AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

Federal Register

Tuesday,
May 17, 2005

Part III

Department of Health and Human Services

42 CFR Parts 50 and 93
Public Health Service Policies on Research Misconduct; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Parts 50 and 93

RIN 0940–AA04

Public Health Service Policies on Research Misconduct

AGENCY: U.S. Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule removes 42 CFR part 50, subpart A, ''Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science,'' and replaces it with a new, more comprehensive part 93, ''Public Health Service Policies on Research Misconduct.'' The proposed part 93 was published for public comment on April 16, 2004. The final rule reflects both substantive and non-substantive amendments in response to public comments and to correct errors and improve clarity, but the general approach of the NPRM is retained. The purpose of the final rule is to implement legislative and policy changes applicable to research misconduct that occurred over the last several years, including the common Federal policies and procedures on research misconduct issued by the Office of Science and Technology Policy on December 6, 2000.

DATES: This final rule will become effective June 16, 2005.

ADDRESSES: Address any comments or questions regarding this final rule to: Chris B. Pascal, J.D., Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852. Some commonly asked questions and answers to them will be posted on the Office of Research Integrity Web site prior to the effective date of the regulation. The URL for the ORI Web site is: *http://ori.hhs.gov*.

You may submit comments and questions on this final rule by sending electronic mail (e-mail) to *research@osophs.dhhs.gov*. Submit electronic comments as either a WordPerfect file, version 9.1 or higher, or a Microsoft Word 97 or 2000 file format. You may also submit comments or questions as an ASCII file avoiding the use of special characters and any form of encryption.

FOR FURTHER INFORMATION CONTACT: Brenda Harrington, (301) 443–3400. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Public Comments—General

The Notice of Proposed Rulemaking (NPRM) proposing to remove 42 CFR part 50, subpart A and replace it with a new part 93 was published in the **Federal Register** on April 16, 2004 (69 FR 20778). Comments were requested on or before June 15, 2004. In addition to this invitation for public comment on any aspect of the proposed rulemaking, the NPRM requested comment on specific aspects of the proposed rule including: (A) Whether there should be any limitation on the ability of institutions to conduct a research misconduct proceeding through a consortium or other entity qualified by practice and experience to conduct research misconduct proceedings (§ 93.306); (B) the use of Administrative Law Judges (ALJs) to conduct HHS research misconduct hearings rather than a panel of three decisionmakers (§ 93.502); (C) treating the decision of the ALJ as a recommended decision to the Assistant Secretary for Health (ASH) as opposed to the current practice in which the decision of the panel on the merits of the HHS findings of misconduct and administrative actions, other than debarment, constitutes final agency action (§§ 93.500(d) and 93.523(c)); (D) authorizing the ALJ to appoint a scientific expert (that appointment is required if requested by either party) to advise the ALJ on scientific issues, but not provide testimony for the record (§ 93.502(b)); (E) consistent with current practice, permitting HHS to amend its findings of research misconduct up to 30 days before the scheduled hearing (§ 93.514); (F) extending the period for retaining records of the research misconduct proceeding, including inquiries, from 3 to 7 years (§ 93.317); (G) imposing a 120-day deadline for the completion of any institutional appeal from a finding of research misconduct (§ 93.314); and (H) whether the HHS estimates on the potential burden of information collection requirements are accurate and whether those requirements are necessary for the proper performance of HHS functions.

Twenty-eight documents commenting on the NPRM were submitted to HHS by mail or e-mail. Most of the documents addressed multiple sections of the proposed rule. A number of the commentators made general positive comments such as that: the proposed rule is well drafted, provides valuable guidance for researchers and institutions and is much improved over the current regulation; the detail and transparency of the procedures will result in a better focus on the merits of a case rather than procedural complications; the proposal recognizes the importance of primary reliance on the institutions to respond to allegations of research misconduct; and the clarification and harmonization of definitions, standards, and procedures are appreciated.

Most of the commentators endorsed the changes in the definition of research misconduct and the incorporation of the three elements necessary for a finding of research misconduct in conformity with the Federal Policy on Research Misconduct issued by the Office of Science and Technology Policy (OSTP). Some expressed support for the PHS practice of excluding coverage of authorship disputes in the absence of a clear allegation of plagiarism. There were expressions of support for the coverage of PHS intramural programs and PHS contractors, the coverage of the plagiarism of a PHS supported research record, even if the respondent does not receive such support, the clarification of the role of the complainant, the adoption of a six-year limitation on the pursuit of misconduct allegations, separation of adjudication and appeal from the inquiry and investigation stages, setting a time limit on the investigation by the institution, and the inclusion of ALJs in the hearing process. These and other supportive comments may be discussed in the consideration of specific changes to the proposed rule that follows.

There were also general, negative comments on the proposed rule, some of which were in direct opposition to positive comments. Some commentators feel that the proposal is overly detailed and thus contrary to the OSTP goal of a more uniform Federal-wide approach. Another criticizes the continuation in the proposed rule of a trend toward legalization of scientific disputes by immediately casting parties into adversarial roles. Other commentators object to the change from a hearing conducted by a three-member panel to one conducted by an ALJ, stating that there has not been any showing of a need to change the current practice. One commentator felt that HHS should be responsible for investigating allegations of misconduct at institutions that have repeatedly failed to properly investigate research misconduct. These and other critical comments may be discussed in the consideration of specific changes that follow.

Some letters of comment repeated comments that had been made in response to the OSTP proposal for a government-wide Federal policy on research misconduct. Because OSTP considered those comments prior to

issuing its final policy and this final rule is consistent with the aspects of the OSTP policy addressed in the comments, those comments will not be further discussed here.

Comments on specific sections of the regulation are addressed below under headings based on the general issue raised by the comments. If that issue encompasses more than one section of the regulation, all those sections will be discussed under that heading.

II. Changes Made in Response to Comments

A. Applicability, Secs. 93.100(b) and 93.102(b)

A number of commentators concluded that the applicability section, 93.102, and the descriptions of applicability in other sections unreasonably extend HHS jurisdiction beyond PHS supported biomedical or behavioral research and research training. One commentator recommended that descriptions of applicability be uniform throughout the regulation. There were specific objections to: (1) The statement in Sec. 93.100(b) that covered institutions must comply with the regulation with respect to allegations of misconduct ''occurring at or involving research or research training projects or staff of the institution''; (2) the coverage, in Sec. 93.102(a) and other sections describing applicability, of ''activities related to that research or research training;'' and (3) the extension of coverage in Sec. 93.102(a) to allegations of misconduct involving any research record generated from covered research, research training, or activities related to that research or training, regardless of whether the user or reviewer receives PHS support or whether an application resulted in any PHS support.

Several clarifying changes have been made in response to these comments, but these changes do not change the intended substance of the provisions in the NPRM. The current regulation, 42 CFR 50.101, covers each entity that applies for a ''research, research-training or research-related grant or cooperative agreement'' under the PHS Act. Such an entity must establish policies and procedures for investigating and reporting instances of alleged misconduct involving ''research or research training or related research activities that are supported with funds available under the PHS Act.'' Thus, applicability to research-related activities is not new. The NPRM was not intended to change the applicability to those activities as it is expressed in the current regulation and has been applied in practice under that regulation.

This rulemaking establishes the necessary HHS jurisdiction to implement the new term ''reviewing research'' in the OSTP definition of research misconduct. In ORI's experience, plagiarism can occur during the review process when a manuscript is submitted for publication. In the great majority of cases where an allegation arises that a PHS supported research record was plagiarized, we expect that the reviewers will be current recipients of PHS research funds because the reviewers are selected based on their subject matter expertise and the research in question is PHS funded biomedical and behavioral research. In cases where the respondent is PHS supported or affiliated with a PHS supported institution, we would expect the misconduct allegation to be pursued by the PHS supported institution. In those cases where the reviewer who is alleged to have committed plagiarism is solely funded by another Federal agency, ORI would refer the allegation to that agency. In addition, jurisdiction does not attach to allegations of plagiarism where there is no PHS support for the research record in question. Thus, we have removed the phrase ''regardless of whether the user or reviewer currently receives PHS support'' from Sec. 93.102.

To eliminate redundancy and clarify the general policy and applicability provisions, Secs. 93.100 and 93.102, we have: (1) Moved the statement of applicability to institutions from Sec. 93.100(b) to Sec. 93.102(b) and rewritten it to be more concise; and (2) moved paragraph (c) of Sec. 93.100 to paragraph (a) of that section and combined the proposed paragraphs (a) and (d) into a new paragraph (b).

The provision setting forth the types of allegations to which the regulation applies has been moved from Sec. 93.102(a) to paragraph (b) of that section and has been amended to clarify that the regulation applies to allegations of research misconduct involving: (i) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training, or activities related to that research or research training, such as the operation of tissue or data banks or the dissemination of research information; (ii) PHS supported biomedical or behavioral extramural or intramural research; (iii) PHS supported biomedical or behavioral extramural or intramural research training programs; (iv) PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks or the dissemination of research information; and (v) plagiarism of research records produced in the course of PHS supported research, research training, or PHS supported activities related to that research or research training. The examples of activities that are related to research or research training are intended to be illustrative, not exhaustive. They are intended to convey the concept that under its research and research training authorities, PHS funds many activities that are closely related to research and research training, but might not be considered to be within the common understanding of what constitutes research or research training. Consistent with the intent of, and practice under the current regulation, allegations of research misconduct involving those funded activities, or applications for the funding of those activities, are covered.

In each section that refers to the applicability of the regulation we have referenced the applicability section or repeated the applicability of the regulation to PHS supported research, research training, and activities related to that research or research training.

B. Subsequent Use Exception to Six Year Limitation on Misconduct Allegations, Sec. 93.105(b)(1)

In response to a comment requesting clarification, we have amended paragraph (b)(1) of Sec. 93.105. The amendment clarifies that even though HHS or an institution does not receive an allegation of research misconduct within six years of when the misconduct is alleged to have occurred, the regulation would apply if, within six years of when the allegation is received, the respondent has cited, republished, or otherwise used for his or her potential benefit the research record that is the subject of the allegation of misconduct.

C. Rebuttable Presumption of Misconduct in the Absence of Records, Secs. 93.106(a)(1) and 93.516(b)

Commentators raised several concerns about proposed Sec. 93.106(a)(1) and Sec. 93.516(b) under which the absence of, or respondent's failure to provide research records adequately documenting the questioned research establishes a presumption of research misconduct that can be rebutted by credible evidence corroborating the research or providing a reasonable explanation for the absence of, or respondent's failure to provide the research records. The concerns included: (1) Retroactive application of the provision where there was no previous requirement for the retention

of the records; (2) holding the respondent responsible for the retention of records over which he/she may have no control; and (3) there is no guidance on what would be a ''reasonable explanation'' for the absence of records.

In response to these comments, we have eliminated the rebuttable presumption of research misconduct. Sections 93.106 and 93.516 have been changed to state that the destruction, absence of, or respondent's failure to provide records adequately documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but failed to do so, or maintained the records, but failed to produce them in a timely manner, and that respondent's conduct constitutes a significant departure from accepted practices of the relevant research community. This is in keeping with the definition of falsification to include omitting data or results such that the research is not accurately represented in the research record (Sec. 93.103(b)) and with the requirements for a finding of research misconduct in Sec. 93.104. This answers the concerns about retroactive application and that the respondent may not have had control over the records by holding the respondent to the accepted practices of his/her research community. The weight to be accorded the evidence of research misconduct under these circumstances must be determined by the trier of fact in each case.

D. Respondent's Burden To Prove Honest Error or Difference of Opinion, Secs. 93.106(a)(2) and 93.516(b)

As proposed, Sec. 93.106(a)(2) provided that once the institution or HHS makes a *prima facie* showing of research misconduct the respondent has the burden of proving any affirmative defenses raised, including honest error or difference of opinion. There were a number of objections to that section on the grounds that shifting the burden of proving honest error or difference of opinion to the respondent effectively shifts the burden of the institution and HHS to prove each element of research misconduct or, at the least, creates confusion. Some of the commentators opined that the institution and the HHS have the burden of proving the absence of honest error or difference of opinion.

As stated in the preamble of the **Federal Register** notice promulgating the final OSTP Research Misconduct Policy (65 FR 76260, Dec. 6, 2000), the exclusion of honest error or difference of opinion from the definition of research misconduct does not create a separate element of proof; institutions and agencies are not required to disprove possible honest error or difference of opinion. Given that guidance, this final rule retains honest error or difference of opinion as an affirmative defense that the respondent has the burden of proving by a preponderance of the evidence.

However, we recognize that there is an overlap between the responsibility of respondents to prove this affirmative defense and the burden of institutions and HHS to prove that research misconduct was committed intentionally, knowingly, or recklessly. Accordingly, consistent with the opinion of the United States Supreme Court in *Martin* v. *Ohio*, 480 U.S. 228, 107 S. Ct. 1098 (1987), we have amended Sec. 93.106 to require consideration of admissible, credible evidence respondent submits to prove honest error or difference of opinion in determining whether the institution and HHS have carried their burden of proving by a preponderance of the evidence that the alleged research misconduct was committed intentionally, knowingly, or recklessly. This consideration would be required, regardless of whether respondent carries his/her burden of proving honest error or difference of opinion by a preponderance of the evidence.

In light of this change, we have removed the reference to the institution or HHS making a *prima facie* showing of research misconduct as unnecessary and confusing. Because this is the only use of *prima facie* in the regulation, we have removed the definition of that term.

E. Coordination With Other Agencies, Sec. 93.109

Some commentators pointed out that Sec. 93.109(a), as proposed, is not consistent with the statement in the OSTP Policy that a lead agency should be designated when more than one agency has jurisdiction. We have amended paragraph (a) to state that if more than one agency of the Federal government has jurisdiction, HHS will cooperate with the other agencies in designating a lead agency. We have added a sentence clarifying that where HHS is not the lead agency, it may, in consultation with the lead agency, take action to protect the health and safety of the public, promote the integrity of the PHS supported research and research process, or to conserve public funds.

F. Definition of Research Record, Sec. 93.224

One commentator recommended that the research record include the comments of the complainant and respondent on the inquiry and investigation reports. We agree that documents and materials provided by the respondent as part of his/her comments on the inquiry and investigation reports, or at any other stage of the research misconduct proceeding do not differ significantly from those provided in response to questions regarding the research. Only the latter were included in the proposed definition of research record. Accordingly, we have amended Sec. 93.224 (formerly Sec. 93.226) so that the definition of research record includes documents and materials that embody the facts resulting from the research that are provided by the respondent at any point in the course of the research misconduct proceeding. The purpose of including documents provided by respondent in the research record is to hold the respondent responsible for the integrity of those research documents regardless of when they were prepared or furnished to the institution or HHS.

Because the complainant is not being held responsible for the record of data or results that embodies the facts resulting from the research at issue, we are not including comments provided by the complainant during the research misconduct proceeding in the definition of the term ''research record.'' Those comments may be considered by the institution and/or HHS and they may be admitted as evidence in any hearing, but they are not part of the research record. If the complainant possesses documents that embody the facts resulting from the research that is the subject of the research misconduct proceeding, those documents are research records and the institution is responsible for maintaining and securing those documents in the same manner as other research records. Those documents are distinct from analyses of research records or results that a complainant may prepare prior to or in the course of a research misconduct proceeding to support his or her allegation of misconduct. Any such documents may be considered evidence pertinent to the allegation, but they are not part of the research record.

G. Reporting Inquiries to ORI, Sec. 93.300(a)

Several commentators interpreted the general language in proposed Sec. 93.300(a), requiring institutions to have policies and procedures for ''reporting

inquiries and investigations of alleged research misconduct in compliance with this part,'' to require the reporting of all inquiries to ORI, contrary to the requirement in Sec. 93.309 for reporting only those inquiries resulting in a finding that an investigation is warranted. We have amended Sec. 93.300(a) to clarify that the institution's policies and procedures must comply with the requirements of the regulation for addressing allegations of research misconduct. This includes the requirements of Sec. 93.309.

It was also recommended that this section be amended to require that the institution's written policies and procedures be provided to the complainant and other interested parties on request. We have added a requirement that the policies and procedures be provided to members of the public upon request to Sec. 93.302(a)(1) because it addresses the availability of the institution's policies and procedures to HHS and ORI upon request.

H. Precautions To Protect Against Conflicts of Interest, Secs. 93.300(b) and 93.304(b)

In response to a general comment that the regulation should ensure that those conducting inquiries and investigations do not have conflicts of interest, we have amended Secs. 93.300(b) and 93.304(b) to require institutions to include precautions against conflicts of interest on the part of those involved in the inquiry or investigation. This expands upon the requirement in Sec. 93.310(f) that institutions take reasonable steps to ensure an impartial investigation, ''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.''

I. Reporting of Aggregated Information by Institutions, Sec. 93.302(c)

Several commentators recommended deletion of proposed Sec. 93.302(c) because its broad language would encompass research misconduct proceedings that are outside the jurisdiction of HHS. We agree with the intent of these comments and have amended this provision to refer to aggregated information on the institution's research misconduct proceedings covered by this part.

J. Responsibility for Securing Research Records and Evidence, Secs. 93.305, 93.307(b) and 93.310(d)

Several commentators recommended that Sec. 93.305 be amended to ensure that any securing of scientific instruments not interfere with ongoing research. Scientific instruments are included in the definition of ''research record'' in Sec. 93.224 to the extent they are, or contain physical or electronic records of data or results that embody the facts resulting from scientific inquiry. In response to these comments we have added language to paragraphs (a) and (c) of Sec. 93.305, paragraph (b) of Sec. 93.307, and paragraph (d) of Sec. 93.310 permitting institutions to secure copies of data or other research records on shared scientific instruments, so long as those copies are substantially equivalent in evidentiary value to the instruments themselves. It is expected that institutions will exercise discretion in determining whether copies of the data are substantially equivalent in evidentiary value to the instruments themselves, consulting with ORI as the institution determines necessary. The evidentiary value of scientific instruments will vary from case to case. In some cases their value may be dependent upon the manner in which they record data, rather than the data they contain. In those cases, it may be reasonable for the institution to permit continued use of the instrument, so long as it remains available for inspection by those conducting the inquiry and investigation.

K. Using a Consortium or Other Entity To Conduct Research Misconduct Proceedings, Sec. 93.306

One commentator recommended that there should be greater detail regarding the kinds of practice and experience that would qualify an outside entity to conduct research misconduct proceedings, how possible conflicts of interest would be handled, and whose responsibility it would be to determine whether the outside entity is qualified.

The proposed Sec. 93.306 contains a catchall phrase providing that an institution may use a consortium or other entity to conduct research misconduct proceedings, if the institution prefers not to conduct its own proceeding. In light of the incorporation of this broad discretion in the proposed section, we have simplified Sec. 93.306 to provide that an institution may use the services of a consortium or person that the institution reasonably determines to be qualified by practice and experience to conduct research misconduct proceedings. Thus, the institution may decide to use an outside consortium or person for any reason and it determines whether that outside consortium or person is qualified. We have substituted the defined term ''person'' for the term ''entity.'' Any outside person conducting a research misconduct proceeding would be subject to the requirements for precautions against conflicts of interest in Secs. 93.300(b) and 93.304(b).

L. Standards for Investigation, Sec. 93.310(g) and (h)

A number of commentators felt that the provisions of proposed Sec. 93.310(g) and (h) establish a performance standard that cannot be met through the use of the terms ''any'' and ''all.'' We have amended paragraphs (g) and (h) to require, respectively, interviews of each person who has been reasonably identified as having information regarding relevant aspects of the investigation, and the pursuit of all significant issues and leads discovered that are determined relevant to the investigation. The institutions are responsible for making the relevancy determinations that are included in these paragraphs.

M. Opportunity To Comment on the Investigation Report and Review the Supporting Evidence, Sec. 93.312(a) and (b)

One commentator proposed language clarifying the period for the respondent to comment on the investigation report. Another commentator felt that the institution should be required to give the respondent an opportunity to review all research records and evidence upon which the investigation report is based. We believe that clarification of the 30-day period for comment by the respondent and for comment by the complainant, at the discretion of the institution, is needed. We have amended paragraphs (a) and (b) of Sec. 93.312 accordingly. In addition, we have amended paragraph (b) to make it clear that institutions have the discretion to provide the complete investigation report to the complainant for comment or relevant portions of it.

The OSTP Guidelines for Fair and Timely Procedures, Section IV of the Uniform Federal Policy, provide that one of the safeguards for subjects of allegations is reasonable access to the data and other evidence supporting the allegations and the opportunity to respond to the allegations, the supporting evidence and the proposed findings of research misconduct, if any. Consistent with that guidance, we have amended Sec. 93.312(a) to require institutions to give the respondent, concurrently with the draft investigation report, a copy of, or supervised access to, the evidence on which the report is based.

N. Institutional Appeals, Sec. 93.314(a)

One commentator requested language clarifying that the 120-day period for completing institutional appeals applies only to appeals from the finding of misconduct, not appeals from personnel actions. We have implemented this comment through the addition of appropriate language to Sec. 93.314(a).

O. Completing the Research Misconduct Process, Sec. 93.316

Several commentators objected to this provision because they interpreted it as requiring that ORI be notified when an inquiry ends in a finding of no misconduct. These commentators recommended that the regulation address the question of whether settlements based on an admission of misconduct are reportable. In response to these comments we have amended Sec. 93.316(a) to require that institutions notify ORI if they plan to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted research misconduct, a settlement with the respondent has been reached, or for any other reason, except a determination at the inquiry stage that an investigation is not warranted, or a finding of no misconduct at the investigation stage, which must be reported to ORI under Sec. 93.315. We have also changed Sec. 93.316(b) to provide for ORI consultation with the institution on its basis for closing a case, rather than simply reviewing the institution's decision, and expanded the actions ORI may take to include approving or conditionally approving closure of the case and taking compliance action.

P. Retention and Custody of Records of the Research Misconduct Proceeding, Sec. 93.317

There were several objections that the seven-year retention period: (1) Creates storage problems; (2) should not apply to scientific instruments; and (3) is contrary to the 3-year retention period for records relating to grants in OMB Circular A–110. One commentator recommended that the term ''records of research misconduct proceedings'' be defined to include a relevancy standard.

In order to clarify what must be retained, we have added a new paragraph (a) to Sec. 93.317 defining records of research misconduct proceedings by referring to the sections of the regulation that describe what records institutions must prepare in the course of research misconduct proceedings. The definition includes a relevancy standard and requires that an institution document any determination that records are irrelevant. We have added two exceptions to the requirement for retention of the records for a period of 7 years that is now in paragraph (b) of Sec. 93.317. The institution is not responsible for maintaining the records if they have been transferred to HHS in accordance with paragraph (c), formerly (b), or ORI has advised the institution in writing that it no longer needs to retain the records.

As stated in the preamble of the NPRM (69 FR at 20784) the 7-year retention period is based on concerns that the 3-year period for retaining inquiry records in the current regulation, 42 CFR 50.103(d)(6) is too short to permit HHS or the Department of Justice to investigate potential civil or criminal fraud cases. While the 7-year retention period is potentially burdensome, that burden will fall on a limited number of institutions, 53 according to the Paperwork Reduction Act burden estimate in the preamble to the NPR, and the burden is mitigated by exceptions for transfer of custody to HHS and for a written notification from ORI that the records do not have to be retained by the institution. Upon the effective date of this final rule, the 7-year retention period for records of research misconduct proceedings will supercede the more general requirements for the retention of records relating to grants. We note that the 7-year retention period is consistent with the provision in the HHS general grants administration regulation, 45 CFR 74.53(b)(1) providing that if any review, claim, financial management review, or audit is started during the 3-year retention period, the pertinent records must be retained until all such matters have been resolved and final action taken.

Q. ORI Allegation Assessments, Sec. 93.402

Several commentators recommended requiring that ORI notify the institution of any allegation received by ORI, regardless of how ORI disposes of the allegation. Consistent with this recommendation, we have amended paragraph (d) of Sec. 93.402 to provide that if ORI decides that an inquiry is not warranted, it will close the case and may forward the allegation in accordance with paragraph (e) which provides that allegations not covered by the regulation may be forwarded to the appropriate HHS component, Federal or State agency, institution or other appropriate entity. In deciding whether to forward a specific allegation to the institution, ORI will consider potential confidentiality issues for the complainant and others. We are open to further dialogue with the research community on this issue.

R. Standard for the Assistant Secretary for Health's Review of the ALJ's Decision, Secs. 93.500(d) and 93.523

One commentator recommended that there be criteria for the Assistant Secretary for Health (ASH) to review the ALJ's decision, similar to the ''arbitrary and capricious, or clearly erroneous'' standard for the HHS debarring official to review the ALJ's decision (paragraph (e) of Sec. 93.500).

In response to this comment, we have added to Sec. 93.523(b) a standard of review for the ASH's review of the decision of the ALJ. The standard of review for the ASH is the same ''arbitrary and capricious or clearly erroneous'' standard that applies to the debarring official's review where debarment or suspension is a recommended HHS administrative action. In addition, we have amended Secs. 93.500 and 93.523 to establish a procedure for the ASH review, clarify the relationship between the ASH review and the debarring official's decision on recommended debarment or suspension actions, and identify what constitutes the final HHS action. The Assistant Secretary for Health notifies the parties of an intention to review the ALJ's recommended decision within 30 days after service of the recommended decision. Upon review, the ASH may modify or reject the decision in whole or in part after determining it, or the part modified or rejected, to be arbitrary and capricious or clearly erroneous. If the ASH does not notify the parties of an intent to review the recommended decision within the 30-day period, that decision becomes final and constitutes the final HHS action, unless debarment or suspension is an administrative action recommended in the decision. If debarment or suspension is a recommended HHS action either in a decision of the ALJ that the ASH does not review, or in the decision of the ASH after review, the decision constitutes proposed findings of fact to the HHS debarring official.

As noted in the discussion of changes not based on comments, we have amended several sections to ensure that the Assistant Secretary for Health cannot be responsible both for making findings of research misconduct and for reviewing the ALJ's recommended decision on those findings, if respondent contests the findings by requesting a hearing. ORI will be responsible for making those findings, consistent with its responsibilities as the reviewer of institutional findings of

research misconduct and as a party to any hearing on those findings. This maintains the separation between investigation and adjudication, because any inquiry or investigation would be conducted by the institution, or if conducted by HHS, it would not be conducted by ORI (Sec. 93.400(a)(4)).

S. Extension for Good Cause To Supplement the Hearing Request, Sec. 93.501(d)

One commentator recommended that the 30-day limit for supplementing the hearing request be measured from notification of the appointment of the ALJ, rather than from receipt of the charge letter. The commentator notes that the ALJ may not be appointed within 30 days after receipt of the charge letter and recommends an amendment providing that the ALJ may grant an additional period of no more than 60 days from the respondent's receipt of notification of the appointment of the ALJ. This comment makes a good point, but 60 days from notice of the appointment of the ALJ is too long a period, given that there may be an additional 30 days for appointment of the ALJ after the request for a hearing is filed. Thus, we have amended paragraph (d) to provide that after receiving notification of the appointment of the ALJ, the respondent has 10 days to file with the ALJ a proposal for supplementation of the hearing request that includes a showing of good cause for supplementation. Note that this 10-day period is consistent with the period for responding to a motion in Sec. 93.510(c) and that in accordance with Sec. 93.509(d), the ALJ may modify the 10-day period for good cause shown.

T. Role of Scientific Expert Appointed by ALJ, Sec. 93.502

It was recommended that advice of the scientific expert appointed to advise the ALJ be part of the record and available to both parties. It was further recommended that the scientific expert be available for questioning by the parties. Another commentator recommended specific guidance in the regulation to assist ALJs in retaining appropriate scientific expertise. Another commentator felt that the appointment of an expert to assist the ALJ should be mandatory in every case, while others felt such an appointment should be mandatory in those cases involving complex scientific, medical or technical issues. For the reasons explained below under the heading, ''Significant Comments Not Resulting in Changes,'' we are not requiring the appointment of an expert to assist the ALJ in every case.

The proposed Sec. 93.502 provides some guidance on the selection of scientific and technical experts by requiring that they have appropriate expertise to assist the ALJ in evaluating scientific or technical issues related to the HHS findings of research misconduct. Furthermore, experts may not have real or apparent conflicts of interest, or as added in this final rule, bias or prejudice that might reasonably impair their objectivity in the proceeding.

In paragraph (b)(1) of Sec. 93.502 of this final rule we are providing further guidance on the selection of an expert to advise the ALJ. Upon a motion by the ALJ or one of the parties to appoint an expert to advise the ALJ, the ALJ must permit the parties to submit nominations. If such a motion is made by a party, the ALJ must appoint an expert, either: (1) The expert, if any, who is agreeable to both parties and found to be qualified by the ALJ; or, (2) if the parties cannot agree upon an expert, the expert chosen by the ALJ.

These provisions will ensure the selection of well-qualified experts, minimize disputes, speed the appointment process by providing precise procedural rules, and enhance fairness by providing for greater involvement of the parties in the process.

Consistent with the greater involvement of the parties in the selection of the expert and with the comment recommending a more formalized process for the expert to provide advice, we are adding Sec. 93.502((b)(2) to clarify the role of the expert appointed by the ALJ. The ALJ may seek advice from the appointed expert at any time during the discovery or hearing phase of the proceeding. Advice must be provided in the form of a written report, containing the expert's background and qualifications, which is served upon the parties. The report and the expert's qualifications and advice may be challenged by the parties in the form of a motion or through testimony of the parties' own experts, unless the ALJ determines such testimony to be inadmissible in accordance with Sec. 93.519, or that such testimony would unduly delay the proceeding. In this manner, the report and any comment on it would be part of the record. These procedures will greatly enhance the detail and quality of the expert advice available for consideration by the ALJ and provide greater transparency and confidence to the scientific community on the expertise provided to the ALJ.

II. Changes Not Based on Comments

A. Grandfather Exception to Six Year Limitation on Receipt of Misconduct Allegations, Sec. 93.105(b)(3)

We have changed the condition for the grandfather exception from ''had the allegation of research misconduct under review or investigation on the effective date of this regulation'' to ''had received the allegation of research misconduct before the effective date of this part.'' This makes the condition for the grandfather exception consistent with the event that tolls the running of the six-year limitation: the receipt of the misconduct allegation by the institution or HHS.

B. Confidentiality, 93.108

Consistent with longstanding practice and with Sec. 93.403, we have added a provision to clarify that ORI is within the category of those who need to know the identity of the respondent and complainant and that an institution may not invoke confidentiality to withhold that information from ORI as it conducts its review under Sec. 93.403.

C. Definition of Deciding Official, Sec. 93.207, and Authority of ORI, Sec. 93.400.

To ensure that the Assistant Secretary for Health is not responsible for both making findings of research misconduct and for reviewing the recommended decision of the ALJ on those findings if respondent contests the findings by requesting a hearing, Sec. 93.400 has been amended to give ORI the authority to make findings of research misconduct. That section and Sec. 93.404 have also been amended to clarify that ORI proposes administrative actions to HHS (defined as the Secretary or his delegate) and upon HHS approval, proceeds to implement those proposed actions in accordance with the procedures in the regulation. Accordingly, the definition of, and references to the term ''deciding official'' have been deleted. Giving ORI the responsibility for making findings of research misconduct is consistent with its responsibilities for reviewing institutional findings of research misconduct and for defending those findings if the respondent challenges them. This change will maintain the separation between investigation and adjudication, because ORI will not conduct any inquiry or investigation on behalf of HHS.

These changes have necessitated changing references to HHS and ORI and other clarifying changes in Secs. 93.403–406, 93.411, 93.500–501, 93.503, and 93.516–517. As provided in Sec.

93.406, the ORI finding of research misconduct is the final HHS action only if the respondent does not contest the charge letter within the prescribed period. The administrative actions, proposed by ORI and approved by HHS, become final in the same manner, except that the debarring official's decision is the final HHS action on any debarment or suspension action.

C. Definition of Good Faith, Sec. 93.210

Under Secs. 93.227 and 93.300(d), committee members are protected against retaliation for good faith cooperation with a research misconduct proceeding. As proposed, Sec. 93.211 (now Sec. 93.210) defined ''good faith'' for complainants and witnesses, but not for committee members. We have added such a definition, stating that a committee member acts in good faith if he/she cooperates with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this regulation. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

D. Definition of Institutional Member, Sec. 93.214

We have added more examples of institutional members.

E. Institutional Policies and Procedures—Reporting the Opening of an Investigation, Sec. 93.304(d)

We have simplified the date for institutions to report the opening of investigations to ORI. This report must be made on or before the date on which the investigation begins. Institutions are encouraged to report the opening of an investigation to ORI as promptly as possible after the decision to open an investigation is made.

F. Taking Custody of and Securing Records at the Beginning of an Inquiry, Sec. 93.307(b)

We have added a requirement that on or before the date on which the respondent is notified of the inquiry, or the inquiry begins, whichever is earlier, the institution must, to the extent it has not already done so, promptly 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. This is consistent with the identical requirements that become applicable when the institution notifies the respondent of the allegation and when the respondent is notified of an investigation. (Secs. 93.305(a) and 93.310(d)). These requirements are necessary because of the potential for the destruction or alteration of the research records. To minimize that potential, an institution should take custody of the records whenever it has reason to believe that the records may be subject to alteration or destruction because of an allegation or potential allegation of research misconduct. This may protect the respondent, as well as the institution.

G. Interaction With Other Offices, Sec. 93.401

To accurately reflect ORI's authority and practices, we have expanded this section to authorize ORI to provide expertise and assistance to the Department of Justice, the HHS Inspector General, PHS and other Federal offices, and State or local offices involved in investigating or otherwise pursuing research misconduct allegations or related matters.

H. Procedures for Debarment or Suspension Actions Based on Misconduct Findings, Secs. 93.405, 93.500–501, 93.503 and 93.523.

We have amended these sections to clarify the relationship between the regulations governing debarment and suspension and the procedures in subpart E for contesting ORI findings of research misconduct and proposed HHS administrative actions. Section 93.500(d) (comparable to Sec. 93.500(c) of the NPRM) explains that the procedures under subpart E provide the notification, opportunity to contest and fact finding required under the HHS regulation governing debarment and suspension. Consistent with that regulation, the debarring official provides notification of the proposed debarment or suspension as part of the charge letter (Sec. 93.405(a)) and makes the final decision on debarment and suspension actions whether that decision is based upon respondent's failure to contest the charge letter (Secs. 93.406, 93.501(a) and 93.503(c)), the decision of the ALJ, or the decision of the ALJ as modified by the Assistant Secretary for Health (Secs. 93.500(c) and 93.523(b) and (c)).

I. HHS Administrative Action—Recovery of Funds, Sec. 93.407(b)

We have clarified what funds HHS may seek to recover in connection with a finding of research misconduct by amending Sec. 93.407(b) to refer to the potential recovery of PHS funds spent in support of activities that involved research misconduct.

J. Appointment of the ALJ—Description of Functions, Sec. 93.502(a)

We have amended Sec. 93.502(a) to describe the functions of the ALJ more completely.

K. Limits on the Authority of the ALJ, Sec. 93.506(a) and (c)

We have added references in Secs. 93.506(a) and (c) stating that the ALJ does not have the authority to find invalid or refuse to follow Federal statutes or regulations, Secretarial delegations of authority, or HHS policies. This is consistent with a similar provision in the regulation upon which the research misconduct hearing process is based, 42 CFR part 1005, which governs the hearing process for OIG exclusion of health care providers.

L. Actions for Violating an Order or Disruptive Conduct, Sec. 93.515(b)(6)

We have changed ''taking a negative inference from the absence of research records, documents, or other information'' to ''drawing the inference that spoliated evidence was unfavorable to the party responsible for its spoliation.'' This change is intended to clarify the nature of the negative inference that may be reached by the ALJ and distinguish the spoliation of evidence during or in anticipation of the hearing, from the absence or destruction of records that may be evidence of research misconduct. In this context, spoliation has essentially the same meaning as is accepted by Federal courts, *i.e.*, the destruction or significant alteration of evidence during or in anticipation of the hearing.

M. Corrections and Minor Changes

In addition to the significant changes not based on comments described above, we have made changes to: (1) Correct errors, such as references to PHS rather than HHS, or to a hearing officer, rather than the ALJ; (2) use uniform language in describing the same condition or event in different sections of the regulation; (3) adding citations to other sections, where appropriate, to make cross-references more concise and

technically correct; and (4) use plain, and more precise language.

III. Significant Comments Not Resulting in Changes

A. Definition of Research Misconduct, Sec. 93.103

Although most commentators supported the new definition of research misconduct, there were a number of comments recommending changes, including that: (1) The definition should be based on deception; (2) the definition of falsification is inadequate because it does not cover the nonexperimental manipulation of human or animal subjects with the goal of influencing research results, or bias in the coding of qualitative data; (3) the definition of plagiarism should expressly exclude authorship and credit disputes; and (4) the definition of misconduct should be expanded to include negligent and intentional mistreatment of animals.

As explained in the preamble of the NPRM, the proposed definition of research misconduct, which is included in this final rule without change, includes OSTP's description of ''fabrication, falsification, and plagiarism.'' That description is clear and sufficiently concrete to provide the basis for reasonable determinations of whether research misconduct has occurred and whether the misconduct was intentional, knowing, or reckless. Given the careful consideration that has been given to this definition and the value of a uniform government-wide definition, we are adopting the definition as it was proposed. We note that the nonexperimental manipulation of human or animal subjects to influence the research results would appear to be a manipulation of research materials or processes within the intendment of the definition of falsification.

B. Confidentiality, Secs. 93.108, 93.300(e) and 93.304(a)

Several commentators recommended including witnesses and committee members and strengthening the confidentiality protections to provide the same protections as the OSTP Policy. Other commentators recommended that: (1) The rule give examples of what disclosures are limited and state when an institution is free to announce the results of an investigation to scientific journals; (2) the identity of the complainant and his/her statement be disclosed to the respondent; and (3) that the sanctions for a violation of confidentiality be specified.

We have not changed Sec. 93.108 or the other provisions requiring institutions to provide confidentiality to respondents, complainants, and research subjects who are identifiable from research records or evidence. We believe these provisions provide the same protections as the OSTP policy. Institutions have considerable discretion in implementing the confidentiality protections and are free to extend them to witnesses and committee members. However, consistent with the limitation of the OSTP confidentiality provision to complainants and respondents, we are not requiring that they do so.

C. Definition of Allegation—Inclusion of Oral Allegations, Sec. 93.201

Several commentators objected to the inclusion of oral allegations in the definition of the term ''allegation.'' Although, the current PHS regulation at 42 CFR part 50, subpart A, does not define the term allegation, it has been longstanding ORI practice to accept oral allegations, including oral, anonymous allegations. Experience has shown that oral allegations may contain relatively complete information, but if they do not, they are often followed by more complete allegations, or lead to more complete information.

The definition of allegation must be considered in the context of the criteria warranting an inquiry. Under Sec. 93.307(a), an inquiry is warranted if the allegation: (1) Falls within the definition of research misconduct; (2) involves PHS supported biomedical or behavioral research, research training, or activities related to that research or research training; and (3) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. Information sufficient to make these determinations can be transmitted orally. If such information is not transmitted orally or by other means, the institution cannot initiate an inquiry based upon the oral allegation. Under Sec. 93.300(b), an institution is obligated to respond to each allegation of research misconduct involving PHS supported biomedical or behavioral research, research training or activities related to that research or research training. The response must consist of assessing the allegation to determine if the criteria for initiating an inquiry are met and should consist of reasonable efforts to obtain further information about the allegation. We do not believe these are unreasonable burdens in response to oral allegations, particularly since oral allegations can, and have conveyed information leading to findings of research misconduct that have protected the integrity of PHS supported research. We also note that the Offices of the Inspector General at various Federal agencies routinely accept oral and anonymous allegations in their pursuit of fraud, waste, and abuse.

D. Definition of Research Record, Sec. 93.226

We did not make any changes in this section in response to comments that the inclusion of oral presentations will inhibit open scientific discourse and objections to the interpretation of ''data and results'' to include computers and scientific equipment. The definition of ''research record'' is consistent with the definition of that term in the OSTP Policy. Oral presentations are a widely accepted method of conveying scientific information and research results. There is no logical reason why scientists should be permitted to falsify, fabricate, and plagiarize PHS supported biomedical and behavioral research, research training and activities related to that research and research training in oral presentations. The interpretation of the OSTP definition to include computers and scientific instruments is reasonable and consistent with the wording of the definition. Laboratory records, ''both physical and electronic,'' are covered in the OSTP definition. Computers and scientific instruments contain electronic records. As explained above, we have made changes to clarify that if those electronic records can be extracted from the computer or instrument without change and recorded for later use, the computer or instrument need not be retained as the repository of the record.

E. Definition of Retaliation, Sec. 93.226; Protection From Retaliation Secs. 93.300(d) and 93.304(l)

One commentator recommended that the definition be amended to include retaliation against the respondent for his/her efforts to defend against the charges of research misconduct. The proposed definition would not include action resulting from research misconduct proceedings or personnel actions. It was also recommended that Secs. 93.300(d) and 93.304(l) be amended to require institutions to protect respondents from retaliation by referring to ''all participants.''

The purpose of the retaliation provision is to encourage researchers to come forward with good faith allegations of research misconduct and to encourage good faith cooperation with a research misconduct proceeding. In ORI's experience, there has been no showing of a need to protect

respondents from retaliation in order to ensure they will take steps to defend against an allegation of misconduct. In contrast, experience has shown a need to restore the reputations of respondents where there is a finding of no misconduct and Sec. 93.304(k) requires institutions to do that. If a need to protect respondents from retaliation is shown, institutions have broad discretion under the rule to address that situation on a case-by-case basis or adopt a policy to remedy the problem.

F. Responsibility of Institutions To Foster Responsible Conduct of Research, Sec. 93.300(c)

Several commentators objected to the requirement that institutions foster a research environment that promotes the responsible conduct of research, arguing that it is beyond the scope of a regulation on research misconduct. One letter, signed by four separate organizations, stated: ''Though responsible conduct of research is clearly an imperative that our institutions embrace, the nature of the general research environment and the promotion of the responsible conduct of research are not tied only to research misconduct as ORI staff have asserted in many venues, and, as a consequence, should not be linked in this particular policy.''

These commentators are reading too much into this provision. This is not a requirement for institutions to establish a new program for the responsible conduct of research. Rather, this provision appropriately updates the language of the current regulation requiring institutions to foster a research environment that discourages misconduct in all research and deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested (42 CFR 50.105). The new provision recognizes the continuing importance of the responsible conduct of research to competent research that is free of any research misconduct. As stated by the Institute of Medicine (IOM) in its 2002 report, Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct, ''instruction in the responsible conduct of research need not be driven by federal mandates, for it derives from a premise fundamental to doing science: the responsible conduct of research is not distinct from research; on the contrary, competency in research encompasses the responsible conduct of that research and the capacity for ethical decisionmaking.'' (Report at p. 9). In the context of this regulation, the directive in Sec. 93.300(c) to foster a research environment that promotes the responsible conduct of research means an environment that promotes competent, ethical research that is free of misconduct. This is directly related to the purposes of the regulation to establish the responsibilities of institutions in responding to research misconduct issues and to promote the integrity of PHS supported research and the research process (Sec. 93.101).

G. Responsibility for Maintenance of Research Records and Evidence, Sec. 93.305

One commentator recommended that this section be amended to require the prompt return to the respondent of records that, upon inventory, are found not to be relevant to the misconduct proceeding. Paragraph (a) of Sec. 93.305 requires the institution to obtain custody of all records and evidence needed to conduct the research misconduct proceeding. That requirement would not extend to records that are reasonably determined by the institution not to be needed to conduct the proceeding. We believe the imposition of an affirmative duty to return records that are determined to be irrelevant could adversely affect inquiries and investigations, because experience has shown that research misconduct proceedings are better served by broadly securing all records thought to be relevant. The respondent is protected by paragraph (b) of Sec. 93.305 under which he/she may obtain copies of the records or reasonable, supervised access.

H. Institutional Inquiry—Consideration of Honest Error or Difference of Opinion, Sec. 93.307

Several commentators recommended amending this section to impose an affirmative burden on institutions to assess whether honest error or difference of opinion exempts the allegation from consideration as research misconduct.

As noted earlier in this supplementary information, we have concluded that honest error or difference of opinion is an affirmative defense based on the statement in the preamble of the OSTP final rule that institutions and agencies are not required to disprove possible honest error or difference of opinion in order to make a finding of research misconduct. However, because of the overlap between this affirmative defense and the responsibility of institutions and HHS to prove that the alleged research misconduct was committed intentionally, knowingly, or recklessly, evidence of honest error or difference of opinion is to be considered in determining whether the institutions and HHS have met their burden of proving that element, a prerequisite to a finding of research misconduct.

Under Sec. 93.307(c), the purpose of an inquiry is to conduct an initial review of the evidence to determine if an investigation is warranted. An investigation is warranted under Sec. 93.307(d) if: (1) There is a reasonable basis for concluding that the allegation involves PHS supported research, research training, or activities related to that research or research training and falls within the definition of research misconduct, and (2) preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance. It is important to note that possible honest error or difference of opinion goes to the issue of whether the alleged research misconduct was committed intentionally, knowingly, or recklessly, not whether the allegation involves fabrication, falsification, or plagiarism. A finding that the research misconduct is conducted intentionally, knowingly, or reckless is necessary for a finding of research misconduct; a finding that is not made until the investigation is completed, absent an admission at an earlier stage.

Given this fact, and the preliminary nature of the fact finding at the inquiry stage, it would be appropriate for the inquiry report to note if there is possible evidence of honest error or difference of opinion for consideration in the investigation, but it would be inappropriate for the inquiry report to conclude, on the basis of an initial review of the evidence of honest error or difference of opinion, that the allegation should be dismissed. The determination of whether the alleged misconduct is intentional, knowing, or reckless, including consideration of evidence of honest error or difference of opinion, should be made at the investigation stage, following a complete review of the evidence. As noted in the preamble of the OSTP final policy, institutions and HHS do not have the burden of disproving possible honest error or differences of opinion.

I. Institutional Investigation, Sec. 93.310 and Investigation Time Limits, Sec. 93.311

Some commentators recommended that complainants be given a right to participate in the process. As explained in the preamble of the NPRM, complainants are witnesses in that they do not control or direct the process, do not have special access to evidence, except as determined by the institution

or ORI, and do not act as decision makers. This ensures that the institution will carry out its responsibility under Sec. 93.310(f) to conduct investigations that are fair.

Other commentators felt that the respondent should have an explicit right to review and comment on evidence and cross-examine witnesses at the investigation stage, and the right to request an extension of time for conducting the investigation. The proposed regulation requires that: (1) Where appropriate, the respondent be given copies of, or reasonable, supervised access to the research records secured by the institution on or before the date it notifies the respondent of the allegation, inquiry or investigation (Sec. 93.305(b)); (2) the respondent be notified in writing of the allegations before the investigation begins (Sec. 93.310(c)); (3) the institution interview the respondent and any witnesses he/she identifies who may have substantive information regarding any relevant aspects of the investigation (Sec. 93.310(g)); and (4) the respondent be given 30 days to review and comment on the investigation report (Sec. 93.312). These provisions have been retained and, as noted above, we have added to this final rule a requirement that respondent be given copies of, or supervised access to the evidence supporting the investigation report, concurrent with the period for comment. We believe these requirements ensure that the respondent will have a fair opportunity to present relevant evidence during the research misconduct proceeding, particularly when viewed in the context of the respondent's right to contest any HHS findings of research misconduct and proposed administrative sanctions before an ALJ. It is important to note that the final rule does not prohibit institutions from giving respondents greater rights during the investigation, so long as they do not contravene HHS requirements; the rule establishes a floor for their participation.

J. Appointment of the ALJ and Scientific Expert, Sec. 93.502

Two scientific societies objected to the ALJ provision, recommending that the current three member adjudication panel be retained. Another scientific society raised concerns about the extent to which scientists would be involved in the process, if they were not part of the adjudication panel (these concerns have been addressed through the changes in this section discussed above) and four associations supported the ALJ provision, provided that scientific or technical experts are required to participate in those cases involving complex scientific, medical or technical issues. As stated in the preamble of the NPRM, we believe that the change to a single decisionmaker will substantially improve and simplify the process for all parties. The change provides a process similar to Medicare and State health care program exclusion cases brought by the Office of the Inspector General (OIG), which have similar impacts on the reputations of the respondents. This process is also consistent with Recommendation 92–7 of the Administrative Conference of the United States that ALJs should hear and decide cases involving the imposition of sanctions having a substantial economic effect. Use of an ALJ with ready access to scientific and technical expertise, rather than multiple decision makers, will streamline the process without compromising the quality of decisions that are dependent upon resolution of scientific, medical, or technical issues.

In addition to the comments recommending mandatory appointment of an expert in complex cases, another commentator recommended that the ALJ be required to appoint a scientific or technical expert to assist the ALJ in every case, rather than the ALJ being authorized to appoint such an expert and being required to appoint such an expert upon the request of one of the parties, as proposed in the NPRM. We are not changing the provision to require the appointment of an expert in every case or in all cases involving complex issues. We believe that such a rigid requirement is not needed to ensure fairness. In complex cases, it will always be in the interest of at least one of the parties to ensure that the ALJ fully understands the issues by requesting the appointment of an expert. Upon such a request, the appointment of an expert is mandatory. Furthermore, the ALJ, who is in the best position to assess the complexity of the case in light of his/her own knowledge and training, may appoint an expert in the absence of any motion by a party. The self-interest of the parties and the duty of the ALJ to exercise his/her discretion to provide a fair hearing should ensure that an expert is appointed where necessary to ensure fairness. We will closely monitor the appointment of experts in future hearings and, if problems are apparent, consider amending the regulations to compel the appointment of an expert in order to ensure that the ALJ will have the benefit of expert advice in cases involving complex issues.

IV. General Issues and Requests for Clarification

Several general comments and requests for clarification are addressed in the following question and answer format.

Q. Is the detail in the final rule contrary to the goal of the OSTP Federal Policy on Research Misconduct to provide a more uniform Federal-wide approach?

A. No, the final rule is consistent with the OSTP Federal Policy. As stated elsewhere in this Supplementary Information we have made some changes in order to adhere more closely to the Federal Policy and refused to make other changes that would have been inconsistent with the Federal Policy. The Supplementary Information section of the Notice of Proposed Rulemaking (69 FR 20778, 20780 (April 16, 2004)) explained that the proposed rule contained more detail than the existing rule because institutions had over the years asked for more detailed guidance and that detailed guidance would ensure thorough and fair inquiries and investigations and greater accountability on the part of all participants in research misconduct proceedings. Similarly, it was explained that the more detailed hearing process was being proposed in response to concerns that the current informal procedures lack the consistency and clarity provided by binding rules of procedure for other types of cases. Thus, the detail in the final rule is necessary to ensure more uniformity among the various institutions that will be conducting research misconduct proceedings and to ensure fair, uniform procedures for the benefit of respondents. The detail in the proposed rule, which is retained in this final rule, is entirely consistent with the goals of the OSTP Federal Policy to provide for fair and timely procedures and to strive for uniformity in implementation.

Q. How should institutions deal with bad faith allegations?

A. The final rule, Sec. 93.300(d), requires institutions to take all reasonable and practical steps to protect the positions and reputations of good faith complainants and protect them from retaliation by respondents and other institutional members. By negative implication, such steps are not required for bad faith complainants. Bad faith complainants are those who, under the definition of ''good faith'' in Sec. 93.210, do not have a belief in the truth of their allegation that a reasonable person in the complainant's position could have based on the information known to the complainant at the time.

We have determined there is no need for the final rule to further address bad faith allegations, given that institutions may have internal standards of conduct that address matters not addressed in the final rule (Sec. 93.319). However, the definition of ''good faith'' provides important guidance for institutions because it makes clear that an allegation can lack sufficient credibility and specificity so that potential evidence of research misconduct cannot be identified (Sec. 93.307(a)(3)), but still may not be a bad faith allegation. Thus, if institutions exercise their discretion to adopt procedures addressing bad faith allegations, we urge them to include fair procedures for determining whether there has been a bad faith allegation. ORI is prepared to work collaboratively with the research community to develop guidance in this area if research institutions and associations desire to do so.

Q. Will the final rule apply retroactively?

A. No, the final rule will become effective 30 days after the date it is published in the **Federal Register** and will apply prospectively. The effect of that prospective application will depend upon how the provisions of the rule interact with the activities of the institution and ORI. Upon the expiration of 30 days, the final rule will immediately apply to institutions that are receiving PHS support for research, research training or activities related to that research or research training. For institutions not receiving such PHS support, the regulation will not apply until they submit an application for that support.

If an institution to which the final rule applies immediately has completed an inquiry or investigation and reports to ORI after the effective date of the final rule, ORI will take further action, make findings, and provide an opportunity for a hearing in accordance with the final rule. If a request for a hearing is received by the DAB Chair after the effective date of the final rule, the hearing will be conducted in accordance with the final rule. This will ensure that respondents have the benefit of the detailed, fair hearing procedures in the final rule. Because it is not possible to address every possible scenario relating to the prospective application of the final rule, institutions that have received allegations of misconduct, or have ongoing inquiries or investigations upon the effective date of this final rule should contact ORI to determine how the rule will apply to those ongoing activities. ORI will make every effort to minimize burdens and ensure that all parties are treated fairly. Generally, if an institution has a research misconduct proceeding pending at the time the new regulation becomes effective with respect to that institution, ORI would expect the new procedural requirements to be applicable to the institution's subsequent steps in that proceeding, unless the institution or respondent would be unduly burdened or treated unfairly. However, the definition of research misconduct that was in effect at the time the misconduct occurred would apply.

Q. Should HHS take action to provide immunity from personal liability for institutions, committee members, and witnesses who participate in research misconduct proceedings?

A. As the commentator who raised this issue implied, a Federal statute, rather than an HHS regulation, would be needed to provide this immunity. Earlier attempts by HHS to develop legislation providing immunity were unsuccessful. ORI does not currently have sufficient data to make the case for Federal legislation. Interested parties are encouraged to submit evidence that would help us in determining whether there is a need for Federal legislation to provide immunity for committee members and witnesses or to propose ways to provide such protection in the absence of such legislation.

Q. Should HHS have primary responsibility for responding to allegations of research misconduct at institutions that have repeatedly failed to handle such allegations properly?

A. Under the final rule, HHS has the discretion to take responsibility for responding to allegations of research misconduct at institutions that are failing to handle such allegations properly. Under Sec. 93.400, ORI may respond directly to any allegation of research misconduct at any time before, during, or after an institution's response to the matter. The ORI response may include, but is not limited to, reviewing an institution's findings and process and recommending that HHS perform an inquiry or investigation. In addition, ORI may make findings and impose HHS administrative actions related to an institution's compliance with the final rule. Where an institution has failed in the past to respond promptly or properly to allegations of research misconduct, ORI will monitor closely its subsequent responses to allegations of research misconduct. However, ORI would intervene only as it determines necessary and would first provide advice and assistance to the institution. ORI would exercise its discretion to respond directly to an allegation of research misconduct only if the institution disregarded that advice or assistance or otherwise continued to fail to properly carry out its responsibilities under the final rule.

Q. Are sanctions required or available for imposition against those who violate the confidentiality requirements in the final rule?

A. The final rule does not provide for specific sanctions against those who violate the confidentiality protections in Sec. 93.108, but an institution would be subject to the general sanctions for failure to comply with the final rule and its assurance if it fails to comply with Sec. 93.108. Section 93.300(e) requires institutions to provide confidentiality to the extent required by Sec. 93.108, and Sec. 93.304 requires that an institution seeking an approved assurance have written policies and procedures that, consistent with Sec. 93.108, provide for protecting the confidentiality of respondents, complainants and research subjects. The final rule does not impose, or require institutions to impose sanctions against institutional members who violate the confidentiality provisions of Sec. 93.108, but institutions have the discretion to impose such sanctions by making compliance with those provisions a condition of employment. Institutions may also wish to develop specific policies addressing actions the institution may take when institutional members violate the confidentiality requirements.

Q. Does a respondent have a right to continue his/her research after allegations of research misconduct have been made?

A. The final rule does not directly address the issue of whether the respondent has a right to continue his/her research after an allegation of research misconduct has been made. Section 93.305 requires the institution to: (1) promptly obtain custody of and sequester all research records and evidence needed to conduct the research misconduct proceeding; and (2) where appropriate, give the respondent copies of, or reasonable, supervised access to the research records. There are at least two reasons for providing such access: to enable the respondent to prepare a defense against the allegation, and/or to continue the research.

As proposed and adopted in this final rule, Sec. 93.305(b) requires the institution to provide the respondent copies of, or supervised access to the research records secured by the institution, unless that would be inappropriate. The determination of when it would be inappropriate to provide such copies or access is left to the discretion of the institution. In exercising this discretion, institutions

should consider separately the issues of whether the respondent should continue the research and whether and under what circumstances the respondent should be given copies of or access to the research records. In considering the former issue, institutions should weigh, among other factors, the special circumstances listed in Sec. 93.318, the importance of continuing the research, and whether the expertise of the respondent is unique. Institutions must also be cognizant of the interests of the PHS funding agency and the need to confer with that agency about suspension or discontinuation of the research or to obtain approval if the Principal Investigator is being replaced. If the respondent does not continue the research, it would be appropriate, absent special circumstances, to give him/her a copy of the records, or reasonable, supervised access to them for the purpose of preparing a defense to the allegations. In order to ensure that the respondent has this opportunity at the investigation stage, Sec. 93.312(a) requires the institution to give the respondent a copy of, or supervised access to the evidence upon which the draft investigation report is based concurrently with the provision of the draft report for comment by the respondent.

Q. Does the 120-day time limit for completing an investigation include the 30-day period for respondent to review and comment on the draft report?

A. Yes. Section 93.311 provides in pertinent part that an institution must complete all aspects of an investigation within 120 days of beginning it, including providing the draft report for comment in accordance with Sec. 93.312, and sending the final report to ORI under Sec. 93.315. Under Sec. 93.313(g), the final report must include and consider any comments made by the respondent or complainant on the draft investigation report. If additional time is needed, the institution can request reasonable extensions for completion of the investigation.

Analysis of Impacts

As discussed in greater detail below, we have examined the potential impact of this final rule as directed by Executive Orders 12866 and 13132, the Unfunded Mandates Act of 1995, the Regulatory Flexibility Act, and the Paperwork Reduction Act of 1995.

We have also determined that this final rule will not: (1) Have an impact on family well-being under section 654 of the Treasury and General Government Appropriations Act of 1999; nor (2) have a significant adverse effect on the supply, distribution, or use of energy sources under Executive Order 13211.

A. Executive Order 12866

These final regulations have been drafted and reviewed in accordance with Executive Order 12866 (58 FR 51735), section 1(b), Principles of Regulation. The Department has determined that this final rule is a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review because it will materially alter the obligations of recipients of PHS biomedical and behavioral research and research training grants. However, the final regulation is not economically significant as defined in section 3(f)(1), because it will not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. Therefore, the information enumerated in section 6(a)(3)(C) of the Executive Order is not required. The final rule has been reviewed by the Office of Management and Budget (OMB) under the terms of the Executive Order.

Recipients of PHS biomedical and behavioral research grants will have to comply with the reporting and record keeping requirements in the proposed regulation. As shown below in the Paperwork Reduction Act analysis, those burdens encompass essentially all of the activities of the institutions that are required under the proposed regulation. The estimated total annual burden is 19,727.5 hours. The U.S. Department of Labor, Bureau of Labor Statistics, sets the mean hourly wage for Educational Administrators, Postsecondary at $ 36.12. The mean hourly wage for lawyers is $ 51.56. The average hourly cost of benefits for all civilian workers would add $ 7.40 to these amounts. In order to ensure that all possible costs are included and to account for potentially higher rates at some institutions, we estimated the cost per burden hour at $ 100. This results in a total annual cost for all institutions of $ 1,972,750.

B. The Unfunded Mandates Reform Act of 1995

Sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532 and 1535) require that agencies prepare several analytic statements before promulgating a rule that may result in annual expenditures of State, local, and tribal governments, or by the private sector, of $100 million or more in any one year. This final rule will not result in expenditures of this magnitude, and thus the Secretary certifies that such statements are not necessary.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) requires agencies to prepare a regulatory flexibility analysis describing the impact of the final rule on small entities, but also permits agency heads to certify that the final rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The primary effect of this rule is to require covered institutions to implement policies and procedures for responding to research misconduct cases. The Department certifies that this rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act, based on the following facts.

Approximately 47 percent (1862) of the 4000 institutions that currently have research misconduct assurances are small entities. The primary impact of the final rule on covered institutions results from the reporting and record keeping provisions which are analyzed in detail under the heading, ''The Paperwork Reduction Act.'' Significant annual burdens apply only if an institution learns of possible research misconduct and begins an inquiry, investigation, or both. In 2001, 86 inquiries and 46 investigations were conducted among all the institutions. No investigations were conducted by a small entity and only one conducted an inquiry. Small entities would be able to avoid entirely the potential burden of conducting an inquiry or investigation by filing a Small Organization Statement under section 93.303. The burden of filing this Statement is .5 hour. Thus, the significant burden of conducting inquiries and investigations will not fall on a substantial number of small entities.

A small organization that files the Small Organization Statement must report allegations of research misconduct to ORI and comply with all provisions of the proposed regulation other than those requiring the conduct of inquiries and investigations. The total annual average burden per response for creating written policies and procedures for addressing research misconduct is approximately 16 hours. However, approximately 99 percent of currently funded institutions already have these policies and procedures in place and spend approximately .5 hour updating

them. The most significant of the burdens that might fall on an entity filing a Small Organization Statement is taking custody of research records and evidence when there is an allegation of research misconduct. The average burden per response is 35 hours, but based on reports of research misconduct over the last three years, less than 5 small entities would have to incur that burden in any year.

Based on the forgoing analysis that was not commented upon when it appeared in the Notice of Proposed Rulemaking, the Department concludes that this final rule will not impose a significant burden on a substantial number of small entities.

D. Executive Order 13132: Federalism

This final rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, we have determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

E. The Paperwork Reduction Act

Sections 300–305, 307–311, 313–318, and 413 of the rule contain information collection requirements that are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). The title, description, and respondent description of the information collection requirements are shown below with an estimate of the annual reporting burdens. Included in the estimates is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information. Public comments on these estimates and other aspects of compliance with the Paperwork Reduction Act were invited in the NPRM.

As indicated in the foregoing discussion of the comments, a number of them addressed reporting and recordkeeping burdens. In response to comments that the proposed reporting requirements in Secs. 93.300(a), 93.302(c) and 93.316 were subject to an overly broad interpretation, we have made clarifying changes to limit their scope. This did not result in any change in the burden estimates, because those estimates were based upon a restrictive interpretation of the requirements. While changes were made to make it easier for institutions to meet the requirements in Secs. 93.305, 93.307, and 93.310 for securing records contained in scientific instruments we do not believe that those changes significantly affect the burden of the collection requirements.

As explained above, the addition of a relevancy standard to Sec. 93.317 and provisions for transferring the custody of records to HHS will lessen the overall burden of retaining records of research misconduct proceedings, although we have added a requirement that the institutions document any determination that records are irrelevant. In addition, we are adding an explanatory note to the burden estimate for Sec. 93.317. This note explains that not all of the 53 respondents that are expected to conduct research misconduct proceedings each year, on average, will have to to retain the records of those proceedings for a full seven years. If ORI determines that a thorough, complete investigation has been conducted and finds that there was no research misconduct or settles a case, it will notify the institution that it does not have to retain the records of the research misconduct proceeding, unless ORI is aware of an action by federal or state government to which the records may pertain. Historically, about 60 percent of cases closed by ORI do not result in PHS misconduct findings or PHS administrative actions. Thus, it is expected that in the majority of cases ORI will notify the institutions that they do not have to retain the records for the full seven-year period.

We have added a burden statement for the requirement in Sec. 93.302(a)(1) that institutions provide their policies and procedures on research misconduct, upon request, to ORI, HHS, and members of the public (this third item was added in response to comments). Based on recent data, we have increased the number of respondents in the items relating to the conduct of investigations by institutions. In addition, we have made minor changes to account for the renumbering of sections and paragraphs and to correct errors. With these changes, the estimates published in the NPRM are adopted as the burden estimates of the final rule. The information collection requirements in the final rule have been submitted to OMB for review.

Title: Public Health Service Policies on Research Misconduct.

Description: This final rule revises the current regulation, 42 CFR 50.101, *et seq.*, in three significant ways and will supersede the current regulation. First, the proposed rule integrates the White House Office of Science and Technology Policy's (OSTP) December 6, 2000, government wide Federal Policy on Research Misconduct. Second, the proposed rule incorporates the recommendations of the HHS Review Group on Research Misconduct and Research Integrity that were approved by the Secretary of HHS on August 25, 1999. Third, the proposed rule integrates a decade's worth of experience and understanding since the agency's first regulations were promulgated.

Description of Respondents: The ''respondents'' for the collection of information described in this regulation are institutions that apply for or receive PHS support through grants, contracts, or cooperative agreements for any project or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training (*see* definition of ''Institution'' at Sec. 93.213).

Subpart C—Responsibilities of Institutions

Compliance and Assurances

Section 93.300(a)

See Sec. 93.304 for burden statement.

Section 93.300(c)

See Sec. 93.302(a)(2)(i) for burden statement.

Section 93.300(i)

See Sec. 93.301(a) for burden statement.

Section 93.301(a)

Covered institutions must provide ORI with an assurance either by submitting the initial certification (500 institutions) or by submitting an annual report (3500 institutions).

Number of Respondents—4000.

Number of Responses per Respondent—1.

Annual Average Burden per Response—.5 hour.

Total Annual Burden—2000 hours.

Section 93.302(a)(1)

Covered institutions must, upon request, provide their policies and procedures on research misconduct to ORI, authorized HHS personnel, and members of the public.

Number of Respondents—2000.

Number of Responses per Respondent—1.

Annual Average Burden per Response—.5 hour.

Total Annual Burden—1000 hours.

Section 93.302(a)(2)(i)

Each applicant institution must inform its research members

participating in or otherwise involved with PHS supported biomedical or behavioral research, research training or activities related to that research or research training, including those applying for PHS support, of the institution's policies and procedures and emphasize the importance of compliance with these policies and procedures.

Number of Respondents—4000.

Number of Responses per Respondent—1.

Annual Average Burden per Response—.5 hour.

Total Annual Burden—2000 hours.

Section 93.302(b)

See Sec. 93.301(a) for burden statement.

Section 93.302(c)

In addition to the annual report, covered institutions must submit aggregated information to ORI on request regarding research misconduct proceedings.

Number of Respondents—100.

Number of Responses per Respondent—1.

Annual Average Burden per Response—1 hour.

Total Annual Burden—100.

Section 93.303

Covered institutions that, due to their small size, lack the resources to develop their own research misconduct policies and procedures may elect to file a ''Small Organization Statement'' with ORI.

Number of Respondents—75.

Number of Responses per Respondent—1.

Annual Average Burden per Response—.5 hour.

Total Annual Burden—37.5 hours.

Section 93.304

Covered institutions with active assurances must have written policies and procedures for addressing research misconduct. Approximately 3500 institutions already have these policies and procedures in place in any given year and spend minimal time (.5 hour) updating them. Approximately 500 institutions each year spend an average of two days creating these policies and procedures for the first time.

Number of Respondents—4000.

Number of Responses per Respondent—1.

Annual Average Burden per Response—2.5 hours.

Total Annual Burden—10,000 hours.

Section 93.305(a), (c), and (d)

When a covered institution learns of possible research misconduct, it must promptly take custody of all research records and evidence and then inventory and sequester them. Covered institutions must also take custody of additional research records or evidence discovered during the course of a research misconduct proceeding. Once the records are in custody, the institutions must maintain them until ORI requests them, HHS takes final action, or as required under Sec. 93.317.

Number of Respondents—53.

Number of Responses per Respondent—1.

Annual Average Burden per Response—35 hours.

Total Annual Burden—1855 hours.

Section 93.305(b)

Where appropriate, covered institutions must give the respondent copies of or reasonable, supervised access to the research record.

Number of Respondents—53.

Number of Responses per Respondent—1.

Annual Average Burden per Response—5 hours.

Total Annual Burden—265 hours.

The Institutional Inquiry

Section 93.307(b)

At the time of or before beginning an inquiry, covered institutions must notify the presumed respondent in writing.

Number of Respondents—53.

Number of Responses per Respondent—1.

Annual Average Burden per Response—1 hour.

Total Annual Burden—53 hours.

Section 93.307(e)

See Sec. 93.309 for burden statement.

Section 93.307(f)

Covered institutions must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments to the report.

Number of Respondents—53.

Number of Responses per Respondent—1.

Annual Average Burden per Response—1 hour.

Total Annual Burden—53 hours.

Section 93.308(a)

Covered institutions must notify the respondent whether the inquiry found that an investigation is warranted.

Number of Respondents—53.

Number of Responses per Respondent—1.

Annual Average Burden per Response—.5 hour.

Total Annual Burden—26.5 hours.

Section 93.309(a)

When a covered institution issues an inquiry report in which it finds that an investigation is warranted, the institution must provide ORI with a specified list of information within 30 days of the inquiry report's issuance.

Number of Respondents—20.

Number of Responses per Respondent—1.

Annual Average Burden per Response—16 hours.

Total Annual Burden—320 hours.

Section 93.309(c)

Covered institutions must keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of reasons why decision was made to forego an investigation.

Number of Respondents—37.

Number of Responses per Respondent—1.

Annual Average Burden per Response—1 hour.

Total Annual Burden—37 hours.

The Institutional Investigation

Section 93.310(b)

See Sec. 93.309(a) for burden statement.

Section 93.310(c)

Covered institutions must notify the respondent of allegations of research misconduct before beginning the investigation.

Number of Respondents—20.

Number of Responses per Respondent—1.

Annual Average Burden per Response—1.

Total Annual Burden—20 hours.

Section 93.310(d)

See Sec. 93.305(a), (c), and (d) for burden statement.

Section 93.310(g)

Covered institutions must 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.

Number of Respondents—20.

Number of Responses per Respondent—1.

Annual Average Burden per Response—15 hours.

Total Annual Burden—300 hours.

Section 93.311(b)

If unable to complete the investigation in 120 days, covered institutions must submit a written request for an extension from ORI.

Number of Respondents—16.

Number of Responses per Respondent—1.
Annual Average Burden per Response—1 hour.
Total Annual Burden—16 hours.

Section 93.313

See Sec. 93.315 for burden statement.

Section 93.314(b)

If unable to complete any institutional appeals process relating to the institutional finding of misconduct within 120 days from the appeal's filing, covered institutions must request an extension in writing and provide an explanation.
Number of Respondents—5.
Number of Responses per Respondent—1.
Annual Average Burden per Response—.5 hour.
Total Annual Burden—2.5 hours.

Section 93.315

At the conclusion of the institutional investigation process, covered institutions must submit four items to ORI: the investigation report (with attachments and appeals), final institutional actions, the institutional finding, and any institutional administrative actions.
Number of Respondents—20.
Number of Responses per Respondent—1.
Annual Average Burden per Response—80 hours.
Total Annual Burden—1600 hours.

Section 93.316(a)

Covered institutions that plan to end an inquiry or investigation before completion for any reason must contact ORI before closing the case and submitting its final report.
Number of Respondents—10.
Number of Responses per Respondent—1.
Annual Average Burden per Response—2 hours.
Total Annual Burden—20 hours.

Other Institutional Responsibilities

Section 93.317(a) and (b)

See Sec. 93.305(a), (c), and (d), for burden statement. It is expected that not all of the 53 respondents that learn of misconduct will have to retain the records of their research misconduct proceedings for seven years. If ORI determines that a thorough, complete investigation has been conducted and finds that there was no research misconduct, or settles the case, it will notify the institution that it does not have to retain the records of the research misconduct proceeding, unless ORI is aware of an action by federal or state government to which the records pertain.

Section 93.318

Covered institutions must notify ORI immediately in the event of any of an enumerated list of exigent circumstances.

Number of Respondents—2.

Number of Responses per Respondent—1.

Annual Average Burden per Response—1 hour.

Total Annual Burden—2 hours.

Subpart D—Responsibilities of the U.S. Department of Health and Human Services Institutional Compliance Issues

Section 93.413(c)(6)

ORI may require noncompliant institutions to adopt institutional integrity agreements.

Number of Respondents—1.

Number of Responses per Respondent—1.

Annual Average Burden per Response—20 hours.

Total Annual Burden—20 hours.

The Department has submitted a copy of this final rule to OMB for its review of these information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Prior to the effective date of this final rule, HHS will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects

42 CFR Part 50

Administrative practice and procedure, Science and technology, Reporting and recordkeeping requirements, Research, Government contracts, Grant programs.

42 CFR Part 93

Administrative practice and procedure, Science and technology, Reporting and recordkeeping requirements, Research, Government contracts, Grant programs.

Dated: January 14, 2005.

Cristina V. Beato,

Acting Assistant Secretary for Health.

Dated: May 3, 2005.

Michael O. Leavitt,

Secretary of Health and Human Services.

■ Accordingly, under the authority of 42 U.S.C. 289b, HHS is amending 42 CFR parts 50 and 93 as follows:

PART 50—POLICIES OF GENERAL APPLICABILITY

■ 1. The authority citation for 42 CFR part 50 continues to as follows:

Authority: Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); Sec. 1006, Public Health Service Act, 84 Stat. 1507 (42 U.S.C. 300a–4), unless otherwise noted.

Subpart A [Removed]

■ 2. Part 50, Subpart A (§§ 50.101–50.105) is removed and reserved.
■ 3. A new Part 93, with subparts A, B, C, D and E is added to read as follows:

PART 93—PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

Sec.
93.25 Organization of this part.
93.50 Special terms.

Subpart A—General

93.100 General policy.
93.101 Purpose.
93.102 Applicability.
93.103 Research misconduct.
93.104 Requirements for findings of research misconduct.
93.105 Time limitations.
93.106 Evidentiary standards.
93.107 Rule of interpretation.
93.108 Confidentiality.
93.109 Coordination with other agencies.

Subpart B—Definitions

93.200 Administrative action.
93.201 Allegation.
93.202 Charge letter.
93.203 Complainant.
93.204 Contract.
93.205 Debarment or suspension.
93.206 Debarring official.
93.207 Departmental Appeals Board or DAB.
93.208 Evidence.
93.209 Funding component.
93.210 Good faith.
93.211 Hearing.
93.212 Inquiry.
93.213 Institution.
93.214 Institutional member
93.215 Investigation.
93.216 Notice.
93.217 Office of Research Integrity or ORI.
93.218 Person.
93.219 Preponderance of the evidence.
93.220 Public Health Service or PHS.
93.221 PHS support.
93.222 Research.
93.223 Research misconduct proceeding.

93.224 Research record.
93.225 Respondent.
93.226 Retaliation.
93.227 Secretary or HHS.

Subpart C—Responsibilities of Institutions

Compliance and Assurances

93.300 General responsibilities for compliance.
93.301 Institutional assurances.
93.302 Institutional compliance with assurances.
93.303 Assurances for small institutions.
93.304 Institutional policies and procedures.
93.305 Responsibility for maintenance and custody of research records and evidence.
93.306 Using a consortium or person for research misconduct proceedings.

The Institutional Inquiry

93.307 Institutional inquiry.
93.308 Notice of the results of the inquiry.
93.309 Reporting to ORI on the decision to initiate an investigation.

The Institutional Investigation

93.310 Institutional investigation.
93.311 Investigation time limits.
93.312 Opportunity to comment on the investigation report.
93.313 Institutional investigation report.
93.314 Institutional appeals.
93.315 Notice to ORI of institutional findings and actions.
93.316 Completing the research misconduct process.

Other Institutional Responsibilities

93.317 Retention and custody of the research misconduct proceeding record.
93.318 Notifying ORI of special circumstances.
93.319 Institutional standards.

Subpart D—Responsibilities of the U.S. Department of Health and Human Services

General Information

93.400 General statement of ORI authority.
93.401 Interaction with other offices and interim actions.

Research Misconduct Issues

93.402 ORI allegation assessments.
93.403 ORI review of research misconduct proceedings.
93.404 Findings of research misconduct and proposed administrative actions.
93.405 Notifying the respondent of findings of research misconduct and HHS administrative actions.
93.406 Final HHS actions.
93.407 HHS administrative actions.
93.408 Mitigating and aggravating factors in HHS administrative actions.
93.409 Settlement of research misconduct proceedings.
93.410 Final HHS action with no settlement or finding of research misconduct.
93.411 Final HHS action with a settlement or finding of misconduct.

Institutional Compliance Issues

93.412 Making decisions on institutional noncompliance.
93.413 HHS compliance actions.

Disclosure of Information

93.414 Notice.

Subpart E—Opportunity to Contest ORI Findings of Research Misconduct and HHS Administrative Actions

General Information

93.500 General policy.
93.501 Opportunity to contest findings of research misconduct and administrative actions.

Hearing Process

93.502 Appointment of the Administrative Law Judge and scientific expert.
93.503 Grounds for granting a hearing request.
93.504 Grounds for dismissal of a hearing request.
93.505 Rights of the parties.
93.506 Authority of the Administrative Law Judge.
93.507 Ex parte communications.
93.508 Filing, forms, and service.
93.509 Computation of time.
93.510 Filing motions.
93.511 Prehearing conferences.
93.512 Discovery.
93.513 Submission of witness lists, witness statements, and exhibits.
93.514 Amendment to the charge letter.
93.515 Actions for violating an order or for disruptive conduct.
93.516 Standard and burden of proof.
93.517 The hearing.
93.518 Witnesses.
93.519 Admissibility of evidence.
93.520 The record.
93.521 Correction of the transcript.
93.522 Filing post-hearing briefs.
93.523 The Administrative Law Judge's ruling.

Authority: 42 U.S.C. 216, 241, and 289b.

§ 93.25 Organization of this part.

This part is subdivided into five subparts. Each subpart contains information related to a broad topic or specific audience with special responsibilities as shown in the following table.

In subpart . . .	You will find provisions related to . . .
A	General information about this rule.
B	Definitions of terms used in this part.
C	Responsibilities of institutions with PHS support.
D	Responsibilities of the U.S. Department of Health and Human Services and the Office of Research Integrity.
E	Information on how to contest ORI research misconduct findings and HHS administrative actions.

§ 93.50 Special terms.

This part uses terms throughout the text that have special meaning. Those terms are defined in Subpart B of this part.

Subpart A—General

§ 93.100 General policy.

(a) Research misconduct involving PHS support is contrary to the interests of the PHS and the Federal government and to the health and safety of the public, to the integrity of research, and to the conservation of public funds.

(b) The U.S. Department of Health and Human Services (HHS) and institutions that apply for or receive Public Health Service (PHS) support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training share responsibility for the integrity of the research process. HHS has ultimate oversight authority for PHS supported research, and for taking other actions as appropriate or necessary, including the right to assess allegations and perform inquiries or investigations at any time. Institutions and institutional members have an affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work, and primary responsibility for responding to and reporting allegations of research misconduct, as provided in this part.

§ 93.101 Purpose.

The purpose of this part is to—

(a) Establish the responsibilities of HHS, PHS, the Office of Research Integrity (ORI), and institutions in responding to research misconduct issues;

(b) Define what constitutes misconduct in PHS supported research;

(c) Define the general types of administrative actions HHS and the PHS may take in response to research misconduct; and

(d) Require institutions to develop and implement policies and procedures for—

(1) Reporting and responding to allegations of research misconduct covered by this part;

(2) Providing HHS with the assurances necessary to permit the institutions to participate in PHS supported research.

(e) Protect the health and safety of the public, promote the integrity of PHS supported research and the research process, and conserve public funds.

§ 93.102 Applicability.

(a) Each institution that applies for or receives PHS support for biomedical or

behavioral research, research training or activities related to that research or research training must comply with this part.

(b)(1) This part applies to allegations of research misconduct and research misconduct involving:

(i) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information;

(ii) PHS supported biomedical or behavioral extramural or intramural research;

(iii) PHS supported biomedical or behavioral extramural or intramural research training programs;

(iv) PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks or the dissemination of research information; and

(v) Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training.

(2) This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.

(c) This part does not supersede or establish an alternative to any existing regulations or procedures for handling fiscal improprieties, the ethical treatment of human or animal subjects, criminal matters, personnel actions against Federal employees, or actions taken under the HHS debarment and suspension regulations at 45 CFR part 76 and 48 CFR subparts 9.4 and 309.4.

(d) This part does not prohibit or otherwise limit how institutions handle allegations of misconduct that do not fall within this part's definition of research misconduct or that do not involve PHS support.

§ 93.103 Research misconduct.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

§ 93.104 Requirements for findings of research misconduct.

A finding of research misconduct made under this part requires that—

(a) There be a significant departure from accepted practices of the relevant research community; and

(b) The misconduct be committed intentionally, knowingly, or recklessly; and

(c) The allegation be proven by a preponderance of the evidence.

§ 93.105 Time limitations.

(a) *Six-year limitation.* This part applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct.

(b) *Exceptions to the six-year limitation.* Paragraph (a) of this section does not apply in the following instances:

(1) *Subsequent use exception.* The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.

(2) *Health or safety of the public exception.* If ORI or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

(3) *''Grandfather'' exception.* If HHS or an institution received the allegation of research misconduct before the effective date of this part.

§ 93.106 Evidentiary standards.

The following evidentiary standards apply to findings made under this part.

(a) *Standard of proof.* An institutional or HHS finding of research misconduct must be proved by a preponderance of the evidence.

(b) *Burden of proof.* (1) The institution or HHS has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

(2) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether HHS or the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

(3) The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.

§ 93.107 Rule of interpretation.

Any interpretation of this part must further the policy and purpose of the HHS and the Federal government to protect the health and safety of the public, to promote the integrity of research, and to conserve public funds.

§ 93.108 Confidentiality.

(a) Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, 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. Provided, however, that:

(1) The institution must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings under § 93.403.

(2) Under § 93.517(g), HHS administrative hearings must be open to the public.

(b) Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.

§ 93.109 Coordination with other agencies.

(a) When more than one agency of the Federal government has jurisdiction of the subject misconduct allegation, HHS will cooperate in designating a lead agency to coordinate the response of the agencies to the allegation. Where HHS is not the lead agency, it may, in consultation with the lead agency, take appropriate action to protect the health and safety of the public, promote the integrity of the PHS supported research and research process and conserve public funds.

(b) In cases involving more than one agency, HHS may refer to evidence or reports developed by that agency if HHS determines that the evidence or reports will assist in resolving HHS issues. In appropriate cases, HHS will seek to resolve allegations jointly with the other agency or agencies.

Subpart B—Definitions

§ 93.200 Administrative action.

Administrative action means—

(a) An HHS action in response to a research misconduct proceeding taken to protect the health and safety of the public, to promote the integrity of PHS supported biomedical or behavioral research, research training, or activities related to that research or research training and to conserve public funds; or

(b) An HHS action in response either to a breach of a material provision of a settlement agreement in a research misconduct proceeding or to a breach of any HHS debarment or suspension.

§ 93.201 Allegation.

Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or HHS official.

§ 93.202 Charge letter.

Charge letter means the written notice, as well as any amendments to the notice, that are sent to the respondent stating the findings of research misconduct and any HHS administrative actions. If the charge letter includes a debarment or suspension action, it may be issued jointly by the ORI and the debarring official.

§ 93.203 Complainant.

Complainant means a person who in good faith makes an allegation of research misconduct.

§ 93.204 Contract.

Contract means an acquisition instrument awarded under the HHS Federal Acquisition Regulation (FAR), 48 CFR Chapter 1, excluding any small purchases awarded pursuant to FAR Part 13.

§ 93.205 Debarment or suspension.

Debarment or *suspension* means the Government wide exclusion, whether temporary or for a set term, of a person from eligibility for Federal grants, contracts, and cooperative agreements under the HHS regulations at 45 CFR part 76 (nonprocurement) and 48 CFR subparts 9.4 and 309.4 (procurement).

§ 93.206 Debarring official.

Debarring official means an official authorized to impose debarment or suspension. The HHS debarring official is either—

(a) The Secretary; or

(b) An official designated by the Secretary.

§ 93.207 Departmental Appeals Board or DAB.

Departmental Appeals Board or *DAB* means, depending on the context—

(a) The organization, within the Office of the Secretary, established to conduct hearings and provide impartial review of disputed decisions made by HHS operating components; or

(b) An Administrative Law Judge (ALJ) at the DAB.

§ 93.208 Evidence.

Evidence means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

§ 93.209 Funding component.

Funding component means any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity that involves the conduct of biomedical or behavioral research, research training or activities related to that research or research training, *e.g.*, agencies, bureaus, centers, institutes, divisions, or offices and other awarding units within the PHS.

§ 93.210 Good faith.

Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

§ 93.211 Hearing.

Hearing means that part of the research misconduct proceeding from the time a respondent files a request for an administrative hearing to contest ORI findings of research misconduct and HHS administrative actions until the time the ALJ issues a recommended decision.

§ 93.212 Inquiry.

Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of §§ 93.307–93.309.

§ 93.213 Institution.

Institution means any individual or person that applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, small research institutions, and independent researchers.

§ 93.214 Institutional member.

Institutional member or *members* means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

§ 93.215 Investigation.

Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include

a recommendation for other appropriate actions, including administrative actions.

§ 93.216 Notice.

Notice means a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or e-mail address of the addressee. Several sections of Subpart E of this part have special notice requirements.

§ 93.217 Office of Research Integrity or ORI.

Office of Research Integrity or *ORI* means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.

§ 93.218 Person.

Person means any individual, corporation, partnership, institution, association, unit of government, or legal entity, however organized.

§ 93.219 Preponderance of the evidence.

Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

§ 93.220 Public Health Service or PHS.

Public Health Service or *PHS* means the unit within the Department of Health and Human Services that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

§ 93.221 PHS support.

PHS support means PHS funding, or applications or proposals therefor, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: Funding for PHS intramural research; PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

§ 93.222 Research.

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

§ 93.223 Research misconduct proceeding.

Research misconduct proceeding means any actions related to alleged research misconduct taken under this part, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings, and administrative appeals.

§ 93.224 Research record.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.

§ 93.225 Respondent.

Respondent means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

§ 93.226 Retaliation.

Retaliation for the purpose of this part means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to—

(a) A good faith allegation of research misconduct; or

(b) Good faith cooperation with a research misconduct proceeding.

§ 93.227 Secretary or HHS.

Secretary or *HHS* means the Secretary of HHS or any other officer or employee of the HHS to whom the Secretary delegates authority.

Subpart C—Responsibilities of Institutions

Compliance and Assurances

§ 93.300 General responsibilities for compliance.

Institutions under this part must—

(a) Have written policies and procedures for addressing allegations of research misconduct that meet the requirements of this part;

(b) Respond to each allegation of research misconduct for which the institution is responsible under this part in a thorough, competent, objective and fair manner, 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;

(c) Foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct;

(d) Take all reasonable and practical steps to protect the positions and reputations of good faith complainants, witnesses and committee members and protect them from retaliation by respondents and other institutional members;

(e) Provide confidentiality to the extent required by § 93.108 to all respondents, complainants, and research subjects identifiable from research records or evidence;

(f) Take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence;

(g) Cooperate with HHS during any research misconduct proceeding or compliance review;

(h) Assist in administering and enforcing any HHS administrative actions imposed on its institutional members; and

(i) Have an active assurance of compliance.

§ 93.301 Institutional assurances.

(a) *General policy.* An institution with PHS supported biomedical or behavioral research, research training or activities related to that research or research training must provide PHS with an assurance of compliance with this part, satisfactory to the Secretary. PHS funding components may authorize

funds for biomedical and behavioral research, research training, or activities related to that research or research training only to institutions that have approved assurances and required renewals on file with ORI.

(b) *Institutional Assurance.* The responsible institutional official must assure on behalf of the institution that the institution—

(1) Has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and

(2) Complies with its own policies and procedures and the requirements of this part.

§ 93.302 Institutional compliance with assurances.

(a) *Compliance with assurance.* ORI considers an institution in compliance with its assurance if the institution—

(1) Establishes policies and procedures according to this part, keeps them in compliance with this part, and upon request, provides them to ORI, other HHS personnel, and members of the public;

(2) Takes all reasonable and practical specific steps to foster research integrity consistent with § 93.300, including—

(i) Informs the institution's research members participating in or otherwise involved with PHS supported biomedical or behavioral research, research training or activities related to that research or research training, including those applying for support from any PHS funding component, about its policies and procedures for responding to allegations of research misconduct, and the institution's commitment to compliance with the policies and procedures; and

(ii) Complies with its policies and procedures and each specific provision of this part.

(b) *Annual report.* An institution must file an annual report with ORI which contains information specified by ORI on the institution's compliance with this part.

(c) *Additional information.* Along with its assurance or annual report, an institution must send ORI such other aggregated information as ORI may request on the institution's research misconduct proceedings covered by this part and the institution's compliance with the requirements of this part.

§ 93.303 Assurances for small institutions.

(a) If an institution is too small to handle research misconduct proceedings, it may file a ''Small Organization Statement'' with ORI in place of the formal institutional policies and procedures required by §§ 93.301 and 93.304.

(b) By submitting a Small Organization Statement, the institution agrees to report all allegations of research misconduct to ORI. ORI or another appropriate HHS office will work with the institution to develop and implement a process for handling allegations of research misconduct consistent with this part.

(c) The Small Organization Statement does not relieve the institution from complying with any other provision of this part.

§ 93.304 Institutional policies and procedures.

Institutions seeking an approved assurance must have written policies and procedures for addressing research misconduct that include the following—

(a) Consistent with § 93.108, protection of the confidentiality of respondents, complainants, and research subjects identifiable from research records or evidence;

(b) A thorough, competent, objective, and fair response to allegations of research misconduct consistent with and within the time limits of this part, 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;

(c) Notice to the respondent, consistent with and within the time limits of this part;

(d) Written notice to ORI of any decision to open an investigation on or before the date on which the investigation begins;

(e) Opportunity for the respondent to provide written comments on the institution's inquiry report;

(f) 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;

(g) Protocols for handling the research record and evidence, including the requirements of § 93.305;

(h) Appropriate interim institutional actions to protect public health, Federal funds and equipment, and the integrity of the PHS supported research process;

(i) Notice to ORI under § 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;

(j) Institutional actions in response to final findings of research misconduct;

(k) All reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made;

(l) 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 these complainants, witnesses, and committee members; and

(m) Full and continuing cooperation with ORI during its oversight review under Subpart D of this part or any subsequent administrative hearings or appeals under Subpart E of this part. This includes 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.

§ 93.305 Responsibility for maintenance and custody of research records and evidence.

An institution, as the responsible legal entity for the PHS supported research, has a continuing obligation under this part to ensure that it maintains adequate records for a research misconduct proceeding. The institution must—

(a) 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 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;

(b) Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records;

(c) Undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding, 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; and

(d) Maintain the research records and evidence as required by § 93.317.

§ 93.306 Using a consortium or other person for research misconduct proceedings.

(a) An institution may use the services of a consortium or person that the institution reasonably determines to be qualified by practice and experience to conduct research misconduct proceedings.

(b) A consortium may be a group of institutions, professional organizations, or mixed groups which will conduct research misconduct proceedings for other institutions.

(c) A consortium or person acting on behalf of an institution must follow the requirements of this part in conducting research misconduct proceedings.

The Institutional Inquiry

§ 93.307 Institutional inquiry.

(a) *Criteria warranting an inquiry.* An inquiry is warranted if the allegation—

(1) Falls within the definition of research misconduct under this part;

(2) Is within § 93.102; and

(3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

(b) *Notice to respondent and custody of research records.* At the time of or before beginning an inquiry, an institution must make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the institution must notify them. To the extent it has not already done so at the allegation stage, the institution must, on or before the date on which the respondent is notified or the inquiry begins, whichever is earlier, promptly 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.

(c) *Review of evidence.* The purpose of an inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation. Therefore, an inquiry does not require a full review of all the evidence related to the allegation.

(d) *Criteria warranting an investigation.* An inquiry's purpose is to decide if an allegation warrants an investigation. An investigation is warranted if there is—

(1) A reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training or activities related to that research or research training, as provided in § 93.102; and

(2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

(e) *Inquiry report.* The institution must prepare a written report that meets the requirements of this section and § 93.309.

(f) *Opportunity to comment.* The institution must provide the respondent an opportunity to review and comment on the inquiry report and attach any comments received to the report.

(g) *Time for completion.* The institution must complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

§ 93.308 Notice of the results of the inquiry.

(a) *Notice to respondent.* The institution must notify the respondent whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to this part and the institution's policies and procedures adopted under its assurance.

(b) *Notice to complainants.* The institution may notify the complainant who made the allegation whether the inquiry found that an investigation is warranted. The institution may provide relevant portions of the report to the complainant for comment.

§ 93.309 Reporting to ORI on the decision to initiate an investigation.

(a) Within 30 days of finding that an investigation is warranted, the institution must provide ORI with the written finding by the responsible institutional official and a copy of the inquiry report which includes the following information—

(1) The name and position of the respondent;

(2) A description of the allegations of research misconduct;

(3) The PHS support, 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.

(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 misconduct 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 records and evidence, to perform forensic or other analyses or as otherwise needed to conduct an HHS inquiry or investigation or for ORI to conduct its review or to present evidence in any proceeding under subparts D and E of this part.

§ 93.318 Notifying ORI of special circumstances.

At any time during a research misconduct proceeding, as defined in § 93.223, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:

(a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

(b) HHS resources or interests are threatened.

(c) Research activities should be suspended.

(d) There is reasonable indication of possible violations of civil or criminal law.

(e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.

(f) The research 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.

(g) The research community or public should be informed.

§ 93.319 Institutional standards.

(a) Institutions may have internal standards of conduct different from the HHS standards for research misconduct under this part. Therefore, an institution may find conduct to be actionable under its standards even if the action does not meet this part's definition of research misconduct.

(b) An HHS finding or settlement does not affect institutional findings or administrative actions based on an institution's internal standards of conduct.

Subpart D—Responsibilities of the U.S. Department of Health and Human Services

General Information

§ 93.400 General statement of ORI authority.

(a) *ORI review.* ORI may respond directly to any allegation of research misconduct at any time before, during, or after an institution's response to the matter. The ORI response may include, but is not limited to—

(1) Conducting allegation assessments;

(2) Determining independently if jurisdiction exists under this part in any matter;

(3) Forwarding allegations of research misconduct to the appropriate institution or HHS component for inquiry or investigation;

(4) Recommending that HHS should perform an inquiry or investigation or issue findings and taking all appropriate actions in response to the inquiry, investigation, or findings;

(5) Notifying or requesting assistance and information from PHS funding components or other affected Federal and state offices and agencies or institutions;

(6) Reviewing an institution's findings and process;

(7) Making a finding of research misconduct; and

(8) Proposing administrative actions to HHS.

(b) *Requests for information.* ORI may request clarification or additional information, documentation, research records, or evidence from an institution or its members or other persons or sources to carry out ORI's review.

(c) *HHS administrative actions.* (1) In response to a research misconduct proceeding, ORI may propose administrative actions against any person to the HHS and, upon HHS approval and final action in accordance with this part, implement the actions.

(2) ORI may propose to the HHS debarring official that a person be suspended or debarred from receiving Federal funds and may propose to other appropriate PHS components the implementation of HHS administrative actions within the components' authorities.

(d) *ORI assistance to institutions.* At any time, ORI may provide information, technical assistance, and procedural advice to institutional officials as needed regarding an institution's participation in research misconduct proceedings.

(e) *Review of institutional assurances.* ORI may review institutional assurances

and policies and procedures for compliance with this part.

(f) *Institutional compliance.* ORI may make findings and impose HHS administrative actions related to an institution's compliance with this part and with its policies and procedures, including an institution's participation in research misconduct proceedings.

§ 93.401 Interaction with other offices and interim actions.

(a) ORI may notify and consult with other offices at any time if it has reason to believe that a research misconduct proceeding may involve that office. If ORI believes that a criminal or civil fraud violation may have occurred, it shall promptly refer the matter to the Department of Justice (DOJ), the HHS Inspector General (OIG), or other appropriate investigative body. ORI may provide expertise and assistance to the DOJ, OIG, PHS offices, other Federal offices, and state or local offices involved in investigating or otherwise pursuing research misconduct allegations or related matters.

(b) ORI may notify affected PHS offices and funding components at any time to permit them to make appropriate interim responses to protect the health and safety of the public, to promote the integrity of the PHS supported research and research process, and to conserve public funds.

(c) The information provided will not be disclosed as part of the peer review and advisory committee review processes, but may be used by the Secretary in making decisions about the award or continuation of funding.

Research Misconduct Issues

§ 93.402 ORI allegation assessments.

(a) When ORI receives an allegation of research misconduct directly or becomes aware of an allegation or apparent instance of research misconduct, it may conduct an initial assessment or refer the matter to the relevant institution for an assessment, inquiry, or other appropriate actions.

(b) If ORI conducts an assessment, it considers whether the allegation of research misconduct appears to fall within the definition of research misconduct, appears to involve PHS supported biomedical or behavior research, research training or activities related to that research or research training, as provided in § 93.102, and whether it is sufficiently specific so that potential evidence may be identified and sufficiently substantive to warrant an inquiry. ORI may review all readily accessible, relevant information related to the allegation.

(c) If ORI decides that an inquiry is warranted, it forwards the matter to the appropriate institution or HHS component.

(d) If ORI decides that an inquiry is not warranted it will close the case and forward the allegation in accordance with paragraph(e) of this section.

(e) ORI may forward allegations that do not fall within the jurisdiction of this part to the appropriate HHS component, Federal or State agency, institution, or other appropriate entity.

§ 93.403 ORI review of research misconduct proceedings.

ORI may conduct reviews of research misconduct proceedings. In conducting its review, ORI may—

(a) Determine whether there is HHS jurisdiction under this part;

(b) Consider any reports, institutional findings, research records, and evidence;

(c) Determine if the institution conducted the proceedings in a timely and fair manner in accordance with this part with sufficient thoroughness, objectivity, and competence to support the conclusions;

(d) Obtain additional information or materials from the institution, the respondent, complainants, or other persons or sources;

(e) Conduct additional analyses and develop evidence;

(f) Decide whether research misconduct occurred, and if so who committed it;

(g) Make appropriate research misconduct findings and propose HHS administrative actions; and

(h) Take any other actions necessary to complete HHS' review.

§ 93.404 Findings of research misconduct and proposed administrative actions.

After completing its review, ORI either closes the case without a finding of research misconduct or—

(a) Makes findings of research misconduct and proposes and obtains HHS approval of administrative actions based on the record of the research misconduct proceedings and any other information obtained by ORI during its review; or

(b) Recommends that HHS seek to settle the case.

§ 93.405 Notifying the respondent of findings of research misconduct and HHS administrative actions.

(a) When the ORI makes a finding of research misconduct or seeks to impose or enforce HHS administrative actions, other than debarment or suspension, it notifies the respondent in a charge letter. In cases involving a debarment or suspension action, the HHS debarring official issues a notice of proposed debarment or suspension to the respondent as part of the charge letter. The charge letter includes the ORI findings of research misconduct and the basis for them and any HHS administrative actions. The letter also advises the respondent of the opportunity to contest the findings and administrative actions under Subpart E of this part.

(b) The ORI sends the charge letter by certified mail or a private delivery service to the last known address of the respondent or the last known principal place of business of the respondent's attorney.

§ 93.406 Final HHS actions.

Unless the respondent contests the charge letter within the 30-day period prescribed in § 93.501, the ORI finding of research misconduct is the final HHS action on the research misconduct issues and the HHS administrative actions become final and will be implemented, except that the debarring official's decision is the final HHS action on any debarment or suspension actions.

§ 93.407 HHS administrative actions.

(a) In response to a research misconduct proceeding, HHS may impose HHS administrative actions that include but are not limited to:

(1) Clarification, correction, or retraction of the research record.

(2) Letters of reprimand.

(3) Imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of PHS grants, contracts, or cooperative agreements.

(4) Suspension or termination of a PHS grant, contract, or cooperative agreement.

(5) Restriction on specific activities or expenditures under an active PHS grant, contract, or cooperative agreement.

(6) Special review of all requests for PHS funding.

(7) Imposition of supervision requirements on a PHS grant, contract, or cooperative agreement.

(8) Certification of attribution or authenticity in all requests for support and reports to the PHS.

(9) No participation in any advisory capacity to the PHS.

(10) Adverse personnel action if the respondent is a Federal employee, in compliance with relevant Federal personnel policies and laws.

(11) Suspension or debarment under 45 CFR Part 76, 48 CFR Subparts 9.4 and 309.4, or both.

(b) In connection with findings of research misconduct, HHS also may

seek to recover PHS funds spent in support of the activities that involved research misconduct.

(c) Any authorized HHS component may impose, administer, or enforce HHS administrative actions separately or in coordination with other HHS components, including, but not limited to ORI, the Office of Inspector General, the PHS funding component, and the debarring official.

§ 93.408 Mitigating and aggravating factors in HHS administrative actions.

The purpose of HHS administrative actions is remedial. The appropriate administrative action is commensurate with the seriousness of the misconduct, and the need to protect the health and safety of the public, promote the integrity of the PHS supported research and research process, and conserve public funds. HHS considers aggravating and mitigating factors in determining appropriate HHS administrative actions and their terms. HHS may consider other factors as appropriate in each case. The existence or nonexistence of any factor is not determinative:

(a) *Knowing, intentional, or reckless.* Were the respondent's actions knowing or intentional or was the conduct reckless?

(b) *Pattern.* Was the research misconduct an isolated event or part of a continuing or prior pattern of dishonest conduct?

(c) *Impact.* Did the misconduct have significant impact on the proposed or reported research record, research subjects, other researchers, institutions, or the public health or welfare?

(d) *Acceptance of responsibility.* Has the respondent accepted responsibility for the misconduct by—

(1) Admitting the conduct;

(2) Cooperating with the research misconduct proceedings;

(3) Demonstrating remorse and awareness of the significance and seriousness of the research misconduct; and

(4) Taking steps to correct or prevent the recurrence of the research misconduct.

(e) *Failure to accept responsibility.* Does the respondent blame others rather than accepting responsibility for the actions?

(f) *Retaliation.* Did the respondent retaliate against complainants, witnesses, committee members, or other persons?

(g) *Present responsibility.* Is the respondent presently responsible to conduct PHS supported research?

(h) *Other factors.* Other factors appropriate to the circumstances of a particular case.

§ 93.409 Settlement of research misconduct proceedings.

(a) HHS may settle a research misconduct proceeding at any time it concludes that settlement is in the best interests of the Federal government and the public health or welfare.

(b) Settlement agreements are publicly available, regardless of whether the ORI made a finding of research misconduct.

§ 93.410 Final HHS action with no settlement or finding of research misconduct.

When the final HHS action does not result in a settlement or finding of research misconduct, ORI may:

(a) Provide written notice to the respondent, the relevant institution, the complainant, and HHS officials.

(b) Take any other actions authorized by law.

§ 93.411 Final HHS action with settlement or finding of research misconduct.

When a final HHS action results in a settlement or research misconduct finding, ORI may:

(a) Provide final notification of any research misconduct findings and HHS administrative actions to the respondent, the relevant institution, the complainant, and HHS officials. The debarring official may provide a separate notice of final HHS action on any debarment or suspension actions.

(b) Identify publications which require correction or retraction and prepare and send a notice to the relevant journal.

(c) Publish notice of the research misconduct findings.

(d) Notify the respondent's current employer.

(e) Take any other actions authorized by law.

Institutional Compliance Issues

§ 93.412 Making decisions on institutional noncompliance.

(a) Institutions must foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with PHS supported research.

(b) ORI may decide that an institution is not compliant with this part if the institution shows a disregard for, or inability or unwillingness to implement and follow the requirements of this part and its assurance. In making this decision, ORI may consider, but is not limited to the following factors—

(1) Failure to establish and comply with policies and procedures under this part;

(2) Failure to respond appropriately when allegations of research misconduct arise;

(3) Failure to report to ORI all investigations and findings of research misconduct under this part;

(4) Failure to cooperate with ORI's review of research misconduct proceedings; or

(5) Other actions or omissions that have a material, adverse effect on reporting and responding to allegations of research misconduct.

§ 93.413 HHS compliance actions.

(a) An institution's failure to comply with its assurance and the requirements of this part may result in enforcement action against the institution.

(b) ORI may address institutional deficiencies through technical assistance if the deficiencies do not substantially affect compliance with this part.

(c) If an institution fails to comply with its assurance and the requirements of this part, HHS may take some or all of the following compliance actions:

(1) Issue a letter of reprimand.

(2) Direct that research misconduct proceedings be handled by HHS.

(3) Place the institution on special review status.

(4) Place information on the institutional noncompliance on the ORI Web site.

(5) Require the institution to take corrective actions.

(6) Require the institution to adopt and implement an institutional integrity agreement.

(7) Recommend that HHS debar or suspend the entity.

(8) Any other action appropriate to the circumstances.

(d) If the institution's actions constitute a substantial or recurrent failure to comply with this part, ORI may also revoke the institution's assurance under §§ 93.301 or 93.303.

(e) ORI may make public any findings of institutional noncompliance and HHS compliance actions.

Disclosure of Information

§ 93.414 Notice.

(a) ORI may disclose information to other persons for the purpose of providing or obtaining information about research misconduct as permitted under the Privacy Act, 5 U.S.C. 552a.

(b) ORI may publish a notice of final agency findings of research misconduct, settlements, and HHS administrative actions and release and withhold information as permitted by the Privacy Act and the Freedom of Information Act, 5 U.S.C. 552.

Subpart E—Opportunity To Contest ORI Findings of Research Misconduct and HHS Administrative Actions

General Information

§ 93.500 General policy.

(a) This subpart provides a respondent an opportunity to contest ORI findings of research misconduct and HHS administrative actions, including debarment or suspension, arising under 42 U.S.C. 289b in connection with PHS supported biomedical and behavioral research, research training, or activities related to that research or research training.

(b) A respondent has an opportunity to contest ORI research misconduct findings and HHS administrative actions under this part, including debarment or suspension, by requesting an administrative hearing before an Administrative Law Judge (ALJ) affiliated with the HHS DAB, when—

(1) ORI has made a finding of research misconduct against a respondent; and

(2) The respondent has been notified of those findings and any proposed HHS administrative actions, including debarment or suspension, in accordance with this part.

(c) The ALJ's ruling on the merits of the ORI research misconduct findings and the HHS administrative actions is subject to review by the Assistant Secretary for Health in accordance with § 93.523. The decision made under that section is the final HHS action, unless that decision results in a recommendation for debarment or suspension. In that case, the decision under § 93.523 shall constitute findings of fact to the debarring official in accordance with 45 CFR 76.845(c).

(d) Where a proposed debarment or suspension action is based upon an ORI finding of research misconduct, the procedures in this part provide the notification, opportunity to contest, and fact-finding required under the HHS debarment and suspension regulations at 45 CFR part 76, subparts H and G, respectively, and 48 CFR Subparts 9.4 and 309.4.

§ 93.501 Opportunity to contest findings of research misconduct and administrative actions.

(a) *Opportunity to contest.* A respondent may contest ORI findings of research misconduct and HHS administrative actions, including any debarment or suspension action, by requesting a hearing within 30 days of receipt of the charge letter or other written notice provided under § 93.405.

(b) *Form of a request for hearing.* The respondent's request for a hearing must be—

(1) In writing;

(2) Signed by the respondent or by the respondent's attorney; and

(3) Sent by certified mail, or other equivalent (*i.e.*, with a verified method of delivery), to the DAB Chair and ORI.

(c) *Contents of a request for hearing.* The request for a hearing must—

(1) Admit or deny each finding of research misconduct and each factual assertion made in support of the finding;

(2) Accept or challenge each proposed HHS administrative action;

(3) Provide detailed, substantive reasons for each denial or challenge;

(4) Identify any legal issues or defenses that the respondent intends to raise during the proceeding; and

(5) Identify any mitigating factors that the respondent intends to prove.

(d) *Extension for good cause to supplement the hearing request.* (1) After receiving notification of the appointment of the ALJ, the respondent has 10 days to submit a written request to the ALJ for supplementation of the hearing request to comply fully with the requirements of paragraph (c) of this section. The written request must show good cause in accordance with paragraph (d)(2) of this section and set forth the proposed supplementation of the hearing request. The ALJ may permit the proposed supplementation of the hearing request in whole or in part upon a finding of good cause.

(2) Good cause means circumstances beyond the control of the respondent or respondent's representative and not attributable to neglect or administrative inadequacy.

Hearing Process

§ 93.502 Appointment of the Administrative Law Judge and scientific expert.

(a) Within 30 days of receiving a request for a hearing, the DAB Chair, in consultation with the Chief Administrative Law Judge, must designate an Administrative Law Judge (ALJ) to determine whether the hearing request should be granted and, if the hearing request is granted, to make recommended findings in the case after a hearing or review of the administrative record in accordance with this part.

(b) The ALJ may retain one or more persons with appropriate scientific or technical expertise to assist the ALJ in evaluating scientific or technical issues related to the findings of research misconduct.

(1) On the ALJ's or a party's motion to appoint an expert, the ALJ must give the parties an opportunity to submit nominations. If such a motion is made by a party, the ALJ must appoint an expert, either:

(i) The expert, if any, who is agreed upon by both parties and found to be qualified by the ALJ; or,

(ii) If the parties cannot agree upon an expert, the expert chosen by the ALJ.

(2) The ALJ may seek advice from the expert(s) at any time during the discovery and hearing phases of the proceeding. The expert(s) shall provide advice to the ALJ in the form of a written report or reports that will be served upon the parties within 10 days of submission to the ALJ. That report must contain a statement of the expert's background and qualifications. Any comment on or response to a report by a party, which may include comments on the expert's qualifications, must be submitted to the ALJ in accordance with § 93.510(c). The written reports and any comment on, or response to them are part of the record. Expert witnesses of the parties may testify on the reports and any comments or responses at the hearing, unless the ALJ determines such testimony to be inadmissible in accordance with § 93.519, or that such testimony would unduly delay the proceeding.

(c) No ALJ, or person hired or appointed to assist the ALJ, may serve in any proceeding under this subpart if he or she has any real or apparent conflict of interest, bias, or prejudice that might reasonably impair his or her objectivity in the proceeding.

(d) Any party to the proceeding may request the ALJ or scientific expert to withdraw from the proceeding because of a real or apparent conflict of interest, bias, or prejudice under paragraph (c) of this section. The motion to disqualify must be timely and state with particularity the grounds for disqualification. The ALJ may rule upon the motion or certify it to the Chief ALJ for decision. If the ALJ rules upon the motion, either party may appeal the decision to the Chief ALJ.

(e) An ALJ must withdraw from any proceeding for any reason found by the ALJ or Chief ALJ to be disqualifying.

§ 93.503 Grounds for granting a hearing request.

(a) The ALJ must grant a respondent's hearing request if the ALJ determines there is a genuine dispute over facts material to the findings of research misconduct or proposed administrative actions, including any debarment or suspension action. The respondent's general denial or assertion of error for each finding of research misconduct, and any basis for the finding, or for the proposed HHS administrative actions in

the charge letter, is not sufficient to establish a genuine dispute.

(b) The hearing request must specifically deny each finding of research misconduct in the charge letter, each basis for the finding and each HHS administrative action in the charge letter, or it is considered an admission by the respondent. If the hearing request does not specifically dispute the HHS administrative actions, including any debarment or suspension actions, they are considered accepted by the respondent.

(c) If the respondent does not request a hearing within the 30-day time period prescribed in § 93.501(a), the finding(s) and any administrative action(s), other than debarment or suspension actions, become final agency actions at the expiration of the 30-day period. Where there is a proposal for debarment or suspension, after the expiration of the 30-day time period the official record is closed and forwarded to the debarring official for a final decision.

(d) If the ALJ grants the hearing request, the respondent may waive the opportunity for any in-person proceeding, and the ALJ may review and decide the case on the basis of the administrative record. The ALJ may grant a respondent's request that waiver of the in-person proceeding be conditioned upon the opportunity for respondent to file additional pleadings and documentation. ORI may also supplement the administrative record through pleadings, documents, in-person or telephonic testimony, and oral presentations.

§ 93.504 Grounds for dismissal of a hearing request.

(a) The ALJ must dismiss a hearing request if the respondent—

(1) Does not file the request within 30 days after receiving the charge letter;

(2) Does not raise a genuine dispute over facts or law material to the findings of research misconduct and any administrative actions, including debarment and suspension actions, in the hearing request or in any extension to supplement granted by the ALJ under § 93.501(d);

(3) Does not raise any issue which may properly be addressed in a hearing;

(4) Withdraws or abandons the hearing request; or

(b) The ALJ may dismiss a hearing request if the respondent fails to provide ORI with notice in the form and manner required by § 93.501.

§ 93.505 Rights of the parties.

(a) The parties to the hearing are the respondent and ORI. The investigating institution is not a party to the case, unless it is a respondent.

(b) Except as otherwise limited by this subpart, the parties may—

(1) Be accompanied, represented, and advised by an attorney;

(2) Participate in any case-related conference held by the ALJ;

(3) Conduct discovery of documents and other tangible items;

(4) Agree to stipulations of fact or law that must be made part of the record;

(5) File motions in writing before the ALJ;

(6) Present evidence relevant to the issues at the hearing;

(7) Present and cross-examine witnesses;

(8) Present oral arguments;

(9) Submit written post-hearing briefs, proposed findings of fact and conclusions of law, and reply briefs within reasonable time frames agreed upon by the parties or established by the ALJ as provided in § 93.522; and

(10) Submit materials to the ALJ and other parties under seal, or in redacted form, when necessary, to protect the confidentiality of any information contained in them consistent with this part, the Privacy Act, the Freedom of Information Act, or other Federal law or regulation.

§ 93.506 Authority of the Administrative Law Judge.

(a) The ALJ assigned to the case must conduct a fair and impartial hearing, avoid unnecessary delay, maintain order, and assure that a complete and accurate record of the proceeding is properly made. The ALJ is bound by all Federal statutes and regulations, Secretarial delegations of authority, and applicable HHS policies and may not refuse to follow them or find them invalid, as provided in paragraph (c)(4) of this section. The ALJ has the authorities set forth in this part.

(b) Subject to review as provided elsewhere in this subpart, the ALJ may—

(1) Set and change the date, time, schedule, and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences with the parties to identify or simplify the issues, or to consider other matters that may aid in the prompt disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Require the attendance of witnesses at a hearing;

(6) Rule on motions and other procedural matters;

(7) Require the production of documents and regulate the scope and timing of documentary discovery as permitted by this part;

(8) Require each party before the hearing to provide the other party and the ALJ with copies of any exhibits that the party intends to introduce into evidence;

(9) Issue a ruling, after an *in camera* inspection if necessary, to address the disclosure of any evidence or portion of evidence for which confidentiality is requested under this part or other Federal law or regulation, or which a party submitted under seal;

(10) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;

(11) Examine witnesses and receive evidence presented at the hearing;

(12) Admit, exclude, or limit evidence offered by a party;

(13) Hear oral arguments on facts or law during or after the hearing;

(14) Upon motion of a party, take judicial notice of facts;

(15) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;

(16) Conduct any conference or oral argument in person, by telephone, or by audio-visual communication;

(17) Take action against any party for failing to follow an order or procedure or for disruptive conduct.

(c) The ALJ does not have the authority to—

(1) Enter an order in the nature of a directed verdict;

(2) Compel settlement negotiations;

(3) Enjoin any act of the Secretary; or

(4) Find invalid or refuse to follow Federal statutes or regulations, Secretarial delegations of authority, or HHS policies.

§ 93.507 Ex parte communications.

(a) No party, attorney, or other party representative may communicate *ex parte* with the ALJ on any matter at issue in a case, unless both parties have notice and an opportunity to participate in the communication. However, a party, attorney, or other party representative may communicate with DAB staff about administrative or procedural matters.

(b) If an *ex parte* communication occurs, the ALJ will disclose it to the other party and make it part of the record after the other party has an opportunity to comment.

(c) The provisions of this section do not apply to communications between an employee or contractor of the DAB and the ALJ.

§ 93.508 Filing, forms, and service.

(a) *Filing.* (1) Unless the ALJ provides otherwise, all submissions required or authorized to be filed in the proceeding must be filed with the ALJ.

(2) Submissions are considered filed when they are placed in the mail, transmitted to a private delivery service for the purpose of delivering the item to the ALJ, or submitted in another manner authorized by the ALJ.

(b) *Forms.* (1) Unless the ALJ provides otherwise, all submissions filed in the proceeding must include an original and two copies. The ALJ may designate the format for copies of nondocumentary materials such as videotapes, computer disks, or physical evidence. This provision does not apply to the charge letter or other written notice provided under § 93.405.

(2) Every submission filed in the proceeding must include the title of the case, the docket number, and a designation of the nature of the submission, such as a ''Motion to Compel the Production of Documents'' or ''Respondent's Proposed Exhibits.''

(3) Every submission filed in the proceeding must be signed by and contain the address and telephone number of the party on whose behalf the document or paper was filed, or the attorney of record for the party.

(c) *Service.* A party filing a submission with the ALJ must, at the time of filing, serve a copy on the other party. Service may be made either to the last known principal place of business of the party's attorney if the party is represented by an attorney, or, if not, to the party's last known address. Service may be made by—

(1) Certified mail;

(2) First-class postage prepaid U.S. Mail;

(3) A private delivery service;

(4) Hand-delivery; or

(5) Facsimile or other electronic means if permitted by the ALJ.

(d) *Proof of service.* Each party filing a document or paper with the ALJ must also provide proof of service at the time of the filing. Any of the following items may constitute proof of service:

(1) A certified mail receipt returned by the postal service with a signature;

(2) An official record of the postal service or private delivery service;

(3) A certificate of service stating the method, place, date of service, and person served that is signed by an individual with personal knowledge of these facts; or

(4) Other proof authorized by the ALJ.

§ 93.509 Computation of time.

(a) In computing any period of time under this part for filing and service or for responding to an order issued by the ALJ, the computation begins with the day following the act or event, and includes the last day of the period unless that day is a Saturday, Sunday, or legal holiday observed by the Federal government, in which case it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government must be excluded from the computation.

(c) Where a document has been filed by placing it in the mail, an additional 5 days must be added to the time permitted for any response. This paragraph does not apply to a respondent's request for hearing under § 93.501.

(d) Except for the respondent's request for a hearing, the ALJ may modify the time for the filing of any document or paper required or authorized under the rules in this part to be filed for good cause shown. When time permits, notice of a party's request for extension of the time and an opportunity to respond must be provided to the other party.

§ 93.510 Filing motions.

(a) Parties must file all motions and requests for an order or ruling with the ALJ, serve them on the other party, state the nature of the relief requested, provide the legal authority relied upon, and state the facts alleged.

(b) All motions must be in writing except for those made during a prehearing conference or at the hearing.

(c) Within 10 days after being served with a motion, or other time as set by the ALJ, a party may file a response to the motion. The moving party may not file a reply to the responsive pleading unless allowed by the ALJ.

(d) The ALJ may not grant a motion before the time for filing a response has expired, except with the parties' consent or after a hearing on the motion. However, the ALJ may overrule or deny any motion without awaiting a response.

(e) The ALJ must make a reasonable effort to dispose of all motions promptly, and, whenever possible, dispose of all outstanding motions before the hearing.

§ 93.511 Prehearing conferences.

(a) The ALJ must schedule an initial prehearing conference with the parties within 30 days of the DAB Chair's assignment of the case.

(b) The ALJ may use the initial prehearing conference to discuss—

(1) Identification and simplification of the issues, specification of disputes of fact and their materiality to the ORI findings of research misconduct and any HHS administrative actions, and amendments to the pleadings, including any need for a more definite statement;

(2) Stipulations and admissions of fact including the contents, relevancy, and authenticity of documents;

(3) Respondent's waiver of an administrative hearing, if any, and submission of the case on the basis of the administrative record as provided in § 93.503(d);

(4) Identification of legal issues and any need for briefing before the hearing;

(5) Identification of evidence, pleadings, and other materials, if any, that the parties should exchange before the hearing;

(6) Identification of the parties' witnesses, the general nature of their testimony, and the limitation on the number of witnesses and the scope of their testimony;

(7) Scheduling dates such as the filing of briefs on legal issues identified in the charge letter or the respondent's request for hearing, the exchange of witness lists, witness statements, proposed exhibits, requests for the production of documents, and objections to proposed witnesses and documents;

(8) Scheduling the time, place, and anticipated length of the hearing; and

(9) Other matters that may encourage the fair, just, and prompt disposition of the proceedings.

(c) The ALJ may schedule additional prehearing conferences as appropriate, upon reasonable notice to or request of the parties.

(d) All prehearing conferences will be audio-taped with copies provided to the parties upon request.

(e) Whenever possible, the ALJ must memorialize in writing any oral rulings within 10 days after the prehearing conference.

(f) By 15 days before the scheduled hearing date, the ALJ must hold a final prehearing conference to resolve to the maximum extent possible all outstanding issues about evidence, witnesses, stipulations, motions and all other matters that may encourage the fair, just, and prompt disposition of the proceedings.

§ 93.512 Discovery.

(a) *Request to provide documents.* A party may only request another party to produce documents or other tangible items for inspection and copying that are relevant and material to the issues identified in the charge letter and in the respondent's request for hearing.

(b) *Meaning of documents.* For purposes of this subpart, the term documents includes information, reports, answers, records, accounts, papers, tangible items, and other data and documentary evidence. This subpart does not require the creation of any document. However, requested data

stored in an electronic data storage system must be produced in a form reasonably accessible to the requesting party.

(c) *Nondisclosable items.* This section does not authorize the disclosure of—

(1) Interview reports or statements obtained by any party, or on behalf of any party, of persons whom the party will not call as witness in its case-in-chief;

(2) Analyses and summaries prepared in conjunction with the inquiry, investigation, ORI oversight review, or litigation of the case; or

(3) Any privileged documents, including but not limited to those protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation.

(d) *Responses to a discovery request.* Within 30 days of receiving a request for the production of documents, a party must either fully respond to the request, submit a written objection to the discovery request, or seek a protective order from the ALJ. If a party objects to a request for the production of documents, the party must identify each document or item subject to the scope of the request and state the basis of the objection for each document, or any part that the party does not produce.

(1) Within 30 days of receiving any objections, the party seeking production may file a motion to compel the production of the requested documents.

(2) The ALJ may order a party to produce the requested documents for *in camera* inspection to evaluate the merits of a motion to compel or for a protective order.

(3) The ALJ must compel the production of a requested document and deny a motion for a protective order, unless the requested document is—

(i) Not relevant or material to the issues identified in the charge letter or the respondent's request for hearing;

(ii) Unduly costly or burdensome to produce;

(iii) Likely to unduly delay the proceeding or substantially prejudice a party;

(iv) Privileged, including but not limited to documents protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation; or

(v) Collateral to issues to be decided at the hearing.

(4) If any part of a document is protected from disclosure under paragraph (d)(3) of this section, the ALJ must redact the protected portion of a document before giving it to the requesting party.

(5) The party seeking discovery has the burden of showing that the ALJ should allow it.

(e) *Refusal to produce items.* If a party refuses to provide requested documents when ordered by the ALJ, the ALJ may take corrective action, including but not limited to, ordering the noncompliant party to submit written answers under oath to written interrogatories posed by the other party or taking any of the actions at § 93.515.

§ 93.513 Submission of witness lists, witness statements, and exhibits.

(a) By 60 days before the scheduled hearing date, each party must give the ALJ a list of witnesses to be offered during the hearing and a statement describing the substance of their proposed testimony, copies of any prior written statements or transcribed testimony of proposed witnesses, a written report of each expert witness to be called to testify that meets the requirements of Federal Rule of Civil Procedure 26(a)(2)(B), and copies of proposed hearing exhibits, including copies of any written statements that a party intends to offer instead of live direct testimony. If there are no prior written statements or transcribed testimony of a proffered witness, the party must submit a detailed factual affidavit of the proposed testimony.

(b) A party may supplement its submission under paragraph (a) of this section until 30 days before the scheduled hearing date if the ALJ determines:

(1) There are extraordinary circumstances; and

(2) There is no substantial prejudice to the objecting party.

(c) The parties must have an opportunity to object to the admission of evidence submitted under paragraph (a) of this section under a schedule set by the ALJ. However, the parties must file all objections before the final prehearing conference.

(d) If a party tries to introduce evidence after the deadlines in paragraph (a) of this section, the ALJ must exclude the offered evidence from the party's case-in-chief unless the conditions of paragraph (b) of this section are met. If the ALJ admits evidence under paragraph (b) of this section, the objecting party may file a motion to postpone all or part of the hearing to allow sufficient time to prepare and respond to the evidence. The ALJ may not unreasonably deny that motion.

(e) If a party fails to object within the time set by the ALJ and before the final prehearing conference, evidence exchanged under paragraph (a) of this section is considered authentic, relevant and material for the purpose of admissibility at the hearing.

§ 93.514 Amendment to the charge letter.

(a) The ORI may amend the findings of research misconduct up to 30 days before the scheduled hearing.

(b) The ALJ may not unreasonably deny a respondent's motion to postpone all or part of the hearing to allow sufficient time to prepare and respond to the amended findings.

§ 93.515 Actions for violating an order or for disruptive conduct.

(a) The ALJ may take action against any party in the proceeding for violating an order or procedure or for other conduct that interferes with the prompt, orderly, or fair conduct of the hearing. Any action imposed upon a party must reasonably relate to the severity and nature of the violation or disruptive conduct.

(b) The actions may include—

(1) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(2) Striking pleadings, in whole or in part;

(3) Staying the proceedings;

(4) Entering a decision by default;

(5) Refusing to consider any motion or other action not timely filed; or

(6) Drawing the inference that spoliated evidence was unfavorable to the party responsible for its spoliation.

§ 93.516 Standard and burden of proof.

(a) *Standard of proof.* The standard of proof is the preponderance of the evidence.

(b) *Burden of proof.* (1) ORI bears the burden of proving the findings of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where ORI establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

(2) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether ORI has carried the burden of proof

imposed by this part, the ALJ shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

(3) ORI bears the burden of proving that the proposed HHS administrative actions are reasonable under the circumstances of the case. The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose HHS administrative actions following a research misconduct proceeding.

§ 93.517 The hearing.

(a) The ALJ will conduct an in-person hearing to decide if the respondent committed research misconduct and if the HHS administrative actions, including any debarment or suspension actions, are appropriate.

(b) The ALJ provides an independent *de novo* review of the ORI findings of research misconduct and the proposed HHS administrative actions. The ALJ does not review the institution's procedures or misconduct findings or ORI's research misconduct proceedings.

(c) A hearing under this subpart is not limited to specific findings and evidence set forth in the charge letter or the respondent's request for hearing. Additional evidence and information may be offered by either party during its case-in-chief unless the offered evidence is—

(1) Privileged, including but not limited to those protected by the attorney-client privilege, attorney-work product doctrine, or Federal law or regulation.

(2) Otherwise inadmissible under §§ 93.515 or 93.519.

(3) Not offered within the times or terms of §§ 93.512 and 93.513.

(d) ORI proceeds first in its presentation of evidence at the hearing.

(e) After both parties have presented their cases-in-chief, the parties may offer rebuttal evidence even if not exchanged earlier under §§ 93.512 and 93.513.

(f) Except as provided in § 93.518(c), the parties may appear at the hearing in person or by an attorney of record in the proceeding.

(g) The hearing must be open to the public, unless the ALJ orders otherwise for good cause shown. However, even if the hearing is closed to the public, the ALJ may not exclude a party or party representative, persons whose presence a party shows to be essential to the presentation of its case, or expert witnesses.

§ 93.518 Witnesses.

(a) Except as provided in paragraph (b) of this section, witnesses must give testimony at the hearing under oath or affirmation.

(b) The ALJ may admit written testimony if the witness is available for cross-examination, including prior sworn testimony of witnesses that has been subject to cross-examination. These written statements must be provided to all other parties under § 93.513.

(c) The parties may conduct direct witness examination and cross-examination in person, by telephone, or by audio-visual communication as permitted by the ALJ. However, a respondent must always appear in-person to present testimony and for cross-examination.

(d) The ALJ may exercise reasonable control over the mode and order of questioning witnesses and presenting evidence to—

(1) Make the witness questioning and presentation relevant to deciding the truth of the matter; and

(2) Avoid undue repetition or needless consumption of time.

(e) The ALJ must permit the parties to conduct cross-examination of witnesses.

(f) Upon request of a party, the ALJ may exclude a witness from the hearing before the witness' own testimony. However, the ALJ may not exclude—

(1) A party or party representative;

(2) Persons whose presence is shown by a party to be essential to the presentation of its case; or

(3) Expert witnesses.

§ 93.519 Admissibility of evidence.

(a) The ALJ decides the admissibility of evidence offered at the hearing.

(b) Except as provided in this part, the ALJ is not bound by the Federal Rules of Evidence (FRE). However, the ALJ may apply the FRE where appropriate (*e.g.*, to exclude unreliable evidence).

(c) The ALJ must admit evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. However, the ALJ may exclude relevant and material evidence if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence under FRE 401–403.

(d) The ALJ must exclude relevant and material evidence if it is privileged, including but not limited to evidence protected by the attorney-client privilege, the attorney-work product doctrine, or Federal law or regulation.

(e) The ALJ may take judicial notice of matters upon the ALJ's own initiative or upon motion by a party as permitted under FRE 201 (Judicial Notice of Adjudicative Facts).

(1) The ALJ may take judicial notice of any other matter of technical, scientific, or commercial fact of established character.

(2) The ALJ must give the parties adequate notice of matters subject to judicial notice and adequate opportunity to show that the ALJ erroneously noticed the matters.

(f) Evidence of crimes, wrongs, or acts other than those at issue in the hearing is admissible only as permitted under FRE 404(b) (Character Evidence not Admissible to Prove Conduct; Exceptions, Other Crimes).

(g) Methods of proving character are admissible only as permitted under FRE 405 (Methods of Proving Character).

(h) Evidence related to the character and conduct of witnesses is admissible only as permitted under FRE Rule 608 (Evidence of Character and Conduct of Witness).

(i) Evidence about offers of compromise or settlement made in this action is inadmissible as provided in FRE 408 (Compromise and Offers to Compromise).

(j) The ALJ must admit relevant and material hearsay evidence, unless an objecting party shows that the offered hearsay evidence is not reliable.

(k) The parties may introduce witnesses and evidence on rebuttal.

(l) All documents and other evidence offered or admitted into the record must be open to examination by both parties, unless otherwise ordered by the ALJ for good cause shown.

(m) Whenever the ALJ excludes evidence, the party offering the evidence may make an offer of proof, and the ALJ must include the offer in the transcript or recording of the hearing in full. The offer of proof should consist of a brief oral statement describing the evidence excluded. If the offered evidence consists of an exhibit, the ALJ must mark it for identification and place it in the hearing record. However, the ALJ may rely upon the offered evidence in reaching the decision on the case only if the ALJ admits it.

§ 93.520 The record.

(a) HHS will record and transcribe the hearing, and if requested, provide a transcript to the parties at HHS' expense.

(b) The exhibits, transcripts of testimony, any other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ.

(c) For good cause shown, the ALJ may order appropriate redactions made to the record at any time.

(d) The DAB may return original research records and other similar items to the parties or awardee institution upon request after final HHS action, unless under judicial review.

§ 93.521 Correction of the transcript.

(a) At any time, but not later than the time set for the parties to file their post-hearing briefs, any party may file a motion proposing material corrections to the transcript or recording.

(b) At any time before the filing of the ALJ's decision and after consideration of any corrections proposed by the parties, the ALJ may issue an order making any requested corrections in the transcript or recording.

§ 93.522 Filing post-hearing briefs.

(a) After the hearing and under a schedule set by the ALJ , the parties may file post-hearing briefs, and the ALJ may allow the parties to file reply briefs.

(b) The parties may include proposed findings of fact and conclusions of law in their post-hearing briefs.

§ 93.523 The Administrative Law Judge's ruling.

(a) The ALJ shall issue a ruling in writing setting forth proposed findings of fact and any conclusions of law within 60 days after the last submission by the parties in the case. If unable to meet the 60-day deadline, the ALJ must set a new deadline and promptly notify the parties, the Assistant Secretary for Health and the debarring official, if debarment or suspension is under review. The ALJ shall serve a copy of the ruling upon the parties and the Assistant Secretary for Health.

(b) The ruling of the ALJ constitutes a recommended decision to the Assistant Secretary for Health. The Assistant Secretary for Health may review the ALJ's recommended decision and modify or reject it in whole or in part after determining it, or the part modified or rejected, to be arbitrary and capricious or clearly erroneous. The Assistant Secretary for Health shall notify the parties of an intention to review the ALJ's recommended decision within 30 days after service of the recommended decision. If that notification is not provided within the 30-day period, the ALJ's recommended decision shall become final. An ALJ decision that becomes final in that manner or a decision by the Assistant Secretary for Health modifying or rejecting the ALJ's recommended decision in whole or in part is the final HHS action, unless debarment or suspension is an administrative action recommended in the decision.

(c) If a decision under § 93.523(b) results in a recommendation for debarment or suspension, the Assistant Secretary for Health shall serve a copy of the decision upon the debarring official and the decision shall constitute findings of fact to the debarring official in accordance with 45 CFR 76.845(c). The decision of the debarring official on debarment or suspension is the final HHS decision on those administrative actions.

[FR Doc. 05–9643 Filed 5–16–05; 8:45 am]

BILLING CODE 4150–31–P