

§93.310

42 CFR Ch. I (10–1–06 Edition)

(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.

(b) The institution must provide the following information to ORI on request—

(1) The 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.

(c) *Documentation of decision not to investigate.* Institutions must keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the institution decided not to conduct an investigation. Consistent with §93.317, institutions must keep these records in a secure manner for at least 7 years after the termination of the inquiry, and upon request, provide them to ORI or other authorized HHS personnel.

(d) *Notification of special circumstances.* In accordance with §93.318, institutions must notify ORI and other PHS agencies, as relevant, of any special circumstances that may exist.

THE INSTITUTIONAL INVESTIGATION

§93.310 Institutional investigation.

Institutions conducting research misconduct investigations must:

(a) *Time.* Begin the investigation within 30 days after determining that an investigation is warranted.

(b) *Notice to ORI.* Notify the ORI Director of the decision to begin an investigation on or before the date the investigation begins and provide an inquiry report that meets the requirements of §93.307 and §93.309.

(c) *Notice to the respondent.* Notify the respondent in writing of the allegations within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins. The institution must give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue

allegations not addressed during the inquiry or in the initial notice of investigation.

(d) *Custody of the records.* To the extent they have not already done so at the allegation or inquiry stages, take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that 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. Whenever possible, the institution must take custody of the records—

(1) Before or at the time the institution notifies the respondent; and

(2) Whenever additional items become known or relevant to the investigation.

(e) *Documentation.* 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.

(f) *Ensuring a fair investigation.* Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation.

(g) *Interviews.* 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 the investigation.

(h) *Pursue leads.* 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.

§ 93.311 Investigation time limits.

(a) *Time limit for completing an investigation.* An institution must complete all aspects of an investigation within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment in accordance with § 93.312, and sending the final report to ORI under § 93.315.

(b) *Extension of time limit.* If unable to complete the investigation in 120 days, the institution must ask ORI for an extension in writing.

(c) *Progress reports.* If ORI grants an extension, it may direct the institution to file periodic progress reports.

§ 93.312 Opportunity to comment on the investigation report.

(a) The institution must give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The comments of the respondent on the draft report, if any, must be submitted within 30 days of the date on which the respondent received the draft investigation report.

(b) The institution may provide the complainant a copy of the draft investigation report or relevant portions of that report. The comments of the complainant, if any, must be submitted within 30 days of the date on which the complainant received the draft investigation report or relevant portions of it.

§ 93.313 Institutional investigation report.

The final institutional investigation report must be in writing and include:

(a) *Allegations.* Describe the nature of the allegations of research misconduct.

(b) *PHS support.* Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.

(c) *Institutional charge.* Describe the specific allegations of research mis-

conduct for consideration in the investigation.

(d) *Policies and procedures.* If not already provided to ORI with the inquiry report, include the institutional policies and procedures under which the investigation was conducted.

(e) *Research records and evidence.* Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.

(f) *Statement of findings.* For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so—

(1) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;

(2) Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;

(3) Identify the specific PHS support;

(4) Identify whether any publications need correction or retraction;

(5) Identify the person(s) responsible for the misconduct; and

(6) List any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies.

(g) *Comments.* Include and consider any comments made by the respondent and complainant on the draft investigation report.

(h) *Maintain and provide records.* Maintain and provide to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

§ 93.314 Institutional appeals.

(a) While not required by this part, if the institution's procedures provide for an appeal by the respondent that could result in a reversal or modification of the findings of research misconduct in the investigation report, the institution must complete any such appeal within 120 days of its filing. Appeals from personnel or similar actions that