

§ 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 re-

search 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.

§ 93.301 Institutional assurances.

- (a) *General policy.* An institution with PHS supported biomedical or behavioral research, research training or activities related to that research or research training must provide PHS with an assurance of compliance with this part, satisfactory to the Secretary.