Public Health Service, HHS

§ 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>In subpart . . .</th>
<th>You will find provisions related to . . .</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>

§ 93.25 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 research misconduct and administrative actions.

HEARING PROCESS

93.502 Appointment of the Administrative Law Judge and scientific expert.
93.503 Grounds for granting a hearing request.
93.504 Grounds for dismissal of a hearing request.
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 ruling.


SOURCE: 70 FR 26384, May 17, 2005, unless otherwise noted.
§ 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) 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