



Policy Title: Research Misconduct & Responding to Allegations

Category: Research

Sponsor: Vice President for Research

Effective Date: 9.15.08

INTRODUCTION AND PURPOSE. Federal regulations state that the University has the affirmative duty to protect federal funds from misuse by ensuring the integrity of federally sponsored work and that the University has primary responsibility for responding to and reporting allegations of research misconduct. This policy is intended to implement those federal regulations and also apply its concepts to all research, regardless of sponsor.

SCOPE AND APPLICABILITY. This policy applies to all research, regardless of sponsor.

POLICY STATEMENTS.

The University recognizes that research misconduct, regardless of its sponsor, is contrary to the interests of the University, contrary to the health and safety of the public, contrary to the integrity of research, and contrary to the conservation of funds entrusted to the University.

The Vice President for Research is delegated authority to and is responsible for developing and implementing written policies and procedures, as well as fostering a research environment, that

- * promotes the responsible conduct of research, research training, and activities related to that research or research training,
- * discourages research misconduct,
- * deals promptly and in a thorough, competent, objective and fair manner with allegations or evidence of possible research misconduct, and
- * complies with and applies the concepts of 42 CFR §§ 93.300, 93.302, and 93.304 (see attachment) to all research, regardless of sponsor.

The Vice President for Research will periodically inform the University's research members of the contents of the University's policies and procedures related to research misconduct and of the requirement and expectation of compliance with those policies and procedures.

The Vice President for Research will ensure an annual report is filed with ORI that contains information specified by ORI about the University's compliance with 42 CFR Part 93.

DEFINITIONS.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. *Fabrication* is making up data or results and recording or reporting them. *Falsification* is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.

§ 93.300 General responsibilities for compliance.

Institutions under this part must—

(a) Have written policies and procedures for addressing allegations of research 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.

§ 93.302 Institutional compliance with assurances.

(a) *Compliance with assurance.* ORI considers an institution in compliance with its assurance if the institution—

(1) Establishes policies and procedures according to this part, keeps them in compliance with this part, and upon request, provides them to ORI, other HHS personnel, and members of the public;

(2) Takes all reasonable and practical specific steps to foster research integrity consistent with § 93.300, including—

(i) Informs the institution's research members participating in or otherwise involved with PHS supported biomedical or behavioral research, research training or activities related to that research or research training, including those applying for support from any PHS funding component, about its policies and procedures for responding to allegations of research misconduct, and the institution's commitment to compliance with the policies and procedures; and

(ii) Complies with its policies and procedures and each specific provision of this part.

(b) *Annual report.* An institution must file an annual report with ORI which contains information specified by ORI on the institution's compliance with this part.

(c) *Additional information.* Along with its assurance or annual report, an institution must send ORI such other aggregated information as ORI may request on the institution's research misconduct proceedings covered by this part and the institution's compliance with the requirements of this part.

§ 93.304 Institutional policies and procedures.

Institutions seeking an approved assurance must have written policies and procedures for addressing research misconduct that include the following—

(a) Consistent with § 93.108, protection of the confidentiality of respondents, complainants, and research subjects identifiable from research records or evidence;

(b) A thorough, competent, objective, and fair response to allegations of research misconduct consistent with and within the time limits of this part, 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) Notice to the respondent, consistent with and within the time limits of this part;

(d) Written notice to ORI of any decision to open an investigation on or before the date on which the investigation begins;

(e) Opportunity for the respondent to provide written comments on the institution's inquiry report;

(f) Opportunity for the respondent to provide written comments on the draft report of the investigation, and provisions for the institutional investigation committee to consider and

address the comments before issuing the final report;

(g) Protocols for handling the research record and evidence, including the requirements of § 93.305;

(h) Appropriate interim institutional actions to protect public health, Federal funds and equipment, and the integrity of the PHS supported research process;

(i) Notice to ORI under § 93.318 and notice of any facts that may be relevant to protect public health, Federal funds and equipment, and the integrity of the PHS supported research process;

(j) Institutional actions in response to final findings of research misconduct;

(k) All reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made;

(l) All reasonable and practical efforts to protect or restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against these complainants, witnesses, and committee members; and

(m) Full and continuing cooperation with ORI during its oversight review under Subpart D of this part or any subsequent administrative hearings or appeals under Subpart E of this part. This includes providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.