

Requirements for Institutional Policies and Procedures on Research Misconduct Under the New PHS Policies on Research Misconduct, 42 CFR Part 93

Effective Date: The new final rule on research misconduct is published at *70 Federal Register (FR)* 28370 (May 17, 2005) (subsequently to be codified at 42 CFR Part 93) and became effective on June 16, 2005. **The final rule is also posted on the ORI home page (see top links) at <http://ori.dhhs.gov/>** Institutions that have a research misconduct assurance should update their policies and procedures to be in compliance with the new rule as soon as practical.

Informational Assistance for Institutions: In order to assist institutions in meeting their obligations under the new final rule, the materials that follow: (1) summarize the requirements for institutional policies and procedures in Section 93.304; (2) set forth sample provisions meeting the requirements of the new rule that institutions can include in their policies and procedures; and (3) include endnotes that further explain those requirements and compare them to the old rule.

The endnotes are not intended for inclusion in institutional policies and procedures. Rather, they provide explanatory and background information appropriate for use by institutional research integrity officers (RIOS), compliance officers, institutional legal counsel, and other institutional officials who are responsible for their institutions' compliance with the new final rule.

Requirements for Institutional Policies and Procedures: These requirements are set forth at Section 93.304 of the new rule. Under that section the policies and procedures of the institution must provide for:

Protection of the confidentiality of respondents, complainants, and research

- subjects identifiable from research records or evidence, consistent with Section 93.108.¹
- **A thorough, competent, objective, and fair response** to allegations of research misconduct consistent with, and within the time limits of the final rule, 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.²
- Notice to the respondent consistent with and within the time limits of the final rule.³
- Written notice to ORI of any decision to open an investigation on or before the date on which the investigation begins.⁴
- An opportunity for the respondent to provide written comments on the institution's inquiry report.⁵

An 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.⁶

Protocols for handling the research records and evidence, including the requirements of Section 93.305.⁷

Appropriate interim institutional actions to protect public health, Federal funds and equipment, and the integrity of the PHS supported research process.⁸

Notice to ORI under Section 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.⁹

Institutional actions in response to final findings of research misconduct.¹⁰

All reasonable and practical efforts, if requested and appropriate, to protect and

- restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.¹¹ **(The institution may make findings of research misconduct or other breaches of research integrity under internal policies and standards adopted by the institution even if no misconduct or other breaches of integrity are found under the HHS regulation.)**

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 those complainants, witnesses and committee members.¹²

Full and continuing cooperation with ORI during its reviews under Subpart D of

- 42 CFR Part 93 or any subsequent hearings or appeals under Subpart E of 42 CFR Part 93 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 research records and evidence under the institution's control, custody, or in the possession of, or accessible to, all persons within its authority.¹³

Changes in Institutional Policies and Procedures: The following sample provisions for institutional policies and procedures comply with the final rule. Institutions may use these provisions to update their current policies and procedures.

SAMPLE PROVISIONS FOR INSTITUTIONAL POLICIES AND PROCEDURES ON RESEARCH MISCONDUCT

These sample provisions meet the minimum requirements in 42 Code of Federal Regulations (CFR) Section 93.304 (summarized above). Institutions may include in their policies and procedures more detail, explanatory material, and requirements beyond those required by the rule, so long as those additional requirements do not contravene the requirements of the HHS final rule (see 42 CFR Section 93.319).

The sample provisions appear in roughly the same order as the requirements for institutional policies and procedures in Section 93.304. Institutions may arrange and format their policies and procedures as they determine appropriate. The term “**shall**” is used in the sample 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 sample 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 should 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 attached); (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 attached); 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 [**give title of responsible official**] 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. [If the institution has an appeal process that could result in the reversal or modification of the findings of the investigation, the institution should include in its policies and procedures a requirement for completion of the appeal within 120 days of its commencement, unless ORI grants an extension in writing for good cause.] 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 attached).

We shall prepare the draft and final institutional investigation reports in writing and provide the draft report for comment as provided elsewhere in these policies and procedures and 42 CFR Section 93.312 (copy attached). 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.
- Appeal. [If the institution provides for an appeal (**this is not required by the HHS regulations**) that could result in the reversal or modification of the findings in the investigation report, it should give the respondent timely notification of that appeal process. Any appeal process must be completed within 120 days unless the institution has requested and received an extension from ORI. This 120 day deadline does not apply to institutional termination hearings that are conducted separately from the appeal process.]

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 [**identify the responsible official by title**] and a copy of the inquiry report containing the information required by 42 CFR Section 93.309(a) (copy attached). 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, all attachments, and any appeals; (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.

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 attached), 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.

[An institution may have internal standards of conduct different from, but not in conflict with, the HHS standards for research misconduct and may impose administrative actions based on those internal standards. In that case, ORI recommends that the institution's policies and procedures clearly delineate between its standards and those in 42 CFR Part 93 and set forth the actions that it may take in response to a final finding of misconduct, or other integrity breaches, under its standards.]

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.

ENDNOTES

1. Section 93.108 limits disclosure of the identity of respondents and complainants, to the extent possible, to those who need to know, consistent with a thorough competent, objective and fair research misconduct proceeding and as allowed by law. However, the institution must disclose those identities to ORI in the course of an ORI review of misconduct proceedings and the HHS administrative proceeding is normally open to the public as provided in Section 93.517(g). Except as may be otherwise prescribed by applicable law, disclosure of any records or evidence from which research subjects might be identified is limited to those who have a need to know to carry out a research misconduct proceeding.

The old rule, 42 CFR Part 50, Subpart A, required institutions to protect to the maximum extent possible the privacy of those who in good faith report apparent misconduct and afford the affected individual(s) confidential treatment to the maximum extent possible.

2. Section 93.307(a) sets forth the criteria warranting an inquiry and Section 93.307(g) requires an inquiry to be completed within 60 calendar days of its initiation, unless circumstances clearly warrant a longer period. If the inquiry exceeds this 60 day period, the inquiry record must include documentation of the reasons. Section 93.307(d) sets forth the criteria warranting an investigation and Section 93.307(e) requires the preparation of a written inquiry report that contains the information set forth in Section 93.309. The old rule contained the same time limits for the completion of the inquiry, but did not contain the criteria for an inquiry or investigation. The old rule required a written inquiry report stating what evidence was reviewed, summarizing relevant interviews, and setting forth the conclusions of the inquiry. Section 93.309 requires that within 30 days of finding that an investigation is warranted, the institution must provide ORI with the inquiry report and the written determination by the responsible official that an investigation is warranted. The old rule required the reporting to ORI of the institution's decision to initiate an investigation, including the name of the person against whom the allegation was made, the general nature of the allegation, and the PHS application or grant number involved.

Section 93.310 requires that an investigation begin 30 days after the determination that it is warranted. The old rule contained the same requirement. Section 93.310 also sets forth requirements for the conduct of the investigation. These requirements are similar to those in the old rule, but are more detailed. For example, Section 93.310(f) requires institutions to 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. The old rule required that institutional policies and procedures take precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

Section 93.311 requires the completion of all aspects of an investigation, including sending the final report to ORI under Section 93.315, within 120 days of beginning the investigation. If unable to complete the investigation in that time period, the institution must ask ORI for an extension in

writing. If ORI grants the extension, it may direct the institution to submit periodic progress reports. The old rule contained the same requirements, except it required that the request for an extension explain the delay and include an interim progress report.

Section 93.313 sets forth what the institution's final investigation report must contain and requires the institution to maintain and provide to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including the recordings or transcripts of all interviews. The old rule contained less detailed requirements for the content of the investigation report, and required the preparation and maintenance of the documentation to substantiate the findings of the investigation.

Section 93.315 sets forth the notice that institutions must give to ORI following the investigation, including the investigation report, the final institutional findings and any pending or completed administrative action against the respondent. The old rule required that the investigation report be submitted to ORI.

3. The institution must: (1) Make a good faith effort to notify the respondent in writing at the time of or before beginning an inquiry. Sections 93.304(c), 93.307 (b); (2) Provide the respondent an opportunity to comment on the inquiry report and attach to the report any comments from the respondent. Sections 93.304(e), 93.307(f); (3) Notify the respondent of the outcome of the inquiry. The notice must include a copy of the inquiry report and include a copy of, or refer to the final rule and the institution's policies and procedures. Section 93.308(a). **If the institution has not yet updated its policies and procedures to comply with the new regulations, it will nevertheless be in compliance if it follows the new HHS regulations.** (4) Within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins (the investigation must begin within 30 days after the determination that it is warranted), notify the respondent in writing of the allegations to be investigated. The institution must give the respondent written notice of any new allegations within a reasonable time after deciding to pursue allegations not addressed in the inquiry or in the initial notice of investigation. Section 93.310(c); (5) 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. Any comments must be submitted within 30 days of the date on which the respondent received the draft report and must be considered by the institution and included in the final report. Sections 93.304(f). 93.312(a).

The old rule required that the investigation report be made available for comment by the subjects of the investigation. It did not contain the other notification requirements in the new rule.

4. Within 30 days of finding that an investigation is warranted (i.e., no later than the date on which the investigation begins) the institution must provide the written finding of the responsible official and a copy of the inquiry report to ORI. Sections 93.304(d), 93.309(a). and 93.310(a) and (b). Where the institution has found that an investigation is warranted, the institution must provide to ORI upon 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. Section 93.309.

The old rule required written notice to ORI of the institution's decision to initiate an investigation within the same time frame as the new rule. The old rule did not contain any provision comparable to the provision of the new rule requiring that certain records relating to the inquiry be made available to ORI

upon its request.

5. See item (2) in endnote 3. above. The old rule required giving a copy of the inquiry report to the individual against whom the allegation was made and including any comments made by that individual in the inquiry report.
6. See item (5) in endnote 3. above. The old rule required that the investigation report be made available for comment by the subjects of the investigation.
7. Section 93.305 requires institutions to: (1) Either before or when the institution notifies the respondent of the allegation, inquiry, or investigation, 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 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. (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 that is discovered during the course of the research misconduct proceeding, subject to the exception stated in (1) above for scientific instruments. (4) Under Section 93.317(b), unless custody of the records and evidence has been transferred to HHS or ORI has advised the institution that it no longer needs to retain the records, the institution must maintain the records of the research misconduct proceedings, as defined in Section 93.317(a), for 7 years after completion of the proceeding, or any ORI or HHS proceeding under Subparts D and E of the final rule, whichever is later.

The old rule required institutions to maintain sufficiently detailed documentation of inquiries to permit a later assessment of the reasons for determining that an investigation was not warranted, if necessary. Those records had to be maintained in a secure manner for at least three years after termination of the inquiry and had to be provided to authorized HHS personnel, upon request. Maintenance of documentation to substantiate the investigation's findings was also required. It had to be made available to ORI.

8. The new rule does not provide any further explanation of this requirement. The old rule contained a similar requirement: that the institution take interim administrative actions, as appropriate, to protect Federal funds and insure that the purposes of the Federal financial assistance are carried out.
9. Section 93.318 requires an institution to immediately notify ORI if at any time during the research misconduct proceeding the institution has reason to believe that any of the following conditions exist: (1) The 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 possible violations of civil or criminal law; (5) Federal action is required to protect the interests of those involved in the research misconduct proceeding; (6) The institution believes 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; and (7) The research community or public should be informed.

The old rule required notification of ORI if the institution at any stage of the inquiry or investigation

ascertained that any of the following conditions exist: (1) There is an immediate health hazard involved; (2) There is an immediate need to protect Federal funds or equipment; (3) There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations, as well as his/her co-investigators and associates, if any; (4) It is probable the alleged incident is going to be reported publicly; or (5) There is a reasonable indication of possible criminal violation, in which case the institution must inform ORI within 24 hours of obtaining the information.

10. Under Section 93.319, institutions may have internal standards of conduct different from the HHS standards and may impose administrative actions for violations of those standards. If an institution has such internal standards and administrative actions, ORI recommends that they be included in its policies and procedures, or clearly cross-referenced so that **researchers are given advance notice** on the institutional response to research misconduct or other integrity violations. In addition, Section 93.315 requires that the institution report to ORI, after it has made a finding of research misconduct, any pending or completed administrative action against the respondent. Institutions should cooperate with HHS in carrying out relevant administrative actions undertaken pursuant to Section 93.407 that HHS may impose upon researchers found to have committed research misconduct. The institution's policies and procedures should provide for that cooperation.

There are no comparable provisions in the old rule.

11. There is no further explanation of this provision in the new rule. The old rule contained a similar provision but it did not condition institutional action to protect or restore the reputation of the respondent upon being asked to do so.

12. There is no further explanation of this provision in the new rule. The old rule required institutions to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

13. On request, institutions must transfer custody, or provide copies of records relevant to the research misconduct proceeding in accordance with Section 93.317(c). Failure to cooperate with ORI's review of a research misconduct proceeding is one of the factors ORI may consider in determining whether an institution is noncompliant under Section 93.412.

The old rule required institutions to maintain and make available to ORI documentation to substantiate the findings of the investigation.