SUBCHAPTER H—HEALTH ASSESSMENTS AND HEALTH EFFECTS STUDIES OF HAZARDOUS SUBSTANCES RELEASES AND FACILITIES

PART 90—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Sec. 90.1 Purpose and applicability.
90.2 Definitions.
90.3 Procedures for requesting health assessments.
90.4 Contents of requests for health assessments.
90.5 Acting on requests.
90.6 Notification of determination to conduct a health assessment in response to a request from the public.
90.7 Decision to conduct health effects study.
90.8 Conduct of health assessments and health effects studies.
90.9 Public health advisory.
90.10 Notice and comment period.
90.11 Reporting of results of health assessments and health effects studies.
90.12 Confidentiality of information.
90.13 Recordkeeping requirements.
90.14 Documentation and cost recovery.

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SOURCE: 55 FR 5138, Feb. 13, 1990, unless otherwise noted.

§ 90.1 Purpose and applicability.


EPA means the U.S. Environmental Protection Agency.

Facility is defined in 42 U.S.C. 9601(9).

Hazardous substance is defined in 42 U.S.C. 9601(14). In addition, the term includes any pollutant or contaminant which the Administrator determines is appropriate for the purposes of carrying out his or her responsibilities under CERCLA.

Health assessment means the evaluation of data and information on the release of hazardous substances into the environment in order to assess any current or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects.

Health effects study means research, investigation, or study performed by ATSDR or other parties pursuant to an agreement with ATSDR to evaluate the health effects of exposure to hazardous substances at specific sites. This term includes, but is not limited to, epidemiological studies, exposure and disease registries, and health surveillance programs. This term does not include health assessments.

Owner or operator is defined in 42 U.S.C. 9601(20).

Peer review means review for scientific quality by a panel consisting of no less than three nor more than seven members, who shall be disinterested scientific experts selected by the Administrator of ATSDR on the basis of their reputation for scientific objectivity and the lack of institutional ties.

ATSDR means the Agency for Toxic Substances and Disease Registry or designee.
with any person involved in the conduct of the study or research under review.

*Person* means an individual, firm, corporation, association, partnership, consortium, joint venture, commercial entity, United States Government, State, municipality, commission, political subdivision of a State, Indian tribe, or any interstate body.

*Pollutant or contaminant* is defined in 42 U.S.C. 9601(33).

*Public health advisory* is a statement by ATSDR containing a finding that a release poses a significant risk to human health and recommending measures to be taken to reduce exposure and eliminate or substantially mitigate the significant risk to human health.

*Release* is defined in 42 U.S.C. 9601(22).

§ 90.3 Procedures for requesting health assessments.

(a) ATSDR will accept requests to perform health assessments for a particular facility or release from any person or group of persons.

(b) All requests to ATSDR to perform health assessments should be addressed to: Assistant Administrator, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road NE., Atlanta, GA 30333.

§ 90.4 Contents of requests for health assessments.

(a) Each request for a health assessment shall contain:

1. The name, address (including zip code), and telephone number of the requestor;

2. The organization or group the requestor represents, if any;

3. The name, location, and description of the facility or release of concern;

4. A statement providing information that individuals have been exposed to a hazardous substance and that the probable source is a release, or sufficient information to allow the Administrator to make such a finding;

5. A statement requesting ATSDR to perform a health assessment.

(b) At his or her discretion, consistent with the requirements of CERCLA, the Administrator may decide not to require the preceding information be submitted with a request for a health assessment.

(c) Each request for a health assessment should include, where possible:

1. Any other information pertaining to the facility or release, such as the nature and amount of the hazardous substances of concern or the identities of parties believed to be potentially responsible for the release;

2. Potential pathways for human exposure, including a description of the media contaminated (e.g. soil, groundwater, air, etc.);

3. The demographic nature and proximity of the potentially affected human population; and

4. Other Federal, State, or local governmental agencies which were notified that investigated the facility or release.

(d) This data collection has been reviewed and approved by OMB in accordance with the Paperwork Reduction Act and assigned the control number 0920–0204.

§ 90.5 Acting on requests.

(a) Upon receipt of a request for a health assessment submitted under this part, ATSDR will determine, in its discretion, whether or not there is a reasonable basis to justify conducting a health assessment. ATSDR will base this determination on, among other factors:

1. Whether individuals have been exposed to a hazardous substance, for which the probable source of such exposure is a release;

2. The location, concentration, and toxicity of the hazardous substances;

3. The potential for further human exposure;

4. The recommendations of other governmental agencies; and

5. The ATSDR resources available and other ATSDR priorities, such as its responsibilities to conduct other health assessments and health effects studies.

(b) Where appropriate, ATSDR will request information from other Federal, State, and local governmental agencies, as well as other persons, pertaining to a facility or release which is the subject of a request from the public to ATSDR to conduct a health assessment.
(c) The requestor will be notified in writing of ATSDR’s determination that either a health assessment will be performed, a health assessment will not be performed, or that further information concerning the facility or release is required before a decision can be made whether a health assessment will be performed.

(d) If a health assessment is not initiated in response to a request from the public, ATSDR shall provide a written explanation to the requestor of why a health assessment is not appropriate.

§ 90.6 Notification of determination to conduct a health assessment in response to a request from the public.

(a) Following a determination by ATSDR to conduct a health assessment in response to a request from the public, ATSDR shall notify in writing, at a minimum, the following parties of its intent to perform a health assessment:

(1) The U.S. Environmental Protection Agency;

(2) The appropriate State government environmental agency;

(3) The appropriate State and local health departments;

(4) The requestor;

(5) The owner or operator of the facility of concern, if their identity is readily available to ATSDR.

In addition, ATSDR will notify, in writing or by telephone, other potentially responsible parties, if their identity is readily available to ATSDR.

§ 90.7 Decision to conduct health effects study.

(a) ATSDR may decide, in its discretion, based upon the results of a health assessment or other available information, to conduct a health effects study for a particular site or sites. Such a decision may, in appropriate circumstances, be made prior to the completion of a health assessment for a site or sites. When deciding whether to conduct a health effects study, ATSDR will consider such factors as the results and recommendations of a health assessment for the site or sites and the need for additional information to determine whether individuals have been exposed to hazardous substances, the degree to which such exposure has occurred, and any possible health effects resulting from such exposure.

(b) Should ATSDR decide, in its discretion, to conduct a health effect study, it will notify the parties as specified in §90.6.

§ 90.8 Conduct of health assessments and health effects studies.

(a) Any interested person or persons may submit data or information to ATSDR for it to consider in its conduct of a health assessment or a health effects study. In performing a health assessment or a health effects study, ATSDR will consider data and information it has independently generated or received from other parties, such as EPA, other Federal agencies, State and local governmental agencies, businesses, citizen organizations, and community groups.

(b) ATSDR may determine it is necessary to conduct a site visit in connection with a health assessment or health effects study. The ATSDR representative may allow the participation of any person in the site visit which he or she, at his or her discretion, determines will aid in the conduct of the health assessment or health effects study.

(c) In the event that the information necessary to perform a health assessment or health effects study is not readily available from other sources, ATSDR may arrange for sampling or additional data gathering at a facility or release for the limited purpose of determining the existence of current or potential health problems.

§ 90.9 Public health advisory.

ATSDR may issue a public health advisory based on the findings of a health assessment, health effects, study, or other ATSDR involvement.

§ 90.10 Notice and comment period.

Following internal review by ATSDR and external peer review of a draft final report of the results of a health effects study, ATSDR will publish a notice that the draft final report is available for public review and comment. At
§ 90.11 Reporting of results of health assessments and health effects studies.

(a) ATSDR shall provide a report of the results of a health assessment or health effects study to EPA, the appropriate State and local governmental agencies, any person requesting ATSDR to conduct the health assessment, and parties potentially responsible for the release, if their identity is readily available to ATSDR. In addition, such reports shall be available to the general public upon request.

(b) In the event that ATSDR or its representatives conduct medical examinations of individuals in the course of a health effects study and the examination reveals a positive significant medical finding, the individual, and a physician if designated by the individual, will be promptly notified of that significant medical finding by ATSDR.

(c) A summary of the findings of all medical examinations for each individual will be sent by ATSDR to that individual.

(d) All studies and results of research conducted under this part (other than health assessments) shall be reported or adopted only after appropriate peer review.

§ 90.12 Confidentiality of information.

(a) ATSDR shall consider any medical information in individually identifiable form to be confidential information and shall release such information only in accordance with the Privacy Act (5 U.S.C. 552a) or other applicable Federal law.

(b) As provided under section 104(e)(7) of CERCLA, any records, reports, or information obtained from any person under this section shall be available to the public, except that upon a showing satisfactory to ATSDR by any person that records, reports, or information, or particular part thereof (other than health or safety effects data), to which any officer, employee, or representative of ATSDR has access under this part if made public would divulge information entitled to protection under the Trade Secrets Act (18 U.S.C. 1905), such information or particular portion thereof shall be considered confidential in accordance with the purposes of that section, except that such record, report, document, or information may be disclosed to other officers, employees, or authorized representatives of the United States concerned with carrying out statutorily mandated duties.

(c) In submitting data to ATSDR, a person may designate the data which such person believes is entitled to protection under paragraph (b) of this section and submit such designated data separately from other data submitted under this part. A designation under this paragraph shall be made in writing to the Administrator. However, should ATSDR at any time question such designation, not less than 15 days notice to the person submitting the information shall be given of the intention to remove such trade secret designation from such information. The person may submit a request to the Administrator to reconsider this intention and may provide additional information in support of the trade secret designation. The Administrator shall notify the person in writing of the decision which will become effective no sooner than 15 days after the date of such notice.

§ 90.13 Recordkeeping requirements.

(a) ATSDR shall maintain a record of all health assessments and health effects studies. The Administrator shall, at his or her discretion, determine the contents of the record. At a minimum, the record shall include:

1. The final ATSDR report of the health assessment or health effects study;

2. Nonconfidential data and other information upon which that report is based or which was considered by ATSDR;
(3) Nonconfidential data or other information submitted by interested persons pertaining to the health assessment or health effects study;

(4) The protocol for the health effects study;

(5) A list of the individuals responsible for external peer review of the report of a health effects study, their comments, and ATSDR’s response to the comments; and

(6) For health effects study, the notice announcing the availability of a draft final report for public review and comment, all comments received in response to the notice, and any responses to the comments by ATSDR.

(b) The record may contain a confidential portion which shall include all information determined to be confidential by the Administrator under this part.

(c) The Administrator may determine other documents are appropriate for inclusion in the record for health assessments or health effects studies.

(d) Predecisional documents, including draft documents, are not documents upon which ATSDR bases its conclusions in health assessments or health effects studies, and are not usually included in the record for health assessments or health effects studies.

(e) The record for ATSDR health assessments and health effects studies will be available for review, upon prior request, at ATSDR headquarters in Atlanta, Georgia.

(f) Nothing in this section is intended to imply that ATSDR’s decisions to conduct health assessments or health effects studies, or the reports of health assessments or health effects studies, are subject to judicial review.

§ 90.14 Documentation and cost recovery.

(a) During all phases of ATSDR health assessments and health effects studies, documentation shall be completed and maintained to form the basis for cost recovery, as specified in section 107 of CERCLA.

(b) Where appropriate, the information and reports compiled by ATSDR pertaining to costs shall be forwarded to the appropriate EPA regional office for cost recovery purposes.

Subpart A—General

93.100 General policy.
93.101 Purpose.
93.102 Applicability.
93.103 Research misconduct.
93.104 Requirements for findings of research misconduct.
93.105 Time limitations.
93.106 Evidentiary standards.
93.107 Rule of interpretation.
93.108 Confidentiality.
93.109 Coordination with other agencies.

Subpart B—Definitions

93.200 Administrative action.
93.201 Allegation.
93.202 Charge letter.
93.203 Complainant.
93.204 Contract.
93.205 Debarment or suspension.
93.206 Debarring official.
93.207 Departmental Appeals Board or DAB.
93.208 Evidence.
93.209 Funding component.
93.210 Good faith.
93.211 Hearing.
93.212 Inquiry.
93.213 Institution.
93.214 Institutional member.
93.215 Investigation.
93.216 Notice.
93.217 Office of Research Integrity or ORI.
93.218 Person.
93.219 Preponderance of the evidence.
93.220 Public Health Service or PHS.
93.221 PHS support.
93.222 Research.
93.223 Research misconduct proceeding.
93.224 Research record.
93.225 Respondent.
93.226 Retaliation.
93.227 Secretary or HHS.

Subpart C—Responsibilities of Institutions

Compliance and assurances

93.300 General responsibilities for compliance.
93.301 Institutional assurances.
93.302 Institutional compliance with assurances.
93.303 Assurances for small institutions.
93.304 Institutional policies and procedures.
93.305 Responsibility for maintenance and custody of research records and evidence.
§ 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>
<thead>
<tr>
<th>Subpart</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>General information about this rule.</td>
</tr>
<tr>
<td>B</td>
<td>Definitions of terms used in this part.</td>
</tr>
<tr>
<td>C</td>
<td>Responsibilities of institutions with PHS support.</td>
</tr>
<tr>
<td>D</td>
<td>Responsibilities of the U.S. Department of Health and Human Services and the Office of Research Integrity.</td>
</tr>
</tbody>
</table>
§ 93.100 General policy.

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

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

§ 93.101 Purpose.

The purpose of this part is to—

(a) Establish the responsibilities of HHS, PHS, the Office of Research Integrity (ORI), and institutions in responding to research misconduct issues;

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

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

(d) Require institutions to develop and implement policies and procedures for—

(1) Reporting and responding to allegations of research misconduct covered by this part;

(2) Providing HHS with the assurances necessary to permit the institutions to participate in PHS supported research.

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

§ 93.102 Applicability.

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

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

(i) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information;

(ii) PHS supported biomedical or behavioral extramural or intramural research;

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

(iv) PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks or the dissemination of research information; and

(v) Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training.

This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for
§ 93.103 Research misconduct.

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

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

§ 93.104 Requirements for findings of research misconduct.

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

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

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

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

§ 93.105 Time limitations.

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

(b) Exceptions to the six-year limitation.

Paragraph (a) of this section does not apply in the following instances:

1. Subsequent use exception. The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.

2. Health or safety of the public exception. If ORI or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

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

§ 93.106 Evidentiary standards.

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

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

(b) Burden of proof. (1) The institution or HHS has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent’s failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent’s conduct constitutes a significant departure from accepted practices of the relevant research community.

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

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

§ 93.107 Rule of interpretation.

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

§ 93.108 Confidentiality.

(a) Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Provided, however, that:

(1) The institution must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings under §93.403.

(2) Under §93.517(g), HHS administrative hearings must be open to the public.

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

§ 93.109 Coordination with other agencies.

(a) When more than one agency of the Federal government has jurisdiction of the subject misconduct allegation, HHS will cooperate in designating a lead agency to coordinate the response of the agencies to the allegation. Where HHS is not the lead agency, it may, in consultation with the lead agency, take appropriate action to protect the health and safety of the public, promote the integrity of the PHS supported research and research process and conserve public funds.

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

Subpart B—Definitions

§ 93.200 Administrative action.

Administrative action means—

(a) An HHS action in response to a research misconduct proceeding taken to protect the health and safety of the public, to promote the integrity of PHS supported biomedical or behavioral research, research training, or activities related to that research or research training and to conserve public funds; or

(b) An HHS action in response either to a breach of a material provision of a settlement agreement in a research misconduct proceeding or to a breach of any HHS debarment or suspension.

§ 93.201 Allegation.

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

§ 93.202 Charge letter.

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

§ 93.203 Complainant.

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

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

§ 93.205 Debarment or suspension.

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

§ 93.206 Debarring official.

Debarring official means an official authorized to impose debarment or suspension. The HHS debarring official is either—
(a) The Secretary; or
(b) An official designated by the Secretary.

§ 93.207 Departmental Appeals Board or DAB.

Departmental Appeals Board or DAB means, depending on the context—
(a) The organization, within the Office of the Secretary, established to conduct hearings and provide impartial review of disputed decisions made by HHS operating components; or
(b) An Administrative Law Judge (ALJ) at the DAB.

§ 93.208 Evidence.

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

§ 93.209 Funding component.

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

§ 93.210 Good faith.

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

§ 93.211 Hearing.

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

§ 93.212 Inquiry.

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

§ 93.213 Institution.

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

§ 93.214 Institutional member.

_Institutional member or members_ means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

§ 93.215 Investigation.

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

§ 93.216 Notice.

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

§ 93.217 Office of Research Integrity or ORI.

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

§ 93.218 Person.

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

§ 93.219 Preponderance of the evidence.

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

§ 93.220 Public Health Service or PHS.

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

§ 93.221 PHS support.

_PHS support_ means PHS funding, or applications or proposals therefor, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: Funding for PHS intramural research; PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

§ 93.222 Research.

_Research_ means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.
§ 93.223 Research misconduct proceeding.

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

§ 93.224 Research record.

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

§ 93.225 Respondent.

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

§ 93.226 Retaliation.

Retaliation for the purpose of this part means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to—

(a) A good faith allegation of research misconduct; or

(b) Good faith cooperation with a research misconduct proceeding.

§ 93.227 Secretary or HHS.

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

Subpart C—Responsibilities of Institutions

COMPLIANCE AND ASSURANCES

§ 93.300 General responsibilities for compliance.

Institutions under this part must—

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

(b) Respond to each allegation of research misconduct for which the institution is responsible under this part in a thorough, competent, objective and fair manner, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses;

(c) Foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct;

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

(e) Provide confidentiality to the extent required by §93.108 to all respondents, complainants, and research subjects identifiable from research records or evidence;

(f) Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence;

(g) Cooperate with HHS during any research misconduct proceeding or compliance review;

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

(i) Have an active assurance of compliance.
Public Health Service, HHS

§ 93.304 Institutional policies and procedures. Institutions seeking an approved assurance must have written policies and procedures for addressing research misconduct that include the following—

(a) Consistent with §93.108, protection of the confidentiality of respondents, complainants, and research subjects identifiable from research records or evidence;

(b) A thorough, competent, objective, and fair response to allegations of research misconduct consistent with and within the time limits of this part, including precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses;

(c) Notice to the respondent, consistent with and within the time limits of this part;

(d) Written notice to ORI of any decision to open an investigation on or before the date on which the investigation begins;
§ 93.305 Responsibility for maintenance and custody of research records and evidence.

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

(a) Either before or when the institution notifies the respondent of the allegation, inquiry or investigation, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments;

(b) Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records;

(c) Undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments; and

(d) Maintain the research records and evidence as required by §93.317.

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

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

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

(c) A consortium or person acting on behalf of an institution must follow the requirements of this part in conducting research misconduct proceedings.
§ 93.307 Institutional inquiry.

(a) Criteria warranting an inquiry. An inquiry is warranted if the allegation—
(1) Falls within the definition of research misconduct under this part;
(2) Is within § 93.102; and
(3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

(b) Notice to respondent and custody of research records. At the time of or before beginning an inquiry, an institution must make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the institution must notify them. To the extent it has not already done so at the allegation stage, the institution must, on or before the date on which the respondent is notified or the inquiry begins, whichever is earlier, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

(c) Review of evidence. The purpose of an inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation. Therefore, an inquiry does not require a full review of all the evidence related to the allegation.

(d) Criteria warranting an investigation. An inquiry’s purpose is to decide if an allegation warrants an investigation. An investigation is warranted if there is—
(1) A reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training or activities related to that research or research training, as provided in § 93.102; and
(2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

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

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

(g) Time for completion. The institution must complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

§ 93.308 Notice of the results of the inquiry.

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

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

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

(a) Within 30 days of finding that an investigation is warranted, the institution must provide ORI with the written finding by the responsible institutional official and a copy of the inquiry report which includes the following information—
(1) The name and position of the respondent;
(2) A description of the allegations of research misconduct;
(3) The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;
§ 93.310  Institutional investigation.

Institutions conducting research misconduct investigations must:

(a) Time. Begin the investigation within 30 days after determining that an investigation is warranted.

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

(c) Notice to the respondent. Notify the respondent in writing of the allegations within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins. The institution must give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation.

(d) Custody of the records. To the extent they have not already done so at the allegation or inquiry stages, take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. Whenever possible, the institution must take custody of the records—

1. Before or at the time the institution notifies the respondent; and

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

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

(f) Ensuring a fair investigation. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation.

(g) Interviews. Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation.

(h) Pursue leads. Pursue diligently all significant issues and leads discovered
§ 93.311 Investigation time limits.

(a) Time limit for completing an investigation. An institution must complete all aspects of an investigation within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment in accordance with §93.312, and sending the final report to ORI under §93.315.

(b) Extension of time limit. If unable to complete the investigation in 120 days, the institution must ask ORI for an extension in writing.

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

§ 93.312 Opportunity to comment on the investigation report.

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

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

§ 93.313 Institutional investigation report.

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

(a) Allegations. Describe the nature of the allegations of research misconduct.

(b) PHS support. Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.

(c) Institutional charge. Describe the specific allegations of research misconduct for consideration in the investigation.

(d) Policies and procedures. If not already provided to ORI with the inquiry report, include the institutional policies and procedures under which the investigation was conducted.

(e) Research records and evidence. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.

(f) Statement of findings. For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so—

(1) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;

(2) Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;

(3) Identify the specific PHS support;

(4) Identify whether any publications need correction or retraction;

(5) Identify the person(s) responsible for the misconduct; and

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

(g) Comments. Include and consider any comments made by the respondent and complainant on the draft investigation report.

(h) Maintain and provide records. Maintain and provide to ORI upon request all relevant research records and records of the institution’s research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

§ 93.314 Institutional appeals.

(a) While not required by this part, if the institution’s procedures provide for an appeal by the respondent that could result in a reversal or modification of the findings of research misconduct in the investigation report, the institution must complete any such appeal within 120 days of its filing. Appeals from personnel or similar actions that
§ 93.315 Notice to ORI of institutional findings and actions.

The institution must give ORI the following:

(a) Investigation Report. Include a copy of the report, all attachments, and any appeals.

(b) Final institutional action. State whether the institution found research misconduct, and if so, who committed the misconduct.

(c) Findings. State whether the institution accepts the investigation’s findings.

(d) Institutional administrative actions. Describe any pending or completed administrative actions against the respondent.

§ 93.316 Completing the research misconduct process.

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

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

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

(2) Directing the institution to complete its process;

(3) Referring the matter for further investigation by HHS;

(4) Taking a compliance action.

OTHER INSTITUTIONAL RESPONSIBILITIES

§ 93.317 Retention and custody of the research misconduct proceeding record.

(a) Definition of records of research misconduct proceedings. As used in this section, the term “records of research misconduct proceedings” includes:

(1) The records that the institution secures for the proceeding pursuant to §§93.305, 93.307(b) and 93.310(d), except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;

(2) The documentation of the determination of irrelevant or duplicate records;

(3) The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate as required by §93.309(d);

(4) The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted pursuant to §93.310(g); and

(5) The complete record of any institutional appeal covered by §93.314.

(b) Maintenance of record. Unless custody has been transferred to HHS under paragraph (c) of this section, or ORI has advised the institution in writing that it no longer needs to retain the records, an institution must maintain records of research misconduct proceedings in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later.

(c) Provision for HHS custody. On request, institutions must transfer custody of or provide copies to HHS, of any institutional record relevant to a research misconduct allegation covered by this part, including the research
§ 93.318 Notifying ORI of special circumstances.

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

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

(b) HHS resources or interests are threatened.

(c) Research activities should be suspended.

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

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

(f) The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.

(g) The research community or public should be informed.

§ 93.319 Institutional standards.

(a) Institutions may have internal standards of conduct different from the HHS standards for research misconduct under this part. Therefore, an institution may find conduct to be actionable under its standards even if the action does not meet this part’s definition of research misconduct.

(b) An HHS finding or settlement does not affect institutional findings or administrative actions based on an institution’s internal standards of conduct.

§ 93.400 General statement of ORI authority.

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

(1) Conducting allegation assessments;

(2) Determining independently if jurisdiction exists under this part in any matter;

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

(4) Recommending that HHS should perform an inquiry or investigation or issue findings and taking all appropriate actions in response to the inquiry, investigation, or findings;

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

(6) Reviewing an institution’s findings and process;

(7) Making a finding of research misconduct; and

(8) Proposing administrative actions to HHS.

(b) Requests for information. ORI may request clarification or additional information, documentation, research records, or evidence from an institution or its members or other persons or sources to carry out ORI’s review.

(c) HHS administrative actions. (1) In response to a research misconduct proceeding, ORI may propose administrative actions against any person to the HHS and, upon HHS approval and final action in accordance with this part, implement the actions.

(2) ORI may propose to the HHS debarring official that a person be suspended or debarred from receiving Federal funds and may propose to other appropriate PHS components the implementation of HHS administrative
§ 93.401 Interaction with other offices and interim actions.

(a) ORI may notify and consult with other offices at any time if it has reason to believe that a research misconduct proceeding may involve that office. If ORI believes that a criminal or civil fraud violation may have occurred, it shall promptly refer the matter to the Department of Justice (DOJ), the HHS Inspector General (OIG), or other appropriate investigative body. ORI may provide expertise and assistance to the DOJ, OIG, PHS offices, other Federal offices, and state or local offices involved in investigating or otherwise pursuing research misconduct allegations or related matters.

(b) ORI may notify affected PHS offices and funding components at any time to permit them to make appropriate interim responses to protect the health and safety of the public, to promote the integrity of the PHS supported research and research process, and to conserve public funds.

(c) The information provided will not be disclosed as part of the peer review and advisory committee review processes, but may be used by the Secretary in making decisions about the award or continuation of funding.
(d) Obtain additional information or materials from the institution, the respondent, complainants, or other persons or sources;

(e) Conduct additional analyses and develop evidence;

(f) Decide whether research misconduct occurred, and if so who committed it;

(g) Make appropriate research misconduct findings and propose HHS administrative actions; and

(h) Take any other actions necessary to complete HHS’ review.

§ 93.404 Findings of research misconduct and proposed administrative actions.

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

(a) Makes findings of research misconduct and proposes and obtains HHS approval of administrative actions based on the record of the research misconduct proceedings and any other information obtained by ORI during its review; or

(b) Recommends that HHS seek to settle the case.

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

(a) When the ORI makes a finding of research misconduct or seeks to impose or enforce HHS administrative actions, other than debarment or suspension, it notifies the respondent in a charge letter. In cases involving a debarment or suspension action, the HHS debarring official issues a notice of proposed debarment or suspension to the respondent as part of the charge letter. The charge letter includes the ORI findings of research misconduct and the basis for them and any HHS administrative actions. The letter also advises the respondent of the opportunity to contest the findings and administrative actions under Subpart E of this part.

(b) The ORI sends the charge letter by certified mail or a private delivery service to the last known address of the respondent or the last known principal place of business of the respondent’s attorney.

§ 93.406 Final HHS actions.

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

§ 93.407 HHS administrative actions.

(a) In response to a research misconduct proceeding, HHS may impose HHS administrative actions that include but are not limited to:

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

(2) Letters of reprimand.

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

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

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

(6) Special review of all requests for PHS funding.

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

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

(9) No participation in any advisory capacity to the PHS.

(10) Adverse personnel action if the respondent is a Federal employee, in compliance with relevant Federal personnel policies and laws.

(11) Suspension or debarment under 45 CFR Part 76, 48 CFR Subparts 9.4 and 309.4, or both.

(b) In connection with findings of research misconduct, HHS also may seek to recover PHS funds spent in support of the activities that involved research misconduct.

(c) Any authorized HHS component may impose, administer, or enforce HHS administrative actions separately or in coordination with other HHS
§ 93.408 Mitigating and aggravating factors in HHS administrative actions.

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

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

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

(c) Impact. Did the misconduct have significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare?

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

(1) Admitting the conduct;
(2) Cooperating with the research misconduct proceedings;
(3) Demonstrating remorse and awareness of the significance and seriousness of the research misconduct; and

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

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

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

(g) Present responsibility. Is the respondent presently responsible to conduct PHS supported research?

(h) Other factors. Other factors appropriate to the circumstances of a particular case.

§ 93.409 Settlement of research misconduct proceedings.

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

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

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

When the final HHS action does not result in a settlement or finding of research misconduct, ORI may:

(a) Provide written notice to the respondent, the relevant institution, the complainant, and HHS officials.

(b) Take any other actions authorized by law.

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

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

(a) Provide final notification of any research misconduct findings and HHS administrative actions to the respondent, the relevant institution, the complainant, and HHS officials. The debarring official may provide a separate notice of final HHS action on any debarment or suspension actions.

(b) Identify publications which require correction or retraction and prepare and send a notice to the relevant journal.

(c) Publish notice of the research misconduct findings.

(d) Notify the respondent’s current employer.

(e) Take any other actions authorized by law.
§ 93.412 Making decisions on institutional noncompliance.

(a) Institutions must foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with PHS supported research.

(b) ORI may decide that an institution is not compliant with this part if the institution shows a disregard for, or inability or unwillingness to implement and follow the requirements of this part and its assurance. In making this decision, ORI may consider, but is not limited to the following factors—

(1) Failure to establish and comply with policies and procedures under this part;
(2) Failure to respond appropriately when allegations of research misconduct arise;
(3) Failure to report to ORI all investigations and findings of research misconduct under this part;
(4) Failure to cooperate with ORI’s review of research misconduct proceedings; or
(5) Other actions or omissions that have a material, adverse effect on reporting and responding to allegations of research misconduct.

§ 93.413 HHS compliance actions.

(a) An institution’s failure to comply with its assurance and the requirements of this part may result in enforcement action against the institution.

(b) ORI may address institutional deficiencies through technical assistance if the deficiencies do not substantially affect compliance with this part.

(c) If an institution fails to comply with its assurance and the requirements of this part, HHS may take some or all of the following compliance actions:

(1) Issue a letter of reprimand.
(2) Direct that research misconduct proceedings be handled by HHS.
(3) Place the institution on special review status.
(4) Place information on the institutional noncompliance on the ORI Web site.

(5) Require the institution to take corrective actions.
(6) Require the institution to adopt and implement an institutional integrity agreement.
(7) Recommend that HHS debar or suspend the entity.
(8) Any other action appropriate to the circumstances.

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

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

DISCLOSURE OF INFORMATION

§ 93.414 Notice.

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

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

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

GENERAL INFORMATION

§ 93.500 General policy.

(a) This subpart provides a respondent an opportunity to contest ORI findings of research misconduct and HHS administrative actions, including debarment or suspension, arising under 42 U.S.C. 289b in connection with PHS supported biomedical and behavioral research, research training, or activities related to that research or research training.

(b) A respondent has an opportunity to contest ORI research misconduct findings and HHS administrative actions under this part, including debarment or suspension, by requesting an
§ 93.501 Opportunity to contest findings of research misconduct and administrative actions.

(a) Opportunity to contest. A respondent may contest ORI findings of research misconduct and HHS administrative actions, including any debarment or suspension action, by requesting a hearing within 30 days of receipt of the charge letter or other written notice provided under §93.405.

(b) Form of a request for hearing. The respondent’s request for a hearing must be—

(1) In writing;

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

(3) Sent by certified mail, or other equivalent (i.e., with a verified method of delivery), to the DAB Chair and ORI.

(c) Contents of a request for hearing. The request for a hearing must—

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

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

(3) Provide detailed, substantive reasons for each denial or challenge;

(4) Identify any legal issues or defenses that the respondent intends to raise during the proceeding; and

(5) Identify any mitigating factors that the respondent intends to prove.

(d) Extension for good cause to supplement the hearing request. (1) After receiving notification of the appointment of the ALJ, the respondent has 10 days to submit a written request to the ALJ for supplementation of the hearing request to comply fully with the requirements of paragraph (c) of this section. The written request must show good cause in accordance with paragraph (d)(2) of this section and set forth the proposed supplementation of the hearing request in whole or in part upon a finding of good cause.

(2) Good cause means circumstances beyond the control of the respondent or respondent’s representative and not attributable to neglect or administrative inadequacy.

Hearing Process

§ 93.502 Appointment of the Administrative Law Judge and scientific expert.

(a) Within 30 days of receiving a request for a hearing, the DAB Chair, in consultation with the Chief Administrative Law Judge, must designate an Administrative Law Judge (ALJ) to determine whether the hearing request should be granted and, if the hearing request is granted, to make recommended findings in the case after a hearing or review of the administrative record in accordance with this part.

(b) The ALJ may retain one or more persons with appropriate scientific or technical expertise to assist the ALJ in evaluating scientific or technical issues related to the findings of research misconduct.

(1) On the ALJ’s or a party’s motion to appoint an expert, the ALJ must give the parties an opportunity to submit nominations. If such a motion is
made by a party, the ALJ must appoint an expert, either:
   (i) The expert, if any, who is agreed upon by both parties and found to be qualified by the ALJ; or,
   (ii) If the parties cannot agree upon an expert, the expert chosen by the ALJ.

(2) The ALJ may seek advice from the expert(s) at any time during the discovery and hearing phases of the proceeding. The expert(s) shall provide advice to the ALJ in the form of a written report or reports that will be served upon the parties within 10 days of submission to the ALJ. That report must contain a statement of the expert’s background and qualifications. Any comment on or response to a report by a party, which may include comments on the expert’s qualifications, must be submitted to the ALJ in accordance with §93.510(c). The written reports and any comment on, or response to them are part of the record. Expert witnesses of the parties may testify on the reports and any comments or responses at the hearing, unless the ALJ determines such testimony to be inadmissible in accordance with §93.519, or that such testimony would unduly delay the proceeding.

(c) No ALJ, or person hired or appointed to assist the ALJ, may serve in any proceeding under this subpart if he or she has any real or apparent conflict of interest, bias, or prejudice that might reasonably impair his or her objectivity in the proceeding.

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

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

§93.503 Grounds for granting a hearing request.

(a) The ALJ must grant a respondent’s hearing request if the ALJ determines there is a genuine dispute over facts material to the findings of research misconduct or proposed administrative actions, including any debarment or suspension action. The respondent’s general denial or assertion of error for each finding of research misconduct, and any basis for the finding, or for the proposed HHS administrative actions in the charge letter, is not sufficient to establish a genuine dispute.

(b) The hearing request must specifically deny each finding of research misconduct in the charge letter, each basis for the finding and each HHS administrative action in the charge letter, or it is considered an admission by the respondent. If the hearing request does not specifically dispute the HHS administrative actions, including any debarment or suspension actions, they are considered accepted by the respondent.

(c) If the respondent does not request a hearing within the 30-day time period prescribed in §93.501(a), the finding(s) and any administrative action(s), other than debarment or suspension actions, become final agency actions at the expiration of the 30-day period. Where there is a proposal for debarment or suspension, after the expiration of the 30-day time period the official record is closed and forwarded to the debarring official for a final decision.

(d) If the ALJ grants the hearing request, the respondent may waive the opportunity for any in-person proceeding, and the ALJ may review and decide the case on the basis of the administrative record. The ALJ may grant a respondent’s request that waiver of the in-person proceeding be conditioned upon the opportunity for respondent to file additional pleadings and documentation. ORI may also supplement the administrative record through pleadings, documents, in-person or telephonic testimony, and oral presentations.
§ 93.504 Grounds for dismissal of a hearing request.

(a) The ALJ must dismiss a hearing request if the respondent—
(1) Does not file the request within 30 days after receiving the charge letter;
(2) Does not raise a genuine dispute over facts or law material to the findings—of research misconduct and any administrative actions, including debarment and suspension actions, in the hearing request or in any extension to supplement granted by the ALJ under §93.501(d);
(3) Does not raise any issue which may properly be addressed in a hearing;
(4) Withdraws or abandons the hearing request; or
(b) The ALJ may dismiss a hearing request if the respondent fails to provide ORI with notice in the form and manner required by §93.501.

§ 93.505 Rights of the parties.

(a) The parties to the hearing are the respondent and ORI. The investigating institution is not a party to the case, unless it is a respondent.
(b) Except as otherwise limited by this subpart, the parties may—
(1) Be accompanied, represented, and advised by an attorney;
(2) Participate in any case-related conference held by the ALJ;
(3) Conduct discovery of documents and other tangible items;
(4) Agree to stipulations of fact or law that must be made part of the record;
(5) File motions in writing before the ALJ;
(6) Present evidence relevant to the issues at the hearing;
(7) Present and cross-examine witnesses;
(8) Present oral arguments;
(9) Submit written post-hearing briefs, proposed findings of fact and conclusions of law, and reply briefs within reasonable time frames agreed upon by the parties or established by the ALJ as provided in §93.522; and
(10) Submit materials to the ALJ and other parties under seal, or in redacted form, when necessary, to protect the confidentiality of any information contained in them consistent with this part, the Privacy Act, the Freedom of Information Act, or other Federal law or regulation.

§ 93.506 Authority of the Administrative Law Judge.

(a) The ALJ assigned to the case must conduct a fair and impartial hearing, avoid unnecessary delay, maintain order, and assure that a complete and accurate record of the proceeding is properly made. The ALJ is bound by all Federal statutes and regulations, Secretarial delegations of authority, and applicable HHS policies and may not refuse to follow them or find them invalid, as provided in paragraph (c)(4) of this section. The ALJ has the authorities set forth in this part.
(b) Subject to review as provided elsewhere in this subpart, the ALJ may—
(1) Set and change the date, time, schedule, and place of the hearing upon reasonable notice to the parties;
(2) Continue or recess the hearing in whole or in part for a reasonable period of time;
(3) Hold conferences with the parties to identify or simplify the issues, or to consider other matters that may aid in the prompt disposition of the proceeding;
(4) Administer oaths and affirmations;
(5) Require the attendance of witnesses at a hearing;
(6) Rule on motions and other procedural matters;
(7) Require the production of documents and regulate the scope and timing of documentary discovery as permitted by this part;
(8) Require each party before the hearing to provide the other party and the ALJ with copies of any exhibits that the party intends to introduce into evidence;
(9) Issue a ruling, after an in camera inspection if necessary, to address the disclosure of any evidence or portion of evidence for which confidentiality is requested under this part or other Federal law or regulation, or which a party submitted under seal;
(10) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;
(11) Examine witnesses and receive evidence presented at the hearing;
(12) Admit, exclude, or limit evidence offered by a party;
(13) Hear oral arguments on facts or law during or after the hearing;
(14) Upon motion of a party, take judicial notice of facts;
(15) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;
(16) Conduct any conference or oral argument in person, by telephone, or by audio-visual communication;
(17) Take action against any party for failing to follow an order or procedure or for disruptive conduct.

(c) The ALJ does not have the authority to—
(1) Enter an order in the nature of a directed verdict;
(2) Compel settlement negotiations;
(3) Enjoin any act of the Secretary; or
(4) Find invalid or refuse to follow Federal statutes or regulations, Secretarial delegations of authority, or HHS policies.

§ 93.507 Ex parte communications.

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

(b) If an ex parte communication occurs, the ALJ will disclose it to the other party and make it part of the record after the other party has an opportunity to comment.

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

§ 93.508 Filing, forms, and service.

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

(2) Submissions are considered filed when they are placed in the mail, transmitted to a private delivery service for the purpose of delivering the item to the ALJ, or submitted in another manner authorized by the ALJ.

(b) Forms. (1) Unless the ALJ provides otherwise, all submissions filed in the proceeding must include an original and two copies. The ALJ may designate the format for copies of non-documentary materials such as videotapes, computer disks, or physical evidence. This provision does not apply to the charge letter or other written notice provided under § 93.405.

(2) Every submission filed in the proceeding must include the title of the case, the docket number, and a designation of the nature of the submission, such as a “Motion to Compel the Production of Documents” or “Respondent’s Proposed Exhibits.”

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

(c) Service. A party filing a submission with the ALJ must, at the time of filing, serve a copy on the other party. Service may be made either to the last known principal place of business of the party’s attorney if the party is represented by an attorney, or, if not, to the party’s last known address. Service may be made by—
(1) Certified mail;
(2) First-class postage prepaid U.S. Mail;
(3) A private delivery service;
(4) Hand-delivery; or
(5) Facsimile or other electronic means if permitted by the ALJ.

(d) Proof of service. Each party filing a document or paper with the ALJ must also provide proof of service at the time of the filing. Any of the following items may constitute proof of service:

(1) A certified mail receipt returned by the postal service with a signature;
(2) An official record of the postal service or private delivery service;
(3) A certificate of service stating the method, place, date of service, and person served that is signed by an individual with personal knowledge of these facts; or
(4) Other proof authorized by the ALJ.
§ 93.509 Computation of time.

(a) In computing any period of time under this part for filing and service or for responding to an order issued by the ALJ, the computation begins with the day following the act or event, and includes the last day of the period unless that day is a Saturday, Sunday, or legal holiday observed by the Federal government, in which case it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government must be excluded from the computation.

(c) Where a document has been filed by placing it in the mail, an additional 5 days must be added to the time permitted for any response. This paragraph does not apply to a respondent’s request for hearing under §93.501.

(d) Except for the respondent’s request for a hearing, the ALJ may modify the time for filing of any document or paper required or authorized under the rules in this part to be filed for good cause shown. When time permits, notice of a party’s request for extension of the time and an opportunity to respond must be provided to the other party.

§ 93.510 Filing motions.

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

(b) All motions must be in writing except for those made during a prehearing conference or at the hearing.

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

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

(e) The ALJ must make a reasonable effort to dispose of all motions promptly, and, whenever possible, dispose of all outstanding motions before the hearing.

§ 93.511 Prehearing conferences.

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

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

1. Identification and simplification of the issues, specification of disputes of fact and their materiality to the ORI findings of research misconduct and any HHS administrative actions, and amendments to the pleadings, including any need for a more definite statement;

2. Stipulations and admissions of fact including the contents, relevancy, and authenticity of documents;

3. Respondent’s waiver of an administrative hearing, if any, and submission of the case on the basis of the administrative record as provided in §93.503(d);

4. Identification of legal issues and any need for briefing before the hearing;

5. Identification of evidence, pleadings, and other materials, if any, that the parties should exchange before the hearing;

6. Identification of the parties’ witnesses, the general nature of their testimony, and the limitation on the number of witnesses and the scope of their testimony;

7. Scheduling dates such as the filing of briefs on legal issues identified in the charge letter or the respondent’s request for hearing, the exchange of witness lists, witness statements, proposed exhibits, requests for the production of documents, and objections to proposed witnesses and documents;

8. Scheduling the time, place, and anticipated length of the hearing; and

9. Other matters that may encourage the fair, just, and prompt disposition of the proceedings.

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

(d) All prehearing conferences will be audio-taped with copies provided to the parties upon request.
(e) Whenever possible, the ALJ must memorialize in writing any oral rulings within 10 days after the prehearing conference.

(f) By 15 days before the scheduled hearing date, the ALJ must hold a final prehearing conference to resolve to the maximum extent possible all outstanding issues about evidence, witnesses, stipulations, motions and all other matters that may encourage the fair, just, and prompt disposition of the proceedings.

§ 93.512 Discovery.

(a) Request to provide documents. A party may only request another party to produce documents or other tangible items for inspection and copying that are relevant and material to the issues identified in the charge letter and in the respondent’s request for hearing. 

(b) Meaning of documents. For purposes of this subpart, the term documents includes information, reports, answers, records, accounts, papers, tangible items, and other data and documentary evidence. This subpart does not require the creation of any document. However, requested data stored in an electronic data storage system must be produced in a form reasonably accessible to the requesting party.

(c) Nondisclosable items. This section does not authorize the disclosure of—

(1) Interview reports or statements obtained by any party, or on behalf of any party, of persons whom the party will not call as witness in its case-in-chief;

(2) Analyses and summaries prepared in conjunction with the inquiry, investigation, ORI oversight review, or litigation of the case; or

(3) Any privileged documents, including but not limited to those protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation.

(d) Responses to a discovery request. Within 30 days of receiving a request for the production of documents, a party must either fully respond to the request, submit a written objection to the discovery request, or seek a protective order from the ALJ. If a party objects to a request for the production of documents, the party must identify each document or item subject to the scope of the request and state the basis of the objection for each document, or any part that the party does not produce.

(1) Within 30 days of receiving any objections, the party seeking production may file a motion to compel the production of the requested documents.

(2) The ALJ may order a party to produce the requested documents for in camera inspection to evaluate the merits of a motion to compel or for a protective order.

(3) The ALJ must compel the production of a requested document and deny a motion for a protective order, unless the requested document is—

(i) Not relevant or material to the issues identified in the charge letter or the respondent’s request for hearing;

(ii) Unduly costly or burdensome to produce;

(iii) Likely to unduly delay the proceeding or substantially prejudice a party;

(iv) Privileged, including but not limited to documents protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation; or

(v) Collateral to issues to be decided at the hearing.

(4) If any part of a document is protected from disclosure under paragraph (d)(3) of this section, the ALJ must redact the protected portion of a document before giving it to the requesting party.

(5) The party seeking discovery has the burden of showing that the ALJ should allow it.

(e) Refusal to produce items. If a party refuses to provide requested documents when ordered by the ALJ, the ALJ may take corrective action, including but not limited to, ordering the noncompliant party to submit written answers under oath to written interrogatories posed by the other party or taking any of the actions at §93.515.

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

(a) By 60 days before the scheduled hearing date, each party must give the ALJ a list of witnesses to be offered during the hearing and a statement describing the substance of their proposed testimony, copies of any prior...
written statements or transcribed testimony of proposed witnesses, a written report of each expert witness to be called to testify that meets the requirements of Federal Rule of Civil Procedure 26(a)(2)(B), and copies of proposed hearing exhibits, including copies of any written statements that a party intends to offer instead of live direct testimony. If there are no prior written statements or transcribed testimony of a proffered witness, the party must submit a detailed factual affidavit of the proposed testimony.

(b) A party may supplement its submission under paragraph (a) of this section until 30 days before the scheduled hearing date if the ALJ determines:

(1) There are extraordinary circumstances; and
(2) There is no substantial prejudice to the objecting party.

(c) The parties must have an opportunity to object to the admission of evidence submitted under paragraph (a) of this section under a schedule set by the ALJ. However, the parties must file all objections before the final prehearing conference.

(d) If a party tries to introduce evidence after the deadlines in paragraph (a) of this section, the ALJ must exclude the offered evidence from the party’s case-in-chief unless the conditions of paragraph (b) of this section are met. If the ALJ admits evidence under paragraph (b) of this section, the objecting party may file a motion to postpone all or part of the hearing to allow sufficient time to prepare and respond to the evidence. The ALJ may not unreasonably deny that motion.

(e) If a party fails to object within the time set by the ALJ and before the final prehearing conference, evidence exchanged under paragraph (a) of this section is considered authentic, relevant and material for the purpose of admissibility at the hearing.

§ 93.514 Amendment to the charge letter.

(a) The ORI may amend the findings of research misconduct up to 30 days before the scheduled hearing.

(b) The ALJ may not unreasonably deny a respondent’s motion to postpone all or part of the hearing to allow sufficient time to prepare and respond to the amended findings.

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

(a) The ALJ may take action against any party in the proceeding for violating an order or procedure or for other conduct that interferes with the prompt, orderly, or fair conduct of the hearing. Any action imposed upon a party must reasonably relate to the severity and nature of the violation or disruptive conduct.

(b) The actions may include—

(1) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;
(2) Striking pleadings, in whole or in part;
(3) Staying the proceedings;
(4) Entering a decision by default;
(5) Refusing to consider any motion or other action not timely filed; or
(6) Drawing the inference that spoliated evidence was unfavorable to the party responsible for its spoliation.

§ 93.516 Standard and burden of proof.

(a) Standard of proof. The standard of proof is the preponderance of the evidence.

(b) Burden of proof. (1) ORI bears the burden of proving the findings of research misconduct. The destruction, absence of, or respondent’s failure to provide research records and destroy them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and the respondent’s conduct constitutes a significant departure from accepted practices of the relevant research community.

(2) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether ORI has carried the burden of proof imposed by
Public Health Service, HHS  

§ 93.519 Admissibility of evidence.

(a) The ALJ decides the admissibility of evidence offered at the hearing.

(b) Except as provided in this part, the ALJ is not bound by the Federal Rules of Evidence (FRE). However, the ALJ may apply the FRE where appropriate (e.g., to exclude unreliable evidence).

§ 93.518 Witnesses.

(a) Except as provided in paragraph (b) of this section, witnesses must give testimony at the hearing under oath or affirmation.

(b) The ALJ may admit written testimony if the witness is available for cross-examination, including prior sworn testimony of witnesses that has been subject to cross-examination. These written statements must be provided to all other parties under §93.513.

(c) The parties may conduct direct witness examination and cross-examination in person, by telephone, or by audio-visual communication as permitted by the ALJ. However, a respondent must always appear in-person to present testimony and for cross-examination.

(d) The ALJ may exercise reasonable control over the mode and order of questioning witnesses and presenting evidence to—

(1) Make the witness questioning and presentation relevant to deciding the truth of the matter; and

(2) Avoid undue repetition or needless consumption of time.

(e) The ALJ must permit the parties to conduct cross-examination of witnesses.

(f) Upon request of a party, the ALJ may exclude a witness from the hearing before the witness' own testimony. However, the ALJ may not exclude—

(1) A party or party representative;

(2) Persons whose presence is shown by a party to be essential to the presentation of its case; or

(3) Expert witnesses.

§ 93.517 The hearing.

(a) The ALJ will conduct an in-person hearing to decide if the respondent committed research misconduct and if the HHS administrative actions, including any debarment or suspension actions, are appropriate.

(b) The ALJ provides an independent de novo review of the ORI findings of research misconduct and the proposed HHS administrative actions. The ALJ does not review the institution's procedures or misconduct findings or ORI's research misconduct proceedings.

(c) A hearing under this subpart is not limited to specific findings and evidence set forth in the charge letter or the respondent's request for hearing. Additional evidence and information may be offered by either party during its case-in-chief unless the offered evidence is—

(1) Privileged, including but not limited to those protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation.

(2) Otherwise inadmissible under §§93.515 or 93.519.

(3) Not offered within the times or terms of §§93.512 and 93.513.

(d) ORI proceeds first in its presentation of evidence at the hearing.

(e) After both parties have presented their cases-in-chief, the parties may offer rebuttal evidence even if not exchanged earlier under §§93.512 and 93.513.

(f) Except as provided in §93.518(c), the parties may appear at the hearing in person or by an attorney of record in the proceeding.

(g) The hearing must be open to the public, unless the ALJ orders otherwise for good cause shown. However, even if the hearing is closed to the public, the ALJ may not exclude a party or party representative, persons whose presence a party shows to be essential to the presentation of its case, or expert witnesses.
§ 93.520 The record.

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

(b) The exhibits, transcripts of testimony, any other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ.

(c) For good cause shown, the ALJ may order appropriate redactions made to the record at any time.

(d) The DAB may return original research records and other similar items to the parties or awardee institution upon request after final HHS action, unless under judicial review.

§ 93.521 Correction of the transcript.

(a) At any time, but not later than the time set for the parties to file their post-hearing briefs, any party may file a motion proposing material corrections to the transcript or recording.

(b) At any time before the filing of the ALJ’s decision and after consideration of any corrections proposed by the parties, the ALJ may issue an order making any requested corrections in the transcript or recording.

§ 93.522 Filing post-hearing briefs.

(a) After the hearing and under a schedule set by the ALJ, the parties may file post-hearing briefs, and the ALJ may allow the parties to file reply briefs.

(b) The parties may include proposed findings of fact and conclusions of law in their post-hearing briefs.
§ 93.523 The Administrative Law Judge's ruling.

(a) The ALJ shall issue a ruling in writing setting forth proposed findings of fact and any conclusions of law within 60 days after the last submission by the parties in the case. If unable to meet the 60-day deadline, the ALJ must set a new deadline and promptly notify the parties, the Assistant Secretary for Health and the debarring official, if debarment or suspension is under review. The ALJ shall serve a copy of the ruling upon the parties and the Assistant Secretary for Health.

(b) The ruling of the ALJ constitutes a recommended decision to the Assistant Secretary for Health. The Assistant Secretary for Health may review the ALJ's recommended decision and modify or reject it in whole or in part after determining it, or the part modified or rejected, to be arbitrary and capricious or clearly erroneous. The Assistant Secretary for Health shall notify the parties of an intention to review the ALJ's recommended decision within 30 days after service of the recommended decision. If that notification is not provided within the 30-day period, the ALJ's recommended decision shall become final. An ALJ decision that becomes final in that manner or a decision by the Assistant Secretary for Health modifying or rejecting the ALJ's recommended decision in whole or in part is the final HHS action, unless debarment or suspension is an administrative action recommended in the decision.

(c) If a decision under § 93.523(b) results in a recommendation for debarment or suspension, the Assistant Secretary for Health shall serve a copy of the decision upon the debarring official and the decision shall constitute findings of fact to the debarring official in accordance with 45 CFR 76.845(c). The decision of the debarring official on debarment or suspension is the final HHS decision on those administrative actions.