

§ 93.401

actions within the components' authorities.

(d) *ORI assistance to institutions.* At any time, ORI may provide information, technical assistance, and procedural advice to institutional officials as needed regarding an institution's participation in research misconduct proceedings.

(e) *Review of institutional assurances.* ORI may review institutional assurances and policies and procedures for compliance with this part.

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

§ 93.401 Interaction with other 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.

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RESEARCH MISCONDUCT ISSUES

§ 93.402 ORI allegation assessments.

(a) When ORI receives an allegation of research misconduct directly or becomes aware of an allegation or apparent instance of research misconduct, it may conduct an initial assessment or refer the matter to the relevant institution for an assessment, inquiry, or other appropriate actions.

(b) If ORI conducts an assessment, it considers whether the allegation of research misconduct appears to fall within the definition of research misconduct, appears to involve PHS supported biomedical or behavior research, research training or activities related to that research or research training, as provided in § 93.102, and whether it is sufficiently specific so that potential evidence may be identified and sufficiently substantive to warrant an inquiry. ORI may review all readily accessible, relevant information related to the allegation.

(c) If ORI decides that an inquiry is warranted, it forwards the matter to the appropriate institution or HHS component.

(d) If ORI decides that an inquiry is not warranted it will close the case and forward the allegation in accordance with paragraph(e) of this section.

(e) ORI may forward allegations that do not fall within the jurisdiction of this part to the appropriate HHS component, Federal or State agency, institution, or other appropriate entity.

§ 93.403 ORI review of research misconduct proceedings.

ORI may conduct reviews of research misconduct proceedings. In conducting its review, ORI may—

(a) Determine whether there is HHS jurisdiction under this part;

(b) Consider any reports, institutional findings, research records, and evidence;

(c) Determine if the institution conducted the proceedings in a timely and fair manner in accordance with this part with sufficient thoroughness, objectivity, and competence to support the conclusions;

(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