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Value(s): *(Drive Innovation & Discovery, Respect
People, Value Integrity, Serve Community)*

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Policy for Responding to Allegations of Research Misconduct

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03/22/2016	<i>Formerly CAMP E-04. Moved to University-Wide Policy Manual on 03/26/2015.</i>
Revised Date:	Change Description:
03/22/2016	Updated the policy's Table of Contents to correctly match existing subheadings within the body of the policy. Removed paragraph showing history of policy edit dates.

Applies to:

All Upstate Medical University Departments

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42 CFR Parts 50 and 93—Public Health Service Policies on Research Misconduct Page 21-55

Policy:

I. Introduction

These policies incorporate and expand upon 42 CFR Part 93—Public Health Services Policies on Research Misconduct. Some sections of the Upstate Medical University Policy include references to the applicable sections of 42 CFR Part 93 and the entire PHS policy is appended.

A. General Policy

Scientific research must be conducted in accordance with the highest regard for standards of honesty. Misconduct of any nature in research is an anathema to the intrinsic goals of all scientific inquiry and dissemination of knowledge. The academic community cannot tolerate plagiarism, fraud, lying, or other types of malfeasance in the conduct of scientific research. Such activities undermine the foundations of our institutions, the fundamental concepts underlying scientific research, and the public's trust in the personal integrity of biomedical scientists. The faculty and administration of the SUNY Upstate Medical University (Upstate) are committed to preserving and encouraging an environment of creativity commensurate with the highest ethical standards of scientific research. To that end, the President of Upstate Medical University has charged the Vice President for Research to hereby establish and implement the following Policy for Responding to Allegations of Research Misconduct by officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents and contractors, subcontractors, and sub-awardees and their employees.

B. Scope

This policy and the associated procedures apply to all individuals at or affiliated with Upstate engaged in research. This includes any person paid by, under the control of, or affiliated with the institution, such as scientists, trainees, technicians, and other staff members, students, fellows, guest researchers, or collaborators at Upstate and sub-awardees of Upstate. This policy covers all research, including research that is supported by or for which support is requested from PHS. The PHS regulation at 42 C.F.R. Part 93 applies to any research, research-training or research-related grant or cooperative agreement with PHS.

The policy and associated procedures will be followed when an allegation of possible research misconduct is received by an institutional official. Particular circumstances in an individual case may also result in referral to other entities in instances of fiscal improprieties, the ethical

treatment of human or animal subjects, criminal matters, and/or personnel matters or when more than one federal or state agency has jurisdiction.

II. Definitions

- A. *Allegation* means any written or oral statement or other indication of possible research misconduct made to an institutional official.
- B. *Complainant* means a person or persons who makes an allegation of research misconduct.
- C. *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias or prejudice may occur due to prior or existing personal or professional relationships.
- D. *Deciding Official* means the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The Deciding Official will have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. At Upstate the Deciding Official is the campus President.
- E. *Good faith allegation* as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have 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 knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding. 42 CFR 93.210
- F. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.
- G. *Investigation* means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred based upon the standard of determination of a preponderance of evidence and, if so, to determine the responsible person and the seriousness of the misconduct.
- H. *Institution* refers to Upstate Medical University, its officials, employees, volunteers, contractors and sub-awardees.
- I. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the research misconduct and research integrity activities of the U.S. Public Health Service.
- J. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.
- K. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 C.F.R. Part 93 entitled "Public Health Service Policies on Research Misconduct." http://ori.hhs.gov/FR_Doc_05-9643
- L. *PHS support* means PHS grants, contracts, cooperative agreements, or applications.
- M. *Research Integrity Officer* means the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

N. *Research misconduct* includes:

- (a) Fabrication, defined as making up data or results and recording or reporting them.
- (b) Falsification, defined as manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- (c) Plagiarism, defined as the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- (d) The destruction, absence of, or the respondent's failure to provide research records adequately documenting the research that is the subject of an allegation of research misconduct. 42 CFR 106(b)(1)
- (e) Mis-expenditure/misappropriation of funds granted to the institution or by the institution to a investigator for the conduct of a specific research project.
- (f) Conducting research without compliance approvals (IRB, CHUA, Biosafety, Radiation Safety) or without following approved research protocols for a research project.
- (g) Misuse of resources in the conduct of research provided to the institution under a Material Transfer Agreement.
- (h) Theft of resources provided to the institution for the conduct of research or released to other institutions without executed Material Transfer Agreements, Confidentiality Agreements, or other required documentation.
- (i) Research misconduct does not include honest error or differences of opinion. 42 CFR 93.103(d)
- (j) Authorship disputes are not usually considered research misconduct although in extreme cases may qualify as plagiarism.
- (k) Misconduct in the reporting of research results by: dual submission of manuscripts, redundant publication of research results or republication of research results, failure to obtain consent for publication from co-authors, failure to disclose conflicts of interest in manuscripts, grants and publications, or otherwise making false statements to journal editors.

O. *Research record* means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research or other aspects of that research that constitutes the subject of an allegation of research misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications, whether published or not; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; grant expenditure reports, patient research files, and other relevant documentation.

P. *Respondent* means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

Q. *Retaliation* means any action or inadequate action taken by an institution or employee that adversely affects the employment or other institutional status of an individual because that individual has in good faith: made an allegation of research misconduct, been a witness in a misconduct proceeding, served on a committee in a misconduct case, or has cooperated in good faith with an investigation of such allegation.

III. Rights and Responsibilities**A. Research Integrity Officer**

The Research Integrity Officer will have primary responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer will be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The Research Integrity Officer will make an initial assessment of the allegation(s) and whether they are made in good faith. The assessment process may involve interviewing the complainant(s), the respondent(s), potential witnesses and conferring with institutional officials or officials at the ORI. It is the Research Integrity Officer's sole responsibility to make a determination of whether the allegations are made in good faith and whether they rise to the level of research misconduct as defined by institutional policies and PHS regulation, and therefore, whether an inquiry should be initiated. The Research Integrity Officer will summarize his/her preliminary findings in an Assessment Report that will include: identification of the respondent(s) and complainant(s), whether the complainant(s) wishes anonymity, summaries of the allegations with sufficient background to understand the nature of the allegations, and a summary of the process by which the Research Integrity Officer made his determination. The Assessment Report will be made available to the complainant(s), the respondent(s), institutional officials as deemed necessary, and The Inquiry Committee if one is required.

The Research Integrity Officer is responsible for identifying any possible exigent circumstances presented by the misconduct case, determining the order and priority of dealing with the exigent circumstances, and notifying the appropriate authorities including the ORI. Exigent circumstances include:

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. The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
7. The research community or public should be informed.

The Research Integrity Officer will oversee the sequestration of research records deemed necessary for inquiry or investigation committees to assess allegations of research

misconduct. It is at the Research Integrity Officer's discretion, in consultation with institutional officials and Inquiry or Investigation Committees, as to what research records should be sequestered and multiple rounds of sequestration may be required. It is the Research Integrity Officer's responsibility to make sure that copies of research records are made available to the respondent as requested by the respondent and/or to allow the respondent supervised access to the sequestered materials for review.

The Research Integrity Officer will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained.

The Research Integrity Officer will assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The Research Integrity Officer will report to ORI as required by regulation and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS 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.

B. Complainant

The complainant(s) will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the Research Integrity Officer has determined that the complainant(s) may be able to provide pertinent information on any portions of the draft report; these portions will be given to the complainant for comment.

The complainant(s) is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of research

misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.

D. Deciding Official

The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. The Deciding Official will consult with the Research Integrity Officer and other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions (see section X).

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with Upstate should report observed, suspected, or apparent misconduct in research to the Research Integrity Officer. Allegations of research misconduct can be communicated to the Research Integrity Officer by letter, e-mail, verbally and/or by phone. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may e-mail the Research Integrity Officer at RIO@upstate.edu or go to the Research Administration Directory for more contact options (<http://www.upstate.edu/researchadmin/directory.php>) to discuss the suspected misconduct informally. All misconduct allegations must be presented to the Research Integrity Officer so that he may initiate the assessment process. If the circumstances described by the individual do not meet the definition of research misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer, Department Chairperson, Dean of the College, or Vice President for Research and will be counseled about appropriate procedures for reporting allegations.

B. Protecting the Complainant and Witnesses

The Research Integrity Officer will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer shall take reasonable steps to ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer.

Also the institution will protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the complainant requests anonymity, the institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The complainant will be advised that if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity may no longer be guaranteed. Institutions are required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations or those that cooperate with misconduct procedures.

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.

Institutional employees accused of research misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case.

D. Ownership of Data

As stated in the institutional Data Retention and Ownership Policy: "Research data are created at SUNY Upstate Medical University ('Upstate') by faculty, staff, students, post-doctoral fellows and visiting scientists, utilizing the facilities of Upstate in the course of their scholarly activities and often while conducting sponsored programs funded by external sponsors. Upstate owns data resulting from such scholarly activities and sponsored programs." It is therefore the right and responsibility of the Research Integrity Officer to sequester and retain any and all research records deemed necessary to assess allegations of research misconduct.

E. Cooperation with Inquiries and Investigations

Institutional employees, including those employed by the Research Foundation of the State University of New York or any entity affiliated with the State University of New York, will cooperate with the Research Integrity Officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the Research Integrity Officer or other institutional officials on misconduct allegations.

F. Preliminary Assessment of Allegations

Upon receiving an allegation of research misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS and/or institutional definitions of research misconduct.

Funding sources other than the PHS may be identified during this assessment. The Research Integrity Officer's findings at the conclusion of the assessment stage will be summarized in an Assessment Report. Independent of the source of funding, if in the opinion of the Research Integrity Officer the allegation(s) if true, rise to the level of research misconduct, an Inquiry will be initiated.

G. Sequestration of the Research Records

After determining that an allegation falls within the definition of misconduct in research, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are immediately secured. The Research Integrity Officer may consult with ORI for advice and assistance in this regard.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up and falls under the PHS and/or institutional definitions of research misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the Research Integrity Officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

B. Appointment of the Inquiry Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within 10 days of the initiation of the inquiry. The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution. Members of the inquiry committee will be required to sign conflict of interest and confidentiality statements prior to serving on the inquiry committee. A member of the University Counsel's office shall be an ex officio, non-voting member of the Inquiry Committee. The Inquiry Committee shall conduct the inquiry by interviewing the complainant, respondent, key witnesses and by examining evidence.

The Research Integrity Officer will notify the respondent of the proposed committee membership within 10 business days. The respondent has 5 business days from the date of notification to submit a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest. Within 5 business days, the Research Integrity

Officer will determine if the respondent's objections have merit and whether to replace the challenged member with a qualified substitute.

C. Charge to the Committee and the First Meeting

The Research Integrity Officer will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states the purpose of the inquiry, which is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation as required by the PHS regulation. The purpose is not to determine whether research misconduct definitely occurred or who was responsible.

At the committee's first meeting, the Research Integrity Officer will review the charge with the committee; discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry; assist the committee with organizing plans for the inquiry; and answer any questions raised by the committee. The Research Integrity Officer and institutional counsel will be available throughout the inquiry to advise the committee as needed.

D. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent and key witnesses as well as examine relevant research records and materials. All interviews are to be recorded. The inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer and institutional counsel, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

Based on its review, the inquiry committee may also identify other individuals as respondents so long as those individuals meet the definition of respondent contained herein.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; the PHS or other extramural support; a summary of the inquiry process used; a list of the research records reviewed; summaries of interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended for each individual allegation. If additional individuals are identified as respondents during the inquiry, they should be identified in the inquiry report. Institutional counsel will review the report for legal sufficiency.

B. Comments on the Draft Report by the Respondent and the Complainant

The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the complainant, if he or she is identifiable, with portions of the draft inquiry report that relate to the complainant's role and testimony in the investigation. If any complainant or witness wishes to remain anonymous, their names will be redacted from the copy of the report provided to the respondent.

1. Confidentiality

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report.

2. Receipt of Comments

Within 14 calendar days of their receipt of the draft report, the complainant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the complainant and/or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the draft report as appropriate.

C. Inquiry Decision and Notification**1. Decision by Deciding Official**

The Research Integrity Officer will transmit the final report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation or if further inquiry is required. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

2. Notification

The Research Integrity Officer will notify both the respondent and the complainant in writing of the Deciding Official's decision of whether to proceed to an investigation along with a copy of the final report and will remind them of their obligation to cooperate in the event an investigation is opened. The Research Integrity Officer will also notify all appropriate institutional officials of the Deciding Official's decision, as well as ORI if PHS funding is involved.

D. Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the Research Integrity Officer no more than 60 calendar days following its first meeting, unless the Research Integrity Officer approves an extension for good cause. If the Research Integrity Officer approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent also will be notified of the extension.

VII. Conducting the Investigation**A. Purpose of the Investigation**

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed and by whom.

The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations and/or additional respondents. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. It is critically important that the scope of the investigation be sufficient, within reason, so as to detect all instances of scientific misconduct in the research record, in particular in research publications so that the institution can pursue appropriate means to correct the scientific record. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records

The Research Integrity Officer will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 business days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee. Members of the investigation committee will be required to sign conflict of interest and confidentiality statements prior to serving on the investigation committee. A member of the University Counsel's office shall be an ex-officio, non-voting member of the investigation committee. The Research Integrity Officer will notify the respondent of the proposed committee membership within 10 business days of the appointment of the committee. The respondent has 5 business days from the date of notification to submit a written objection to any

appointed member of the inquiry committee based on bias or conflict of interest. Within 5 business days, the Research Integrity Officer will determine if the respondent's objections have merit and whether to replace the challenged member with a qualified substitute and notify the respondent of this decision.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, define research misconduct, and identify the names of the complainant and respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and who was responsible.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents and/or allegations, the committee will notify the Research Integrity Officer, who will determine whether it is necessary to notify the respondent of the new subject matter and/or new allegations or to provide notice to additional respondents.

2. The First Meeting

The Research Integrity Officer, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of this Upstate policy and, where PHS funding is involved, relevant PHS regulations. At the first meeting, members of the investigation committee will be required to sign conflict of interest and confidentiality statements.

E. Investigation Process

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation and the Deciding Official concurs.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, e-mail messages, and notes of telephone calls. Whenever possible, the committee should interview the complainant(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations. All interviews should be recorded, summarized and transcribed. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file. The finalized investigation report needs to be approved by the Deciding Official and submitted to ORI within 120 days of the initiation of the investigation, unless an extension(s) has been requested by the Research

Integrity Officer and approved by the ORI. All extension requests and responses shall become part of the investigation files.

Based on its review, the investigation committee may also identify other individuals as respondents so long as those individuals meet the definition of respondent contained herein.

VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation report must be in writing and include the nature of the allegations of research misconduct; a specific description of the allegations of research misconduct charged to the respondent; an identification and summary of research records and evidence reviewed, as well as evidence taken into custody but not reviewed; for each allegation, a statement of findings as to whether research misconduct did or did not occur; for every finding of research misconduct, identification of the category of research misconduct and if it was intentional, knowing, or in reckless disregard; a summary of the facts and analysis that support the findings; listing of any publications needing correction or retraction; and comments made by the respondent and complainant to the draft investigation report and the consideration given to these comments. If the allegations involve research supported by the Public Health Service, the report should additionally include a description of PHS support, including grant numbers, applications, contracts, and publications that supported the research that is the subject of the research misconduct allegations and a listing of current or pending PHS support. It is appropriate for the investigation committee to include in the investigation report recommendations to the Deciding Official concerning actions to be taken to manage and mitigate the chances for future misconduct by the respondent, for example whether an oversight committee might be required. If the investigation and/or inquiry identified multiple respondents, separate and complete investigation reports must be prepared specific to each respondent.

If additional individuals are identified as respondents during the investigation, they should be identified in the investigation report. Institutional counsel will review the report for legal sufficiency.

B. Comments on the Draft Report

- 1. Within ~80 days of the initiation of the investigation, the Investigation Committee will produce a draft investigation report, unless an extension(s) has been requested by the Research Integrity Officer and granted by the ORI.**

- 2. Respondent**

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 30 calendar days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

3. Complainant

The Research Integrity Officer will provide the complainant, if he or she is identifiable, with portions of the draft investigation report that relate to the complainant's role and testimony in the investigation. The report should be modified, as appropriate, based on the complainant's comments. The complainant has 30 days to respond to the draft investigation report.

4. Institutional Counsel

The draft investigation report will be transmitted to the institutional counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

5. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and complainant, the Research Integrity Officer will inform the recipients of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the Research Integrity Officer may request the recipients to sign confidentiality statements or to come to his or her office to review the report.

C. Transmittal of the Final Investigation Report to the Deciding Official

After comments have been received from the respondent(s) and complainant(s) and any necessary changes have been made to the draft report by the investigation committee, the investigation committee shall transmit the final report with attachments, including the respondent's and complainant's comments, to the Deciding Official, through the Research Integrity Officer.

D. Institutional Review and Decision

Based on a preponderance of the evidence, the Deciding Official will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter transmitting the report to ORI or other extramural sponsors and the Research Integrity Officer. The Deciding Official's explanation should be consistent with the PHS definition of scientific misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official may also return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the Research Integrity Officer will notify ORI, the respondent and the complainant in writing. In addition, the Deciding Official will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of

the case. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of all funding or sponsoring agencies.

E. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the complainant(s) and respondent(s) for comment, submitting the final report to the Deciding Official for approval, and submitting the report to the ORI or other extramural funding agency. If an extension is deemed necessary, the Research Integrity Officer will submit a request for an extension and its reasons to the ORI for approval. The extension request and ORI response shall become part of the investigatory record.

IX. Requirements for Reporting to ORI

- A. An institution's decision to initiate an investigation must be reported in writing to the Director, ORI within 30 days of finding that an investigation is warranted. At a minimum, the notification should include the name and position of the respondent; a description of the allegations of research misconduct; the PHS support, including grant numbers, grant applications, contracts, and publications listing PHS support; the basis for recommending that the alleged actions warrant an investigation; and any comments on the report by the respondent or the complainant. 93.309(a)**
- B. Following completion of an investigation report, a copy of the final report with all attachments; the findings of research misconduct, including who committed the misconduct; a statement of whether or not the institution accepted the investigation committee's findings; and a description of any pending or completed administrative actions against the respondent.**
- C. When PHS funding or applications for funding are involved and an admission of research misconduct is made by a respondent, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI. Similar actions may be undertaken following notification of and in consultation with other relevant sponsors.**
- D. If the institution determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.**

- E. The Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:
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. The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
 7. The research community or public should be informed. 42 CFR 318

X. Institutional Administrative Actions

Upstate will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated. These actions may be imposed by Upstate, regardless of the funding source of the research in question.

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Officer. The actions may include:

- A. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found. This includes any thesis submitted as part of meeting degree requirements for a degree either in the process of being conferred or that had been previously granted. If it is determined that a thesis should be withdrawn, a recommendation may be made to the SUNY Board of Trustees, by the Deciding Official, to revoke any degrees previously conferred for which the thesis was a supporting document.
- B. Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment.
- C. Restitution of funds as appropriate.
- D. If the respondent is a student of SUNY Upstate Medical University, or was a student at the time of the misconduct, the Research Integrity Officer will refer potential violations of the Code of Student Conduct to the Dean of Student Affairs. At the discretion of the Dean of Student Affairs, a parallel judicial process may be initiated to charge the student with violation of the Student Code of Conduct, provided that process does not interfere with the investigation of research misconduct as outlined in this policy.

- E. It is the Research Integrity Officer's responsibility to ensure that the administrative actions are enforced.

XI. Other Considerations

- A. **Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation.**

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

- B. **Restoration of the Respondent's Reputation**

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, the Research Integrity Officer will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, and/or expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

- C. **Protection of the Complainant(s) and Others**

Regardless of whether the institution or ORI determines that research misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect complainants that made allegations of research misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Deciding Official will determine, after consulting with complainants, witnesses, committee members, and/or any other individuals that cooperated with the investigation, what steps, if any, are needed to restore the position or reputations of such individuals. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against complainants, witnesses, committee members, or any other individuals that cooperated with the investigation. When the allegations of retaliation appear to have substance, the RIO will provide evidence to the Deciding Official, the individual's chairperson, the Vice President for Research, the appropriate Dean, and/or Human Resources for possible sanctions. The RIO has the authority and responsibility to require interim actions by other administrators during the

pendency of the review of an allegation of misconduct to protect those who, in the RIO's judgment, are at high risk for retaliation or may already have been retaliated against. This may require reassigning employees to work in other locations and/or the appointing of a senior administrator to monitor the welfare of those at risk of retaliation.

D. Allegations Not Made in Good Faith

If relevant, the Research Integrity Officer, will investigate and determine whether the complainant's allegations of research misconduct were made in good faith. If an allegation was not made in good faith, the Research Integrity Officer will determine whether any administrative action should be taken. This may include referring the matter to the Deciding Official, the complainant's chairperson, the Vice President for Research, the appropriate Dean, and/or Human Resources for possible sanctions. The Institution's legal and policy protections for good faith complaints do not apply to individuals found to be operating in bad faith.

E. Other Acts of Bad Faith

If any witness or committee member is found to have acted in bad faith during a misconduct inquiry or investigation, the Research Integrity Officer will determine whether any administrative action should be taken against such individuals. This may include referring the matter to the Deciding Official, the complainant's chairperson, and/or Human Resources for possible sanctions.

F. Interim Administrative Actions

Institutional officials will take interim administrative actions, as appropriate, to protect federal funds and ensure that the purposes of the federal financial assistance are carried out. Similar actions will be taken in consultation with other sponsors.

XII. Record Retention

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will keep the file for seven years after completion of the case, as required by ORI. ORI or other authorized DHHS personnel will be given access to the records upon request when a case involves PHS funding.

Attachment #1: 42 CFR 93 PART 50--POLICIES OF GENERAL APPLICABILITY

1. The authority citation for 42 CFR part 50 continues to as follows:
Authority: Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); Sec. 1006, Public Health Service Act, 84 Stat. 1507 (42 U.S.C. 300a-4), unless otherwise noted.
Subpart A [Removed]
2. Part 50, Subpart A (Sec. Sec. 50.101-50.105) is removed and reserved.
3. A new Part 93, with subparts A, B, C, D and E is added to read as follows:

PART 93--PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

Section

- 93.25 Organization of this part.
- 93.50 Special terms.

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- 93.101 Purpose.
- 93.102 Applicability.
- 93.103 Research misconduct.
- 93.104 Requirements for findings of research misconduct.
- 93.105 Time limitations.
- 93.106 Evidentiary standards.
- 93.107 Rule of interpretation.
- 93.108 Confidentiality.
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Subpart B--Definitions

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- 93.201 Allegation.
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- 93.207 Departmental Appeals Board or DAB.
- 93.208 Evidence.
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- 93.210 Good faith.
- 93.211 Hearing.
- 93.212 Inquiry.
- 93.213 Institution.
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- 93.218 Person.
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- 93.222 Research.
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- 93.301 Institutional assurances.
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- 93.407 HHS administrative actions.
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93.523 The Administrative Law Judge's ruling.

Authority: 42 U.S.C. 216, 241, and 289b.

Sec. 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.

In subpart:	You will find provisions related to:
A.....	General information about this rule.
B.....	Definitions of terms 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 HHS administrative actions.

Sec. 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.

Subpart A--General

Sec. 93.100 General policy.

- (a) Research misconduct involving PHS support is contrary to the interests of the PHS and the Federal government and 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 Public Health Service (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 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.

Sec. 93.101 Purpose.

The purpose of this part is to--

- (a) Establish the responsibilities of HHS, PHS, the Office of Research Integrity (ORI), and institutions in responding to research misconduct issues;
- (b) Define what constitutes misconduct in PHS supported research;
- (c) Define the general types of administrative actions HHS and the PHS may take in response to research misconduct; and
- (d) Require institutions to develop and implement policies and procedures for—

- (1) Reporting and responding to allegations of research misconduct covered by this part;
- (2) Providing HHS with the assurances necessary to permit the institutions to participate in PHS supported research.
- (e) Protect the health and safety of the public, promote the integrity of PHS supported research and the research process, and conserve public funds.

Sec. 93.102 Applicability.

- (a) Each institution that applies for or receives PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with this part.
- (b)(1) This part applies to allegations of research misconduct and research misconduct involving:
 - (i) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information;
 - (ii) PHS supported biomedical or behavioral extramural or intramural research;
 - (iii) PHS supported biomedical or behavioral extramural or intramural research training programs;
 - (iv) PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks or the dissemination of research information; and
 - (v) Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training.
- (2) This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.
 - (a) This part does not supersede or establish an alternative to any existing regulations or procedures for handling fiscal improprieties, the ethical treatment of human or animal subjects, criminal matters, personnel actions against Federal employees, or actions taken under the HHS debarment and suspension regulations at 45 CFR part 76 and 48 CFR subparts 9.4 and 309.4.
 - (b) 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.

Sec. 93.103 Research misconduct.

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

- (a) Fabrication is making up data or results and recording or reporting them.
- (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- (d) Research misconduct does not include honest error or differences of opinion.

Sec. 93.104 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.

Sec. 93.105 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 citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.
 - (2) **Health or safety of the public exception.** If ORI or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.
 - (3) **"Grandfather" exception.** If HHS or an institution received the allegation of research misconduct before the effective date of this part.

Sec. 93.106 Evidentiary standards.

The following evidentiary standards apply to findings made under this part.

- (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.** The destruction, absence of, or respondent's failure to provide research records adequately 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, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.
 - (2) **The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses 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 that are relevant to a decision to impose administrative actions following a research misconduct proceeding.**

Sec. 93.107 Rule of interpretation.

Any interpretation of this part must further the policy and purpose of the HHS and the Federal government to protect the health and safety of the public, to promote the integrity of research, and to conserve public funds.

Sec. 93.108 Confidentiality.

- (a) Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Provided, however, that:
- (1) The institution must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings under Sec. 93.403.
 - (2) Under Sec. 93.517(g), HHS administrative hearings must be open to the public.
- (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 have a need to know to carry out a research misconduct proceeding.

Sec. 93.109 Coordination with other agencies.

- (a) When more than one agency of the Federal government has jurisdiction of the subject misconduct allegation, HHS will cooperate 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 to protect the health and safety of the public, promote the integrity of the PHS supported research and research process and conserve public funds.
- (b) In cases involving more than one agency, HHS may refer to evidence or reports developed by that agency if HHS determines that the evidence or reports will assist in resolving HHS issues. In appropriate cases, HHS will seek to resolve allegations jointly with the other agency or agencies.

Subpart B--Definitions

Sec. 93.200 Administrative action.

Administrative action means--

- (a) An HHS action in response to a research misconduct proceeding taken to protect the health and safety of the public, to promote the integrity of PHS supported biomedical or behavioral research, research training, or activities related to that research or research training and to conserve public funds; or
- (b) An HHS action in response either to a breach of a material provision of a settlement agreement in a research misconduct proceeding or to a breach of any HHS debarment or suspension.

Sec. 93.201 Allegation.

Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or HHS official.

Sec. 93.202 Charge letter.

Charge letter means the written notice, as well as any amendments to the notice, that are sent to the respondent stating the findings of research misconduct and any HHS administrative actions. If the charge letter includes a debarment or suspension action, it may be issued jointly by the ORI and the debarring official.

Sec. 93.203 Complainant.

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

Sec. 93.204 Contract.

Contract means an acquisition instrument awarded under the HHS Federal Acquisition Regulation (FAR), 48 CFR Chapter 1, excluding any small purchases awarded pursuant to FAR Part 13.

Sec. 93.205 Debarment or suspension.

Debarment or suspension means the Government wide exclusion, whether temporary or for a set term, of a person from eligibility for Federal grants, contracts, and cooperative agreements under the HHS regulations at 45 CFR part 76 (nonprocurement) and 48 CFR subparts 9.4 and 309.4 (procurement).

Sec. 93.206 Debarring official.

Debarring official means an official authorized to impose debarment or suspension. The HHS debarring official is either--

- (a) The Secretary; or**
- (b) An official designated by the Secretary.**

Sec. 93.207 Departmental Appeals Board or DAB.

Departmental Appeals Board or DAB means, depending on the context--

- (a) The organization, within the Office of the Secretary, established to conduct hearings and provide impartial review of disputed decisions made by HHS operating components; or**
- (b) An Administrative Law Judge (ALJ) at the DAB.**

Sec. 93.208 Evidence.

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

Sec. 93.209 Funding component.

Funding component means any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity that involves the conduct of biomedical or behavioral research, research training or activities related to that research or research training, e.g., agencies, bureaus, centers, institutes, divisions, or offices and other awarding units within the PHS.

Sec. 93.210 Good faith.

Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have 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 knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

Sec. 93.211 Hearing.

Hearing means that part of the research misconduct proceeding from the time a respondent files a request for an administrative hearing to contest ORI findings of research misconduct and HHS administrative actions until the time the ALJ issues a recommended decision.

Sec. 93.212 Inquiry.

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

Sec. 93.213 Institution.

Institution means any individual or 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, small research institutions, and independent researchers.

Sec. 93.214 Institutional member.

Institutional member or members means a person 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, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

Sec. 93.215 Investigation.

Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

Sec. 93.216 Notice.

Notice means a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or e-mail address of the addressee. Several sections of Subpart E of this part have special notice requirements.

Sec. 93.217 Office of Research Integrity or ORI.

Office of Research Integrity or ORI means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.

Sec. 93.218 Person.

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

Sec. 93.219 Preponderance of the evidence.

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

Sec. 93.220 Public Health Service or PHS.

Public Health Service or PHS means the unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

Sec. 93.221 PHS support.

PHS support means PHS funding, or applications or proposals therefor, 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 or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

Sec. 93.222 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) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

Sec. 93.223 Research misconduct proceeding.

Research misconduct proceeding means any actions related to alleged research misconduct taken under this part, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals.

Sec. 93.224 Research record.

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

Sec. 93.225 Respondent.

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

Sec. 93.226 Retaliation.

Retaliation for the purpose of this part 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.

Sec. 93.227 Secretary or HHS.

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

Subpart C--Responsibilities of Institutions**Compliance and Assurances****Sec. 93.300 General responsibilities for compliance.**

Institutions under this part 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 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 the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct;
- (d) Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses and committee members and protect them from retaliation by respondents and other institutional members;
- (e) Provide confidentiality to the extent required by Sec. 93.108 to all respondents, complainants, and research subjects identifiable from research records or 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 evidence;
- (g) Cooperate with HHS during any research misconduct proceeding or compliance review;
- (h) Assist in administering and enforcing any HHS administrative actions imposed on its institutional members; and
- (i) Have an active assurance of compliance.

Sec. 93.301 Institutional assurances.

- (a) **General policy.** An institution with PHS supported biomedical or behavioral research, research training or activities related to that research or research training must provide PHS with an assurance of compliance with this part, satisfactory to the Secretary. PHS funding components may authorize funds for biomedical and behavioral research, research training, or activities related to that research or research training only to institutions that have approved assurances and required renewals on file with ORI.
- (b) **Institutional Assurance.** The responsible institutional official must assure on behalf of the institution that the institution—

- (1) Has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and
- (2) Complies with its own policies and procedures and the requirements of this part.

Sec. 93.302 Institutional compliance with assurances.

- (a) **Compliance with assurance.** ORI considers an institution in compliance with its assurance if the institution--
 - (1) Establishes policies and procedures according to this part, keeps them in compliance with this part, and upon request, provides them to ORI, other HHS personnel, and members of the public;
 - (2) Takes all reasonable and practical specific steps to foster research integrity consistent with Sec. 93.300, including--
 - (i) Informs the institution's research members participating in or otherwise involved with PHS supported biomedical or behavioral research, research training or activities related to that research or research training, including those applying for support from any PHS funding component, about its policies and procedures for responding to allegations of research misconduct, and the institution's commitment to compliance with the policies and procedures; and
 - (ii) Complies with its policies and procedures and each specific provision of this part.
- (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.
- (c) **Additional information.** Along with its assurance or annual report, an institution must send ORI such other aggregated 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.

Sec. 93.303 Assurances for small institutions.

- (a) If an institution is too small to handle research misconduct proceedings, it may file a "Small Organization Statement" with ORI in place of the formal institutional policies and procedures required by Sec. Sec. 93.301 and 93.304.
- (b) By submitting a Small Organization 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 implement a process for handling allegations of research misconduct consistent with this part.
- (c) The Small Organization Statement does not relieve the institution from complying with any other provision of this part.

Sec. 93.304 Institutional policies and procedures.

Institutions seeking an approved assurance must have written policies and procedures for addressing research misconduct that include the following--

- (a) Consistent with Sec. 93.108, protection of the confidentiality of respondents, complainants, and research subjects identifiable from research records or evidence;
- (b) A thorough, competent, objective, and fair response to allegations of research misconduct consistent with and within the time limits of this part, including 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) Notice to the respondent, consistent with and within the time limits of this part;

- (d) Written notice to ORI of any decision to open an investigation on or before the date on which the investigation begins;
- (e) Opportunity for the respondent to provide written comments on the institution's inquiry report;
- (f) Opportunity for the respondent to provide written comments on the draft report of the investigation, and provisions for the institutional investigation committee to consider and address the comments before issuing the final report;
- (g) Protocols for handling the research record and evidence, including the requirements of Sec. 93.305;
- (h) Appropriate interim institutional actions to protect public health, Federal funds and equipment, and the integrity of the PHS supported research process;
- (i) Notice to ORI under Sec. 93.318 and notice of any facts that may be relevant to protect public health, Federal funds and equipment, and the integrity of the PHS supported research process;
- (j) Institutional actions in response to final findings of research misconduct;
- (k) 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;
- (l) All reasonable and practical efforts to protect or restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against these complainants, witnesses, and committee members; and
- (m) Full and continuing cooperation with ORI during its oversight review under Subpart D of this part or any subsequent administrative hearings or appeals under Subpart E of this part. This includes providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

Sec. 93.305 Responsibility for maintenance and custody of research records and evidence.

An institution, as the responsible legal entity for the PHS supported research, has a continuing obligation under this part to ensure that it maintains adequate records for a research misconduct proceeding. The institution must--

- (a) Either before or when the institution notifies the respondent of the allegation, inquiry or investigation, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments;
- (b) Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records;
- (c) Undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments; and
- (d) Maintain the research records and evidence as required by Sec. 93.317.

Sec. 93.306 Using a consortium or other person for research misconduct proceedings.

- (a) An institution may use the services of a consortium or person that the institution reasonably determines to be qualified by practice and experience to conduct research misconduct proceedings.

- (b) A consortium may be a group of institutions, professional organizations, or mixed groups which will conduct research misconduct proceedings for other institutions.
- (c) A consortium or person acting on behalf of an institution must follow the requirements of this part in conducting research misconduct proceedings.

The Institutional Inquiry

Sec. 93.307 Institutional inquiry.

- (a) *Criteria warranting an inquiry.* An inquiry is warranted if the allegation--
 - (1) Falls within the definition of research misconduct under this part;
 - (2) Is within Sec. 93.102; and
 - (3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.
- (b) *Notice to respondent and custody of research records.* 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. To the extent it has not already done so at the allegation stage, the institution must, on or before the date on which the respondent is notified or the inquiry begins, whichever is earlier, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
- (c) *Review of evidence.* The purpose of an inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation. Therefore, an inquiry does not require a full review of all the evidence related to the allegation.
- (d) *Criteria warranting an investigation.* An inquiry's purpose is to decide if an allegation warrants an investigation. An investigation is warranted if there is--
 - (1) 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, research training or activities related to that research or research training, as provided in Sec. 93.102; and
 - (2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.
- (e) *Inquiry report.* The institution must prepare a written report that meets the requirements of this section and Sec. 93.309.
- (f) *Opportunity to comment.* The institution must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments received to the report.
- (g) *Time for completion.* The institution must complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

Sec. 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 assurance.
- (b) **Notice to complainants.** The institution may notify the complainant who made the allegation whether the inquiry found that an investigation is warranted. The institution may provide relevant portions of the report to the complainant for comment.

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

- (a) **Within 30 days of finding that an investigation is warranted, the institution must provide ORI with the written finding by the responsible institutional official and a copy of the inquiry report which includes the following information--**
 - (1) **The name and position of the respondent;**
 - (2) **A description of the allegations of research misconduct;**
 - (3) **The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;**
 - (4) **The basis for recommending that the alleged actions warrant an investigation; and**
 - (5) **Any comments on the report by the respondent or the complainant.**
- (b) **The institution must provide the following information to ORI on request--**
 - (1) **The institutional policies and procedures under which the inquiry was conducted;**
 - (2) **The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and**
 - (3) **The charges for the investigation to consider.**
- (c) ***Documentation of decision not to investigate.*** Institutions must keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the institution decided not to conduct an investigation. Consistent with Sec. 93.317, institutions must keep these records in a secure manner for at least 7 years after the termination of the inquiry, and upon request, provide them to ORI or other authorized HHS personnel.
- (d) ***Notification of special circumstances.*** In accordance with Sec. 93.318, institutions must notify ORI and other PHS agencies, as relevant, of any special circumstances that may exist.

The Institutional Investigation**Sec. 93.310 Institutional investigation.**

Institutions conducting research misconduct investigations must:

- (a) ***Time.*** Begin the investigation within 30 days after determining that an investigation is warranted.
- (b) ***Notice to ORI.*** Notify the ORI Director 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 Sec. 93.307 and Sec. 93.309.
- (c) ***Notice to the respondent.*** Notify the respondent in writing of the allegations within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins. The institution must give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation.
- (d) ***Custody of the records.*** To the extent they have not already done so at the allegation or inquiry stages, take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and

evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. Whenever possible, the institution must take custody of the records--

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

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

- (e) *Documentation.* Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations.
- (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 with those involved with the inquiry or investigation.
- (g) *Interviews.* Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation.
- (h) *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.

Sec. 93.311 Investigation time limits.

- (a) *Time limit for completing an investigation.* An institution must complete all aspects of an investigation within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment in accordance with Sec. 93.312, and sending the final report to ORI under Sec. 93.315.
- (b) *Extension of time limit.* If unable to complete the investigation in 120 days, the institution must ask ORI for an extension in writing.
- (c) *Progress reports.* If ORI grants an extension, it may direct the institution to file periodic progress reports.

Sec. 93.312 Opportunity to comment on the 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 evidence on which the report is based. The comments of the respondent on the draft report, if any, must be submitted within 30 days of the date on which the respondent received 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.

Sec. 93.313 Institutional investigation report.

The final institutional investigation report must be in writing and include:

- (a) *Allegations*. Describe the nature of the allegations of research misconduct.
- (b) *PHS support*. Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.
- (c) *Institutional charge*. Describe the specific allegations of research misconduct for consideration in the investigation.
- (d) *Policies and procedures*. If not already provided to ORI with the inquiry report, include the institutional policies and procedures under which the investigation was conducted.
- (e) *Research records and evidence*. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.
- (f) *Statement of findings*. For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so--
 - (1) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
 - (2) Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
 - (3) Identify the specific PHS support;
 - (4) Identify whether any publications need correction or retraction;
 - (5) Identify the person(s) responsible for the misconduct; and
 - (6) List any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies.
- (g) *Comments*. Include and consider any comments made by the respondent and complainant on the draft investigation report.
- (h) *Maintain and provide records*. Maintain and provide to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

Sec. 93.314 Institutional appeals.

- (a) While not required by this part, if the institution's procedures provide for an appeal by the respondent that could result in a reversal or modification of the findings of research misconduct in the investigation report, the institution must complete any such appeal within 120 days of its filing. Appeals from personnel or similar actions that would not result in a reversal or modification of the findings of research misconduct are excluded from the 120-day limit.
- (b) If unable to complete any appeals within 120 days, the institution must ask ORI for an extension in writing and provide an explanation for the request.
- (c) ORI may grant requests for extension for good cause. If ORI grants an extension, it may direct the institution to file periodic progress reports.

Sec. 93.315 Notice to ORI of institutional findings and actions.

The institution must give ORI the following:

- (a) *Investigation Report*. Include a copy of the report, all attachments, and any appeals.
- (b) *Final institutional action*. State whether the institution found research misconduct, and if so, who committed the misconduct.
- (c) *Findings*. State whether the institution accepts the investigation's findings.
- (d) *Institutional administrative actions*. Describe any pending or completed administrative actions against the respondent.

Sec. 93.316 Completing the research misconduct process.

- (a) ORI expects institutions to carry inquiries and investigations through to completion and to pursue diligently all significant issues. An institution must notify ORI in advance if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage, which must be reported to ORI under Sec. 93.315.
- (b) 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) Referring the matter for further investigation by HHS; or,
 - (4) Taking a compliance action.

Other Institutional Responsibilities**Sec. 93.317 Retention and custody of the research misconduct proceeding record.**

- (a) *Definition of records of research misconduct proceedings.* As used in this section, the term "records of research misconduct proceedings" includes:
- (1) The records that the institution secures for the proceeding pursuant to Sec. Sec. 93.305, 93.307(b) and 93.310(d), except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;
 - (2) The documentation of the determination of irrelevant or duplicate records;
 - (3) The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate as required by Sec. 93.309(d);
 - (4) The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted pursuant to Sec. 93.310(g); and
 - (5) The complete record of any institutional appeal covered by Sec. 93.314.
- (b) *Maintenance of record.* Unless custody has been transferred to HHS under paragraph (c) of this section, or ORI has advised the institution in writing that it no longer needs to retain the records, an institution must maintain records of research misconduct proceedings in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later.
- (c) *Provision for HHS custody.* On request, institutions must transfer custody of or provide copies to HHS, of any institutional record relevant to a research misconduct allegation covered by this part, including the research records and evidence, to perform forensic or other analyses or as otherwise needed to conduct an HHS inquiry or investigation or for ORI to conduct its review or to present evidence in any proceeding under subparts D and E of this part.

Sec. 93.318 Notifying ORI of special circumstances.

At any time during a research misconduct proceeding, as defined in Sec. 93.223, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:

- (a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
- (b) HHS resources or interests are threatened.
- (c) Research activities should be suspended.
- (d) There is reasonable indication of possible violations of civil or criminal law.
- (e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
- (f) The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
- (g) The research community or public should be informed.

Sec. 93.319 Institutional standards.

- (a) Institutions may have internal standards of conduct different from the HHS standards for research misconduct under this part. Therefore, an institution may find conduct to be actionable under its standards even if the action does not meet this part's definition of research misconduct.
- (b) An HHS finding or settlement does not affect institutional findings or administrative actions based on an institution's internal standards of conduct.

**Subpart D--Responsibilities of the U.S. Department of Health and Human Services
General Information****Sec. 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 if jurisdiction exists under this part in any matter;
 - (3) Forwarding allegations of research misconduct to the appropriate institution or HHS component for inquiry or investigation;
 - (4) Recommending that HHS should perform an inquiry or investigation or issue findings and taking all appropriate actions in response to the inquiry, investigation, or findings;
 - (5) Notifying or requesting assistance and information from PHS funding components or other affected Federal and state offices and agencies or institutions;
 - (6) Reviewing an institution's findings and process;
 - (7) Making a finding of research misconduct; and
 - (8) Proposing administrative actions to HHS.
- (b) *Requests for information.* ORI may request clarification or additional information, documentation, research records, or evidence from an institution or its members or other persons or sources to carry out ORI's review.
- (c) *HHS administrative actions.*

- (1) In response to a research misconduct proceeding, ORI may propose administrative actions against any person to the HHS and, upon HHS approval and final action in accordance with this part, implement the actions.
- (2) ORI may propose to the HHS debaring official that a person be suspended or debarred from receiving Federal funds and may propose to other appropriate PHS components the implementation of HHS administrative actions within the components' authorities.
- (d) *ORI assistance to institutions.* At any time, ORI may provide information, technical assistance, and procedural advice to institutional officials as needed regarding an institution's participation in research misconduct proceedings.
- (e) *Review of institutional assurances.* ORI may review institutional assurances and policies and procedures for compliance with this part.
- (f) *Institutional compliance.* ORI may make findings and impose HHS administrative 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.

Sec. 93.401 Interaction with other offices and interim actions.

- (a) ORI may notify and consult with other offices at any time if it has reason to believe that a research misconduct proceeding may involve that office. 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 Inspector General (OIG), or other appropriate investigative body. 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.
- (b) ORI may notify affected PHS offices and funding components at any time to permit them to make appropriate interim responses to protect the health and safety of the public, to promote the integrity of the PHS supported research and research process, and to conserve public funds.
- (c) 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.

Research Misconduct Issues**Sec. 93.402 ORI allegation assessments.**

- (a) When ORI receives an allegation of research misconduct directly or becomes aware of an allegation or apparent instance of research misconduct, it may conduct an initial assessment or refer the matter to the relevant institution for an assessment, inquiry, or other appropriate actions.
- (b) If ORI conducts an assessment, it considers whether the allegation of research misconduct appears to fall within the definition of research misconduct, appears to involve PHS supported biomedical or behavior research, research training or activities related to that research or research training, as provided in Sec. 93.102, and whether it is sufficiently specific so that potential evidence may be identified and sufficiently substantive to warrant an inquiry. ORI may review all readily accessible, relevant information related to the allegation.
- (c) If ORI decides that an inquiry is warranted, it forwards the matter to the appropriate institution or HHS component.
- (d) If ORI decides that an inquiry is not warranted it will close the case and forward the allegation in accordance with paragraph(e) of this section.

- (e) ORI may forward allegations that do not fall within the jurisdiction of this part to the appropriate HHS component, Federal or State agency, institution, or other appropriate entity.

Sec. 93.403 ORI review of research misconduct proceedings.

ORI may conduct reviews of research misconduct proceedings. In conducting its review, ORI may--

- (a) Determine whether there is HHS jurisdiction under this part;
- (b) Consider any reports, institutional findings, research records, and evidence;
- (c) Determine if 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;
- (d) Obtain additional information or materials from the institution, the respondent, complainants, or other persons or sources;
- (e) Conduct additional analyses and develop evidence;
- (f) Decide whether research misconduct occurred, and if so who committed it;
- (g) Make appropriate research misconduct findings and propose HHS administrative actions; and
- (h) Take any other actions necessary to complete HHS' review.

Sec. 93.404 Findings of research misconduct and proposed administrative actions.

After completing its review, ORI either closes the case without a finding of research misconduct or--

- (a) Makes findings of research misconduct and proposes and obtains HHS approval of administrative actions based on the record of the research misconduct proceedings and any other information obtained by ORI during its review; or
- (b) Recommends that HHS seek to settle the case.

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

- (a) When the ORI makes a finding of research misconduct or seeks to impose or enforce HHS administrative actions, other than debarment or suspension, it notifies the respondent in a charge letter.
- (b) In cases involving a debarment or suspension action, the HHS debarring official issues a notice of proposed debarment or suspension to the respondent as part of the charge letter. The charge letter includes the ORI findings of research misconduct and the basis for them and any HHS administrative actions. The letter also advises the respondent of the opportunity to contest the findings and administrative actions under Subpart E of this part.
- (c) The ORI sends the charge letter by certified mail or a private delivery service to the last known address of the respondent or the last known principal place of business of the respondent's attorney.

Sec. 93.406 Final HHS actions.

Unless the respondent contests the charge letter within the 30-day period prescribed in Sec. 93.501, the ORI finding of research misconduct is the final HHS action on the research misconduct issues and the HHS administrative actions become final and will be implemented, except that the debarring official's decision is the final HHS action on any debarment or suspension actions.

Sec. 93.407 HHS administrative actions.

- (a) In response to a research misconduct proceeding, HHS may impose HHS administrative actions that include but are not limited to:
 - (1) Clarification, correction, or retraction of the research record.

- (2) Letters of reprimand.
 - (3) Imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of PHS grants, contracts, or cooperative agreements.
 - (4) Suspension 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 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 the PHS.
 - (9) No participation in any advisory capacity to the PHS.
 - (10) Adverse personnel action if the respondent is a Federal employee, in compliance with relevant Federal personnel policies and laws.
 - (11) Suspension or debarment under 45 CFR Part 76, 48 CFR Subparts 9.4 and 309.4, or both.
- (b) In connection with findings of research misconduct, HHS also may seek to recover PHS funds spent in support of the activities that involved research misconduct.
- (c) Any authorized HHS component may impose, administer, or enforce HHS administrative actions separately or in coordination with other HHS components, including, but not limited to ORI, the Office of Inspector General, the PHS funding component, and the debaring official.

Sec. 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. HHS considers aggravating and mitigating factors in determining appropriate HHS administrative actions and their terms. HHS may consider other factors as appropriate in each case. The existence or nonexistence of any factor is not determinative:

- (a) *Knowing, intentional, or reckless.* Were the respondent's actions knowing or intentional or was the conduct 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 persons?
- (g) *Present responsibility.* Is the respondent presently responsible to conduct PHS supported research?
- (h) *Other factors.* Other factors appropriate to the circumstances of a particular case.

Sec. 93.409 Settlement of research misconduct proceedings.

- (a) HHS may settle a research misconduct proceeding at any time it concludes 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 the ORI made a finding of research misconduct.

Sec. 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:

- (a) Provide written notice to the respondent, the relevant institution, the complainant, and HHS officials.
- (b) Take any other actions authorized by law.

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

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

- (a) Provide final notification of any research misconduct findings and HHS administrative actions to the respondent, the relevant institution, the complainant, and HHS officials. The debarring official may provide a separate notice of final HHS action on any debarment or suspension actions.
- (b) Identify publications which require correction or retraction and prepare and send a notice to the relevant journal.
- (c) Publish notice of the research misconduct findings.
- (d) Notify the respondent's current employer.
- (e) Take any other actions authorized by law.

Institutional Compliance Issues**Sec. 93.412 Making decisions on institutional noncompliance.**

- (a) Institutions must foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with PHS supported research.
- (b) ORI may decide that an institution is not compliant with this part if the institution shows a disregard for, or inability or unwillingness to implement and follow the requirements of this part and its assurance. In making this decision, ORI may consider, but is not limited to the following factors--
 - (1) Failure to establish and comply with policies and procedures under this part;
 - (2) Failure to respond appropriately when allegations of research misconduct arise;
 - (3) Failure to report to ORI all investigations and findings of research misconduct under this part;
 - (4) Failure to cooperate with ORI's review of research misconduct proceedings; or
 - (5) Other actions or omissions that have a material, adverse effect on reporting and responding to allegations of research misconduct.

Sec. 93.413 HHS compliance actions.

- (a) An institution's failure to comply with its assurance and the requirements of this part may result in enforcement action against the institution.
- (b) ORI may address institutional deficiencies through technical assistance if the deficiencies do not substantially affect compliance with this part.
- (c) If an institution fails to comply with its assurance and the requirements of this part, HHS may take some or all of the following compliance actions:
 - (1) Issue a letter of reprimand.

- (2) Direct that research misconduct proceedings be handled by HHS.
 - (3) Place the institution on special review status.
 - (4) Place information on the institutional noncompliance on the ORI Web site.
 - (5) Require the institution to take corrective actions.
 - (6) Require the institution to adopt and implement an institutional integrity agreement.
 - (7) Recommend that HHS debar or suspend the entity.
 - (8) Any other action appropriate to the circumstances.
- (d) If the institution's actions constitute a substantial or recurrent failure to comply with this part, ORI may also revoke the institution's assurance under Sec. Sec. 93.301 or 93.303.
- (e) ORI may make public any findings of institutional noncompliance and HHS compliance actions.

Disclosure of Information

Sec. 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.
- (b) ORI may publish a notice of final agency findings of research misconduct, settlements, and HHS administrative actions and release and 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 HHS Administrative Actions

General Information

Sec. 93.500 General policy.

- (1) This subpart provides a respondent an opportunity to contest ORI findings of research misconduct and HHS administrative actions, including debarment or suspension, arising under 42 U.S.C. 289b in connection with PHS supported biomedical and behavioral research, research training, or activities related to that research or research training.
- (2) A respondent has an opportunity to contest ORI research misconduct findings and HHS administrative actions under this part, including debarment or suspension, by requesting an administrative hearing before an Administrative Law Judge (ALJ) affiliated with the HHS DAB, when-
 - (a) ORI has made a finding of research misconduct against a respondent; and
 - (b) The respondent has been notified of those findings and any proposed HHS administrative actions, including debarment or suspension, in accordance with this part.
 - (c) The ALJ's ruling on the merits of the ORI research misconduct findings and the HHS administrative actions is subject to review by the Assistant Secretary for Health in accordance with Sec. 93.523. The decision made under that section is the final HHS action, unless that decision results in a recommendation for debarment or suspension. In that case, the decision under Sec. 93.523 shall constitute findings of fact to the debarring official in accordance with 45 CFR 76.845(c).
- (d) Where a proposed debarment or suspension action is based upon an ORI finding of research misconduct, the procedures in this part provide the notification, opportunity to contest, and fact-finding required under the HHS debarment and suspension regulations at 45 CFR part 76, subparts H and G, respectively, and 48 CFR Subparts 9.4 and 309.4.

Sec. 93.501 Opportunity to contest findings of research misconduct and administrative actions.

- (a) **Opportunity to contest.** A respondent may contest ORI findings of research misconduct and HHS administrative actions, including any debarment or suspension action, by requesting a hearing within 30 days of receipt of the charge letter or other written notice provided under Sec. 93.405.
- (b) **Form of a request for hearing.** The respondent's request for a hearing must be--
- (1) **In writing;**
 - (2) **Signed by the respondent or by the respondent's attorney; and**
 - (3) **Sent by certified mail, or other equivalent (i.e., with a verified method of delivery), to the DAB Chair and ORI.**
- (c) **Contents of a request for hearing.** The request for a hearing must--
- (1) **Admit or deny each finding of research misconduct and each factual assertion made in support of the finding;**
 - (2) **Accept or challenge each proposed HHS administrative action;**
 - (3) **Provide detailed, substantive reasons for each denial or challenge;**
 - (4) **Identify any legal issues or defenses that the respondent intends to raise during the proceeding; and**
 - (5) **Identify any mitigating factors that the respondent intends to prove.**
- (d) **Extension for good cause to supplement the hearing request.**
- (1) **After receiving notification of the appointment of the ALJ, the respondent has 10 days to submit a written request to the ALJ for supplementation of the hearing request to comply fully with the requirements of paragraph (c) of this section. The written request must show good cause in accordance with paragraph (d)(2) of this section and set forth the proposed supplementation of the hearing request. The ALJ may permit the proposed supplementation of the hearing request in whole or in part upon a finding of good cause.**
 - (2) **Good cause means circumstances beyond the control of the respondent or respondent's representative and not attributable to neglect or administrative inadequacy.**

Hearing Process**Sec. 93.502 Appointment of the Administrative Law Judge and scientific expert.**

- (a) **Within 30 days of receiving a request for a hearing, the DAB Chair, in consultation with the Chief Administrative Law Judge, must designate an Administrative Law Judge (ALJ) to determine whether the hearing request should be granted and, if the hearing request is granted, to make recommended findings in the case after a hearing or review of the administrative record in accordance with this part.**
- (b) **The ALJ may retain one or more persons with appropriate scientific or technical expertise to assist the ALJ in evaluating scientific or technical issues related to the findings of research misconduct.**
- (1) **On the ALJ's or a party's motion to appoint an expert, the ALJ must give the parties an opportunity to submit nominations. If such a motion is made by a party, the ALJ must appoint an expert, either:**
 - (i) **The expert, if any, who is agreed upon by both parties and found to be qualified by the ALJ; or,**
 - (ii) **If the parties cannot agree upon an expert, the expert chosen by the ALJ.**
 - (2) **The ALJ may seek advice from the expert(s) at any time during the discovery and hearing phases of the proceeding. The expert(s) shall provide advice to the ALJ in the form of a written report or reports that will be served upon the parties within 10 days of submission to the**

ALJ. That report must contain a statement of the expert's background and qualifications. Any comment on or response to a report by a party, which may include comments on the expert's qualifications, must be submitted to the ALJ in accordance with Sec. 93.510(c). The written reports and any comment on, or response to them are part of the record. Expert witnesses of the parties may testify on the reports and any comments or responses at the hearing, unless the ALJ determines such testimony to be inadmissible in accordance with Sec. 93.519, or that such testimony would unduly delay the proceeding.

- (c) No ALJ, or person hired or appointed to assist the ALJ, may serve in any proceeding under this subpart if he or she has any real or apparent conflict of interest, bias, or prejudice that might reasonably impair his or her objectivity in the proceeding.
- (d) Any party to the proceeding may request the ALJ or scientific expert to withdraw from the proceeding because of a real or apparent conflict of interest, bias, or prejudice under paragraph (c) 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.
- (e) An ALJ must withdraw from any proceeding for any reason found by the ALJ or Chief ALJ to be disqualifying.

Sec. 93.503 Grounds for granting a hearing request.

- (a) The ALJ must grant a respondent's hearing request if the ALJ determines there is a genuine dispute over facts material to the findings of research misconduct or proposed administrative actions, including any debarment or suspension action. The respondent's general denial or assertion of error for each finding of research misconduct, and any basis for the finding, or for the proposed HHS administrative actions in the charge letter, is not sufficient to establish a genuine dispute.
- (b) The hearing request must specifically deny each finding of research misconduct in the charge letter, each basis for the finding and each HHS administrative action in the charge letter, or it is considered an admission by the respondent. If the hearing request does not specifically dispute the HHS administrative actions, including any debarment or suspension actions, they are considered accepted by the respondent.
- (c) If the respondent does not request a hearing within the 30-day time period prescribed in Sec. 93.501(a), the finding(s) and any administrative action(s), other than debarment or suspension actions, become final agency actions at the expiration of the 30-day period. Where there is a proposal for debarment or suspension, after the expiration of the 30-day time period the official record is closed and forwarded to the debarring official for a final decision.
- (d) If the ALJ grants the hearing request, the respondent may waive the opportunity for any in-person proceeding, and the ALJ may review and decide the case on the basis of the administrative record. The ALJ may grant a respondent's request that waiver of the in-person proceeding be conditioned upon the opportunity for respondent to file additional pleadings and documentation. ORI may also supplement the administrative record through pleadings, documents, in-person or telephonic testimony, and oral presentations.

Sec. 93.504 Grounds for dismissal of a hearing request.

- (a) The ALJ must dismiss a hearing request if the respondent--
 - (1) Does not file the request within 30 days after receiving the charge letter;
 - (2) Does not raise a genuine dispute over facts or law material to the findings of research misconduct and any administrative actions, including debarment and suspension actions, in the hearing request or in any extension to supplement granted by the ALJ under Sec. 93.501(d);

- (3) Does not raise any issue which may properly be addressed in a hearing;
- (4) Withdraws or abandons the hearing request; or
- (b) The ALJ may dismiss a hearing request if the respondent fails to provide ORI with notice in the form and manner required by Sec. 93.501.

Sec. 93.505 Rights of the parties.

- (a) The parties to the hearing 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;
 - (3) Conduct discovery of documents and other tangible items;
 - (4) Agree to stipulations of fact or law that must be made part of the record;
 - (5) File motions in writing before the ALJ;
 - (6) Present evidence relevant to the issues at the hearing;
 - (7) Present and cross-examine witnesses;
 - (8) Present oral arguments;
 - (9) Submit written post-hearing briefs, proposed findings of fact and conclusions of law, and reply briefs within reasonable time frames agreed upon by the parties or established by the ALJ as provided in Sec. 93.522; and
 - (10) Submit materials to the ALJ and other parties under seal, or in redacted form, when necessary, to protect the confidentiality of any information contained in them consistent with this part, the Privacy Act, the Freedom of Information Act, or other Federal law or regulation.

Sec. 93.506 Authority of the Administrative Law Judge.

- (a) The ALJ assigned to the case must conduct a fair and impartial hearing, avoid unnecessary delay, maintain order, and assure that a complete and accurate record of the proceeding is properly made. The ALJ is bound by all Federal statutes and regulations, Secretarial delegations of authority, and applicable HHS policies and may not refuse to follow them or find them invalid, as provided in paragraph (c)(4) of this section. The ALJ has the authorities set forth in this part.
- (b) Subject to review as provided elsewhere in this subpart, the ALJ may--
 - (1) Set and change the date, time, schedule, and place of the hearing upon reasonable notice to the parties;
 - (2) Continue or recess the hearing in whole or in part for a reasonable period of time;
 - (3) 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;
 - (4) Administer oaths and affirmations;
 - (5) Require the attendance of witnesses at a hearing;
 - (6) Rule on motions and other procedural matters;
 - (7) Require the production of documents and regulate the scope and timing of documentary discovery as permitted by this part;
 - (8) Require each party before the hearing to provide the other party and the ALJ with copies of any exhibits that the party intends to introduce into evidence;
 - (9) Issue a ruling, after an in camera inspection if necessary, to address the disclosure of any evidence or portion of evidence for which confidentiality is requested under this part or other Federal law or regulation, or which a party submitted under seal;
 - (10) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;

- (11) Examine witnesses and receive evidence presented at the hearing;
 - (12) Admit, exclude, or limit evidence offered by a party;
 - (13) Hear oral arguments on facts or law during or after the hearing;
 - (14) Upon motion of a party, take judicial notice of facts;
 - (15) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;
 - (16) Conduct any conference or oral argument in person, by telephone, or by audio-visual communication;
 - (17) 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; or
 - (4) Find invalid or refuse to follow Federal statutes or regulations, Secretarial delegations of authority, or HHS policies.

Sec. 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. However, a party, attorney, or other party representative may communicate with DAB staff about administrative or procedural matters.
- (b) If an ex parte communication occurs, the ALJ will disclose it to the other party and make it part of the record after the other party has 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.

Sec. 93.508 Filing, forms, 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 placed in the mail, transmitted to a private delivery service for the purpose of delivering the item to the ALJ, or submitted in another manner authorized by the ALJ.
- (b) **Forms.**
 - (1) Unless the ALJ provides otherwise, all submissions filed in the proceeding must include an original and two copies. 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 Sec. 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, such as a "Motion to Compel the Production of Documents" or "Respondent's Proposed Exhibits."
 - (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.** A party filing a submission with the ALJ must, at the time of filing, serve a copy on the other party. Service may be made either to the last known principal place of business of the party's attorney if the party is represented by an attorney, or, if not, to the party's last known address. Service may be made by--
- (1) Certified mail;
 - (2) First-class postage prepaid U.S. Mail;
 - (3) A private delivery service;
 - (4) Hand-delivery; or
 - (5) Facsimile or other electronic means if permitted by the ALJ.
- (d) **Proof of service.** Each party filing a document or paper with the ALJ must also provide proof of service at the time of the filing. Any of the following items may constitute proof of service:
- (1) A certified mail receipt returned by the postal service with a signature;
 - (2) An official record of the postal service or private delivery service;
 - (3) A certificate of service stating the method, place, date of service, and person served that is signed by an individual with personal knowledge of these facts; or
 - (4) Other proof authorized by the ALJ.

Sec. 93.509 Computation of time.

- (a) In computing any period of time under this part for filing and service or for responding to an order issued by the ALJ, the computation begins with the day following the act or event, and includes the last day of the period unless that day is a Saturday, Sunday, or legal holiday observed by the Federal government, in which case it includes the next business day.
- (b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government must be excluded from the computation.
- (c) Where a document has been filed by placing it in the mail, an additional 5 days must be added to the time permitted for any response. This paragraph does not apply to a respondent's request for hearing under Sec. 93.501.
- (d) Except for the respondent's request for a hearing, the ALJ may modify the time for the filing of any document or paper required or authorized under the rules in this part to be filed for good cause shown. When time permits, notice of a party's request for extension of the time and an opportunity to respond must be provided to the other party.

Sec. 93.510 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.
- (b) All motions must be in writing except for those made during a prehearing conference or at the hearing.
- (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 responsive pleading 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 or after a hearing on the motion. 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, and, whenever possible, dispose of all outstanding motions before the hearing.

Sec. 93.511 Prehearing conferences.

- (a) The ALJ must schedule an initial prehearing conference with the parties within 30 days of the DAB Chair's assignment of the case.
- (b) The ALJ may use the initial prehearing conference to discuss--
 - (1) Identification and simplification of the issues, specification of disputes of fact and their materiality to the ORI findings of research misconduct and any HHS administrative actions, and amendments to the pleadings, including any need for a more definite statement;
 - (2) Stipulations and admissions of fact including the contents, relevancy, and authenticity of documents;
 - (3) Respondent's waiver of an administrative hearing, if any, and submission of the case on the basis of the administrative record as provided in Sec. 93.503(d);
 - (4) Identification of legal issues and any need for briefing before the hearing;
 - (5) Identification of evidence, pleadings, and other materials, if any, that the parties should exchange before the hearing;
 - (6) Identification of the parties' witnesses, the general nature of their testimony, and the limitation on the number of witnesses and the scope of their testimony;
 - (7) Scheduling dates such as the filing of briefs on legal issues identified in the charge letter or the respondent's request for hearing, the exchange of witness lists, witness statements, proposed exhibits, requests for the production of documents, and objections to proposed witnesses and documents;
 - (8) Scheduling the time, place, and anticipated length of the hearing; and
 - (9) Other matters that may encourage the fair, just, and prompt disposition of the proceedings.
- (c) The ALJ may schedule additional prehearing conferences as appropriate, upon reasonable notice to or request of the parties.
- (d) All prehearing conferences will be audio-taped with copies provided to the parties upon request.
- (e) Whenever possible, the ALJ must memorialize in writing any oral rulings within 10 days after the prehearing conference.
- (f) By 15 days before the scheduled hearing date, the ALJ must hold a final prehearing conference to resolve to the maximum extent possible all outstanding issues about evidence, witnesses, stipulations, motions and all other matters that may encourage the fair, just, and prompt disposition of the proceedings.

Sec. 93.512 Discovery.

- (a) Request to provide documents. A party may only request another party to produce documents or other tangible items for inspection and copying that are relevant and material to the issues identified in the charge letter and in the respondent's request for hearing.
- (b) Meaning of documents. For purposes of this subpart, the term documents includes information, reports, answers, records, accounts, papers, tangible items, and other data and documentary evidence. This subpart does not require the creation of any document. However, requested data stored in an electronic data storage system must be produced in a form reasonably accessible to the requesting party.
- (c) Nondisclosable items. This section does not authorize the disclosure of--
 - (1) Interview reports or statements obtained by any party, or on behalf of any party, of persons whom the party will not call as witness in its case-in-chief;
 - (2) Analyses and summaries prepared in conjunction with the inquiry, investigation, ORI oversight review, or litigation of the case; or
 - (3) Any privileged documents, including but not limited to those protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation.

- (d) Responses to a discovery request. Within 30 days of receiving a request for the production of documents, a party must either fully respond to the request, submit a written objection to the discovery request, or seek a protective order from the ALJ. If a party objects to a request for the production of documents, the party must identify each document or item subject to the scope of the request and state the basis of the objection for each document, or any part that the party does not produce.
- (1) Within 30 days of receiving any objections, the party seeking production may file a motion to compel the production of the requested documents.
 - (2) The ALJ may order a party to produce the requested documents for in camera inspection to evaluate the merits of a motion to compel or for a protective order.
 - (3) The ALJ must compel the production of a requested document and deny a motion for a protective order, unless the requested document is--
 - (i) Not relevant or material to the issues identified in the charge letter or the respondent's request for hearing;
 - (ii) Unduly costly or burdensome to produce;
 - (iii) Likely to unduly delay the proceeding or substantially prejudice a party;
 - (iv) Privileged, including but not limited to documents protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation; or
 - (v) Collateral to issues to be decided at the hearing.
 - (4) If any part of a document is protected from disclosure under paragraph (d)(3) of this section, the ALJ must redact the protected portion of a document before giving it to the requesting party.
 - (5) The party seeking discovery has the burden of showing that the ALJ should allow it.
- (e) Refusal to produce items. If a party refuses to provide requested documents when ordered by the ALJ, the ALJ may take corrective action, including but not limited to, ordering the noncompliant party to submit written answers under oath to written interrogatories posed by the other party or taking any of the actions at Sec. 93.515.

Sec. 93.513 Submission of witness lists, witness statements, and exhibits.

- (a) By 60 days before the scheduled hearing date, each party must give the ALJ a list of witnesses to be offered during the hearing and a statement describing the substance of their proposed testimony, copies of any prior written statements or transcribed testimony of proposed witnesses, a written report of each expert witness to be called to testify that meets the requirements of Federal Rule of Civil Procedure 26(a)(2)(B), and copies of proposed hearing exhibits, including copies of any written statements that a party intends to offer instead of live direct testimony. If there are no prior written statements or transcribed testimony of a proffered witness, the party must submit a detailed factual affidavit of the proposed testimony.
- (b) A party may supplement its submission under paragraph (a) of this section until 30 days before the scheduled hearing date if the ALJ determines:
 - (1) There are extraordinary circumstances; and
 - (2) There is no substantial prejudice to the objecting party.
- (c) The parties must have an opportunity to object to the admission of evidence submitted under paragraph (a) of this section under a schedule set by the ALJ. However, the parties must file all objections before the final prehearing conference.

- (d) If a party tries to introduce evidence after the deadlines in paragraph (a) of this section, the ALJ must exclude the offered evidence from the party's case-in-chief unless the conditions of paragraph (b) of this section are met. If the ALJ admits evidence under paragraph (b) of this section, the objecting party may file a motion to postpone all or part of the hearing to allow sufficient time to prepare and respond to the evidence. The ALJ may not unreasonably deny that motion.
- (e) If a party fails to object within the time set by the ALJ and before the final prehearing conference, evidence exchanged under paragraph (a) of this section is considered authentic, relevant and material for the purpose of admissibility at the hearing.

Sec. 93.514 Amendment to the charge letter.

- (a) The ORI may amend the findings of research misconduct up to 30 days before the scheduled hearing.
- (b) The ALJ may not unreasonably deny a respondent's motion to postpone all or part of the hearing to allow sufficient time to prepare and respond to the amended findings.

Sec. 93.515 Actions for violating an order or for disruptive conduct.

- (a) The ALJ may take action against any party in the proceeding for violating an order or procedure or for other conduct that interferes with the prompt, orderly, or fair conduct of the hearing. Any action imposed upon a party must reasonably relate to the severity and nature of the violation or disruptive conduct.
- (b) The actions may include--
 - (1) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;
 - (2) Striking pleadings, in whole or in part;
 - (3) Staying the proceedings;
 - (4) Entering a decision by default;
 - (5) Refusing to consider any motion or other action not timely filed; or
 - (6) Drawing the inference that spoliated evidence was unfavorable to the party responsible for its spoliation.

Sec. 93.516 Standard and burden of proof.

- (a) Standard of proof. The standard of proof is the preponderance of the evidence.
- (b) Burden of proof.
 - (1) ORI bears the burden of proving the findings of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where ORI establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.
 - (2) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether ORI has carried the burden of proof imposed by this part, the ALJ shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

- (3) ORI bears the burden of proving that the proposed HHS administrative actions are reasonable under the circumstances of the case. The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose HHS administrative actions following a research misconduct proceeding.

Sec. 93.517 The hearing.

- (a) The ALJ will conduct an in-person hearing to decide if the respondent committed research misconduct and if the HHS administrative actions, including any debarment or suspension actions, are appropriate.
- (b) The ALJ provides an independent de novo review of the ORI findings of research misconduct and the proposed HHS administrative actions. The ALJ does not review the institution's procedures or misconduct findings or ORI's research misconduct proceedings.
- (c) A hearing under this subpart is not limited to specific findings and evidence set forth in the charge letter or the respondent's request for hearing. Additional evidence and information may be offered by either party during its case-in-chief unless the offered evidence is--
- (1) Privileged, including but not limited to those protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation.
 - (2) Otherwise inadmissible under Sec. Sec. 93.515 or 93.519.
 - (3) Not offered within the times or terms of Sec. Sec. 93.512 and 93.513.
- (d) ORI proceeds first in its presentation of evidence at the hearing.
- (e) After both parties have presented their cases-in-chief, the parties may offer rebuttal evidence even if not exchanged earlier under Sec. Sec. 93.512 and 93.513.
- (f) Except as provided in Sec. 93.518(c), the parties may appear at the hearing in person or by an attorney of record in the proceeding.
- (g) The hearing must be open to the public, unless the ALJ orders otherwise for good cause shown. However, even if the hearing is closed to the public, the ALJ may not exclude a party or party representative, persons whose presence a party shows to be essential to the presentation of its case, or expert witnesses.

Sec. 93.518 Witnesses.

- (a) Except as provided in paragraph (b) of this section, witnesses must give testimony at the hearing under oath or affirmation.
- (b) The ALJ may admit written testimony if the witness is available for cross-examination, including prior sworn testimony of witnesses that has been subject to cross-examination. These written statements must be provided to all other parties under Sec. 93.513.
- (c) The parties may conduct direct witness examination and cross-examination in person, by telephone, or by audio-visual communication as permitted by the ALJ. However, a respondent must always appear in-person to present testimony and for cross-examination.
- (d) The ALJ may exercise reasonable control over the mode and order of questioning witnesses and presenting evidence to--
- (1) Make the witness questioning and presentation relevant to deciding the truth of the matter; and
 - (2) Avoid undue repetition or needless consumption of time.
- (e) The ALJ must permit the parties to conduct cross-examination of witnesses.

- (f) Upon request of a party, the ALJ may exclude a witness from the hearing before the witness' own testimony. However, the ALJ may not exclude--
- (1) A party or party representative;
 - (2) Persons whose presence is shown by a party to be essential to the presentation of its case; or
 - (3) Expert witnesses.

Sec. 93.519 Admissibility of evidence.

- (a) The ALJ decides the admissibility of evidence offered at the hearing.
- (b) Except as provided in this part, the ALJ is not bound by the Federal Rules of Evidence (FRE). However, the ALJ may apply the FRE where appropriate (e.g., to exclude unreliable evidence).
- (c) The ALJ must admit evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. However, the ALJ may exclude relevant and material evidence if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence under FRE 401-403.
- (d) The ALJ must exclude relevant and material evidence if it is privileged, including but not limited to evidence protected by the attorney-client privilege, the attorney-work product doctrine, or Federal law or regulation.
- (e) The ALJ may take judicial notice of matters upon the ALJ's own initiative or upon motion by a party as permitted under FRE 201 (Judicial Notice of Adjudicative Facts).
- (1) The ALJ may take judicial notice of any other matter of technical, scientific, or commercial fact of established character.
 - (2) The ALJ must give the parties adequate notice of matters subject to judicial notice and adequate opportunity to show that the ALJ erroneously noticed the matters.
- (f) Evidence of crimes, wrongs, or acts other than those at issue in the hearing is admissible only as permitted under FRE 404(b) (Character Evidence not Admissible to Prove Conduct; Exceptions, Other Crimes).
- (g) Methods of proving character are admissible only as permitted under FRE 405 (Methods of Proving Character).
- (h) Evidence related to the character and conduct of witnesses is admissible only as permitted under FRE Rule 608 (Evidence of Character and Conduct of Witness).
- (i) Evidence about offers of compromise or settlement made in this action is inadmissible as provided in FRE 408 (Compromise and Offers to Compromise).
- (j) The ALJ must admit relevant and material hearsay evidence, unless an objecting party shows that the offered hearsay evidence is not reliable.
- (k) The parties may introduce witnesses and evidence on rebuttal.
- (l) All documents and other evidence offered or admitted into the record must be open to examination by both parties, unless otherwise ordered by the ALJ for good cause shown.
- (m) Whenever the ALJ excludes evidence, the party offering the evidence may make an offer of proof, and the ALJ must include the offer in the transcript or recording of the hearing in full. The offer of proof should consist of a brief oral statement describing the evidence excluded. If the offered evidence consists of an exhibit, the ALJ must mark it for identification and place it in the hearing record. However, the ALJ may rely upon the offered evidence in reaching the decision on the case only if the ALJ admits it.

Sec. 93.520 The record.

- (a) HHS will record and transcribe the hearing, and if requested, provide a transcript to the parties at HHS' expense.

- (b) The exhibits, transcripts of testimony, any other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ.
- (c) For good cause shown, the ALJ may order appropriate redactions made to the record at any time.
- (d) The DAB may return original research records and other similar items to the parties or awardee institution upon request after final HHS action, unless under judicial review.

Sec. 93.521 Correction of the transcript.

- (a) At any time, but not later than the time set for the parties to file their post-hearing briefs, any party may file a motion proposing material corrections to the transcript or recording.
- (b) At any time before the filing of the ALJ's decision and after consideration of any corrections proposed by the parties, the ALJ may issue an order making any requested corrections in the transcript or recording.

Sec. 93.522 Filing post-hearing briefs.

- (a) After the hearing and under a schedule set by the ALJ, the parties may file post-hearing briefs, and the ALJ may allow the parties to file reply briefs.
- (b) The parties may include proposed findings of fact and conclusions of law in their post-hearing briefs.

Sec. 93.523 The Administrative Law Judge's ruling.

- (a) The ALJ shall issue a ruling in writing setting forth proposed findings of fact and any conclusions of law within 60 days after the last submission by the parties in the case. If unable to meet the 60-day deadline, the ALJ must set a new deadline and promptly notify the parties, the Assistant Secretary for Health and the debarring official, if debarment or suspension is under review. The ALJ shall serve a copy of the ruling upon the parties and the Assistant Secretary for Health. The ruling of the ALJ constitutes a recommended decision to the Assistant Secretary for Health. The Assistant Secretary for Health may review the ALJ's recommended decision and modify or reject it in whole or in part after determining it, or the part modified or rejected, to be arbitrary and capricious or clearly erroneous. The Assistant Secretary for Health shall notify the parties of an intention to review the ALJ's recommended decision within 30 days after service of the recommended decision. If that notification is not provided within the 30-day period, the ALJ's recommended decision shall become final. An ALJ decision that becomes final in that manner or a decision by the Assistant Secretary for Health modifying or rejecting the ALJ's recommended decision in whole or in part is the final HHS action, unless debarment or suspension is an administrative action recommended in the decision.
- (b) If a decision under Sec. 93.523(b) results in a recommendation for debarment or suspension, the Assistant Secretary for Health shall serve a copy of the decision upon the debarring official and the decision shall constitute findings of fact to the debarring official in accordance with 45 CFR 76.845(c). The decision of the debarring official on debarment or suspension is the final HHS decision on those administrative actions.

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Education/Related Resources:

None

Form Name(s) and Number(s):

None

Originating Department: Research

Contributing Department(s): None

References/Evidence-Based References:

None