EPSTEIN BECKER GREEN

Redline of

Final Revisions to the Public Health Service (PHS)

Policies on Research Misconduct (September 12, 2024)

Against

Proposed Revisions to the PHS Policies on Research Misconduct (October 5, 2023)

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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 final revisions to the PHS Policies on Research Misconduct. For more information on the final revisions to the PHS Policies on Research Misconduct, including the relevant regulatory preamble, consult the official version of the final revisions to the PHS Policies on Research Misconduct, which is scheduled to be published in the Federal Register on September 17, 2024.

PART 93—PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

Sec.

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Subpart C—Responsibilities of Institutions

Compliance and Assurances

The Institutional Assessment

The Institutional Inquiry

The Institutional Investigation

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

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

Table 1 to § 93.25

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

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

§ 93.75 Application of effective date to research misconduct proceedings.
(a) An institution must follow this part for allegations received by the institution on or after January 1, 2026, except for the policies and procedures required under §§ 93.300(a) and 93.302(b), which must be implemented and submitted by due date of the annual report covering the 2025 reporting year, as specified by ORI.
(b) For allegations received by an institution before January 1, 2026, unless the institution and the respondent both elect in writing to follow this part, an institution must follow this part as published in the 2005 edition of the Code of Federal Regulations.

Subpart A—General

§ 93.100 General policy.
(a) Research misconduct involving Public Health Service (PHS) support is contrary to the

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

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

§ 93.102 Applicability.
(a) Every extramural or intramural institution ~~(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) This part applies to allegations of research misconduct involving:
(1) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, biomedical or behavioral research training, or activities related to that research or research training;
(2) PHS-supported biomedical or behavioral extramural or intramural research;
(3) PHS-supported biomedical or behavioral extramural or intramural research training programs;
(4) PHS-supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as, but not limited to, the operation of tissue and data banks or the dissemination of research information;
(5) Research records produced during PHS-supported research, research training, or activities related to that research or research training; and
(6) Research proposed, performed, reviewed, or reported, as well as any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in an awarded grant, contract, cooperative agreement, ~~sub-award~~subaward, or other form of PHS support.
(c) This part does not supersede or establish an alternative to any applicable statutes,

regulations, policies, or procedures for handling fiscal improprieties, the ethical treatment of human or animal subjects, criminal matters, personnel actions against Federal employees, or addressing whistleblowers and/or retaliation.

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

~~debarment regulations as set forth 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 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).~~

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

§ 93.103 ~~Research misconduct.~~

~~(a) As defined below, research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results (see § 93.238).~~

~~(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~~104 Time limitations.

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

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

(1) Subsequent use exception. The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the use of, republication of, or citation to the portion(s) of the research record (e.g., processed data, journal articles, funding proposals, data repositories) ~~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~~research misconduct that appears subject to the subsequent use exception, ~~an institution~~institutions must ~~inform ORI of the relevant facts before concluding~~document their determination that the subsequent use exception does not apply. ~~ORI will make the final decision about the subsequent use exception for each allegation~~Such documentation must be retained in accordance with § 93.318.

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

§ 93.105 Evidentiary standards.

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

(b) Burden of proof. (1) The institution or HHS has the burden of proof for making a finding of research misconduct. A respondent's destruction of research records documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. A respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request.

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

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

§ 93.106 Confidentiality.

(a) Disclosure of the identity of respondents, complainants, and witnesses ~~in~~ while conducting the research misconduct proceedings is limited, to the extent possible, to those who need to know, as determined by the institution, consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. ~~Institutions must inform respondents, complainants, and witnesses, before they are interviewed, if and how their identity may be disclosed. Provided, however, that the institution~~Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. This limitation on disclosure of the identity of respondents, complainants, and witnesses no longer applies once an institution has made a final determination of research misconduct findings. The institution, however, must disclose the identity of respondents, complainants, or other relevant persons to ORI pursuant to an ORI review of research misconduct proceedings under this part.

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

~~maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who need to know to carry out a research misconduct proceeding.~~

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

§ 93.107 Coordination with other agencies.
(a) When more than one agency of the Federal Government has jurisdiction over ~~the subject~~a research misconduct allegation, HHS will cooperate with the other agencies in designating a lead agency to coordinate the response of the agencies to the allegation. Where HHS is not the lead agency, it may, in consultation with the lead agency, take appropriate action.
(b) In research misconduct proceedings involving more than one agency, HHS may refer to the other agency's (or agencies') evidence or reports if HHS determines that the evidence or reports will assist in resolving HHS issues. In appropriate cases, HHS ~~will~~may seek to resolve allegations jointly with the other agency or agencies.

Subpart B—Definitions

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

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

§ 93.202 Administrative record.
Administrative record comprises: the institutional record; any information provided by the respondent to ORI, including but not limited to the ~~verbatim~~ transcript of any virtual or in-person meetings under § 93.403(b) 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 Allegation.
Allegation means a disclosure of possible research misconduct through any means of communication and brought directly to the attention of an institutional or HHS official.

§ 93.204 ~~Appeal~~Assessment.

~~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~~205 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 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.~~207~~206 Complainant.
Complainant means an individual who in good faith makes an allegation of research misconduct.

§ 93.~~208~~207 Contract.
Contract means an acquisition instrument awarded under the Federal Acquisition Regulation (FAR), 48 CFR chapter 1.

§ 93.~~209~~208 Day.
Day means calendar day unless otherwise specified. If a deadline falls on a Saturday, Sunday, or Federal holiday, the deadline will be extended to the next day that is not a Saturday, Sunday, or Federal holiday. ~~Sunday, or Federal holiday.~~

§ 93.~~210~~209 Departmental Appeals Board or DAB.
Departmental Appeals Board or DAB means the organization, within the HHS Office of the Secretary, established to conduct hearings and provide impartial review of disputed decisions made by HHS operating components.

~~**§ 93.211 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~~210 Evidence.**
Evidence means anything offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony.

§ 93.~~213~~211 Fabrication.
Fabrication means making up data or results and recording or reporting them.

§ 93.~~214~~212 Falsification.
Falsification means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

§ 93.~~215~~213 Funding component.
Funding component means any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity covered by this part involving research or research training; funding components may be agencies, bureaus, centers, institutes, divisions, offices, or other awarding units within the PHS.

§ 93.~~216~~214 Good faith.
(a) Good faith as applied to a complainant or witness means having a reasonable belief in the truth of one's allegation or testimony, based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with ~~knowing~~knowledge of or reckless disregard for information that would negate the allegation or testimony.
(b) Good faith as applied to an institutional or committee member means cooperating with the research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities under this part. An institutional or committee member does not act in good faith if their acts or omissions during the research misconduct proceedings are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.
~~(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.~~

~~§ 93.218~~215 Inquiry.
Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of ~~§§~~§ 93.307 through § 93.309.

§ 93.~~219~~216 Institution.
Institution means any person that applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to, colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, ~~small~~ research institutions, and independent researchers.

§ 93.~~220~~217 Institutional ~~certifying official~~Certifying Official.
Institutional ~~certifying official~~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~~The Institutional

Certifying Official is responsible for certifying the content of the institution's annual report, which contains information specified by ORI on the institution's compliance with this part, and ensuring the report is submitted to ORI, as required.

§ 93.~~221~~218 Institutional ~~deciding official~~Deciding Official.
Institutional ~~deciding official~~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~~Institutional Deciding Official and the ~~research integrity officer~~Research Integrity Officer.

§ 93.~~222~~219 Institutional member.
Institutional member or members means an individual (or individuals) who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, technicians, postdoctoral and other fellows, students, volunteers, subject matter experts, consultants, or attorneys, or employees or agents of contractors, subcontractors, or sub-awardees.

§ 93.~~223~~220 Institutional record.
The institutional record comprises:
(a) The records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. These records include, but are not limited to: ~~pursuant to §§ 93.305 through 93.316, except to~~(1) Documentation of 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. These records include, but are not limited to:~~
~~(1) The~~ assessment ~~report~~ as required by § 93.306(~~d);~~c).
(2) If an inquiry is conducted, the inquiry report and all records (other than drafts of the report) ~~in support of that report~~considered or relied on during the inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate as required by § 93.309(c~~);~~).
(3) If an investigation is conducted, the investigation report and all records (other than drafts of the report) ~~in support of that report~~considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to § 93.310(g), and information the respondent provided to the institution~~;~~.
(4) Decision(s) by the ~~institutional deciding official~~Institutional Deciding Official, such as the written decision from the ~~institutional deciding official with the final determination of research misconduct findings~~Institutional Deciding Official under § 93.314.
~~(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~~consistent with § 93.~~314;~~315.
~~(b) The documentation of the determination of irrelevant or duplicate records; and~~
~~(c) A~~ (b) A single index listing all ~~documents in~~ the research records and evidence that the institution compiled during the research misconduct proceeding, except records the institution did not consider or rely on.
(c) A general description of the ~~institutional record~~records that were sequestered but not considered or relied on.

§ 93.~~224~~221 Intentionally.
To act intentionally means to act with the aim of carrying out the act.

§ 93.~~225~~222 Investigation.
Investigation means the formal development of a factual record and the examination of that record that meets the criteria and follows the procedures of §§ 93.310 through 93.~~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~~317.

§ 93.~~226~~223 Knowingly.
To act knowingly means to act with ~~the~~ awareness of the act.

§ 93.~~227~~224 Notice.
Notice means a written or electronic communication served in person or sent by mail or its equivalent to the last known street address, facsimile number, or ~~e-mail~~email address of the addressee.

§ 93.~~228~~225 Office of Research Integrity or ORI.
Office of Research Integrity or ORI means the office established by Public Health Service Act section 493 (42 U.S.C. 289b) and to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS-supported activities.

§ 93.~~229~~226 Person.
Person means any individual, corporation, partnership, institution, association, unit of government, or other legal entity, however organized.

§ 93.~~230~~227 Plagiarism.
Plagiarism means the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit.
(a) Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work~~, which~~ that materially ~~mislead~~misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly- identical phrases ~~which~~that describe a commonly- used methodology.
(b) Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

§ 93.~~231~~228 Preponderance of the evidence.
Preponderance of the evidence means proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.

§ 93.~~232~~229 Public Health Service or PHS.
Public Health Service or PHS consists of the following components within ~~the~~ HHS: the Office of the Assistant Secretary for Health, the Office of Global Affairs, the Administration for Strategic Preparedness and Response, the Advanced Research Projects Agency for Health, the Agency for Healthcare Research and Quality, the Agency for Toxic Substances and Disease Registry, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the

Indian Health Service, the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, and any other components of HHS designated or established as components of the Public Health Service.

§ 93.~~233~~230 PHS support.
PHS support means PHS funding, or applications or proposals ~~therefor~~for PHS funding, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: funding for PHS intramural research; PHS grants, cooperative agreements, or contracts; ~~or~~ subawards, contracts, or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements, or contracts.

§ 93.~~234~~231 Recklessly.
To act recklessly means to ~~act without proper caution despite~~propose, perform, or review research, or report research results, with indifference to a known risk ~~for harm~~of fabrication, falsification, or plagiarism.

§ 93.~~235~~232 Research.
Research means a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating, or confirming information or underlying mechanisms related to biological causes, functions, or effects; diseases; treatments; or related matters to be studied.

~~**§ 93.236 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**~~**233 Research Integrity Officer or RIO.**
Research Integrity Officer or RIO refers to the institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with this part.

§ 93.~~238~~234 Research misconduct.
Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

§ 93.~~239~~235 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, and appeals under subpart E of this part.

§ 93.~~240~~236 Research record.
Research record means the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items,

materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, ~~internet and~~ online content, ~~internal~~lab meeting reports, and journal articles.

§ 93.~~241~~237 Respondent.
Respondent means the individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

§ 93.~~242~~238 Retaliation.
Retaliation means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to: (a) A good faith allegation of research misconduct; or (b) Good faith cooperation with a research misconduct proceeding.

§ 93.~~243~~239 Secretary or HHS.
Secretary or HHS means the Secretary of HHS or any other official or employee of ~~the~~ HHS to whom the Secretary delegates authority.

§ 93.~~244~~240 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~~241 Suspension and ~~debarment~~Debarment Official or SDO.
Suspension and Debarment Official (SDO) means the HHS official authorized to impose suspension and debarment ~~mean~~, which are the actions that Federal agencies take to disqualify persons deemed not presently responsible from doing business with the ~~government~~Federal 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 must:
(a) Have written policies and procedures for addressing allegations of research misconduct that meet the requirements of this part;
(b) Respond to each allegation of research misconduct for which the institution is responsible under this part in a thorough, competent, objective, and fair manner, including taking precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses;
(c) Foster a research environment that promotes research integrity and the responsible conduct of research, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct;
(d) Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses, and committee members and to protect these individuals from retaliation by respondents and/or other institutional members;
(e) Provide confidentiality ~~to the extent required by~~consistent with § 93.106 to all respondents, complainants, and witnesses in a research misconduct proceeding, and to research subjects identifiable from research records or other evidence;
(f) Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and other evidence;
(g) Cooperate with HHS during any research misconduct proceeding or compliance review, including addressing deficiencies or additional allegations in the institutional record if directed by ORI;
(h) Assist in administering and enforcing any HHS administrative actions imposed on its institutional members; and
(i) Have an active research integrity assurance.

§ 93.301 Research integrity assurances.
(a) General policy. (1) An institution that applies for or receives PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, must provide HHS with an assurance of compliance with this part by establishing and then maintaining an active research integrity assurance.
(2) PHS funding components may only authorize release of funds for extramural biomedical and behavioral research, biomedical and behavioral research training, or activities related to that research or research training, to institutions ~~that have~~with an active research integrity assurance on file with ORI.
(b) Research integrity assurance. The Institutional Certifying Official must assure on behalf of the institution, initially and then annually thereafter, that the institution:

(1) Has written policies and procedures for addressing allegations of research misconduct, in compliance with this part~~;~~.
(2) Complies with its policies and procedures for addressing allegations of research misconduct~~; and~~.
(3) Complies with all provisions of this part.

§ 93.302 Maintaining active research integrity assurances.
(a) Compliance with this part. ORI considers an institution in compliance with this part when it:
(1) Has policies and procedures for addressing allegations of research misconduct according to this part, keeps ~~them~~those policies in compliance with this part, and upon request, provides them to ORI and other HHS ~~personnel;~~components.
(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) Informing the institution's members about its policies and procedures for addressing allegations of research misconduct, and the institution's commitment to compliance with the policies and procedures; and
(ii) Making its policies and procedures for addressing allegations of research misconduct publicly available.
(b) Annual report. An institution must file an annual report with ORI, which contains information specified by ORI, on the institution's compliance with this part. The Institutional Certifying Official is responsible for certifying the content of this report and for ensuring the report is submitted as required.
(c) Additional information. Along with its ~~research integrity assurance or~~ annual report, an institution must send ORI such other information as ORI may request on the institution's research misconduct proceedings covered by this part and the institution's compliance with the requirements of this part.

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

§ 93.304 Institutional policies and procedures.
Institutions seeking an approved research integrity assurance must have written policies and procedures for addressing allegations of research misconduct. Such policies and procedures must:
(a) Address and be consistent with all applicable requirements pertaining to institutional responsibilities included in this part;
(b) Include and be consistent with applicable definitions in this part; and
~~(c) Be made available to ORI in English.~~
(c) Provide for all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

§ 93.305 General conduct of research misconduct proceedings.

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

Whenever possible, the institution must obtain the research records or other evidence:

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

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

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

(c) Maintenance of ~~the institutional record. An institution, as the responsible legal entity for the PHS supported research, has a continuing obligation under this part to ensure that it maintains an adequate institutional record for a research misconduct proceeding.~~sequestered research records and other evidence. An institution must maintain the ~~institutional record~~sequestered research records and other evidence as required by § 93.~~317~~318.

(d) Multiple respondents. ~~Institutions must consider whether any~~If an institution identifies 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,~~ an inquiry~~, and/~~ or ~~subsequent~~ investigation~~. If any~~, the institution is not required to conduct a separate inquiry for each new respondent. However, each additional respondent~~(s) are identified throughout the inquiry/investigation, they must be notified~~ must be provided notice of and an opportunity to respond to the allegations, ~~in accordance~~consistent with this subpart. ~~§§ 93.307(c), 93.308(a), and 93.310(c).~~

(e) Multiple institutions. When allegations involve research conducted at 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 and other evidence pertinent to the ~~inquiry/investigation and witness' testimonies~~proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.

(f) ~~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, support, or 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~~(1) An institution must address any potential, perceived, or actual personal, professional, or financial conflicts of interest between members of the committee or consortium, or ~~the qualified~~other person, and the complainant, respondent, or witnesses.

~~(3) A consortium may be a group of institutions, professional organizations, mixed groups, or individuals that will conduct research misconduct proceedings for other institutions.~~

~~(4~~(2) An institution must ensure that a committee, consortium, or person acting on its behalf conducts research misconduct proceedings in compliance with the requirements of this part.

~~(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~~(g) Notifying ORI of special circumstances. At any time during a research misconduct proceeding, as defined in § 93.~~239~~235, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:

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

(2) HHS resources or interests are threatened.

(3) Research activities should be suspended.

(4) There is reasonable indication of possible violations of civil or criminal law.

(5) Federal action is required to protect the interests of those involved in the research misconduct proceeding.

(6) HHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved.

The Institutional Assessment

§ 93.306 Institutional assessment.

(a) Purpose. An assessment's purpose is to ~~decide if~~determine whether 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~~1) Falls within the definition of research misconduct under this part~~,~~;

(~~ii~~2) Is within the ~~jurisdictional~~applicability criteria of ~~42 CFR~~§ 93.102~~,~~; and

(~~iii~~3) 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).~~

(c) Assessment results. (1) An inquiry must be conducted if the allegation meets the three assessment criteria ~~at § 93.306(b)(1).~~in paragraph (b) of this section.

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

(i) Document the assessment~~, in the form of an assessment report (see § 93.306(d));~~; and

(ii) Promptly ~~take all reasonable and practical steps to obtain~~sequester 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~~,~~(a), and promptly initiate the inquiry.

(~~2~~3) If the RIO or another designated institutional official determines that requirements for an inquiry are not met, they must keep sufficiently detailed documentation of the assessment to permit a later review by ORI of the reasons why the institution ~~decided~~did not ~~to~~ conduct an inquiry. Such documentation must be retained in accordance with § 93.318.

~~(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 meets the following three criteria:

~~(1) Was not assessed within the 30-day period for review provided in § 93.306(e); or~~

~~(2) Meets the following three criteria:~~

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

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

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

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

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

~~specific to a particular respondent are to be included in the notification to that respondent.~~

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

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

(2) Person conducting the inquiry. Institutions may~~, 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 the inquiry~~ review~~.

(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.~~

~~(4)~~ Interviews. Institutions may~~, but are not required to, call~~ interview 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 investigation is warranted if:

(i) There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS--supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, as provided in § 93.102; and

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

~~allegation may have substance.~~
~~(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~~(2) Findings of research misconduct. Findings of research misconduct, including the determination of whether the alleged misconduct is intentional, knowing, or reckless, cannot be made at the inquiry stage.
(g) Inquiry report. (1) The institution must prepare a written report that meets the requirements of this section and § 93.309.
(2) If there is potential evidence of honest error or difference of opinion, the institution must note this in the inquiry report.
(3) The institution must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments received to the report.
(h) Time for completion. (1) The institution must complete the inquiry within ~~60~~90 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~~90 days to complete, the inquiry report must document the reasons for exceeding the ~~60~~90-day period.

§ 93.308 Notice of the results of the inquiry.
(a) Notice to respondent. The institution must notify the respondent whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to this part and the institution's policies and procedures adopted under its research integrity assurance.
(b) Notice to ~~complainants~~complainant. The institution is not required to notify ~~the~~a complainant~~(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~~a 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 ~~deciding~~determining that an investigation is warranted, the institution must provide ORI with ~~the written decision by the institutional deciding official and~~ a copy of the inquiry report, which includes the following information:
(1) The names, professional aliases, and positions of the respondent and complainant;
(2) A description of the allegation(s) of research misconduct;
(3) The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;
(4) The composition of the inquiry committee, if used, including name(s), position(s), and subject matter expertise;
(5) Inventory of sequestered research records and other evidence and description of how sequestration was conducted;
(6) Transcripts of any transcribed interviews~~, if conducted~~;
(7) Timeline and procedural history;

(8) Any scientific or forensic analyses conducted;
(9) The basis for recommending that the allegation(s) warrant an investigation;
(10) The basis on which any allegation(s) do not merit ~~further~~an investigation;
(11) Any comments on the inquiry report by the respondent or the complainant; and
(12) Any institutional actions implemented, including communications with journals or funding agencies~~; and~~.
~~(13) Written decision from the institutional deciding official that an investigation is warranted.~~
(b) The institution must provide the following information to ORI whenever requested:
(1) The institutional policies and procedures under which the inquiry was conducted; and
(2) The research records and other evidence reviewed, ~~transcripts of any interviews,~~ and copies of all relevant documents~~; and~~.
~~(3) The charges for the investigation to consider.~~
(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~~investigate. Such documentation must be retained in accordance with § 93.318.
(d) In accordance with § 93.305(~~i~~g), 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 deciding ~~that~~ an investigation is warranted.
(b) Notice to ORI. Notify ORI of the decision to begin an investigation on or before the date the investigation begins and provide an inquiry report that meets the requirements of §§ 93.307 and § 93.309.
(c) Notice to the respondent. Notify the respondent in writing of the allegation(s) within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins.
(1) The institution must give the respondent written notice of any allegation(s) of research misconduct not addressed during the inquiry or in the initial notice of investigation within a reasonable amount of time of deciding to pursue such allegation(s).
(2) If the institution identifies additional respondents during the investigation ~~that were not identified during the inquiry~~, the institution may but is not required to conduct a separate inquiry~~.~~ for each new respondent. If any additional respondent(s) are identified during the investigation, the institution must notify them of the allegation(s~~).~~) and provide them an opportunity to respond consistent with this subpart.
(3) While an investigation into multiple respondents can convene with the same investigation committee members, separate investigation reports and research misconduct determinations are required for each respondent.
(d) Sequestration of ~~the~~ records. ~~An institution must obtain~~Obtain all research records and other evidence needed to conduct the ~~research misconduct proceeding~~investigation, consistent with § 93.305(a).
(e) Documentation. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and other evidence relevant to reaching a decision on the merits of the allegation(s).
(f) Ensuring a fair investigation. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest relevant to the

investigation. An institution may use the same committee members from the inquiry in their subsequent investigation.

(g) Interviews. ~~Conduct interviews, consistent with § 93.305(g).~~During the investigation, an institution must interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent.

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

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

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

(4) The transcript(s) with any corrections and numbered exhibits must be included in the ~~(h) Pursue leads. Pursue diligently all significant issues and leads, consistent with the requirements of § 93.305(f), and continue the investigation to completion. Once a proceeding reaches~~institutional record of the investigation ~~stage, the institution may choose to add to or expand the ongoing investigation by including any allegation(s) pertaining to the same~~.

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

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

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

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

§ 93.311 Investigation time limits.

(a) Time limit for completing an investigation. An institution must complete all aspects of an investigation within 180 days of beginning it, including conducting the investigation, preparing the draft investigation report for each respondent, providing the draft report to each respondent for comment in accordance with § 93.312, and ~~sending~~transmitting the ~~final~~ institutional record including the final investigation report and decision by the Institutional Deciding Official to ORI ~~under~~in accordance with § 93.~~315~~316.

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

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

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

§ 93.312 Opportunity to comment on the draft investigation report.

(a) The institution must give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the ~~records on which the report is based. The~~research records and other evidence that the investigation committee considered or relied on. The respondent must submit any comments on the draft report to the institution within 30 days of receiving the draft investigation report. ~~respondent must submit any comments on the draft report to the institution within 30 days of the~~

~~date on which the respondent received the draft investigation report.~~
(b) The institution ~~is not required to~~may 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~~The comments of the complainant ~~must submit any comments on the draft report to the institution~~, if any, must be submitted within 30 days of the date on which the complainant received the draft investigation report or relevant portions of it.

§ 93.313 Investigation report.
A final investigation report for each respondent must be in writing and include:
(a) ~~Describe~~Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.
(b) ~~Describe~~Description and ~~document~~documentation of the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.
(c) ~~Describe~~Description of the specific allegation(s) of research misconduct for consideration in the investigation ~~for each~~of the respondent.
(d) Composition of investigation committee, including name(s), position(s), and subject matter expertise.
(e) Inventory of sequestered research records~~/~~ and other evidence ~~and~~ , except records the institution did not consider or rely on; and a description of how any sequestration was conducted during the investigation~~, if applicable.~~
~~(f) Listing of all~~. This inventory must include manuscripts~~,~~ and funding proposals~~, and research records~~ that were ~~examined~~
considered or relied on during the investigation.
(~~g~~f) Transcripts of all interviews conducted, as described in § 93.~~305~~310(g).
(g~~).~~
~~(h~~) Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS ~~grant/contract~~funding applications, progress reports, presentations, posters, or other research records that allegedly contained the falsified, fabricated, or plagiarized material. ~~or plagiarized material.~~
~~(i~~(h) Any scientific or forensic analyses conducted.
(~~j~~i) If not already provided to ORI ~~with the inquiry report, include~~, the institutional policies and procedures under which the investigation was conducted.
~~(k) Identify and summarize the research records and other evidence reviewed and identify any evidence obtained and sequestered but not reviewed.~~
~~(l) For~~ (j) Any comments made by the respondent and complainant on the draft investigation report and the investigation committee's consideration of those comments.
(k) A statement for each separate allegation of whether the investigation committee recommends a finding of research misconduct ~~identified during the investigation,~~.
~~provide a finding as to whether research misconduct did or did not occur, and if so:~~
(1) If the investigation committee recommends a finding of research misconduct for an allegation, the investigation report must, for that allegation:
(i) Identify the individual(s) ~~responsible for~~who committed the research misconduct~~;~~.
(~~2~~ii) Indicate whether the research misconduct was falsification, fabrication, and/or plagiarism~~; and if the~~.
(iii) Indicate whether the research misconduct was committed intentionally, knowingly, or recklessly.
(iv) State whether the other requirements for a finding of research misconduct, as described in § 93.~~104~~103, have been met. ~~Voting or split decisions by the investigation committee members are not permitted in the final recommendation in the investigation report.~~

(~~3~~v) Summarize the facts and the analysis which support the conclusion and consider the merits of any explanation by the respondent~~;~~.
(4vi) Identify the specific PHS support~~;~~.
(~~5~~vii) Identify whether any publications need correction or retraction~~; and~~.
~~(6) List~~(2) If the investigation committee does not recommend a finding of research misconduct for an allegation, the investigation report must provide a detailed rationale.
(3) List of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.
~~Include and consider any comments made by the respondent and complainant on the draft investigation report.~~
~~(n) The basis on which allegation(s) did not result in a research misconduct determination.~~
~~(o) Any~~

§ 93.314 Decision by the Institutional Deciding Official.
The Institutional Deciding Official is responsible for making a final determination of research misconduct findings. This determination must be provided in a written decision that includes:
(a) Whether the institution found research misconduct and, if so, who committed the misconduct; and
(b) A description of relevant institutional actions ~~recommended~~taken or ~~implemented including communications~~to be taken.
~~with journals or funding agencies.~~

§ 93.~~314~~315 Institutional appeals.
~~(a) While not required by this part, if the 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 initiation. Appeals of institutional personnel actions or 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 that includes the 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~~(a) If a respondent appeals an institution's finding(s) of research misconduct or institutional actions, the institution must promptly notify ORI.
(b) If the institution has not transmitted its institutional record to ORI in accordance with § 93.316 prior to the appeal, the institution must wait until the appeal is concluded to transmit its institutional record. The institution must ensure that the complete record of the appeal is included in the institutional record consistent with § 93.220(a)(5).
(c) If the institution has transmitted its institutional record to ORI in accordance with § 93.316 prior to the appeal, the institution must provide ORI a complete record of the appeal once the appeal is concluded.

§ 93.316 Transmittal of the institutional record to ORI.
~~The institution must transmit~~ After the Institutional Deciding Official has made a final determination of research misconduct findings in accordance with § 93.314, the institution must transmit the institutional record to ORI~~ the institutional record.~~. The institutional record must be consistent with § 93.~~223~~220 and logically organized.

§ 93.~~316~~317 Completing the research misconduct process.

(a) ORI expects institutions to carry inquiries and investigations through to completion and to pursue diligently all significant issues and credible allegations of research misconduct. Institutions must notify ORI in advance if the institution plans to close a research misconduct proceeding at the assessment, inquiry, investigation, or appeal stage on the basis that the respondent has admitted to committing research misconduct~~,~~ or a settlement with the respondent has been reached~~, 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~~103 and must be provided to ORI before the institution closes its research misconduct proceeding. The institution must also provide a statement to ORI describing how it determined that the scope of the misconduct was fully addressed by the admission and confirmed the respondent's culpability.

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

(1) Approving or conditionally approving closure of the case;

(2) Directing the institution to complete its process;

(3) Directing the institution to address deficiencies in the institutional record;

(4) Referring the matter for further investigation by HHS; or~~,~~

(5) Taking a compliance action.

Other Institutional Responsibilities

§ 93.~~317~~318 Retention and custody of the institutional record and all sequestered evidence.

(a) Maintenance of institutional record~~. Unless custody has been transferred to HHS under paragraph (b) of this section, or ORI has advised the institution in writing that it no longer needs to retain the institutional record, an~~ and all sequestered evidence. An institution must maintain the institutional record and all sequestered evidence including physical objects (regardless of whether the evidence is part of the institutional record) in a secure manner for ~~7~~seven years after completion of the proceeding or the completion of any ~~PHS~~HHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later, unless custody has been transferred to HHS under paragraph (b) of this section or ORI advises otherwise in writing.

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

§ 93.~~318~~319 Institutional standards of conduct.

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

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

General Information

§ 93.400 General statement of ORI authority.

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

(1) Conducting allegation assessments;

(2) Determining independently ~~if~~whether jurisdiction exists under this part;

(3) Forwarding allegations of research misconduct to the appropriate institution or HHS component for inquiry or investigation;
~~component for inquiry or investigation;~~

(4) Requesting clarification or additional information, documentation, research records, or other evidence as necessary from an institution or its members or other persons or sources to carry out ORI's review;

(5) Notifying or requesting assistance and information from PHS funding components ~~or~~, other affected Federal and state offices and agencies, or institutions;

(6) Reviewing the institutional record and directing the institution to address deficiencies or additional allegations in the institutional record;

(7) Making a finding of research misconduct; and

~~(8) Proposing or taking administrative actions.~~

(8) Taking actions as necessary to protect the health and safety of the public, to promote the integrity of PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, or to conserve public funds.

(b) ORI assistance to institutions. ORI ~~will~~may:

(1) Provide information, technical assistance, and procedural advice to institutional officials as needed regarding an institution's research misconduct proceedings and the sufficiency of the institutional record~~.~~; and

(2) Issue guidance and provide information to support institutional implementation of and/or compliance with the requirements of this part.

(c) Review of institutional research integrity assurances. ORI will review institutional research integrity assurances and policies and procedures for compliance with this part.

(d) Institutional compliance. ORI may make findings and impose ~~HHS~~ORI compliance actions related to an institution's compliance with this part and with its policies and procedures, including an institution's participation in research misconduct proceedings.

§ 93.401 Interaction with other entities and interim actions.

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

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

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

(~~c~~d) ORI may notify affected PHS offices and funding components at any time to enable them to take appropriate interim actions.
(~~d~~e) The information provided will not be disclosed as part of the peer review and advisory committee review processes but may be used by the Secretary in making decisions about the award or continuation of funding.
(f) ORI may refer a research misconduct matter to the SDO at any time for consideration under the HHS suspension and debarment regulations. ORI may provide technical assistance and share other information that the SDO needs to know to consider the referred matter.

Research Misconduct Issues

§ 93.402 ORI allegation assessments.
(a) When ORI receives an allegation, it may conduct an assessment or refer the matter to the relevant institution for an assessment, inquiry, or other appropriate actions.
(b) If ORI ~~decides that~~conducts an assessment and determines an inquiry is warranted, it forwards the matter to the appropriate institution or HHS component.
(c) If ORI ~~decides that~~conducts an assessment and determines an inquiry is not warranted, it will close the case and forward the allegation in accordance with paragraph (d) ~~of~~in this section.
(d) ORI may ~~forward~~refer allegations that do not fall within the jurisdiction of this part to the appropriate HHS component, Federal or state agency, institution, organization, journal, or other appropriate entity.

§ 93.403 ORI review of research misconduct proceedings.
(a) In conducting its review of research misconduct proceedings, ORI will:
(1) Determine whether ~~PHS has jurisdiction under~~ this part applies;
(2) Consider the institutional record and ~~decide~~determine whether the institutional record is sufficient, provide instructions to the institution(s) if ORI determines that revisions are needed or additional allegations of research misconduct should be addressed, and require institutions to provide the respondent with an opportunity to respond to information or allegations added to the institutional record;
(3) Determine ~~if~~whether the institution conducted the proceedings in a timely and fair manner in accordance with this part with sufficient thoroughness, objectivity, and competence to support the conclusions; and
(4) After reviewing in accordance with paragraphs (a)(1) through (3) of this section, ~~decide~~determine whether to close the case without further action or proceed with the case.
(b) If ORI ~~decides~~determines to proceed with the case, ORI will:
(1) Obtain additional information or materials from the institution, the respondent, complainants, or other sources, as needed;
(2) Conduct additional analyses, as needed;
(3) Provide the respondent the opportunity to access the institutional record, any additional information provided to ORI while the case is pending before ORI, and any analysis or additional information generated or obtained by ORI;
(4) Provide the respondent the opportunity to submit information to ORI;
(5) Allow the respondent and the respondent's attorney, if represented, to meet virtually or in person with ORI to discuss the information that the respondent has provided to ORI ~~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~~(6) Have ORI's virtual or in-person meeting(s) with the respondent transcribed and provide a copy of the transcript to the respondent for review and suggested correction;

(7) Close the administrative record following paragraphs (b)(3) through (~~5~~6) of this section;
(~~7~~8) Provide the respondent the opportunity to access the complete administrative record; and ~~and~~
~~(8~~(9) Take any other actions necessary to complete ORI's review of the research misconduct proceedings.

§ 93.404 Findings of research misconduct and proposed HHS administrative actions.
(a) After completing its review of the administrative record, ORI ~~can~~may:
(1) Close the case without a separate ORI finding of research misconduct;
(2) Make findings of research misconduct and propose and take HHS administrative actions based on the administrative record; or
(3) Seek to settle the case.
(b) The lack of an ORI finding of research misconduct does not overturn an institution's determination that the conduct constituted professional or research misconduct warranting remediation under the institution's policy.

§ 93.405 Notifying the respondent of findings of research misconduct and proposed HHS administrative actions.
(a) When ORI makes a finding of research misconduct or ~~seeks to impose~~proposes HHS administrative actions, ~~other than suspension or debarment,~~ it notifies the respondent in a charge letter. The charge letter ~~includes the ORI~~:
(1) Includes ORI's findings of research misconduct, including the basis for such findings in the administrative record, and any proposed HHS administrative actions~~. The charge letter also advises~~;
(2) Advises the respondent how ~~they can~~to access the administrative record; and
(3) Informs the respondent of the opportunity to contest the findings and proposed HHS administrative actions under subpart E of this part. ~~In 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, private delivery service, or electronic mail or other electronic means to the last known address of the respondent or the last known principal place of business of the respondent's attorney, if represented.

§ 93.406 Final HHS actions.
~~(a)~~ Unless the respondent contests the findings and/or the ~~administrative actions, other than suspension and/or~~ proposed ~~debarment,~~HHS administrative actions contained in the charge letter within the 30-day period prescribed in § 93.501~~,~~(a), the ORI ~~finding of~~findings and HHS administrative actions~~, other than suspension and/or proposed debarment, proposed for research misconduct issues~~ 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 debarment decision in the matter. Respondents may request reconsideration of a final debarment decision with the SDO.~~

§ 93.407 HHS administrative actions.
(a) Based on the administrative record, HHS may impose administrative actions that include but are not limited to:
(1) Clarification, correction, or retraction of the research record.

(2) ~~Letters~~Letter(s) of reprimand.
(3) Imposition of special certification or research integrity assurance requirements to ensure compliance with applicable regulations or terms of ~~PHS~~HHS grants, contracts, or cooperative agreements.
(4) Suspension of award activities under, or termination of, a PHS grant, contract, or cooperative agreement.
(5) Restriction on specific activities or expenditures under an active PHS grant, contract, or cooperative agreement.
(6) Special review of all the respondent's requests for PHS funding.
(7) Imposition of supervision requirements on a PHS grant, contract, or cooperative agreement.
(8) Certification of attribution or authenticity in all requests for support and reports to ~~the PHS.~~ PHS.
(9) Prohibition ~~on~~ of the respondent in participating in any advisory capacity ~~to~~with the PHS.
(10) ~~Adverse~~Recommending that the relevant agency take adverse personnel action(s), if the respondent is a Federal employee, in compliance with relevant Federal personnel policies and laws.
~~(11) Suspension or debarment 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 findings, HHS also may seek to recover PHS funds spent ~~in support of the~~supporting activities ~~that involved~~involving research misconduct.
(c) Any authorized HHS component may impose, administer, or enforce administrative actions separately or in coordination with other HHS components, including, but not limited to ORI, OIG, and the PHS funding component~~, and the SDO~~.
(d) HHS administrative actions under this part do not include suspension or debarment. Regardless of whether HHS administrative actions are imposed under this part, HHS may pursue suspension and debarment under the HHS suspension and debarment regulations.

§ 93.408 Mitigating and aggravating factors in HHS administrative actions.
The purpose of HHS administrative actions is remedial. The appropriate administrative action is commensurate with the seriousness of the misconduct and the need to protect the health and safety of the public, promote the integrity of the PHS–supported research and research process, and conserve public funds. ORI considers the following aggravating and mitigating factors in determining appropriate HHS administrative actions and their terms. ~~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 actions knowing or intentional or were the actions reckless?
(b) Pattern. Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?
(c) Impact. Did the misconduct have significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare?
(d) Acceptance of responsibility. Has the respondent accepted responsibility for the misconduct by:
(1) Admitting the conduct;

(2) Cooperating with the research misconduct proceedings;
(3) Demonstrating remorse and awareness of the significance and seriousness of the research misconduct; and
(4) Taking steps to correct or prevent the recurrence of the research misconduct?
(e) Failure to accept responsibility. Does the respondent blame others rather than accepting responsibility for the actions?
(f) Retaliation. Did the respondent retaliate against complainants, witnesses, committee members, or other individuals?
(g) Continued risk to PHS funding. Does the respondent demonstrate responsible stewardship of research resources?
(h) Other factors. Are other factors relevant to the circumstances of a particular case?

§ 93.409 Settlement of research misconduct proceedings.
(a) HHS may settle a research misconduct proceeding at any time it ~~concludes~~determines that settlement is in the best interests of the Federal Government and the public health or welfare.
~~(b~~(b) Settlement agreements are publicly available, regardless of whether ORI made a finding of research misconduct.
(c) A settlement agreement precludes the respondent from contesting any ORI findings of research misconduct, HHS administrative actions ~~(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 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~~:~~
~~(a) Provide~~ provide written notice to the respondent, the relevant institution, the complainant, and HHS officials~~, as it deems necessary~~.
~~(b) 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 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~~,~~(s), ORI may:
(a) ~~Shall provide~~Provide final notification of any research misconduct findings and HHS administrative actions to the respondent, the relevant institution, and ~~HHS officials, including the SDO. The SDO shall provide a separate notice of final HHS action on any suspension or debarment actions~~appropriate HHS officials.
(b) ~~May provide~~Provide final notification of any research misconduct findings and HHS administrative actions to the complainant(s).
(c) ~~Shall send~~Send a notice to the relevant journal, publisher, data repository, or other similar entity identifying publications or research records ~~which~~that require correction or retraction.
(d) ~~Shall publish~~Publish notice of the research misconduct findings.
(e) ~~Shall notify~~Notify the respondent's current employer~~,~~ if the employer is an institution subject to this part.

Institutional Compliance Issues

§ 93.412 Making decisions on institutional noncompliance.

ORI may ~~decide that~~determine an institution is not compliant with this part if the institution does not implement and follow the requirements of this part and its own research integrity assurance.

In making this decision, ORI may consider, but is not limited to the following factors:

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

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

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

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

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

§ 93.413 ~~HHS~~ORI compliance actions.

(a) ~~An institution's failure to comply~~If ORI determines an institution is not compliant with ~~the requirements of~~ this part, it may ~~result in enforcement~~take a compliance action against the institution.

(b) If ORI determines an institution ~~fails to comply~~is not compliant with ~~the requirements of~~ this part, ~~HHS~~ORI may take ~~some~~any or all of the following compliance actions:

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

(2) Issue a letter of reprimand.

(3) Require the institution to take corrective actions.

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

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

~~(6) Recommend that HHS debar or suspend the institution.~~

~~(7~~(6) Any other action appropriate to the circumstances.

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

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

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

Disclosure of Information

§ 93.414 Notice.

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

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

~~(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 Contest ORI Findings of Research Misconduct and ~~HHS~~Proposed ~~Administrative Actions~~

HHS Administrative Actions

General Information

§ 93.500 General policy.
(a) This subpart provides a respondent an opportunity to contest ORI findings of research misconduct and/or proposed HHS administrative actions~~, other than suspension or proposed debarment,~~ included in a charge letter.
~~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 may contest ~~ORI~~ORI's research misconduct findings and proposed HHS administrative actions~~, other than suspension and proposed debarment,~~ by filing a notice of appeal with an Administrative Law Judge (ALJ) at the DAB.
(c) Based on the administrative record, the ALJ shall rule on ~~the reasonableness of the ORI~~whether ORI's research misconduct findings and ~~the~~any proposed HHS administrative actions ~~other than suspension~~are reasonable and not based on a material error of law or ~~debarment.~~fact. The ALJ's ruling constitutes a recommended decision to the Assistant Secretary for Health (ASH) in accordance with § 93.511(b).
~~(d) The ALJ's ruling made under § 93.512 is the final HHS action with respect to the research misconduct findings 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.~~
(d) A respondent must exhaust all available administrative remedies under this subpart before seeking judicial review of ORI's findings and/or HHS administrative actions. The contested findings and/or administrative actions shall be inoperative while the respondent is pursuing administrative remedies under this subpart.

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

§ 93.501 Notice of appeal.

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

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

(1) In writing;

(2) Signed by the respondent or by the ~~respondent's~~respondent's attorney; and

(3) Submitted to the DAB Chair through the DAB electronic filing system, with a copy sent to ORI by certified mail, electronic mail, or other equivalent (i.e., with a verified method of delivery~~), to 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 notice of appeal. The notice of appeal must:

(1) Admit or deny each ORI finding of research misconduct and each factual assertion made in support of each finding;

(2) Accept or challenge each proposed HHS administrative action;

(3) Provide detailed, substantive reasons for each denial or challenge with references to the administrative record;

(4) Identify any legal issues or defenses that the respondent intends to raise during the proceeding, with references to the administrative record; and

(5) Identify any mitigating factors in the administrative record~~; and~~.

~~(6) State whether a suspension or proposed debarment is also being contested under 2 CFR part 180 or 48 CFR 9.406 and 9.407.~~

§ 93.502 Appointment of the Administrative Law Judge.

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

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

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

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

§ 93.503 Filing of the administrative record.

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

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

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

§ 93.504 Standard of review.

(a) The ALJ shall review the administrative record to determine whether ~~ORI's~~the ORI research misconduct findings and ~~HHS's~~ proposed HHS 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.

(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 material to the ORI findings of research misconduct or HHS administrative actions other than suspension and debarment, the ALJ may hold a limited hearing to resolve that genuine factual dispute.~~

§ 93.505 Rights of the parties.

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

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

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

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

(3) File motions or briefs in writing before the ALJ~~;~~

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

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

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

§ 93.506 Authority of the Administrative Law Judge.

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

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

~~(1) Review the administrative record and issue a ruling without convening a hearing;~~

~~(2~~(1) Hold conferences with the parties to identify or simplify the issues, or to consider other matters that may aid in the prompt disposition of the proceeding;

(~~3~~2) Rule on motions and other procedural matters;

(~~4~~3) Except for the respondent's notice of appeal, modify the time for the filing of any document required or authorized under the rules in this subpart~~.~~;

(~~5~~4) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;

(~~6~~5) Regulate the course of the appeal and the conduct of representatives~~,~~ and parties~~,~~; and ~~witnesses;~~

(~~7~~6) 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;
(4) Review suspension or proposed debarment;
(5) Find invalid or refuse to follow Federal statutes or regulations, Secretarial delegations of authority, or HHS policies;
(6) Authorize the parties to engage in discovery; and
(7) Modify the time for filing the respondent's notice of appeal.
(d) The Federal Rules of Evidence and the Federal Rules of Civil Procedure do not govern the proceedings under this subpart.

§ 93.507 Ex parte communications.
(a) No party, attorney, or other party representative may communicate ex parte with the ALJ on any matter at issue in a case, unless both parties have notice and an opportunity to participate in the communication.
(b) If an ex parte communication occurs, the ALJ will disclose it to the other party and offer the other party an opportunity to comment.
(c) The provisions of this section do not apply to communications between an employee or contractor of the DAB and the ALJ.

§ 93.508 Filing, format, and service.
(a) Filing. (1) Unless the ALJ provides otherwise, all submissions required or authorized to be filed in the proceeding must be filed with the ALJ.
(2) Submissions are considered filed when they are filed with the DAB according to the DAB's filing guidance.
(b) Format. (1) The ALJ may designate the format for copies of nondocumentary materials such as videotapes, computer disks, or physical evidence. This provision does not apply to the charge letter or other written notice provided under § 93.405.
(2) Every submission filed in the proceeding must include the title of the case, the docket number, and a designation of the nature of the submission.
(3) Every submission filed in the proceeding must be signed by and contain the address and telephone number of the party on whose behalf the document or paper was filed, or the attorney of record for the party.
(c) Service. Service of a submission on other parties is accomplished by filing the submission with the ALJ through the DAB electronic filing system.

§ 93.509 Filing motions.
(a) Parties must file all motions and requests for an order or ruling with the ALJ, serve them on the other party, state the nature of the relief requested, provide the legal authority relied upon, and state the facts alleged in support of the motion or request.
(b) All motions must be in writing ~~except for those made during a prehearing conference or at 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 response unless allowed by the ALJ.
(d) The ALJ may not grant a motion before the time for filing a response has expired, except with the parties' consent ~~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~~.

§ 93.510 Conferences.
(a) The ALJ must schedule an initial conference with the parties within 30 days of the DAB Chair's assignment of the case.
(b) The ALJ may use the initial conference to discuss:
(1) Identification and simplification of the issues, specification of genuine disputes of fact and their materiality to the ORI findings of research misconduct, and any proposed HHS administrative actions;
(2) Identification of material legal issues and any need for briefing;
(3) Scheduling dates for the filing of briefs based on the administrative record ~~or the 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 conferences as appropriate, upon reasonable notice to or request of the parties.
(d) All conferences will be recorded with copies provided to the parties upon request.
(e) ~~The~~Whenever possible, the ALJ shall memorialize in writing any oral rulings within 10 days after a conference is held.
~~(f) By 15 days before the scheduled hearing date, if applicable, the ALJ must hold a prehearing conference to resolve to the maximum extent possible all outstanding issues about evidence, witnesses, motions and all other matters that may encourage the fair, just, and prompt resolution of genuine factual disputes.~~

§ 93.511 ~~Hearing to resolve genuine factual dispute.~~
~~(a) The ALJ may hold a virtual or in-person hearing that is limited to resolving a genuine factual dispute.~~
~~(b) The ALJ shall permit the parties to call witnesses and to question witnesses. The ALJ 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.~~
~~(e) The hearing will be transcribed, and the parties will have an opportunity to review the transcript and submit proposed corrections to the ALJ.~~
~~(f) Following receipt of the transcript and proposed corrections to the transcript, the ALJ may permit the parties to file briefs with suggested factual findings based on the transcript.~~
~~(g) The ALJ will issue findings of fact to the parties that resolves the genuine factual dispute.~~

~~§ 93.512~~ **The Administrative Law Judge's ruling.**
(a) 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 within 60 days after the last submission by the parties in the case, setting forth whether ORI's research misconduct findings and ~~HHS's~~ proposed HHS 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~~. If the ALJ is unable to meet the 60-day deadline, the ALJ must set a new deadline and promptly notify the parties ~~and the SDO if a suspension or proposed debarment is contested.~~. The ALJ shall serve a copy of the ruling upon the parties~~. If a 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~~ and the ASH.

~~(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.~~

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

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