Public Health Service Policies on Research Misconduct

Warning: this abridged list is an unofficial interpretation of the regulations. For a complete understanding of the regulation consult the final rule (42 CFR Par 93) in the federal register

Research environment. Institutions must

- Foster a research environment that promotes:
  - Responsible conduct of research
  - Research training
  - Activities related to research and research training
- Discourage research misconduct
- Deal promptly with allegations or evidence of possible research misconduct
- Inform scientific and administrative staff of the
  - Policies and procedures for handling allegations of misconduct
  - Importance of compliance with those policies and procedures
  - Institution's commitment to compliance with the policies and procedures.

Assurance. Institutions must:

- Have approved assurances of compliance and required renewals on file at ORI to receive PHS funding.
- Have written policies and procedures in compliance with PHS regulation for inquiring into and investigating allegations of research misconduct that comply with PHS regulation, including protocols for:
  - Handling the research record and evidence;
  - Protecting public health, federal funds and equipment
  - Maintaining the integrity of the research process
- Comply with its own policies and procedures and requirements for addressing allegations of research misconduct.
- Upon request, provide their policies and procedures on research misconduct to ORI, authorized HHS personnel, and members of the public.
- Submit to ORI an annual report including but not limited to aggregated information regarding research misconduct proceedings

Additional PHS requirements for institutional compliance with assurance are described in 42 CFR 93 and should be consulted.

Allegations. Institutions must:

- Respond promptly to each allegation of research misconduct in a thorough, competent, objective, and fair manner

Confidentiality. Institutions must

- Provide confidentiality to the extent possible to all respondents, complainants, and research participants identifiable from research records or evidence

Reputation. Institutions must:

- Make all reasonable and practical efforts to protect or restore the position and reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

Retaliation. Institutions must:

- Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses and committee members and protect and counter any potential or actual retaliation against them by others.

Cooperation. Institutions must:

- Ensure that each respondent and persons involved in research misconduct proceedings cooperates, including providing all information, records, and evidence.
- Cooperate fully and continually with HHS/ORI during any research misconduct proceeding, administrative hearing or appeal, oversight review, or compliance review, including 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.
- Assist in administering and enforcing any HHS administrative actions imposed on its institutional members

Sequestering data. Institutions must:
- When it learns of possible research misconduct, promptly take custody of all research records and evidence and then inventory and sequester them.
- Take custody of additional research records or evidence discovered during the course of a research misconduct proceeding.
- Maintain all records in custody until ORI requests them and HHS takes final action
- Where appropriate, give respondent copies of, or reasonable supervised access to, the research record.
- Maintain detailed documentation of an inquiry
- Archive all documentation of an inquiry

Inquires. Institutions must:
- Notify respondent in writing on or before beginning an inquiry
- Provide respondent an opportunity to review and attach any comments to the inquiry report.
- Keep sufficiently detailed documentation of inquiries for at least 7 years after an inquiry has ended to permit later assessment by ORI of reasons why decisions were made to forego investigations.
- Provide the inquiry report and additional information specified in §93.309 to ORI within 30 days of finding that an investigation is warranted.

Investigations. Institutions must:
- Ensure persons involved in misconduct proceedings do not have unresolved personal, professional, or financial conflicts of interests with complainants, respondents, or witnesses
- Notify respondent whether the inquiry found that an investigation is warranted
- Notify the respondent of allegations of research misconduct before beginning an investigation.
- Notify ORI in writing on or before opening an investigation.
- Record or transcribe all witness interviews, provide the recording or transcript to the witness for correction, and include the recording or transcript in the record of the investigation.
- Provide respondent an opportunity to review and write comments on the draft investigation report for the committee to consider and address before issuing the final report.
- At the conclusion of the institutional investigation, submit to ORI: the investigation report (with attachments and appeals), final institutional actions, the institutional finding, and any institutional administrative actions.
- Contact ORI before closing the case and submitting its final report if it plans to end an inquiry or investigation before completion for any reason must.

Timeliness. Institutions must:
- Initiate an immediate inquiry into an allegation to determine during a period of information-gathering generally not to exceed 60 days, if the allegation warrants an investigation.
- Begin an Investigation within 30 days after determining an investigation is warranted and complete it within 120 days. If unable to complete the investigation in 120 days, submit a written request for an extension from ORI.

Appeals. Institutions must:
- If unable to complete any institutional appeals process relating to the institutional finding of misconduct within 120 days from the appeal's filing, request an extension in writing and provide an explanation.

Transparency
- HHS administrative hearings must be open to the public

Jurisdiction
- In cases involving more than one agency… HHS will seek to resolve allegations jointly

Sanctions

- Appropriate sanctions must be Imposed on individuals when an allegation of misconduct is substantial