Jaeb Center for Health Research

Institutional Policies and Procedures on Research Misconduct

January 2012

INSTITUTIONAL POLICIES AND PROCEDURES ON RESEARCH MISCONDUCT

These provisions meet the minimum requirements in 42 Code of Federal Regulations (CFR) Section 93.304 (copy on file).

The provisions appear in approximately the same order as the requirements for institutional policies and procedures in Section 93.304. The term **"shall"** is used in the provisions for those actions that are required by the final rule. The terms **"will" or "should"** refer to those actions that would be appropriate to carry out the intent of the final rule and which do not contravene the provisions of the final rule.

The provisions refer to various sections of the final rule, instead of repeating all the requirements of those sections, and state that those sections are attached to the policies and procedures. Because an important function of an institution's policies and procedures on research misconduct is to inform the research members of the institution as to how the institution will respond to allegations of research misconduct in accordance with the final rule (see Section 93.302(a)(2)(i)), the policies and procedures include a copy of all of the provisions of the final rule, not just those that are cross-referenced.

Confidentiality

To the extent allowed by law, we shall maintain the identity of respondents and complainants securely and confidentially and shall not disclose any identifying information, except to:

(1) those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and
(2) ORI as it conducts its review of the research misconduct proceeding and any subsequent proceedings.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the research misconduct proceeding.

Research Misconduct Proceedings–Criteria, Reports, and Time Limitations

Promptly after receiving an allegation of research misconduct, defined as a disclosure of possible research misconduct through any means of communication, we shall assess the allegation to determine if:

(1) it meets the definition of research misconduct in 42 CFR Section 93.103 (copy on file);
(2) it involves either the PHS supported research, applications for PHS research support, or research records specified in 42 CFR Section 93.102(b) (copy on file); and,
(3) the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

If it is determined that an inquiry (i.e., an initial review of the evidence to determine if the criteria for conducting an investigation have been met) is warranted, we shall complete the inquiry, including preparation of the inquiry report and giving the respondent a reasonable opportunity to comment on it, within 60 calendar days of its initiation, unless the circumstances warrant a longer period. If the inquiry takes longer than 60 days to complete, we shall include documentation of the reasons for the delay in the inquiry record. The inquiry report shall contain the following information:

(1) The name and position of the respondent(s);
(2) A description of the allegations of research misconduct;
(3) The PHS support involved, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;
(4) The basis for recommending that the alleged actions warrant an investigation; and
(5) Any comments on the report by the respondent or the complainant.

The Director of Research Administration will make a written determination of whether an investigation is warranted. If the inquiry results in a determination that an investigation is warranted, we shall begin the investigation within 30 calendar days of that determination and, on or before the date on which the investigation begins, send the inquiry report and the written determination to the ORI. We shall use our best efforts to complete the investigation within 120 calendar days of the date on which it began, including conducting the investigation, preparing the report of findings, providing the draft report for comment, and sending the final report to ORI.

If it becomes apparent that we cannot complete the investigation within that period, we shall promptly request an extension in writing from ORI. This time period does not apply to separate termination hearings.

In conducting all investigations, we shall:

(1) Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations;
(2) Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of investigation;
(3) Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion; and
(4) Otherwise comply with the requirements for conducting an investigation in 42 CFR Section 93.310 (copy on file).

We shall prepare the draft and final institutional investigation reports in writing and provide the draft report to the respondent(s) for comment as provided elsewhere in these policies and procedures and 42 CFR Section 93.312 (copy on file). Comments

are due 30 days after the respondent(s) receive the draft investigation report. The final investigation report shall:

(1) Describe the nature of the allegations of research misconduct;
(2) Describe and document the PHS support, including, for example any grant numbers, grant applications, contracts, and publications listing PHS support;
(3) Describe the specific allegations of research misconduct considered in the investigation;
(4) Include the institutional policies and procedures under which the investigation was conducted, if not already provided to ORI;
(5) Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody, but not reviewed. **The report should also describe any relevant records and evidence not taken into custody and explain why.**
(6) Provide a finding as to whether research misconduct did or did not occur for each separate allegation of research misconduct identified during the investigation, and if misconduct was found, (i) identify it as falsification, fabrication, or plagiarism and whether it was intentional, knowing, or in reckless disregard, (ii) summarize the facts and the analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent and any evidence that rebuts the respondent's explanations, (iii) identify the specific PHS support; (iv) identify any publications that need correction or retraction; (v) identify the person(s) responsible for the misconduct, and (vi) list any current support or known applications or proposals for support that the respondent(s) has pending with non-PHS Federal agencies; and
(7) Include and consider any comments made by the respondent and complainant on the draft investigation report.

We shall maintain and provide to ORI upon request all relevant research records and records of our research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

Ensuring a Fair Research Misconduct Proceeding

We shall take all reasonable steps to ensure an impartial and unbiased research misconduct proceeding to the maximum extent practicable. We shall select those conducting the inquiry or investigation on the basis of scientific expertise that is pertinent to the matter and, prior to selection, we shall screen them for any unresolved personal, professional, or financial conflicts of interest with the respondent, complainant, potential witnesses, or others involved in the matter. Any such conflict which a reasonable person would consider to demonstrate potential bias shall disqualify the individual from selection.

Notice to Respondent

During the research misconduct proceeding, we shall provide the following notifications to all identified respondents:

- Initiation of Inquiry. Prior to or at the beginning of the inquiry, we shall provide the

respondent(s) written notification of the inquiry and contemporaneously sequester all research records and other evidence needed to conduct the research misconduct proceeding. If the inquiry subsequently identifies additional respondents, they shall be promptly notified in writing.

- Comment on Inquiry Report. We shall provide the respondent(s) an opportunity to comment on the inquiry report in a timely fashion so that any comments can be attached to the report.
- Results of the Inquiry. We shall notify the respondent(s) of the results of the inquiry and attach to the notification copies of the inquiry report and these institutional policies and procedures for the handling of research misconduct allegations.
- Initiation of Investigation. Within a reasonable time after our determination that an investigation is warranted, but not later than 30 calendar days after that determination, we shall notify the respondent(s) in writing of the allegations to be investigated. We shall give respondent(s) written notice of any new allegations within a reasonable time after determining to pursue allegations not addressed in the inquiry or in the initial notice of the investigation.
- Scheduling of Interview. We will notify the respondent sufficiently in advance of the scheduling of his/her interview in the investigation so that the respondent may prepare for the interview and arrange for the attendance of legal counsel, if the respondent wishes.
- Comment on Draft Investigation Report. We shall give the respondent(s) a copy of the draft investigation report, and concurrently, a copy of, or supervised access to, the evidence on which the report is based and notify the respondent(s) that any comments must be submitted within 30 days of the date on which he/she received the draft report. We shall ensure that these comments are included and considered in the final investigation report.

Notifying ORI of the Decision to Open an Investigation and of Institutional Findings and Actions Following the Investigation.

On or before the date on which the investigation begins (the investigation must begin within 30 calendar days of our finding that an investigation is warranted), we shall provide ORI with the written finding by the Director of Research Administration and a copy of the inquiry report containing the information required by 42 CFR Section 93.309(a) (copy on file).

Upon a request from ORI we shall promptly send them:
(1) a copy of our institutional policies and procedures under which the inquiry was conducted;
(2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
(3) the charges for the investigation to consider.

We shall promptly provide to ORI after the investigation:
(1) A copy of the investigation report and all attachments;

(2) A statement of whether the institution found research misconduct and, if so, who committed it;
(3) A statement of whether the institution accepts the findings in the investigation report; and
(4) A description of any pending or completed administrative actions against the respondent.

Notification to IRB, FDA and OHRP

We will provide notification to the JCHR Institutional Review Board, the Food and Drug Administration and the Office of Human Research Protection as and when appropriate during the course of the inquiry and any subsequent investigation.

Maintenance and Custody of Research Records and Evidence

We shall take the following specific steps to obtain, secure, and maintain the research records and evidence pertinent to the research misconduct proceeding:

(1) **Either before or when we notify the respondent of the allegation**, we shall promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory those materials, and sequester them in a secure manner, except in those cases where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
(2) Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records.
(3) Undertake all reasonable and practical efforts to take custody of additional research records and evidence discovered during the course of the research misconduct proceeding, including at the inquiry and investigation stages, or if new allegations arise, subject to the exception for scientific instruments in (1) above.
(4) We shall maintain all records of the research misconduct proceeding, as defined in 42 CFR Section 93.317(a) (copy on file), for 7 years after completion of the proceeding, or any ORI or HHS proceeding under Subparts D and E of 42 CFR Part 93 (copies attached), whichever is later, unless we have transferred custody of the records and evidence to HHS, or ORI has advised us that we no longer need to retain the records.

Interim Protective Actions

At any time during a research misconduct proceeding, we shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the PHS supported research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

Notifying ORI of Special Circumstances that may Require Protective Actions

At any time during a research misconduct proceeding, we shall notify ORI immediately if we have reason to believe that any of the following conditions exist:

(1) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
(2) HHS resources or interests are threatened.
(3) Research activities should be suspended.
(4) There is a reasonable indication of violations of civil or criminal law.
(5) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
(6) We believe 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.
(7) We believe the research community or public should be informed.

Institutional Actions in Response to Final Findings of Research Misconduct

We will cooperate with and assist ORI and HHS, as needed, to carry out any administrative actions HHS may impose as a result of a final finding of research misconduct by HHS.

Restoring Reputations

Respondents. We shall undertake all reasonable, practical, and appropriate efforts to protect and restore the reputation of any person alleged to have engaged in research misconduct, but against whom no finding of research misconduct was made, if that person or his/her legal counsel or other authorized representative requests that we do so.

Complainants, Witnesses, and Committee Members. We shall undertake all reasonable and practical efforts to protect and restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against those complainants, witnesses and committee members.

Cooperation with ORI

We shall cooperate fully and on a continuing basis with ORI during its oversight reviews of this institution and its research misconduct proceedings and during the process under which the respondent may contest ORI findings of research misconduct and proposed HHS administrative actions. This includes providing, as necessary to develop a complete record of relevant evidence, all witnesses, research records, and other evidence under our control or custody, or in the possession of, or accessible to, all persons that are subject to our authority.

Reporting to ORI

We will report to ORI any proposed settlements, admissions of research misconduct, or institutional findings of misconduct that arise at any stage of a misconduct proceeding, including the allegation and inquiry stages.