EPSTEIN BECKER GREEN

Redline of
Proposed Revisions to the Public Health Service (PHS)
Policies on Research Misconduct (October 5, 2023)
Against
Current PHS Policies on Research Misconduct (May 17, 2005)

This redline was prepared on October 6, 2023 by Epstein Becker & Green, P.C. For more information, please feel free to contact one of the following attorneys of the firm:

Kate Gallin Heffernan
617-737-3539
kheffernan@ebglaw.com

Marylana Saadeh Helou
617-737-8738
mhelou@ebglaw.com

Olivia Plinio
212-351-3774
oplinio@ebglaw.com

Note: This redline is being provided for reference purposes only and should not be relied upon as an exact statement of either the current PHS Policies on Research Misconduct (42 C.F.R. Part 93) or the proposed revisions to the PHS Policies on Research Misconduct. For more information on the proposed revisions to the PHS Policies on Research Misconduct, including the relevant regulatory preamble, consult the official version of the proposed revisions to the PHS Policies on Research Misconduct published in the Federal Register at 88 Fed. Reg. 69583 (October 6, 2023).

PART 93—PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

Sec.

Key

Added text
~~Deleted text~~
~~Text moved from here~~
Text move to here

Subpart C—Responsibilities of Institutions
Compliance and Assurances

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

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

Process for Contesting Research Misconduct Findings and/or Administrative Actions
93.501 Notice of appeal.
~~administrative actions.~~

~~Hearing Process~~
93.502~~-~~ Appointment of the Administrative Law Judge~~ and scientific expert~~.
93.503~~ Grounds for granting a hearing request~~ Filing of the administrative record.
93.504~~ Grounds for dismissal of a hearing request~~ Standard of review.
93.505 Rights of the parties.
93.506~~-~~ Authority of the Administrative Law Judge.
93.507 Ex parte communications.
93.508 Filing, ~~forms~~format, and service.
93.509 ~~Computation of time.~~
~~93.510~~ Filing motions.
93.510 Conferences.
93.511 ~~Prehearing conferences~~Hearing to resolve genuine factual dispute.
93.512 ~~Discovery.~~
~~93.513 Submission of witness lists, witness statements, and exhibits.~~
~~93.514 Amendment to the charge letter.~~
~~93.515 Actions for violating an order or for disruptive conduct.~~
~~93.516 Standard and burden of proof.~~
~~93.517 The hearing.~~
~~93.518 Witnesses.~~
~~93.519 Admissibility of evidence.~~
~~93.520 The record.~~
~~93.521 Correction of the transcript.~~
~~93.522 Filing post-hearing briefs.~~
~~93.523~~ The Administrative Law Judge's ruling.

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

§ 93.50 Special terms.

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

Subpart A—General

§ 93.100 General policy.
(a) Research misconduct involving Public Health Service (PHS) support is contrary to the interests of the PHS and the Federal ~~government and~~Government, to the health and safety of the public, to the
integrity of research, and to the conservation of public funds.
(b) The U.S. Department of Health and Human Services (HHS) and institutions that apply for or receive ~~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.

§ 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~~addressing allegations of research misconduct ~~issues; ~~;
(b) Define what constitutes research misconduct in PHS supported research;
~~(c~~(c) Establish the requirements for a finding of research misconduct;
(d) Define the general types of administrative actions HHS ~~and the PHS~~ may take in response to research misconduct; ~~and~~
(~~d~~e) Require institutions to ~~develop~~:
(1) Develop and implement policies and procedures for— reporting and addressing
~~(1) Reporting and responding to~~ allegations of research misconduct covered by this part;
(2) ~~Providing~~Provide HHS with the assurances necessary to permit the institutions to participate in
PHS supported research.
(~~e~~f) Protect the health and safety of the public, promote the integrity of PHS supported research and the research process, and conserve public funds.

§ 93.102 Applicability.
(a) ~~Each~~ Every extramural or intramural institution (see § 93.219) that applies for or receives PHS support for biomedical or behavioral research, biomedical or behavioral research training~~,~~, or activities related to that research or research training must comply with this part. Further, each recipient of such support is responsible for the compliance of their subrecipients with this part.
(b~~)~~
~~(1~~) This part applies to allegations of research misconduct ~~and research misconduct~~ involving:

~~(i~~(1) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, biomedical or behavioral research training, or activities related to that research or research training~~, such as the operation of tissue and data banks and the dissemination of research information; ~~;
(~~ii~~2) PHS supported biomedical or behavioral extramural or intramural research;
(~~iii~~3) PHS supported biomedical or behavioral extramural or intramural research training programs;
(~~iv~~4) PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as, but not limited to, the operation of tissue and data banks or the dissemination of research information; ~~and~~

~~(v) Plagiarism of research~~(5) Research records produced ~~in the course of~~during PHS supported research, research training, or
activities related to that research or research training~~.~~; and
~~(2) This includes any research~~(6) Research proposed, performed, reviewed, or reported, ~~or~~as well as any research record
generated from that research, regardless of whether an application or proposal for PHS funds resulted in ~~a~~an awarded grant, contract, cooperative agreement, sub-award, or other form of PHS ~~support.~~
support.
(c) This part does not supersede or establish an alternative to any ~~existing~~ applicable statutes, regulations, policies, or procedures for handling fiscal improprieties, the ethical treatment of human or animal subjects, criminal matters, personnel actions against Federal employees, or ~~actions taken under the~~
addressing whistleblowers and/or retaliation.
(d) This part does not supersede or establish an alternative to the HHS ~~debarment and~~ suspension and
debarment regulations as set forth under the Nonprocurement Common Rule (NCR) at ~~45~~2 CFR ~~part 76 and~~
part 180 for nonprocurement transactions (as further implemented by HHS at 2 CFR part 376) or the Federal Acquisition Regulation (FAR) at 48 CFR ~~subparts~~ 9.~~44~~06 and 9.407 for procurement transactions (as further supplemented by HHS at 48 CFR 309.4~~.~~).
(~~d~~e) This part does not prohibit or otherwise limit how institutions handle allegations of misconduct that do not fall within this ~~part's~~part's definition of research misconduct or that do not~~-~~ involve PHS support.

§ 93.103 Research misconduct.
~~Research~~(a) As defined below, research misconduct ~~means~~is fabrication, falsification, or plagiarism in
proposing, performing, or reviewing research, or in reporting research results~~.~~ (see § 93.238).
~~(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~~(b) Research misconduct does not include honest error or differences of opinion.

§ 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 must be proven by a preponderance of the evidence.

§ 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, use of, republication of, or other use forcitation to the potential benefit of the respondentportion(s) of the research record (e.g., processed data, journal articles, funding proposals, data repositories) that is alleged to have been fabricated, falsified, or plagiarized., for the potential benefit of the respondent.

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

(ii) For allegations which may fall under this exception, an institution must inform ORI of the relevant facts before concluding the exception does not apply. ORI will make the final decision about the subsequent use exception for each allegation.

(2) HealthException for the health or safety of the public. If ORI or the institution, following exception. If ORI or the institution, following consultation with ORI, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public., this exception applies.

(3) "Grandfather" exception. If HHS or an institution received the allegation of research misconduct before the effective date of this part.

§ 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.~~

~~§ 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.~~

~~§ 93.108~~ **Confidentiality.**
(a) Disclosure of the identity of respondents ~~and~~, complainants, and witnesses 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. Institutions must inform respondents, complainants, and witnesses, before they are interviewed, if and how their identity may be disclosed. Provided, however, that~~:~~ the institution
~~(1) The institution~~ must disclose the identity of respondents ~~and~~, complainants, or other relevant persons to ORI
pursuant to an ORI review of research misconduct proceedings under ~~§ 93.403.~~ this part.
~~(2) Under § 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.
(c) Disclosure of ongoing research misconduct proceedings under this part is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding, or the purpose of this part as described in § 93.101(f). In this context, "those who need to know" may include public and private entities.
(d) Disclosure of concerns related to the reliability of the research record that is alleged to have been fabricated, falsified, or plagiarized is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding, or the purpose of this part as described in § 93.101(f). In this context, "those who need to know" may include journals, editors, publishers, and public and private entities.
(e) For officials at institutions other than the institution where the research misconduct proceedings are being conducted, their need to know occurs when the institution:
(1) May possess records relevant to allegations under review;
(2) Employs a respondent alleged or found to have committed research misconduct; or
(3) Funds research being conducted by a respondent alleged or found to have committed research misconduct.

§ 93.107 ~~§ 93.109~~ **Coordination with other agencies.**
(a) When more than one agency of the Federal ~~government~~Government has jurisdiction ~~of~~over 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~~ .
(b) In research ~~process and conserve public funds.~~
~~(b) In cases~~misconduct proceedings involving more than one agency, HHS may refer to the other agency's (or agencies') 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

§ 93.200 Accepted practices of the relevant research community.
Accepted practices of the relevant research community means those practices established by 42 CFR part 93 and by PHS funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS grants. These practices must be consistent with the definition of research integrity.

§ 93.201 Administrative action.
Administrative action means—
~~(a) An~~ an HHS action~~-~~, consistent with § 93.407, taken 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, biomedical or behavioral research training, or activities related to that research or research training ~~and~~, or 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.~~

§ 93.202 Administrative record.
Administrative record comprises: the institutional record; any information provided by the respondent to ORI, including but not limited to the verbatim transcript of any meetings under § 93.403 between the respondent and ORI, whether in person, by phone, or by videoconference, and correspondence between the respondent and ORI; any additional information provided to ORI while the case is pending before ORI; and any analysis or additional information generated or obtained by ORI. Any analysis or additional information generated or obtained by ORI will also be made available to the respondent.

§ 93.203~~§ 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~~ and brought directly to the attention of an institutional or HHS official.

§ 93.~~202~~204 Appeal.
Appeal means a request that is made by a respondent to the institution or HHS, consistent

with § 93.314 and subpart E, to reverse or modify findings, decisions, and/or actions related to allegations of research misconduct, against the respondent.

§ 93.205 Assessment.
Assessment means a consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct; appears to involve PHS supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, as provided in § 93.102; and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The assessment only involves the review of readily accessible information relevant to the allegation.

§ 93.206 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.~~
sent to the respondent stating the findings of research misconduct and any proposed HHS administrative actions. If the charge letter includes a suspension or debarment action, it may be issued jointly by ORI and the Suspension and Debarment Official (SDO).

§ 93.~~203~~207 Complainant.
Complainant means ~~a person~~an individual who in good faith makes an allegation of research misconduct.

§ 93.~~204~~208 Contract.
Contract means an acquisition instrument awarded under the ~~HHS~~ Federal Acquisition Regulation (FAR), 48 CFR ~~Chapter~~chapter 1~~, excluding any small purchases awarded pursuant to FAR Part 13.~~ .

§ 93.~~205 Debarment or suspension~~209 Day.
~~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).~~

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

§ 93.~~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.~~

~~§ 93.207~~**210 Departmental Appeals Board or DAB.**

Departmental Appeals Board or DAB ~~–~~means~~, depending on~~ the ~~context –~~

~~(a) The~~ organization, within the HHS Office of the Secretary, established to conduct hearings and provide impartial review of disputed decisions made by HHS operating components~~; or~~ .

§ 93.211 ~~(b) An Administrative Law Judge (ALJ) at the DAB.~~

~~§ 93.208~~**Difference of opinion.**
Difference of opinion means an alternative view held by a researcher who is substantively engaged in the scientific subject area. It generally contrasts with a prevailing opinion included in a published research record or generally accepted by the relevant scientific community. The differing opinion must concern scientific data, methodology, analysis, interpretations, or conclusions, not policy opinions or decisions unrelated to data practices.

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

§ 93.~~209~~213 Fabrication.
Fabrication means making up data or results and recording or reporting them.

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

§ 93.215 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~~covered by this part involving research~~,~~ or research training ~~or activities related to that research or research training, e.g.,~~; funding components may be agencies, bureaus, centers, institutes, divisions, ~~or~~ offices ~~and~~, or other awarding units within the PHS.

§ 93.~~210~~216 Good faith.
(a) Good faith as applied to a complainant or witness~~,~~ means having a reasonable belief in the truth of ~~one's~~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.
(b) Good faith as applied to ~~a~~ an institutional or committee member means cooperating with the research misconduct proceeding by impartially carrying out the duties assigned ~~impartially~~ for the

purpose of helping an institution meet its responsibilities under this part. ~~A~~ An institutional or committee member does not act in good faith if ~~his/her~~their acts or omissions ~~on~~during the ~~committee~~research misconduct proceedings are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.
(c) Good faith as applied to a respondent means acting with reasonable belief that respondent's actions are consistent with accepted practices of the relevant research community.

§ 93.217 Honest error.
Honest error means a mistake made in good faith.

~~§ 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.~~

§ 93.~~212~~218 Inquiry.
Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of §§ 93.307~~–~~ through 93.309.

§ 93.~~213~~219 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.~~
other research institutes, small research institutions, and independent researchers.

§ 93.~~214~~220 Institutional certifying official.
Institutional certifying official means the institutional official responsible for assuring on behalf of an institution that the institution has written policies and procedures for addressing allegations of research misconduct, in compliance with this part; and complies with its own policies and procedures and the requirements of this part. The institutional certifying official also is responsible for certifying the content of the institution's annual report, which contains information specified by ORI on the institution's compliance with this part, and ensuring the report is submitted to ORI, as required.

§ 93.221 Institutional deciding official.
Institutional deciding official means the institutional official who makes final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as the institutional deciding official and the research integrity officer.

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

§ 93.223 Institutional record.
The institutional record comprises:
(a) The records that the institution compiled during the research misconduct proceeding pursuant to §§ 93.305 through 93.316, except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the~~215~~ records duplicate other records that are being retained. These records include, but are not limited to:
(1) The assessment report as required by § 93.306(d);
(2) If an inquiry is conducted, the inquiry report and all records (other than drafts of the report) in support of that report, including, but not limited to, research records and the transcripts of any interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate as required by § 93.309(c);
(3) If an investigation is conducted, the investigation report and all records (other than drafts of the report) in support of that report, including, but not limited to, research records, the transcripts of each interview conducted pursuant to § 93.310(g), and information the respondent provided to the institution;
(4) Decision(s) by the institutional deciding official, such as the written decision from the institutional deciding official with the final determination of research misconduct findings (whether the institution found research misconduct, and if so, who committed the misconduct) and implemented institutional actions; and
(5) The complete record of any institutional appeal under § 93.314;
(b) The documentation of the determination of irrelevant or duplicate records; and
(c) A single index listing all documents in the institutional record.

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

§ 93.225 Investigation.
Investigation ~~–~~means the formal development of a factual record and the examination of ~~that record leading~~
that record that meets the criteria and follows the procedures of §§ 93.310 through 93.316 and leads 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 institutional and administrative actions.

§ 93.~~216~~226 Knowingly.
To act knowingly means to act with the awareness of the act.

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

§ 93.~~217~~228 Office of Research Integrity or ORI.
Office of Research Integrity or ORI –means the office established by Public Health Service Act section 493 (42 U.S.C. 289b) and to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported ~~activities.~~
activities.

§ 93.~~218~~229 Person.

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

§ 93.~~219~~230 Plagiarism.
Plagiarism means the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit.
(a) Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work, which materially mislead the reader regarding the contributions of the author. It does not include the limited use of identical or nearly-identical phrases which describe a commonly-used methodology.
(b) Plagiarism does not include self-plagiarism or authorship or credit disputes including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

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

§ 93.~~220~~232 Public Health Service or PHS.
Public Health Service or PHS ~~means~~consists of the ~~unit~~following components within the ~~Department of Health and Human Services that includes the~~ HHS: the Office of ~~Public Health and Science~~the Assistant Secretary for Health, the Office of Global Affairs, the Administration for Strategic Preparedness and ~~the following Operating Divisions:~~Response, the Advanced Research Projects Agency for Health, the Agency for Healthcare Research and Quality, the Agency for Toxic Substances and Disease Registry, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, ~~and~~ the Substance Abuse and Mental Health Services Administration, and ~~the offices of the Regional Health Administrators.~~ any other

components of HHS designated or established as components of the Public Health Service.

§ 93.~~221~~233 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.~~
behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through funding for PHS intramural research; PHS grants, cooperative agreements, contracts; or subawards, contracts, or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements, or contracts.

§ 93.~~222~~234 Recklessly.
To act recklessly means to act without proper caution despite a known risk for harm.

§ 93.235 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~~mechanisms related to~~,~~ biological causes, functions, or effects~~,~~; diseases~~,~~; treatments~~,~~; or related matters to be studied.

§ 93.~~223~~236 Research integrity.
Research integrity refers to the use of honest and verifiable methods in proposing, performing, and evaluating research; reporting research results and maintaining the research record with particular attention to adherence to rules, regulations, and guidelines; and following accepted practices of the relevant research community.

§ 93.237 Research Integrity Officer or RIO.
Research Integrity Officer or RIO refers to the institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with this part.

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

§ 93.239 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.

§ 93.~~224~~240 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.~~
scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, oral presentations, internet and online content, internal reports, and journal articles.

§ 93.~~225~~241 Respondent.
Respondent means the ~~person~~individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

§ 93.~~226~~242 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.
~~(a) A good faith allegation of research misconduct; or~~
~~(b) Good faith cooperation with a research misconduct proceeding.~~

§ 93.~~227~~243 Secretary or HHS.
Secretary or HHS means the Secretary of HHS or any other ~~officer~~official or employee of the HHS to whom the Secretary delegates authority.

§ 93.244 Small institution.
Small institution means an institution that receives PHS research funds but may be too small to conduct an inquiry or investigation into an allegation of research misconduct as required by this part without actual or apparent conflicts of interest. A small institution typically has a total of 10 or fewer institutional members.

§ 93.245 Suspension and debarment.
Suspension and debarment mean the actions that Federal agencies take to disqualify persons deemed not presently responsible from doing business with the government.
(a) Suspension refers to the temporary disqualification of a person or entity for up to 18 months, typically during the pendency of an investigation and ensuing legal proceedings.
(b) Debarment, meanwhile, refers to a final decision to disqualify a person or entity for a fixed period of time. Both suspension and debarment have government-wide effect: if an entity is suspended or debarred by one agency, it is prohibited from obtaining any Federal contracts or participating in nonprocurement transactions.
(c) Policies and procedures governing suspension and debarment from procurement programs are set forth in the Federal Acquisition Regulation (FAR) at 48 CFR 9.406 and 9.407 (as further supplemented by HHS at 48 CFR 309.4).

(d) Policies and procedures governing suspension and debarment from nonprocurement programs are set forth in the Nonprocurement Common Rule (NCR) at 2 CFR part 180 (as further implemented by HHS at 2 CFR part 376).
(e) Actions undertaken under the FAR and NCR have reciprocal effect; exclusions issued under one system will result in ineligibility for all government procurement and nonprocurement programs.

§ 93.246 Suspension and Debarment Official or SDO.
Suspension and Debarment Official or SDO means the HHS official authorized to impose suspension and debarment.

§ 93.247 This part.
This part means 42 CFR part 93 in its entirety, unless otherwise explicitly noted. When referring to only a portion of 42 CFR part 93, that portion may be described as "subpart" (see § 93.25), or as "section" (text within a specific portion of the subpart).

Subpart C—Responsibilities of Institutions

Compliance and Assurances

§ 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 research integrity and 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~~these individuals from retaliation by respondents and/or other institutional members;
(e) Provide confidentiality to the extent required by § 93.~~108~~106 to all respondents, complainants, and witnesses in a research misconduct proceeding, and to research subjects identifiable from research records or other evidence;
(f) Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and other evidence;
(g) Cooperate with HHS during any research misconduct proceeding or compliance review~~;~~, including addressing deficiencies or additional allegations in the institutional record if directed by ORI;
(h) Assist in administering and enforcing any HHS administrative actions imposed on its

institutional members; and
(i) Have an active research integrity assurance ~~of compliance.~~ .

§ 93.301 ~~Institutional~~ Research integrity assurances.
(a) General policy. (1) An institution ~~with~~that applies for or receives PHS ~~supported~~ support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, must provide ~~PHS~~HHS with an assurance of compliance
with this part~~, satisfactory to the Secretary.~~ by establishing and then maintaining an active research integrity assurance.
(2) PHS funding components may only authorize release of funds for extramural biomedical and behavioral research, biomedical and behavioral research training, or activities related to that research or research training ~~only,~~ to institutions that have ~~approved assurances and required renewals~~ an active research integrity
assurance on file with ORI.

(b) ~~Institutional Assurance.~~ Research integrity assurance. The ~~responsible institutional official~~Institutional Certifying Official must assure on
behalf of the institution, initially and then annually thereafter, that the institution~~—~~:
(1) Has written policies and procedures ~~in compliance with this part for inquiring into and investigating~~for addressing allegations of research ~~misconduct; and~~
misconduct, in compliance with this part;
(2) Complies with its ~~own~~ policies and procedures ~~and the requirements~~for addressing allegations of ~~this part.~~ research misconduct; and
(3) Complies with all provisions of this part.

§ 93.302 ~~Institutional compliance with~~Maintaining active research integrity assurances.
(a) Compliance with ~~assurance.~~ this part. ORI considers an institution in compliance with ~~its assurance if the institution~~ this part when it:
(1) ~~Establishes~~Has policies and procedures for addressing allegations of research misconduct according to this part, keeps them in compliance with this part, and upon request, provides them to ORI~~;~~ and other HHS personnel~~, and members of the public; ;~~
~~(2~~(2) Complies with its policies and procedures for addressing allegations of research misconduct;
(3) Complies with all provisions of this part; and
(4) Takes all reasonable and practical specific steps to foster research integrity consistent with § 93.300, including~~—~~, but not limited to:
(i) ~~Informs~~Informing the ~~institution's research~~institution's 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~~ addressing allegations of research misconduct, and the ~~institution's~~institution's commitment to compliance with the ~~policies and procedures; and~~
policies and procedures; and
(ii) ~~Complies with~~Making its policies and procedures ~~and each specific provision~~for addressing allegations of ~~this part.~~ research misconduct

publicly available.
(b) Annual report. -An institution must file an annual report with ORI, which contains information specified by ORI, on the ~~institution's~~institution's compliance with this part. The Institutional
Certifying Official is responsible for certifying the content of this report and for ensuring the report is submitted as required.
(c) Additional information. -Along with its research integrity assurance or annual report, an institution must send ORI such other ~~aggregated~~ information as ORI may request on the ~~institution's~~institution's research misconduct proceedings covered by this part and the ~~institution's~~institution's compliance with the
requirements of this part.

§ 93.303 ~~Assurances~~Research integrity assurances for small institutions.
(a) ~~If an institution is too small to handle research misconduct proceedings, it~~Small institutions may file a "Small ~~Organization~~Institution Statement" with ORI in place of the ~~formal~~ institutional policies and procedures required by §§ 93.300(a), 93.301, and 93.304~~.~~, upon approval by ORI.
(b) The Small Institution Statement does not relieve the institution from complying with any other provision of this part.
(c) By submitting a Small ~~Organization~~Institution Statement, the institution agrees to report all allegations of research misconduct to ORI. ORI or another appropriate HHS office will work with the institution to develop and ~~implement~~/or advise on 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.~~
misconduct consistent with this part.
(d) If a small institution has or believes it has a conflict of interest during any phase of a research misconduct proceeding, the small institution should contact ORI for guidance.

§ 93.304 Institutional policies and procedures.
Institutions seeking an approved research integrity assurance must have written policies and procedures for addressing ~~research misconduct that include the following:~~
~~(a) Consistent with § 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;~~ . Such policies and procedures
~~(c) Notice to the respondent,~~ must:
(a) Address and be consistent with ~~and within the time limits of~~ all applicable requirements pertaining to institutional
responsibilities included in 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~~ (b) Include and be consistent with applicable definitions in this part; and
(c) Be made available to ORI in English.

§ 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 § 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~~ **General conduct of research misconduct**~~;~~ **proceedings.**
(~~k) All reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputationa~~) Sequestration 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 other 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.~~

~~§ 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~~ all research records and other evidence, which
may include copies of the data or other evidence ~~on such instruments,~~ so long as those copies are substantially equivalent ~~to the~~in evidentiary value ~~of the instruments;~~ , needed to conduct the research misconduct proceeding;
~~(b) Where appropriate, give~~inventory the ~~respondent copies of, or reasonable, supervised access to the research~~ records~~;~~
~~(c) Undertake all reasonable~~ and ~~practical efforts to take custody of additional~~ other evidence; and sequester them in a secure manner. Where the

research records or ~~evidence that is discovered during the course of a research misconduct proceeding, except that where the research records or~~other evidence are located on or encompass scientific instruments shared by ~~a number of~~ multiple users, ~~custody~~institutions may ~~be limited to~~obtain copies of the data or other evidence ~~on~~from such instruments, so long as those copies are substantially equivalent to the evidentiary value of the ~~instruments; and~~

~~(d) Maintain~~instruments. Whenever possible, the institution must obtain the research records ~~and evidence as required by § 93.317.~~

~~§ 93.306 Using a consortium~~ or other ~~person for research misconduct proceedings.~~evidence:

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

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

(b) Access to research records. Where appropriate, an institution must give the respondent copies of, or reasonable supervised access to, the research records that are sequestered in accordance with § 93.305(a).

(c) Maintenance of the institutional record. An institution ~~may use~~, as the ~~services of~~responsible legal entity for the PHS supported research, has a ~~consortium or person~~continuing obligation under this part to ensure that ~~the~~ it maintains an adequate institutional record for a research misconduct proceeding. An institution must maintain the institutional record as required by § 93.317.

(d) Multiple respondents. Institutions must consider whether any additional researchers are responsible for the alleged research misconduct. Notably, the principal investigator, other coauthors on the publication(s), co-investigators on the funding proposal(s), collaborators, and laboratory members who were involved in conducting the experiments that generated the primary data or in generating the text and figures in the research records (e.g., published papers and funding proposals) must be considered as potential respondents during the assessment, inquiry, and/or subsequent investigation. If any additional respondent(s) are identified throughout the inquiry/investigation, they must be notified of the allegations, in accordance with §§ 93.307(c), 93.308(a), and 93.310(c).

(e) Multiple institutions. When multiple institutions are involved in the allegations, one institution must be designated as the lead institution if a joint research misconduct proceeding (inquiry and/or investigation) is conducted. In a joint research misconduct proceeding, the lead institution should obtain research records pertinent to the inquiry/investigation and witness' testimonies from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and which institutional actions are to be taken may be made by the institutions jointly or the responsibilities tasked to the lead institution.

(f) Pursue leads. An institution must diligently pursue all significant issues and leads discovered in information obtained from evidence and/or testimony during the inquiry and/or investigation that are determined relevant to the inquiry and/or investigation, including any evidence of additional instances of possible research misconduct. The pursuit of any such issues and/or leads may extend to the examination of additional research records (e.g., published

papers, grant applications) of the respondent(s) that contain similar data elements as that of the initial allegation(s). If additional allegations are raised during the inquiry or investigation, the respondent(s) must be notified in writing of the additional allegations raised against them.
(g) Interviews. An institution must interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent. Institutions may, but are not required to, conduct interviews during the assessment or inquiry. Interviews conducted during an assessment, inquiry, and/or investigation must be consistent with the requirements of this section.
(1) Interviews must be transcribed.
(2) Any exhibits shown to the interviewee during the interview must be numbered and referred to by that number in the interview.
(3) The transcript of the interview must be made available to the relevant interviewee for correction.
(4) The transcript(s) with any corrections and numbered exhibits must be included in the record of the investigation.
(5) The respondent must not be present during the witnesses' interviews but must be provided a transcribed copy of the interview.
Using a committee, consortium, or other person for research misconduct proceedings. (1) An institution may use the services of a committee, consortium, or person that the institution reasonably determines to be qualified by practice and/or experience to conduct ~~research misconduct proceedings.~~, support, or
~~(b~~participate in the research misconduct proceedings. An institution may choose to use the same committee, consortium, or person for the assessment, inquiry, and/or investigation.
(2) An institution must address any potential, perceived, or actual personal, professional, or financial conflicts of interest between members of the committee or consortium, or the qualified person and the complainant, respondent, or witnesses.
(3) A consortium may be a group of institutions, professional organizations, ~~or~~ mixed groups ~~which~~, or individuals that will conduct research misconduct proceedings for other institutions.
(~~c) A~~4) An institution must ensure that a committee, consortium, or person acting on its behalf ~~of an institution must follow~~conducts research misconduct proceedings in compliance with the requirements of this part ~~in conducting.~~
(5) An institution is not required to provide respondents or complainants the opportunity to object to the person or to one or more committee or consortium members chosen to conduct, support, or participate in the research misconduct proceedings. If an institution chooses to provide one respondent the opportunity to object in a proceeding, it must provide all respondents the opportunity to object in that proceeding. If an institution chooses to provide one complainant the opportunity to object in a proceeding, it must provide all complainants the opportunity to object in that proceeding.
(i) Notifying ORI of special circumstances. At any time during a research misconduct ~~proceedings.~~
proceeding, as defined in § 93.239, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:
(1) Health or safety of the public is at risk, including an immediate need to protect human

or animal subjects.
(2) HHS resources or interests are threatened.
(3) Research activities should be suspended.
(4) There is reasonable indication of possible violations of civil or criminal law.
(5) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
(6) HHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved.

The Institutional Assessment

§ 93.306 Institutional assessment.
(a) Purpose. An assessment's purpose is to decide if an allegation warrants an inquiry.
(b) Conducting the institutional assessment. (1) Upon receiving an allegation of research misconduct, the RIO or another designated institutional official must promptly assess the allegation to determine whether the allegation:
(i) Falls within the definition of research misconduct under this part,
(ii) Is within the jurisdictional criteria of 42 CFR 93.102, and
(iii) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.
(2) In conducting the assessment, the RIO or another designated institutional official must review readily accessible information relevant to the allegation. The RIO or another designated institutional official does not need to interview the complainant, respondent, or other witnesses, or gather information beyond what may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. Should it be necessary to conduct interviews or gather information, such interviews must be conducted according to the requirements of § 93.305(g).
Assessment results. (1) An inquiry must be conducted if the allegation meets the three assessment criteria at § 93.306(b)(1).
(2) If the RIO or another designated institutional official determines that requirements for an inquiry are met, they must:
(i) Document the assessment, in the form of an assessment report (see § 93.306(d)); and
(ii) Promptly take all reasonable and practical steps to obtain all research records and other evidence that are needed, before or at the time the institution notifies the respondent of the allegation(s), consistent with § 93.305, and promptly initiate the inquiry.
(2) If the RIO or another designated institutional official determines that requirements for an inquiry are not met, they must keep sufficiently detailed documentation of the assessment to permit a later review by ORI of the reasons why the institution decided not to conduct an inquiry.
(d) Assessment report. (1) The RIO or another designated institutional official must document the process undertaken and the outcome of the assessment, including:
(i) The allegation(s) assessed;
(ii) The name(s), professional alias(es), and position(s) of the respondent(s);
(iii) Any evidence reviewed;
(iv) Whether the allegation falls within the definition of research misconduct under this part;

(v) Whether the allegation is within the jurisdictional criteria of § 93.102;
(vi) Whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; and
(vii) Whether the institution will proceed to inquiry. If the assessment automatically moves to inquiry as required by § 93.306(e)(2), the assessment report must document this action.
(2) The assessment report must be completed within 15 days of when the decision is made to move to inquiry under § 93.306(c) or the institution moves to inquiry under § 93.306(e)(2).
(3) Institutions must keep these records in a secure manner for at least 7 years after the assessment was conducted, and upon request, provide them to ORI.
(e) Time for completion. (1) The institution must complete the assessment within 30 days of its initiation.
(2) If the assessment will take longer than 30 days, the institution must initiate an inquiry consistent with § 93.307.

The Institutional Inquiry

§ 93.307 Institutional inquiry.
(a) Criteria warranting an inquiry. ~~-~~An inquiry is warranted if the allegation~~—~~:
~~(1~~(1) Was not assessed within the 30-day period for review provided in § 93.306(e); or
(2) Meets the following three criteria:
(i) Falls within the definition of research misconduct under this part;
(~~2~~ii) Is within the jurisdictional criteria of § 93.102; and
(~~3~~iii) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.
(b) Purpose. An inquiry's purpose is to conduct an initial review of the evidence to decide if an allegation warrants an investigation.
(c) 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~~ Only allegations specific to a particular respondent are to be included in the notification to that respondent.
(d) Sequestration of the records. An 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 other evidence needed to conduct the research misconduct proceeding, ~~inventory the records and evidence, and sequester~~consistent with § 93.305(a).
(e) Conducting the inquiry—(1) Multiple institutions. A joint research misconduct proceeding must be conducted consistent with § 93.305(e).
(2) Person conducting the inquiry. Institutions may, but are not required to, convene committees of experts to conduct reviews at the inquiry stage to determine whether an investigation is warranted. The inquiry review may be done by a RIO or another designated institutional official in lieu of a committee, with the caveat that if needed, these individuals may utilize one or more subject matter experts to assist them in ~~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.~~ the inquiry review.
(~~c~~3) 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)~~ (4) Interviews. Institutions may, but are not required to, call witnesses or respondents for interviews that would provide additional information for the institution's review. Any interviews conducted must follow the requirements of § 93.305(g).
(5) Pursue leads. Institutions must diligently pursue all significant issues and leads, consistent with the requirements of § 93.305(f).
(f) Inquiry results—(1) Criteria warranting an investigation. ~~An inquiry's purpose is to decide if an allegation warrants an investigation. An investigation is warranted if there is~~ —An investigation is
~~(1) A~~warranted if:
(i) There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, biomedical or behavioral research~~, research~~ training, or activities related to that research or
research training, as provided in § 93.102; and
(~~2~~ii) Preliminary information-gathering and ~~preliminary~~ fact-finding from the inquiry indicates that the
allegation may have substance.

~~(e~~(2) Honest error and difference of opinion. (i) A conclusion of honest error or difference of opinion must not be made at the inquiry stage.
(ii) An inquiry cannot determine that an allegation lacks sufficient substance based solely on a respondent's unsubstantiated claim that the alleged research misconduct was a result of honest error or difference of opinion.
(3) Findings of research misconduct. Findings of research misconduct, including the determination of whether the alleged misconduct is intentional, knowing, or reckless, cannot be made at the inquiry stage.
(g) Inquiry report. (1) The institution must prepare a written report that meets the requirements of this section and § 93.309.
~~(f) Opportunity to comment.~~ (2) If there is potential evidence of honest error or difference of opinion, the institution
must note this in the inquiry report.
(3) The institution must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments received to the report.
(~~g~~h) Time for completion. (1) The institution must complete the inquiry within 60 ~~calendar~~ days of
its initiation unless circumstances clearly warrant a longer period.
(2) If the inquiry will take longer than 60 days, the institution must notify ORI and request an extension. As part of the request, the institution must describe the particular circumstances or issues that would warrant additional time to complete the inquiry.
(3) If the inquiry takes longer than 60 days to complete, the inquiry ~~record~~report must ~~include documentation of~~ document

the reasons for exceeding the 60-day period.

§ 93.308 Notice of the results of the inquiry.

(a) Notice to respondent. ~~-~~The institution must notify the respondent whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to this part and the ~~institution's~~institution's policies and procedures adopted
under its research integrity assurance.

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

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

(a) Within 30 days of ~~finding~~deciding that an investigation is warranted, the institution must provide ORI with the written ~~finding~~decision by the ~~responsible~~ institutional deciding official and a copy of the
inquiry report which includes the following information~~—~~:

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

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

(3) The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;

(4) The composition of the inquiry committee, including name(s), position(s), and subject matter expertise;

(5) Inventory of sequestered research records and other evidence and description of how sequestration was conducted;

(6) Transcripts of interviews, if conducted;

(7) Timeline and procedural history;

(8) Any scientific or forensic analyses conducted;

(9) The basis for recommending that the ~~alleged actions~~ allegation(s) warrant an investigation; ~~and~~

~~(5)~~ (10) The basis on which any allegation(s) do not merit further investigation;

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

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

(13) Written decision from the institutional deciding official that an investigation is warranted.

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

(1) The institutional policies and procedures under which the inquiry was conducted;

(2) The research records and other 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.~~ (c) 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 § 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 § 93.~~318,~~305(i), institutions must notify ORI and other PHS agencies, as relevant, of any special circumstances that may exist.

The Institutional Investigation

§ 93.310 Institutional investigation.
Institutions conducting research misconduct investigations must:

(a) Time. ~~-~~Begin the investigation within 30 days after ~~determining~~deciding 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 ~~§~~ §§ 93.307 and ~~§~~ 93.309.
(c) Notice to the respondent. ~~-~~Notify the respondent in writing of the ~~allegations~~allegation(s) within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins.
(1) The institution must give the respondent written notice of any ~~new allegations~~allegation(s) 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~~.~~ within a reasonable amount of time of deciding to pursue such allegation(s).
(2) If the institution identifies additional respondents during the investigation that were not identified during the inquiry, the institution is not required to conduct a separate inquiry. If any additional respondent(s) are identified during the investigation, the institution must notify them of the allegation(s).
(3) While an investigation into multiple respondents can convene with the same investigation committee members, separate investigation reports and research misconduct determinations are required for each respondent.
(d) ~~Custody~~Sequestration 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~~An institution must obtain ~~custody of~~ all ~~the~~ research records and other 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~~ consistent with § 93.305(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 other evidence relevant to reaching a decision on the merits of the ~~allegations.~~ allegation(s).
(f) Ensuring a fair investigation. ~~-~~Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest ~~with those involved with~~relevant to the ~~inquiry or~~ investigation. An institution may use the same committee members from the inquiry in their subsequent investigation.
(g) Interviews. Conduct interviews, consistent with § 93.305(g).
~~(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,~~, consistent with the requirements of § 93.305(f), and continue the investigation to completion. Once a proceeding reaches the investigation stage, the institution may choose to add to or expand the ongoing investigation by including any allegation(s) pertaining to the same respondent or research records in question (e.g., manuscripts or funding proposals) that come to the institution's attention during the investigation, rather than opening an inquiry to review those allegation(s).
(i) Multiple respondents. Consider, consistent with § 93.305(d), the prospect of additional researchers being responsible for the alleged research misconduct.
(j) Multiple institutions. A joint research misconduct proceeding must be conducted consistent with § 93.305(e).

§ 93.311 Investigation time limits.
(a) Time limit for completing an investigation. ~~-~~An institution must complete all aspects of an investigation within ~~120~~180 days of beginning it, including conducting the investigation, preparing the draft investigation report ~~of findings~~for each respondent, providing the draft report to each respondent for comment in accordance with § 93.312, and sending the final institutional record including the final report to ORI under § 93.315.
(b) Extension of time limit. ~~-~~If unable to complete the investigation in ~~120~~180 days, the institution must ask ORI for an extension in writing~~.~~ that includes the circumstances or issues warranting additional time.
(c) Progress reports. ~~-~~If ORI grants an extension, it may direct the institution to file periodic progress reports.
(d) Investigation report. If the investigation takes longer than 180 days to complete, the investigation report must include the reasons for exceeding the 180-day period.

§ 93.312 Opportunity to comment on the draft investigation report.

(a) The institution must give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the ~~evidence~~records on which the report is based. The respondent must submit any comments ~~of the respondent~~ on the draft report~~, if any, must be submitted~~ to the institution within 30 days of the date on which the respondent received the draft investigation report.

(b) The institution ~~may~~is not required to provide the complainant(s) a copy of the draft investigation report or relevant portions of that report. Should the institution choose to do so, all complainants must be treated in the same way – absent extenuating circumstances. The ~~comments of the~~ complainant~~, if~~ must submit any~~, must be submitted~~ comments on the draft report to the institution within 30 days of the date on which the complainant received the draft investigation report or relevant portions of it.

§ 93.313 ~~Institutional investigation~~Investigation report.

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

(a) ~~Allegations.~~ Describe the nature of the ~~allegations~~allegation(s) of research misconduct~~.~~, including any additional allegation(s) addressed during the research misconduct proceeding.

(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~~allegation(s) of research misconduct for consideration in the ~~investigation.~~

~~(d) Policies~~investigation for each respondent.

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

(e) Inventory of sequestered research records/other evidence and how sequestration was conducted during the investigation, if applicable.

(f) Listing of all manuscripts, funding proposals, and research records that were examined during the investigation.

(g) Transcripts of all interviews conducted, as described in § 93.305(g).

(h) Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS grant/contract applications, progress reports, presentations, posters, or other research records that allegedly contained the falsified, fabricated, or plagiarized material.

(i) Any scientific or forensic analyses conducted.

(j) 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.~~ (k) Identify and summarize the research records and other evidence reviewed~~,~~ and identify any evidence ~~taken into custody~~obtained and sequestered but not reviewed.

~~(f) Statement of findings.~~ (l) 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 the individual(s) responsible for the misconduct;
(2) Indicate whether the research misconduct was falsification, fabrication, and/or plagiarism~~, and if it was intentional, knowing, or in reckless disregard;~~ ; and if the requirements for a finding of research misconduct, as described in § 93.104,
~~(2~~have been met. Voting or split decisions by the investigation committee members are not permitted
in the final recommendation in the investigation report.
(3) Summarize the facts and the analysis which support the conclusion and consider the merits of any ~~reasonable~~ explanation by the respondent;
(~~3~~4) Identify the specific PHS support;
(~~4~~5) Identify whether any publications need correction or retraction; and
~~(5) Identify the person(s) responsible for the misconduct; and~~
(6) List any current support or known applications or proposals for support that the respondent has pending with PHS and 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.~~
(n) The basis on which allegation(s) did not result in a research misconduct determination.
(o) Any institutional actions recommended or implemented including communications with journals or funding agencies.

§ 93.314 Institutional appeals.
(a) While not required by this part, if the ~~institution's~~ institution's policies and 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 notify ORI of and complete any such appeal within 120 days of its ~~filing~~initiation. Appeals ~~from~~of institutional personnel actions or ~~similar~~
other 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~~that includes the ~~request.~~ circumstances or issues warranting additional time.
(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.

§ 93.315 ~~Notice to ORI~~**Transmittal of the institutional** ~~findings and actions~~**record to ORI.**
The institution must ~~give~~transmit to 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.~~ record. The institutional record
~~(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.~~
must be consistent with § 93.223 and logically organized.

§ 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 § 93.315.~~
~~(b~~and to pursue diligently all significant issues and credible allegations of research misconduct. Institutions must notify ORI in advance if the institution plans to close a research misconduct proceeding at the assessment, inquiry, investigation, or appeal stage on the basis that the respondent has admitted to committing research misconduct, a settlement with the respondent has been reached, or for any other reason.
(b) A respondent's admission of research misconduct must be made in writing and signed by the respondent. An admission must specify the falsification, fabrication, and/or plagiarism that occurred and which research records were affected. The admission statement must meet all the elements required for a research misconduct finding under § 93.104 and must be provided to ORI before the institution closes its research misconduct proceeding. The institution must also provide a statement to ORI describing how it determined that the scope of the misconduct was fully addressed by the admission and confirmed the respondent's culpability.
(c) After consulting with the institution on its basis for closing a case under paragraph (a) of this section, ORI may conduct an oversight review of the ~~institution's~~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~~(3) Directing the institution to address deficiencies in the institutional record;
(4) Referring the matter for further investigation by HHS; or,
(~~4~~5) Taking a compliance action.

Other Institutional Responsibilities

§ 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 §§ 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 § 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 § 93.310(g); and~~

~~(5) The complete record of any~~ **institutional** ~~appeal covered by § 93.314.~~ **record.**
(~~b~~a) Maintenance of institutional record.~~-~~ Unless custody has been transferred to HHS under paragraph (~~c~~b) of this section, or ORI has advised the institution in writing that it no longer needs to retain the ~~records~~institutional record, an institution must maintain ~~records of research misconduct proceedings~~ the institutional record 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~~b) Provision for HHS custody. ~~-~~On request, institutions must transfer custody of or provide copies to HHS~~,~~ of ~~any~~the institutional record ~~relevant to~~or any component of the institutional record and any sequestered physical objects, such as 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~~computer hard drive, for ORI to conduct its oversight review, to develop the administrative record, or to present ~~evidence in~~ the administrative record in any proceeding under subparts D and E of this part.

§ 93.318 ~~Notifying ORI of special circumstances.~~
~~At any time during a research misconduct proceeding, as defined in § 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.~~

~~§ 93.319~~ **Institutional standards of conduct.**

(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~~conduct does not meet this ~~part's~~part's definition of research misconduct.
(b) An HHS or ORI finding or settlement on research misconduct findings does not affect institutional findings or ~~administrative~~ actions taken based on an ~~institution's internal~~institution's standards of conduct.

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

General Information

§ 93.400 General statement of ORI authority.
(a) ORI review. ~~-~~ORI may respond directly to any allegation of research misconduct at any time before, during, or after an ~~institution's~~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;~~
(4) Requesting clarification or additional information, documentation, research records, or other evidence as necessary from an institution or its members or other persons or sources to carry out ORI's review;
(5) Notifying or requesting assistance and information from PHS funding components or other affected Federal and state offices and agencies or institutions;
(6) Reviewing ~~an institution's findings and process; ~~the institutional record and directing the institution to address deficiencies
or additional allegations in the institutional record;
(7) Making a finding of research misconduct; and
(8) Proposing or taking 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 debarring 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~~will:
(1) Provide information, technical assistance, and procedural advice to institutional

officials as needed regarding an ~~institution's participation in~~institution's research misconduct proceedings~~.~~ and the
~~(~~esufficiency of the institutional record.
(2) Issue guidance and provide information to support institutional implementation of and/or compliance with the requirements of this part.
(c) Review of institutional research integrity assurances. ~~-~~ORI ~~may~~will review institutional research integrity assurances and policies and procedures for compliance with this part.
(~~f~~d) Institutional compliance. ~~-~~ORI may make findings and impose HHS ~~administrative~~ compliance
actions related to an ~~institution's~~institution's compliance with this part and with its policies and procedures, ~~including an institution's participation in research misconduct proceedings.~~ including an institution's participation in research misconduct proceedings.

§ 93.401 Interaction with other ~~offices~~entities and interim actions.
(a) ORI may notify and consult with other ~~offices~~entities including government funding agencies, institutions, private organizations, journals, publishers, and editors at any time if ~~it has reason~~those
entities have a need to ~~believe that~~know about or have information relevant to a research misconduct
proceeding ~~may involve that office.~~.
(b) If ORI believes that a criminal or civil fraud violation may have occurred, it shall promptly refer the matter to the Department of Justice (DOJ), the HHS 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~~c) ORI may notify affected PHS offices and funding components at any time to ~~permit~~ enable them to ~~make~~take 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.~~ actions.
(~~c~~d) 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

§ 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 § 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~~c) If ORI decides that an inquiry is not warranted it will close the case and forward the allegation in accordance with paragraph (~~e~~d) of this section.
(~~e~~d) ORI may forward allegations that do not fall within the jurisdiction of this part to the appropriate HHS component, Federal or ~~State~~state agency, institution, organization, journal, or other
appropriate entity.

§ 93.403 ORI review of research misconduct proceedings.
~~ORI may conduct reviews~~(a) In conducting its review of research misconduct proceedings~~. In conducting its review~~, ORI ~~may~~ will:
(~~a~~1) Determine whether ~~there is HHS~~PHS has jurisdiction under this part;
(~~b~~2) Consider ~~any reports,~~the institutional ~~findings, research records,~~record and ~~evidence;~~ decide whether the institutional record is
(~~c~~sufficient, provide instructions to the institution(s) if ORI determines that revisions are needed or
additional allegations of research misconduct should be addressed, and require institutions to provide the respondent with an opportunity to respond to information or allegations added to the institutional record;
(3) Determine 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; and
(~~d~~(4) After reviewing in accordance with paragraphs (a)(1) through (3) of this section, decide whether to close the case without further action or proceed with the case.
(b) If ORI decides to proceed with the case, ORI will:
(1) Obtain additional information or materials from the institution, the respondent, complainants, or other ~~persons or~~ sources~~;~~, as needed;
(~~e~~2) Conduct additional analyses ~~and develop evidence;~~ , as needed;
~~(f) Decide whether research misconduct occurred, and if so who committed it;~~
~~(g) Make appropriate research misconduct findings~~(3) Provide the respondent the opportunity to access the institutional record, any
additional information provided to ORI while the case is pending before ORI, and ~~propose HHS~~any analysis
or additional information generated or obtained by ORI;
(4) Provide the respondent the opportunity to submit information to ORI;
(5) Allow the respondent and the respondent's attorney, if represented, to meet virtually or in person with ORI to discuss the information that the respondent has provided to ORI and have ORI's meetings with the respondent transcribed, with a copy of the transcript provided to the respondent for review and suggested correction;
(6) Close the administrative ~~actions; and~~ record following paragraphs (b)(3) through (5) of this (~~h~~section;
(7) Provide the respondent the opportunity to access the complete administrative record; and
(8) Take any other actions necessary to complete ~~HHS'~~ORI's review.

§ 93.404 Findings of research misconduct and proposed administrative actions.

(a) After completing its review of the administrative record, ORI ~~either closes~~can:

(1) Close the case without a separate ORI finding of research misconduct~~ or ~~;

(~~a) Makes~~2) Make findings of research misconduct and ~~proposes~~propose 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~~ take administrative actions

~~(b) Recommends that HHS seek~~based on the administrative record; or

(3) Seek to settle the case.

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

§ 93.405 Notifying the respondent of findings of research misconduct and 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 or debarment, it notifies the respondent in a charge letter. ~~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~~, including the basis for ~~them~~such findings in the administrative record, and any ~~HHS~~proposed administrative actions. The charge letter also advises the respondent ~~of~~ how they can access the administrative record and of the opportunity to contest the findings and administrative actions under ~~Subpart~~subpart E of this part. In ~~(b) The~~cases involving a suspension or debarment action, the HHS SDO issues a notice of suspension or proposed debarment to the respondent as part of the charge letter. The notice of suspension or proposed debarment issued by the HHS SDO will include instructions on how the respondent can contest the suspension and/or proposed debarment.

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

§ 93.406 Final HHS actions.

(a) Unless the respondent contests the findings and/or the administrative actions, other than suspension and/or proposed debarment, contained in the charge letter within the 30-day period prescribed in § 93.501, the ORI finding of ~~research misconduct is the final HHS action on the~~ and HHS administrative actions, other than suspension and/or proposed debarment, proposed for research misconduct issues ~~and the HHS administrative actions become~~ are final.

(b) Unless the respondent contests a suspension and/or proposed debarment within the 30-day period prescribed in the NCR or FAR, respectively, the SDO may close the record and issue a final ~~and will be implemented, except that the debarring official's~~debarment decision ~~is the~~ in the matter. Respondents may request reconsideration of a final ~~HHS action on any~~ debarment ~~or suspension actions.~~ decision with the SDO.

§ 93.407 HHS administrative actions.

~~(a) In response to a research misconduct proceeding~~(a) Based on the administrative record, 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 research integrity 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~~Prohibition on participating 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.~~ administrative actions under the Nonprocurement Common Rule (NCR) at 2 CFR part 180 for nonprocurement transactions (as further implemented by HHS at 2 CFR part 376) or under the Federal Acquisition Regulation (FAR) at 48 CFR 9.406 and 9.407 for procurement transactions (as further supplemented by HHS at 48 CFR 309.4). Such administrative actions have reciprocal effect; exclusions issued under one system will result in ineligibility for all government procurement and nonprocurement programs.

(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~~OIG, the PHS funding component, and the ~~debarring official.~~ SDO.

§ 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:~~ The appropriate administrative

action is commensurate with the seriousness of the misconduct and the need to protect the health and safety of the public, promote the integrity of the PHS supported research and research

process, and conserve public funds. ORI considers the following aggravating and mitigating factors in determining appropriate HHS administrative actions and their terms. Distinct from ORI's process, the SDO considers the aggravating and mitigating factors listed in the NCR or FAR, whichever is appropriate to the funding mechanism, when considering suspension and debarment actions. The existence or nonexistence of any factor is not determinative.
(a) Knowing, intentional, or reckless. -Were the ~~respondent's~~respondent's actions knowing or intentional or ~~was~~were the ~~conduct~~actions reckless?
(b) Pattern. -Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?
(c) Impact. -Did the misconduct have significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare?
(d) Acceptance of responsibility. -Has the respondent accepted responsibility for the misconduct by~~—~~:
(1) Admitting the conduct;
(2) Cooperating with the research misconduct proceedings;
(3) Demonstrating remorse and awareness of the significance and seriousness of the research misconduct; and
(4) Taking steps to correct or prevent the recurrence of the research misconduct~~.~~?
(e) Failure to accept responsibility. -Does the respondent blame others rather than accepting responsibility for the actions?
(f) Retaliation. -Did the respondent retaliate against complainants, witnesses, committee members, or other ~~persons?~~ individuals?
(g) ~~Present responsibility. Is~~Continued risk to PHS funding. Does the respondent ~~presently~~demonstrate responsible ~~to conduct PHS supported~~ stewardship of research~~?~~ resources?
(h) Other factors. ~~Other~~Are other factors ~~appropriate~~relevant to the circumstances of a particular case~~.~~?

§ 93.409 Settlement of research misconduct proceedings.
(a) HHS may settle a research misconduct proceeding at any time it concludes that ~~settlement is in the best interests of the Federal government and the public health or welfare.~~
~~(b~~settlement is in the best interests of the Federal Government and the public health or welfare.
(b) A settlement agreement precludes the respondent from contesting any ORI findings of research misconduct, HHS administrative actions (other than a suspension or debarment decision), or ORI's jurisdiction in handling the research misconduct proceeding.
(c) Settlement agreements are publicly available, regardless of whether ~~the~~ ORI made a finding of research misconduct.

§ 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:~~
ORI may:
(a) Provide written notice to the respondent, the relevant institution, the complainant, and HHS officials~~.~~, as it deems necessary.
(b) ~~Take any other~~ To the extent permitted by the Privacy Act, 5 U.S.C. 552a, and ORI's system of

records notice for research misconduct proceedings, publish notice of institutional research misconduct findings and implemented institutional actions ~~authorized by law.~~ related to the falsified, fabricated, or
plagiarized material in the research record, but not the names or other identifying information of the respondent(s), if doing so is within the best interests of HHS to protect the health and safety of the public, to promote the integrity of the PHS supported research and research process, or to conserve public funds.

§ 93.411 Final HHS action with a settlement or finding of ~~research~~ misconduct.
When a final HHS action results in a settlement or research misconduct finding, ORI ~~may: :~~
(a) ~~Provide~~Shall provide final notification of any research misconduct findings and HHS administrative actions to the respondent, the relevant institution, ~~the complainant,~~ and HHS officials, including the
SDO. The ~~debarring official may~~SDO shall provide a separate notice of final HHS action on any ~~debarment or~~ suspension ~~actions.~~ or
~~(b) Identify~~debarment actions.
(b) May provide final notification of any research misconduct findings and HHS administrative actions to the complainant(s).
(c) Shall send a notice to the relevant journal, publisher, data repository, or other similar entity identifying publications or research records 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~~Shall publish notice of the research misconduct findings.
(e) Shall notify the respondent's current employer~~.~~, if the employer is an institution
~~(e) Take any other actions authorized by law.~~

subject to this part.
Institutional Compliance Issues

§ 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~~does
not implement and follow the requirements of this part and its own research integrity assurance. In making this decision, ORI may consider, but is not limited to the following factors~~—~~:
(~~1~~a) Failure to establish and comply with policies and procedures under this part;
(~~2~~b) Failure to respond appropriately when allegations of research misconduct arise;
(~~3~~c) Failure to report to ORI all investigations and findings of research misconduct under this part;
(~~4~~d) Failure to cooperate with ~~ORI's~~ORI's review of research misconduct proceedings; or
(~~5~~e) Other actions or omissions that have a material, adverse effect on reporting and responding to allegations of research misconduct.

§ 93.413 HHS compliance actions.

(a) An ~~institution's~~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~~ (b) 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) Require the institution to accept and/or implement technical assistance provided by HHS.
(2) Issue a letter of reprimand.
~~(2~~(3) Require the institution to take corrective actions.
(4) Place the institution on special review status. For a designated period, ORI will closely monitor the institution's activities for compliance with this part. Monitoring may consist of, but is not limited to, compliance reviews and/or audits.
(5) Direct that research misconduct proceedings be handled by HHS.
~~(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~~(6) Recommend that HHS debar or suspend the ~~entity.~~ institution.
(~~8~~7) Any other action appropriate to the circumstances.
(~~d~~c) If the ~~institution's~~institution's actions constitute a substantial or recurrent failure to comply with
this part, ORI may ~~also~~ revoke the ~~institution's~~ institution's research integrity assurance under ~~§§§~~ 93.301 or §
93.303.
(~~e~~d) ORI may make public any findings of institutional noncompliance and HHS compliance actions.

Disclosure of Information

§ 93.414 Notice.
(a) ORI may disclose information to other persons for the purpose of providing or obtaining information about research misconduct as permitted under the Privacy Act, 5 U.S.C. 552a~~.~~ and ORI's system of records notice for research misconduct proceedings.
(b) ORI ~~may~~shall disclose or publish a notice ~~of final agency findings of research misconduct,~~regarding settlements~~,~~ and HHS administrative
actions, and release ~~and~~or withhold information as permitted by the Privacy Act and the Freedom of
Information Act, 5 U.S.C. 552.
(c) ORI shall disclose or publish final findings of research misconduct when they become final.
(1) HHS may publish the respondent's name, professional alias, respondent's current and/or former position, a detailed summary of the findings, and corrective actions imposed, in any venue it deems appropriate.

(2) Such venues include, but are not limited to, Federal Government exclusionary lists (if relevant), the Federal Register, ORI's website, other HHS publications, professional journals and other publications, and media outlets.
(d) To the extent allowed by law, ORI will not release information that would reveal a confidential source.
(e) When ORI closes a case without a settlement or a finding of research misconduct, disclosure may be made to the respondent, relevant institution, and complainant(s). Prior to making any disclosure, ORI will first consider the privacy interests of respondent(s), complainant(s), witnesses, research subjects or others who may be identified in the disclosure and determine whether limited disclosures or confidentiality agreements are needed to protect those interests.
(f) Any publications or disclosures pursuant to this section are not considered appealable "administrative actions" under this part.

Subpart E— - Opportunity ~~To~~to Contest ORI Findings of Research Misconduct and HHS Administrative Actions

General Information

§ 93.500 General policy.
(a) This subpart provides a respondent an opportunity to contest ORI findings of research misconduct and/or HHS administrative actions, ~~including debarment or~~ other than 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.~~ proposed debarment,
included in a charge letter. To contest a suspension or proposed debarment included in a charge letter, the respondent must provide the SDO directly with information and argument in opposition to the suspension or proposed debarment in accordance with 2 CFR part 180 (or successor regulation) or with 48 CFR 9.406 and 9.407, as governed by the mechanism of PHS funding involved. A respondent may contest ORI findings and/or HHS administrative actions other than suspension and proposed debarment under this subpart; contest only the suspension or proposed debarment action under 2 CFR part 180 or 48 CFR 9.406 and 9.407; or both.
(b) A respondent ~~has an opportunity to~~may contest ORI research misconduct findings and HHS administrative
actions ~~under this part, including debarment or~~, other than suspension and proposed debarment, by ~~requesting~~filing a notice of appeal with an ~~administrative hearing before an~~ Administrative Law Judge (ALJ) ~~affiliated with~~at the ~~HHS~~ DAB~~, when~~ .
~~(1) ORI has made a finding of research misconduct against a respondent; and~~
~~(2) 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~~ Based on the ~~merits of the~~ administrative record, the ALJ shall rule on the reasonableness of the
ORI research misconduct findings and the HHS administrative actions ~~is subject to review by the Assistant Secretary for Health in accordance with § 93.523. The decision made under that section~~other than suspension or
debarment.

(d) The ALJ's ruling made under § 93.512 is the final HHS action~~, unless that decision results in a recommendation for debarment or suspension. In that case, the decision under § 93.523 shall constitute findings of fact to the debarring official in accordance~~ with ~~45 CFR 76.845(c).~~ respect to the
~~(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.~~
research misconduct findings and
~~§ 93.501 Opportunity to contest findings of research misconduct and~~ administrative actions~~.~~, other than suspension or proposed
debarment. Where a respondent contests a suspension or proposed debarment, the ALJ shall provide a copy of the ruling to the SDO to be included in the official record under 2 CFR part 180 or 48 CFR 9.406 and 9.407; the SDO decides the debarment action under the appropriate regulation.

Process for Contesting Research Misconduct Findings and/or Administrative Actions

§ 93.501 ~~(a) Opportunity to contest.~~ Notice of appeal.

(a) Time to file. A respondent may contest ORI findings of research misconduct and~~-~~/or HHS administrative actions~~, including any debarment or~~ other than suspension ~~action,~~ and proposed debarment by ~~requesting~~filing a ~~hearing~~notice of
appeal within 30 days of receipt of the charge letter ~~or other written notice~~ provided under § 93.405.
(b) Form of a ~~request for hearing.~~ notice of appeal. The respondent's ~~request for a hearing~~notice of appeal must be~~—~~:
(1) In writing;
(2) Signed by the respondent or by the respondent's attorney; and
(3) ~~Sent~~Submitted to the DAB Chair through the DAB electronic filing system with a copy sent by certified mail, electronic mail, or other equivalent (i.e., with a verified method of delivery), to ~~the DAB Chair and ORI.~~ ORI. If the respondent is also contesting suspension or proposed debarment under 2
CFR part 180, the respondent must send a courtesy copy of the notice of appeal to the SDO.
(c) Contents of a ~~request for hearing.~~ notice of appeal. The ~~request for a hearing~~notice of appeal must~~—~~:
(1) Admit or deny each finding of research misconduct and each factual assertion made in support of ~~the~~each finding;
(2) Accept or challenge each proposed ~~HHS~~ administrative action;
(3) Provide detailed, substantive reasons for each denial or challenge~~;~~ with references to the administrative record;
(4) Identify any legal issues or defenses that the respondent intends to raise during the proceeding~~; and~~ with references to the administrative record;
(5) Identify any mitigating factors ~~that~~in the ~~respondent intends to prove.~~ administrative record; and
(~~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~~6) State whether 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~~ suspension or 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.~~ debarment is also being contested under 2
~~(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~~

CFR part 180 or 48 CFR 9.406 and 9.407.

§ 93.502 Appointment of the Administrative Law Judge ~~and scientific expert~~**.**
(a) Within 30 days of receiving a ~~request for a hearing~~notice of appeal, the DAB Chair, in consultation with
the Chief ~~Administrative Law Judge~~ALJ, must designate an ~~Administrative Law Judge (~~ALJ~~)~~ to determine whether the ~~hearing request should be granted and, if the hearing request~~notice of appeal is ~~granted, to make recommended findings in the case after a hearing or review of the administrative record in accordance with this part.~~ timely filed
~~(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)~~ and within the ALJ's jurisdiction under this subpart. If the appeal is determined to be timely and
within the ALJ's jurisdiction, the ALJ shall decide the reasonableness of the ORI research misconduct findings and administrative actions in accordance with this subpart. The ALJ shall dismiss an appeal if it is untimely or not within the ALJ's jurisdiction under this subpart.
(b) No ALJ~~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 § 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 § 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~~they have any ~~real~~actual or apparent conflict of interest, bias, or prejudice that might reasonably impair ~~his or her~~their objectivity in ~~the proceeding.~~
~~(d~~the proceeding.
(c) Any party to the proceeding may request the ALJ ~~or scientific expert~~ to withdraw from the proceeding because of ~~a real~~an actual or apparent conflict of interest, bias, or prejudice under paragraph (~~c~~b) of this section. The motion to disqualify must be timely and state with particularity the grounds for disqualification. The ALJ may rule upon the motion or certify it to the Chief ALJ for decision. If the ALJ rules upon the motion, either party may appeal the decision to the Chief ALJ.

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

§ 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~~**Filing of the 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.~~ **record.**
~~(c) If the respondent does not request a hearing within the 30-day time period prescribed in § 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.~~

(a) For appeals that are not dismissed under § 93.502(a), ORI will file the administrative record for this appeal.
(b) The ALJ's review will be based on the administrative record.
(c) The parties have no right to supplement the administrative record.

§ 93.504 ~~Grounds for dismissal of a hearing request~~Standard of review.

(a) The ALJ ~~must dismiss a hearing request if~~shall review the ~~respondent —~~administrative record to determine whether ORI's findings

~~(1) Does not file the request within 30 days after receiving~~ and HHS's proposed administrative actions, other than suspension and debarment, reflected in the charge letter~~;~~ are reasonable and not based on a material error of law or fact.

~~(2) Does not raise a~~ (b) The ALJ may permit the parties to file briefs making legal and factual arguments based on the administrative record.

(c) If the ALJ determines that there is a genuine dispute over facts ~~or law~~ material to the ORI findings of research misconduct ~~and any~~or HHS administrative actions~~, including debarment and~~ other than suspension ~~actions, in the hearing request or in any extension to supplement granted by the ALJ under § 93.501(d);~~ and

~~(3) Does not raise any issue which may properly be addressed in a hearing;~~

~~(4) Withdraws or abandons~~debarment, the ~~hearing request; or~~

~~(b) The~~ ALJ may ~~dismiss~~hold a limited hearing ~~request if the respondent fails~~ to ~~provide ORI with notice in the form and manner required by § 93.501.~~ resolve that genuine factual dispute.

§ 93.505 Rights of the parties.

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

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

(1) Be accompanied, represented, and advised by an attorney;

(2) Participate in any case-related conference held by the ALJ;

(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 or briefs in writing before the ALJ;

(~~6~~4) Present evidence relevant to the factual issues at ~~the~~a hearing~~;~~, if applicable; and

(~~7~~5) Present and cross-examine witnesses~~;~~ at a hearing, if applicable.

~~(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~~c) The parties ~~or established by~~have no right to discovery before the ALJ ~~as provided in § 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.~~

§ 93.506 Authority of the Administrative Law Judge.

(a) The ALJ assigned to the case must conduct a fair and impartial ~~hearing~~proceeding, avoid unnecessary delay, maintain order, and assure that a complete and accurate record of the proceeding is properly made. The ALJ is bound by~~.~~, and may not refuse to follow or find invalid, all Federal statutes and regulations, Secretarial delegations of authority, and applicable HHS policies ~~and may not refuse to follow them or find them invalid,~~, as provided in paragraph (c)(~~4~~5) 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~~Review the administrative record and ~~change the date, time, schedule, and place of the~~issue a ruling without convening a 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~~(2) 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~~(3) Rule on motions and other procedural matters;
(~~7) Require~~ 4) Except for the ~~production of documents and regulate~~respondent's notice of appeal, modify the ~~scope and timing of documentary discovery as permitted by this part;~~
~~(8) Require each party before~~time for the ~~hearing to provide the other party and the ALJ with copies~~filing 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~~document required or authorized under the rules in this subpart.
(5) 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~~(6) Regulate the course of the appeal and the conduct of representatives, parties, and witnesses;
(7) Take action against any party for failing to follow an order or procedure or for disruptive conduct~~.~~ ;
(8) Set and change the date, time, schedule, and place of the hearing, if applicable, upon reasonable notice to the parties;
(9) Continue or recess the hearing, if applicable, in whole or in part for a reasonable period of time;
(10) Administer oaths and affirmations at the hearing, if applicable;
(11) Require each party before the hearing, if applicable, to provide the other party and the ALJ with copies of any exhibits that the party intends to introduce into evidence; and
(12) Examine witnesses and receive evidence presented at the hearing, if applicable.
(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~~(4) Review suspension or proposed debarment;
(5) Find invalid or refuse to follow Federal statutes or regulations, Secretarial delegations of authority, or HHS policies~~.~~ ;
(6) Authorize the parties to engage in discovery; and

(7) Modify the time for filing the respondent's notice of appeal.
(d) The Federal Rules of Evidence and the Federal Rules of Civil Procedure do not govern the proceedings under this subpart.

§ 93.507 Ex parte communications.

(a) No party, attorney, or other party representative may communicate ex parte with the ~~ALJ on any matter at issue in a case, unless both parties have notice and an opportunity to participate in the communication. However, a party, attorney, or other party representative may communicate with DAB staff about administrative or procedural matters.~~
ALJ on any matter at issue in a case, unless both parties have notice and an opportunity to participate in the communication.
(b) If an ex parte communication occurs, the ALJ will disclose it to the other party and ~~make it part of the record after~~
offer 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.

§ 93.508 Filing, ~~forms~~format, and service.

(a) Filing.
(1) Unless the ALJ provides otherwise, all submissions required or authorized to be filed in the proceeding must be filed with the ALJ.
(2) Submissions are considered filed when they are ~~placed in the mail, transmitted to a private delivery service for the purpose of delivering the item~~filed with the DAB according to the ~~ALJ, or submitted in another manner authorized by the ALJ.~~
DAB's filing guidance.
(b) ~~Forms.~~
~~(1) Unless the ALJ provides otherwise, all submissions filed in the proceeding must include an original and two copies.~~Format. (1) The ALJ may designate the format for copies of nondocumentary
materials such as videotapes, computer disks, or physical evidence. This provision does not apply to the charge letter or other written notice provided under § 93.405.
(2) Every submission filed in the proceeding must include the title of the case, the docket number, and a designation of the nature of the submission~~, 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~~(c) Service. Service of a submission on other parties is accomplished by filing the submission with the ALJ through the DAB 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:~~ system.
~~(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.~~

§ 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 § 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.~~

~~§ 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.~~ upon, and state the facts alleged in support of the motion or request.
(b) All motions must be in writing except for those made during a prehearing conference or at ~~the~~a 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~~ response unless allowed by the ALJ.
(d) The ALJ may not grant a motion before the time for filing a response has expired, except with the ~~parties'~~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.

§ 93.~~511 Prehearing conferences~~510 Conferences.
(a) The ALJ must schedule an initial ~~prehearing~~ conference with the parties within 30 days of the

DAB ~~Chair's~~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 genuine 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 § 93.503(d);~~
~~(4)~~ Identification of material 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~~3) Scheduling dates ~~such as~~for the filing of briefs based on ~~legal issues identified in~~ the ~~charge letter~~administrative record 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~~hearing, if applicable; and
(4) 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~~recorded with copies provided to the parties upon request.
(e) ~~Whenever possible, the~~The ALJ ~~must~~shall memorialize in writing any oral rulings within 10 days after ~~the prehearing~~ a
conference~~.~~ is held.
(f) By 15 days before the scheduled hearing date, if applicable, 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.~~
resolution of genuine factual disputes.

§ 93.~~512 Discovery.~~
~~(a) Request~~**511 Hearing 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.~~ **resolve genuine factual dispute.**
~~(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~~(a) 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 § 93.515.~~

~~§ 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.~~

~~§ 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.~~

~~§ 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.~~

~~§ 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.~~

~~§ 93.517 The hearing.~~
~~(a) The ALJ will conduct an~~ may hold a virtual or 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.~~ that is limited to resolving a genuine
~~(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 §§ 93.515 or 93.519.~~
~~(3) Not offered within the times or terms of §§ 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 §§ 93.512 and 93.513.~~
~~(f) Except as provided in § 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.~~

~~§ 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 § 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~~ factual dispute.
(b) The ALJ shall permit the parties to ~~conduct cross-examination of~~call witnesses and to question witnesses. The ALJ~~.~~

~~(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.~~

~~§ 93.519 Admissibility of evidence.~~
~~(a) The ALJ decides the admissibility of evidence offered~~may also question witnesses.
(c) The parties are not required to submit prehearing briefs.
(d) The parties are not required to give opening or closing statements 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~~hearing will be transcribed, 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~~ will have an opportunity to ~~show that the ALJ erroneously noticed the matters.~~ review the
~~(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.~~

~~§ 93.520 The record.~~
~~(a) HHS will record and transcribe the hearing, and if requested, provide a~~ transcript and submit proposed corrections to the ALJ.
(f) Following receipt of the 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.~~

~~§ 93.521 Correction of~~ and proposed corrections to the transcript~~.~~, the ALJ
~~(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.~~

~~§ 93.522 Filing post-hearing~~ may permit the parties to file 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~~ with suggested factual findings ~~of fact and conclusions of law in their post-hearing briefs.~~ based on the transcript.
(g) The ALJ will issue findings of fact to the parties that resolves the genuine factual dispute.

§ 93.~~523~~512 The Administrative Law ~~Judge's~~Judge's ruling.
(a) ~~The~~Based on the administrative record and any findings of fact as a result of a hearing, if applicable, the ALJ shall issue a ruling in writing setting forth ~~proposed~~ whether ORI's findings ~~of fact~~ and ~~any conclusions~~

HHS's proposed administrative actions, other than suspension and debarment, reflected in the charge letter are reasonable and not based on a material error of law or fact 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,~~SDO if ~~debarment or~~a suspension or proposed debarment is ~~under review~~contested. The ALJ shall serve a copy of the ruling upon the parties ~~and the Assistant Secretary for Health.~~ . If a

~~(b) 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.~~

~~(c) If a decision under § 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.~~suspension or proposed debarment is contested, the ALJ shall provide a copy of the ruling to the SDO to be included in the official record under 2 CFR part 180.

(b) The ruling of the ALJ constitutes the final HHS action on the findings of research misconduct and administrative actions other than suspension or debarment. The decision of the SDO constitutes the final HHS action regarding suspension or debarment under 2 CFR part 180.