Any scientific or forensic analyses conducted.

(i) If not already provided to ORI, the institutional policies and procedures under which the investigation was conducted.

(j) Any comments made by the respondent and complainant on the draft investigation report and the investigation committee's consideration of those comments.

(k) A statement for each separate allegation of whether the investigation committee recommends a finding of research misconduct.

(1) If the investigation committee recommends a finding of research misconduct for an allegation, the investigation report must, for that allegation:

(i) Identify the individual(s) who committed the research misconduct.

(ii) Indicate whether the research misconduct was falsification, fabrication, and/or plagiarism.

(iii) Indicate whether the research misconduct was committed intentionally, knowingly, or recklessly.

(iv) State whether the other requirements for a finding of research misconduct, as described in § 93.103, have been met.

(v) Summarize the facts and the analysis which support the conclusion and consider the merits of any explanation by the respondent.

(vi) Identify the specific PHS support.

(vii) Identify whether any publications need correction or retraction.

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

(3) List of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.

§ 93.314 Decision by the Institutional Deciding Official.

The Institutional Deciding Official is responsible for making a final determination of research misconduct findings. This determination must be provided in a written decision that includes:

(a) Whether the institution found research misconduct and, if so, who committed the misconduct; and

(b) A description of relevant institutional actions taken or to be taken.

§ 93.315 Institutional appeals.

(a) If a respondent appeals an institution's finding(s) of research misconduct or institutional actions, the institution must promptly notify ORI.

(b) If the institution has not transmitted its institutional record to ORI in accordance with § 93.316 prior to the appeal, the institution must wait until the appeal is concluded to transmit its institutional record. The institution must ensure that the complete record of the appeal is included in the institutional record consistent with § 93.220(a)(5).

(c) If the institution has transmitted its institutional record to ORI in accordance with § 93.316 prior to the appeal, the institution must provide ORI a complete record of the appeal once the appeal is concluded.

§ 93.316 Transmittal of the institutional record to ORI.

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

§ 93.317 Completing the research misconduct process.

(a) ORI expects institutions to carry inquiries and investigations through to completion and to pursue diligently all significant issues and credible allegations of research misconduct. Institutions must notify 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 to committing research misconduct or a settlement with the respondent has been reached.

(b) A respondent's admission of research misconduct must be made in writing and signed by the respondent. An admission must specify the falsification, fabrication, and/or plagiarism that occurred and which research records were affected. The admission statement must meet all elements required for a research misconduct finding under § 93.103 and must be provided to ORI before the institution closes its research misconduct proceeding. The institution must also provide a statement to ORI

describing how it determined that the scope of the misconduct was fully addressed by the admission and confirmed the respondent's culpability.

(c) After consulting with the institution on its basis for closing a case under paragraph (a) of this section, ORI may conduct an oversight review of the institution's handling of the case and take appropriate action including:

- (1) Approving or conditionally approving closure of the case;
- (2) Directing the institution to complete its process;
- (3) Directing the institution to address deficiencies in the institutional record;
- (4) Referring the matter for further investigation by HHS; or
- (5) Taking a compliance action.

Other Institutional Responsibilities

§ 93.318 Retention and custody of the institutional record and all sequestered evidence.

(a) *Maintenance of institutional record and all sequestered evidence.* An institution must maintain the institutional record and all sequestered evidence including physical objects (regardless of whether the evidence is part of the institutional record) in a secure manner for seven years after completion of the proceeding or the completion of any HHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later, unless custody has been transferred to HHS under paragraph (b) of this section or ORI advises otherwise in writing.

(b) *Provision for HHS custody.* On request, institutions must transfer custody, or provide copies, to HHS of the institutional record or any component of the institutional record and any sequestered evidence (regardless of whether the evidence is included in the institutional record) for ORI to conduct its oversight review, develop the administrative record, or present the administrative record in any proceeding under subparts D and E of this part.

§ 93.319 Institutional standards of conduct.

Institutions may have standards of conduct different from the standards for research misconduct under this part. ORI findings of research misconduct or HHS settlements of research misconduct proceedings, or the absence thereof, do not affect institutional findings or actions taken based on an institution's standards of conduct.

Subpart D—Responsibilities of the U.S. Department of Health and Human Services

General Information

§ 93.400 General statement of ORI authority.

(a) *ORI review.* ORI may respond directly to any allegation of research misconduct at any time before, during, or after an institution's response to the matter. The ORI response may include but is not limited to:

- (1) Conducting allegation assessments;
- (2) Determining independently whether jurisdiction exists under this part;
- (3) Forwarding allegations of research misconduct to the appropriate institution or HHS component for inquiry or investigation;
- (4) Requesting clarification or additional information, documentation, research records, or other evidence as necessary from an institution or its members or other persons or sources to carry out ORI's review;
- (5) Notifying or requesting assistance and information from PHS funding components, other affected Federal and state offices and agencies, or institutions;
- (6) Reviewing the institutional record and directing the institution to address deficiencies or additional allegations in the institutional record;
- (7) Making a finding of research misconduct; and
- (8) Taking actions as necessary to protect the health and safety of the public, to promote the integrity of PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, or to conserve public funds.

(b) *ORI assistance to institutions.* ORI may:

- (1) Provide information, technical assistance, and procedural advice to institutional officials as needed regarding an institution's research misconduct proceedings and the sufficiency of the institutional record; and
 - (2) Issue guidance and provide information to support institutional implementation of and/or compliance with the requirements of this part.
- (c) *Review of institutional research integrity assurances.* ORI will review institutional research integrity assurances and policies and procedures for compliance with this part.
- (d) *Institutional compliance.* ORI may make findings and impose ORI compliance actions related to an

institution's compliance with this part and with its policies and procedures, including an institution's participation in research misconduct proceedings.

§ 93.401 Interaction with other entities and interim actions.

(a) ORI may notify and consult with other entities, including government funding agencies, institutions, journals, publishers, and editors, at any time if those entities have a need to know about or have information relevant to a research misconduct proceeding.

(b) If ORI believes that a criminal or civil fraud violation may have occurred, it shall promptly refer the matter to the Department of Justice (DOJ), the HHS Office of Inspector General (OIG), or other appropriate investigative body.

(c) ORI may provide expertise and assistance to the DOJ, OIG, PHS offices, other Federal offices, and state or local offices involved in investigating or otherwise pursuing research misconduct allegations or related matters.

(d) ORI may notify affected PHS offices and funding components at any time to enable them to take appropriate interim actions.

(e) The information provided will not be disclosed as part of the peer review and advisory committee review processes but may be used by the Secretary in making decisions about the award or continuation of funding.

(f) ORI may refer a research misconduct matter to the SDO at any time for consideration under the HHS suspension and debarment regulations. ORI may provide technical assistance and share other information that the SDO needs to know to consider the referred matter.

Research Misconduct Issues

§ 93.402 ORI allegation assessments.

(a) When ORI receives an allegation, it may conduct an assessment or refer the matter to the relevant institution for an assessment, inquiry, or other appropriate actions.

(b) If ORI conducts an assessment and determines an inquiry is warranted, it forwards the matter to the appropriate institution or HHS component.

(c) If ORI conducts an assessment and determines an inquiry is not warranted, it will close the case and forward the allegation in accordance with paragraph (d) in this section.

(d) ORI may refer allegations that do not fall within the jurisdiction of this part to the appropriate HHS component, Federal or state agency, institution, organization, journal, or other appropriate entity.

§ 93.403 ORI review of research misconduct proceedings.

(a) In conducting its review of research misconduct proceedings, ORI will:

- (1) Determine whether this part applies;
- (2) Consider the institutional record and determine whether the institutional record is sufficient, provide instructions to the institution(s) if ORI determines that revisions are needed or additional allegations of research misconduct should be addressed, and require institutions to provide the respondent with an opportunity to respond to information or allegations added to the institutional record;

(3) Determine whether the institution conducted the proceedings in a timely and fair manner in accordance with this part with sufficient thoroughness, objectivity, and competence to support the conclusions; and

(4) After reviewing in accordance with paragraphs (a)(1) through (3) of this section, determine whether to close the case without further action or proceed with the case.

(b) If ORI determines to proceed with the case, ORI will:

(1) Obtain additional information or materials from the institution, the respondent, complainants, or other sources, as needed;

(2) Conduct additional analyses, as needed;

(3) Provide the respondent the opportunity to access the institutional record, any additional information provided to ORI while the case is pending before ORI, and any analysis or additional information generated or obtained by ORI;

(4) Provide the respondent the opportunity to submit information to ORI;

(5) Allow the respondent and the respondent's attorney, if represented, to meet virtually or in person with ORI to discuss the information that the respondent has provided to ORI;

(6) Have ORI's virtual or in-person meeting(s) with the respondent transcribed and provide a copy of the transcript to the respondent for review and suggested correction;

(7) Close the administrative record following paragraphs (b)(3) through (6) of this section;

(8) Provide the respondent the opportunity to access the complete administrative record; and

(9) Take any other actions necessary to complete ORI's review of the research misconduct proceedings.

§ 93.404 Findings of research misconduct and proposed HHS administrative actions.

(a) After completing its review of the administrative record, ORI may:

- (1) Close the case without a separate ORI finding of research misconduct;
- (2) Make findings of research misconduct and propose and take HHS administrative actions based on the administrative record; or
- (3) Seek to settle the case.

(b) The lack of an ORI finding of research misconduct does not overturn an institution's determination that the conduct constituted professional or research misconduct warranting remediation under the institution's policy.

§ 93.405 Notifying the respondent of findings of research misconduct and proposed HHS administrative actions.

(a) When ORI makes a finding of research misconduct or proposes HHS administrative actions, it notifies the respondent in a charge letter. The charge letter:

(1) Includes ORI's findings of research misconduct, including the basis for such findings in the administrative record, and any proposed HHS administrative actions;

(2) Advises the respondent how to access the administrative record; and

(3) Informs the respondent of the opportunity to contest the findings and proposed HHS administrative actions under subpart E of this part.

(b) ORI sends the charge letter by certified mail, private delivery service, or electronic mail or other electronic means to the last known address of the respondent or the last known principal place of business of the respondent's attorney, if represented.

§ 93.406 Final HHS actions.

Unless the respondent contests the findings and/or the proposed HHS administrative actions contained in the charge letter within the 30-day period prescribed in § 93.501(a), the ORI findings and HHS administrative actions are final.

§ 93.407 HHS administrative actions.

(a) Based on the administrative record, HHS may impose administrative actions that include but are not limited to:

(1) Clarification, correction, or retraction of the research record.

(2) Letter(s) of reprimand.

(3) Imposition of special certification or research integrity assurance requirements to ensure compliance with applicable regulations or terms of HHS grants, contracts, or cooperative agreements.

(4) Suspension of award activities under, or termination of, a PHS grant, contract, or cooperative agreement.

(5) Restriction on specific activities or expenditures under an active PHS grant, contract, or cooperative agreement.

(6) Special review of all the respondent's requests for PHS funding.

(7) Imposition of supervision requirements on a PHS grant, contract, or cooperative agreement.

(8) Certification of attribution or authenticity in all requests for support and reports to PHS.

(9) Prohibition of the respondent in participating in any advisory capacity with the PHS.

(10) Recommending that the relevant agency take adverse personnel action(s), if the respondent is a Federal employee, in compliance with relevant Federal personnel policies and laws.

(b) In connection with research misconduct findings, HHS also may seek to recover PHS funds spent supporting activities involving research misconduct.

(c) Any authorized HHS component may impose, administer, or enforce administrative actions separately or in coordination with other HHS components, including, but not limited to ORI, OIG, and the PHS funding component.

(d) HHS administrative actions under this part do not include suspension or debarment. Regardless of whether HHS administrative actions are imposed under this part, HHS may pursue suspension and debarment under the HHS suspension and debarment regulations.

§ 93.408 Mitigating and aggravating factors in HHS administrative actions.

The purpose of HHS administrative actions is remedial. The appropriate administrative action is commensurate with the seriousness of the misconduct and the need to protect the health and safety of the public, promote the integrity of the PHS-supported research and research process, and conserve public funds. ORI considers the following aggravating and mitigating factors in determining appropriate HHS administrative actions and their terms. The existence or nonexistence of any factor is not determinative.

(a) *Knowing, intentional, or reckless.* Were the respondent's actions knowing or intentional or were the actions reckless?

(b) *Pattern.* Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?

(c) *Impact.* Did the misconduct have significant impact on the proposed or

reported research record, research subjects, other researchers, institutions, or the public health or welfare?

(d) *Acceptance of responsibility.* Has the respondent accepted responsibility for the misconduct by:

(1) Admitting the conduct;

(2) Cooperating with the research misconduct proceedings;

(3) Demonstrating remorse and awareness of the significance and seriousness of the research misconduct; and

(4) Taking steps to correct or prevent the recurrence of the research misconduct?

(e) *Failure to accept responsibility.* Does the respondent blame others rather than accepting responsibility for the actions?

(f) *Retaliation.* Did the respondent retaliate against complainants, witnesses, committee members, or other individuals?

(g) *Continued risk to PHS funding.* Does the respondent demonstrate responsible stewardship of research resources?

(h) *Other factors.* Are other factors relevant to the circumstances of a particular case?

§ 93.409 Settlement of research misconduct proceedings.

(a) HHS may settle a research misconduct proceeding at any time it determines that settlement is in the best interests of the Federal Government and the public health or welfare.

(b) Settlement agreements are publicly available, regardless of whether ORI made a finding of research misconduct.

(c) A settlement agreement precludes the respondent from contesting any ORI findings of research misconduct, HHS administrative actions, or ORI's jurisdiction in handling the research misconduct proceeding.

§ 93.410 Final HHS action with no settlement or finding of research misconduct.

When the final HHS action does not result in a settlement or finding of research misconduct, ORI may provide written notice to the respondent, the relevant institution, the complainant, and HHS officials.

§ 93.411 Final HHS action with a settlement or finding of research misconduct.

When a final HHS action results in a settlement or research misconduct finding(s), ORI may:

(a) Provide final notification of any research misconduct findings and HHS administrative actions to the respondent, the relevant institution, and appropriate HHS officials.

(b) Provide final notification of any research misconduct findings and HHS administrative actions to the complainant(s).

(c) Send a notice to the relevant journal, publisher, data repository, or other similar entity identifying publications or research records that require correction or retraction.

(d) Publish notice of the research misconduct findings.

(e) Notify the respondent's current employer if the employer is an institution subject to this part.

Institutional Compliance Issues

§ 93.412 Making decisions on institutional noncompliance.

ORI may determine an institution is not compliant with this part if the institution does not implement and follow the requirements of this part and its own research integrity assurance. In making this decision, ORI may consider, but is not limited to the following factors:

(a) Failure to establish and comply with policies and procedures under this part;

(b) Failure to respond appropriately when allegations of research misconduct arise;

(c) Failure to report to ORI all investigations and findings of research misconduct under this part;

(d) Failure to cooperate with ORI's review of research misconduct proceedings; or

(e) Other actions or omissions that have a material, adverse effect on reporting and responding to allegations of research misconduct.

§ 93.413 ORI compliance actions.

(a) If ORI determines an institution is not compliant with this part, it may take a compliance action against the institution.

(b) If ORI determines an institution is not compliant with this part, ORI may take any or all of the following compliance actions:

(1) Require the institution to accept and/or implement technical assistance provided by ORI.

(2) Issue a letter of reprimand.

(3) Require the institution to take corrective actions.

(4) Place the institution on special review status. For a designated period, ORI will closely monitor the institution's activities for compliance with this part. Monitoring may consist of, but is not limited to, compliance reviews and/or audits.

(5) Direct that research misconduct proceedings be handled by HHS.

(6) Any other action appropriate to the circumstances.

(c) If an institution fails to comply with the requirements of this part, ORI may refer the institution to the SDO for consideration under the HHS suspension and debarment regulations.

(d) If the institution's actions constitute a substantial or recurrent failure to comply with this part, ORI may revoke the institution's research integrity assurance under § 93.301 or § 93.303.

(e) ORI may make public any findings of institutional noncompliance and ORI compliance actions.

Disclosure of Information

§ 93.414 Notice.

(a) ORI may disclose information to other persons for the purpose of providing or obtaining information about research misconduct as permitted under the Privacy Act, 5 U.S.C. 552a and ORI's system of records notice for research misconduct proceedings.

(b) ORI may disclose or publish a notice regarding settlements, ORI findings of research misconduct, and HHS administrative actions, and release or withhold information as permitted by the Privacy Act and the Freedom of Information Act, 5 U.S.C. 552.

Subpart E—Opportunity To Contest ORI Findings of Research Misconduct and Proposed HHS Administrative Actions

General Information

§ 93.500 General policy.

(a) This subpart provides a respondent an opportunity to contest ORI findings of research misconduct and/or proposed HHS administrative actions included in a charge letter.

(b) A respondent may contest ORI's research misconduct findings and proposed HHS administrative actions by filing a notice of appeal with an Administrative Law Judge (ALJ) at the DAB.

(c) Based on the administrative record, the ALJ shall rule on whether ORI's research misconduct findings and any proposed HHS administrative actions are reasonable and not based on a material error of law or fact. The ALJ's ruling constitutes a recommended decision to the Assistant Secretary for Health (ASH) in accordance with § 93.511(b).

(d) A respondent must exhaust all available administrative remedies under this subpart before seeking judicial review of ORI's findings and/or HHS administrative actions. The contested findings and/or administrative actions shall be inoperative while the

respondent is pursuing administrative remedies under this subpart.

Process for Contesting Research Misconduct Findings and/or Proposed HHS Administrative Actions

§ 93.501 Notice of appeal.

(a) *Time to file.* A respondent may contest ORI's findings of research misconduct and/or proposed HHS administrative actions by filing a notice of appeal within 30 days of receipt of the charge letter provided under § 93.405.

(b) *Form of a notice of appeal.* The respondent's notice of appeal must be:

- (1) In writing;
- (2) Signed by the respondent or by the respondent's attorney; and
- (3) Submitted to the DAB Chair through the DAB electronic filing system, with a copy sent to ORI by certified mail, electronic mail, or other equivalent (*i.e.*, with a verified method of delivery).

(c) *Contents of a notice of appeal.* The notice of appeal must:

- (1) Admit or deny each ORI finding of research misconduct and each factual assertion made in support of each finding;
- (2) Accept or challenge each proposed HHS administrative action;
- (3) Provide detailed, substantive reasons for each denial or challenge with references to the administrative record;
- (4) Identify any legal issues or defenses that the respondent intends to raise during the proceeding, with references to the administrative record; and
- (5) Identify any mitigating factors in the administrative record.

§ 93.502 Appointment of the Administrative Law Judge.

(a) Within 30 days of receiving a notice of appeal, the DAB Chair, in consultation with the Chief ALJ, must designate an ALJ to determine whether the notice of appeal is timely filed and within the ALJ's jurisdiction under this subpart. If the appeal is determined to be timely and within the ALJ's jurisdiction, the ALJ shall decide the reasonableness of the ORI research misconduct findings and proposed HHS administrative actions in accordance with this subpart. The ALJ shall dismiss an appeal if it is untimely or not within the ALJ's jurisdiction under this subpart.

(b) No ALJ may serve in any proceeding under this subpart if they have any actual or apparent conflict of interest, bias, or prejudice that might reasonably impair their objectivity in the proceeding.

(c) Any party to the proceeding may request the ALJ to withdraw from the proceeding because of an actual or apparent conflict of interest, bias, or prejudice under paragraph (b) of this section. The motion to disqualify must be timely and state with particularity the grounds for disqualification. The ALJ may rule upon the motion or certify it to the Chief ALJ for decision. If the ALJ rules upon the motion, either party may appeal the decision to the Chief ALJ.

(d) An ALJ must withdraw from any proceeding for any reason found by the ALJ or Chief ALJ to be disqualifying.

§ 93.503 Filing of the administrative record.

(a) For appeals that are not dismissed under § 93.502(a), ORI will file the administrative record for the appeal.

(b) The ALJ's review will be based on the administrative record.

(c) The parties have no right to supplement the administrative record.

§ 93.504 Standard of review.

(a) The ALJ shall review the administrative record to determine whether the ORI research misconduct findings and proposed HHS administrative actions reflected in the charge letter are reasonable and not based on a material error of law or fact.

(b) The ALJ may permit the parties to file briefs making legal and factual arguments based on the administrative record.

§ 93.505 Rights of the parties.

(a) The parties to the appeal are the respondent and ORI. The investigating institution is not a party to the case unless it is a respondent.

(b) Except as otherwise limited by this subpart, the parties may:

- (1) Be accompanied, represented, and advised by an attorney;
- (2) Participate in any case-related conference held by the ALJ; and
- (3) File motions or briefs in writing before the ALJ.

(c) The parties have no right to discovery before the ALJ.

§ 93.506 Authority of the Administrative Law Judge.

(a) The ALJ assigned to the case must conduct a fair and impartial proceeding, avoid unnecessary delay, maintain order, and assure that a complete and accurate record of the proceeding is properly made. The ALJ is bound by, and may not refuse to follow or find invalid, all Federal statutes and regulations, Secretarial delegations of authority, and applicable HHS policies, as provided in paragraph (c)(5) of this section.

(b) Subject to review as provided elsewhere in this subpart, the ALJ may:

(1) Hold conferences with the parties to identify or simplify the issues, or to consider other matters that may aid in the prompt disposition of the proceeding;

(2) Rule on motions and other procedural matters;

(3) Except for the respondent's notice of appeal, modify the time for the filing of any document required or authorized under the rules in this subpart;

(4) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;

(5) Regulate the course of the appeal and the conduct of representatives and parties; and

(6) Take action against any party for failing to follow an order or procedure or for disruptive conduct.

(c) The ALJ does not have the authority to:

(1) Enter an order in the nature of a directed verdict;

(2) Compel settlement negotiations;

(3) Enjoin any act of the Secretary;

(4) Review suspension or proposed debarment;

(5) Find invalid or refuse to follow Federal statutes or regulations, Secretarial delegations of authority, or HHS policies;

(6) Authorize the parties to engage in discovery; and

(7) Modify the time for filing the respondent's notice of appeal.

(d) The Federal Rules of Evidence and the Federal Rules of Civil Procedure do not govern the proceedings under this subpart.

§ 93.507 Ex parte communications.

(a) No party, attorney, or other party representative may communicate ex parte with the ALJ on any matter at issue in a case, unless both parties have notice and an opportunity to participate in the communication.

(b) If an ex parte communication occurs, the ALJ will disclose it to the other party and offer the other party an opportunity to comment.

(c) The provisions of this section do not apply to communications between an employee or contractor of the DAB and the ALJ.

§ 93.508 Filing, format, and service.

(a) *Filing.* (1) Unless the ALJ provides otherwise, all submissions required or authorized to be filed in the proceeding must be filed with the ALJ.

(2) Submissions are considered filed when they are filed with the DAB according to the DAB's filing guidance.

(b) *Format.* (1) The ALJ may designate the format for copies of

nondocumentary materials such as videotapes, computer disks, or physical evidence. This provision does not apply to the charge letter or other written notice provided under § 93.405.

(2) Every submission filed in the proceeding must include the title of the case, the docket number, and a designation of the nature of the submission.

(3) Every submission filed in the proceeding must be signed by and contain the address and telephone number of the party on whose behalf the document or paper was filed, or the attorney of record for the party.

(c) *Service.* Service of a submission on other parties is accomplished by filing the submission with the ALJ through the DAB electronic filing system.

§ 93.509 Filing motions.

(a) Parties must file all motions and requests for an order or ruling with the ALJ, serve them on the other party, state the nature of the relief requested, provide the legal authority relied upon, and state the facts alleged in support of the motion or request.

(b) All motions must be in writing.

(c) Within 10 days after being served with a motion, or other time as set by the ALJ, a party may file a response to the motion. The moving party may not file a reply to the response unless allowed by the ALJ.

(d) The ALJ may not grant a motion before the time for filing a response has expired, except with the parties' consent. However, the ALJ may overrule or deny any motion without awaiting a response.

(e) The ALJ must make a reasonable effort to dispose of all motions promptly.

§ 93.510 Conferences.

(a) The ALJ must schedule an initial conference with the parties within 30 days of the DAB Chair's assignment of the case.

(b) The ALJ may use the initial conference to discuss:

(1) Identification and simplification of the issues, specification of genuine disputes of fact and their materiality to the ORI findings of research misconduct, and any proposed HHS administrative actions;

(2) Identification of material legal issues and any need for briefing;

(3) Scheduling dates for the filing of briefs based on the administrative record; and

(4) Other matters that may encourage the fair, just, and prompt disposition of the proceedings.

(c) The ALJ may schedule additional conferences as appropriate, upon reasonable notice to or request of the parties.

(d) All conferences will be recorded with copies provided to the parties upon request.

(e) Whenever possible, the ALJ shall memorialize in writing any oral rulings within 10 days after a conference is held.

§ 93.511 The Administrative Law Judge's ruling.

(a) Based on the administrative record, the ALJ shall issue a ruling in writing within 60 days after the last submission by the parties in the case,

setting forth whether ORI's research misconduct findings and proposed HHS administrative actions reflected in the charge letter are reasonable and not based on a material error of law or fact. If the ALJ is unable to meet the 60-day deadline, the ALJ must set a new deadline and promptly notify the parties. The ALJ shall serve a copy of the ruling upon the parties and the ASH.

(b) The ruling of the ALJ constitutes a recommended decision to the ASH. The ASH may review the ALJ's recommended decision and adopt, modify, or reject it (in whole or in part) as needed to ensure that the decision is reasonable and not based on a material error of law or fact. Within 30 days after service of the ALJ's recommended decision, the ASH shall notify the parties of the ASH's intent to review or not to review the ALJ's recommended decision. If the ASH does not provide notice of intent within the 30-day period or notifies the parties that the ASH does not intend to review the ALJ's recommended decision, the ALJ's recommended decision shall become final. An ALJ's recommended decision that becomes final in that manner or the ASH's decision after review constitutes the final HHS action on both ORI's findings of research misconduct and any HHS administrative actions.

Dated: September 9, 2024.

Xavier Becerra,

Secretary.

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