

§ 93.318

records and evidence, to perform forensic or other analyses or as otherwise needed to conduct an HHS inquiry or investigation or for ORI to conduct its review or to present evidence in any proceeding under subparts D and E of this part.

§ 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.

42 CFR Ch. I (10–1–14 Edition)

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

GENERAL INFORMATION

§ 93.400 General statement of ORI authority.

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

- (1) Conducting allegation assessments;
- (2) Determining independently if 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 debarbing 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