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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

would not result in a reversal or modification of the findings of research misconduct are excluded from the 120-day limit.

- (b) If unable to complete any appeals within 120 days, the institution must ask ORI for an extension in writing and provide an explanation for the request.
- (c) ORI may grant requests for extension for good cause. If ORI grants an extension, it may direct the institution to file periodic progress reports.

§ 93.315 Notice to ORI of institutional findings and actions.

The institution must give ORI the following:

- (a) Investigation Report. Include a copy of the report, all attachments, and any appeals.
- (b) Final institutional action. State whether the institution found research misconduct, and if so, who committed the misconduct.
- (c) Findings. State whether the institution accepts the investigation's findings.
- (d) Institutional administrative actions. Describe any pending or completed administrative actions against the respondent.

§ 93.316 Completing the research misconduct process.

- (a) ORI expects institutions to carry inquiries and investigations through to completion and to pursue diligently all significant issues. An institution must notify ORI in advance if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage, which must be reported to ORI under § 93.315.
- (b) After consulting with the institution on its basis for closing a case under paragraph (a) of this section, ORI may conduct an oversight review of the institution's handling of the case and take appropriate action including:
- (1) Approving or conditionally approving closure of the case;

- (2) Directing the institution to complete its process;
- (3) Referring the matter for further investigation by HHS; or,
 - (4) Taking a compliance action.

OTHER INSTITUTIONAL RESPONSIBILITIES

§ 93.317 Retention and custody of the research misconduct proceeding record.

- (a) Definition of records of research misconduct proceedings. As used in this section, the term "records of research misconduct proceedings" includes:
- (1) The records that the institution secures for the proceeding pursuant to §§93.305, 93.307(b) and 93.310(d), except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained:
- (2) The documentation of the determination of irrelevant or duplicate records:
- (3) The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate as required by \$93.309(d):
- (4) The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted pursuant to §93.310(g); and
- (5) The complete record of any institutional appeal covered by §93.314.
- (b) Maintenance of record. Unless custody has been transferred to HHS under paragraph (c) of this section, or ORI has advised the institution in writing that it no longer needs to retain the records, an institution must maintain records of research misconduct proceedings in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later.
- (c) Provision for HHS custody. On request, institutions must transfer custody of or provide copies to HHS, of any institutional record relevant to a research misconduct allegation covered by this part, including the research