

§ 93.25

42 CFR Ch. I (10–1–06 Edition)

93.306 Using a consortium or person for re-
search misconduct proceedings.

THE INSTITUTIONAL INQUIRY

93.307 Institutional inquiry.
93.308 Notice of the results of the inquiry.
93.309 Reporting to ORI on the decision to
initiate an investigation.

THE INSTITUTIONAL INVESTIGATION

93.310 Institutional investigation.
93.311 Investigation time limits.
93.312 Opportunity to comment on the in-
vestigation report.
93.313 Institutional investigation report.
93.314 Institutional appeals.
93.315 Notice to ORI of institutional find-
ings and actions.
93.316 Completing the research misconduct
process.

OTHER INSTITUTIONAL RESPONSIBILITIES

93.317 Retention and custody of the re-
search misconduct proceeding record.
93.318 Notifying ORI of special cir-
cumstances.
93.319 Institutional standards.

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

GENERAL INFORMATION

93.400 General statement of ORI authority.
93.401 Interaction with other offices and in-
terim actions.

RESEARCH MISCONDUCT ISSUES

93.402 ORI allegation assessments.
93.403 ORI review of research misconduct
proceedings.
93.404 Findings of research misconduct and
proposed administrative actions.
93.405 Notifying the respondent of findings
of research misconduct and HHS admin-
istrative actions.
93.406 Final HHS actions.
93.407 HHS administrative actions.
93.408 Mitigating and aggravating factors in
HHS administrative actions.
93.409 Settlement of research misconduct
proceedings.
93.410 Final HHS action with no settlement
or finding of research misconduct.
93.411 Final HHS action with a settlement
or finding of misconduct.

INSTITUTIONAL COMPLIANCE ISSUES

93.412 Making decisions on institutional
noncompliance.
93.413 HHS compliance actions.

DISCLOSURE OF INFORMATION

93.414 Notice.

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

GENERAL INFORMATION

93.500 General policy.
93.501 Opportunity to contest findings of re-
search misconduct and administrative
actions.

HEARING PROCESS

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

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

SOURCE: 70 FR 28384, May 17, 2005, unless
otherwise noted.

§ 93.25 Organization of this part.

This part is subdivided into five sub-
parts. Each subpart contains informa-
tion related to a broad topic or specific
audience with special responsibilities
as shown in the following table.

Table with 2 columns: In subpart . . . and You will find provisions related to . . . . Rows A through D describe the content of each subpart.

In subpart . . .	You will find provisions related to . . .
E .....	Information on how to contest ORI research misconduct findings and HHS administrative actions.

**§ 93.50 Special terms.**

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

**Subpart A—General**

**§ 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)(1) This part applies to allegations of research misconduct and research misconduct involving:

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

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

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

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

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

(2) This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for