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Department of Health and Human Services

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Parts 50 and 93

RIN 0940–AA04

Public Health Service Policies on Research Misconduct

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department proposes substantial revisions to the existing regulation at 42 CFR part 50, subpart A, ''Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science,'' 54 FR 32446 (Aug. 8, 1989) (final rule). We propose to delete this regulation, which implemented section 493 of the PHS Act, and add a new part 93, subparts A, B, C, D, and E. The purpose of this proposed rule is to implement legislative and policy changes that have occurred since the regulation was issued, including the common Federal policies and procedures on research misconduct issued by the Office of Science and Technology Policy. We have developed the proposed changes based on over 12 years of experience with the existing final rule. The proposed rule would help to ensure public confidence in the integrity of scientific data and the Public Health Service (PHS) supported research process.

DATES: Submit comments on or before June 15, 2004.

ADDRESSES: You may submit comments, identified by RIN #0940–AA04, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: Research@osophs.dhhs.gov,* attaching either a WordPerfect file—version 9.1 or higher, a Microsoft Word 97 or 2000 file, or an ASCII file (avoiding special characters and any form of encryption).
- *Mail:* Chris B. Pascal, J.D., Director, Office of Research Integrity, 1011 Wooten Parkway, Suite 750, Rockville MD 20852. Address all comments concerning this proposal to: Chris B. Pascal, J.D., Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852.

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

SUPPLEMENTARY INFORMATION:

I. Background

The National Institutes of Health Revitalization Act of 1993 (NIH Act), Pub. L. 103–43, which amended the PHS Act, contains important provisions that affect this proposed rule. Section 161 of the NIH Act established the Office of Research Integrity (ORI) as an independent entity reporting to the Secretary of the U.S. Department of Health and Human Services (HHS). Section 162 of the NIH Act required the establishment of a Commission on Research Integrity to review a broad range of administrative and policy issues relating to research integrity, including the definition of research misconduct, and to provide a report to the Secretary and the Congress with recommendations for PHS policies on research integrity. The Commission began its work in 1994 and sent its final report to Congress and the HHS Secretary on November 3, 1995. Section 163 of the NIH Act also requires the Secretary to promulgate a regulation on the protection of whistleblowers involved in cases of possible research misconduct. *See* section 493 of the PHS Act, 42 U.S.C. 289b. We proposed separate regulations to implement the whistleblower provisions and published a Notice of Proposed Rulemaking, ''Public Health Service Standards for the Protection of Research Misconduct Whistleblowers,'' 56 FR 70830 (Nov. 28, 2000); 65 FR 70830 (Dec. 29, 2000). We have postponed finalizing that regulation to ensure that its provisions are consistent with the proposed research misconduct rule.

In implementing the statutory provisions, the Secretary carefully reviewed: (1) The report issued by the Commission on Research Integrity; (2) the recommendations of an internal HHS review group established to evaluate HHS procedures for handling allegations of research misconduct; (3) the governmentwide policies on research misconduct developed by the Office of Science and Technology Policy (OSTP); and (4) other statutory and regulatory authorities such as 42 U.S.C. 216 and 241 and 42 CFR part 52 which confer broad authority upon the Secretary to regulate the use of PHS funds and to operate and manage PHS programs, including the authority to investigate and oversee investigations of allegations concerning the integrity of researchers who apply for or receive PHS funds and to take appropriate administrative actions to protect Federal funds and the public health, safety, and welfare. We developed this proposed rule to codify several important changes described below.

Section 493 of the PHS Act directs the Secretary to promulgate regulations requiring each entity that applies for or receives funds under the PHS Act for the conduct of biomedical or behavioral research to submit assurances that the entity: (1) Has established an administrative process that conforms with the regulation to review reports of research misconduct in PHS biomedical or behavioral research; (2) will report to the Secretary any investigation of alleged research misconduct; and (3) will comply with the regulations. The statute also requires the Secretary to establish by regulation the process by which the ORI reviews allegations and institutional reports of research misconduct and takes appropriate actions in response to findings of misconduct.

In response to the original section 493 of the PHS Act, and to carry out its overall responsibilities in this area, the PHS established two offices in 1989 for dealing with research misconduct and published a Final Rule that contains requirements for extramural institutions applying for or receiving PHS research funds. The two offices were the Office of Scientific Integrity (OSI), located at the National Institutes of Health (NIH), and the Office of Scientific Integrity Review (OSIR), located in the Office of the Assistant Secretary for Health. OSI had the primary responsibility for overseeing investigations of research misconduct carried out by institutions and for conducting investigations when necessary. OSIR provided a second level of review for investigations and developed research integrity policies for the PHS.

On August 8, 1989, HHS published its final regulation at 42 CFR part 50, subpart A. 54 FR 32446. The rule assigns to applicant and awardee institutions the primary responsibility for investigating possible research misconduct. The regulation requires these institutions to file an initial assurance that they have established policies and procedures for investigations. Institutions also must report annually on the numbers and types of allegations and inquiries dealt with during the calendar year. The regulation codified the existing PHS definition of research misconduct and established general principles for the conduct of institutional inquiries and investigations.

Based on our experience with the 1989 regulation and concerns raised by Congress and the public about the effectiveness of the existing office structure, we announced the reorganization of our research misconduct operations in the **Federal Register** on June 8, 1992. 57 FR 24262. The reorganization abolished OSI and OSIR and transferred their functions to the newly established ORI within the

Office of the Assistant Secretary for Health. On November 6, 1992, we announced the new PHS procedures for administrative hearing procedures before a Research Integrity Adjudications Panel of the HHS Departmental Appeals Board. 57 FR 53125 (1992), revised 59 FR 29809 (June 9, 1994). Subsequently, a 1995 reorganization of the Office of the Assistant Secretary for Health placed ORI within the Office of Public Health and Science in the Office of the Secretary. 60 FR 56605 (Nov. 9, 1995).

In 1996, the Secretary created the HHS Review Group on Research Misconduct and Research Integrity, consisting of senior HHS officials representing the PHS and the Office of the Secretary, to review ORI's policies and procedures. In July of 1999, the HHS Review Group made 14 recommendations to improve the quality, effectiveness, and efficiency of the system for responding to allegations of research misconduct and promoting research integrity. The Secretary approved these recommendations in October of 1999, and we have implemented them through policy changes. Some of the more significant changes are included in this NPRM.

In March of 1999, NIH issued a report entitled "NIH Initiative to Reduce Regulatory Burden—Identification of Issues and Potential Solutions.'' We have carefully reviewed the "Research Integrity'' section of the report. We have already implemented a number of the recommendations, such as assigning institutions primary responsibility for investigating misconduct, promoting increased education programs in research integrity, separating adjudication and appeals from the inquiry and investigation stages, and providing some flexibility to institutions in the assessment, inquiry, and investigation processes. Where appropriate, we propose to codify them in this proposed regulation.

In October of 1999, OSTP proposed a governmentwide definition of research misconduct for adoption and implementation by Federal agencies that conduct and support research. 64 FR 55722 (Oct. 14, 1999). After receiving comments, OSTP published a final notice consisting of a definition of research misconduct and policies and procedures for handling misconduct allegations. 65 FR 76260 (Dec. 6, 2000). The OSTP called upon all Federal agencies to adopt a common Federal framework for responding to research misconduct. Although our current practices are already substantially similar to the new OSTP policy, this proposed rule would bring the PHS procedures into conformity in the few divergent areas. Therefore, we propose to adopt and incorporate the OSTP governmentwide definition and pertinent policy, procedures, and guidelines in the proposed regulation.

On May 12, 2000, the Secretary approved organizational changes that moved the responsibility for making proposed findings of research misconduct and administrative actions from ORI to the Assistant Secretary for Health. The reorganization also moved direct inquiries and investigations previously conducted by ORI to components of the PHS for intramural research and to the Office of the Inspector General for extramural research. ORI continues, among other things, to direct PHS research integrity activities on behalf of the Secretary, to coordinate the development of research integrity policies regarding whistleblowers and respondents, and to perform oversight review of research misconduct inquiries and investigations. 65 FR 30600 (May 12, 2000). ORI also has the responsibility of proposing findings of research misconduct to the Assistant Secretary for Health and, if the Respondent challenges those findings, supporting them before the HHS Departmental Appeals Board. These changes are included in the proposed regulation.

As discussed above, the NIH Revitalization Act of 1993 amended section 493 of the PHS Act to establish ORI by statute, and, among other things, to change the term "scientific misconduct'' to "research misconduct.'' The proposed rule would implement these statutory amendments and a number of policy changes that we believe are necessary and appropriate, with the exception of the statutory provision regarding whistleblowers which we are promulgating in a separate regulation at 42 CFR part 94. The proposed rule incorporates many of the features of the existing Final Rule concerning responsibilities of awardee and applicant institutions, and it sets out our procedures for responding to research misconduct.

We invite public comments on all aspects of this proposed regulation and, in particular, on the following topics:

II. Proposed Changes

A. Applicability

1. *Inclusion of PHS Intramural Programs:* Based on the OSTP policy and a recommendation from the internal HHS review groups, we propose to codify a major difference between the existing Final Rule and current practice. Under section 93.102 of the proposed rule, PHS intramural programs would be treated similarly to extramural research institutions. Because the procedures for conducting inquiries and investigations are largely the same for both extramural and intramural institutions, we have consolidated the procedures in the proposed regulation.

Therefore, in addition to investigating allegations of misconduct within their programs, the intramural programs would also submit assurances to ORI that they have established administrative processes to address allegations of misconduct in connection with research conducted by the intramural institution. ORI would continue to provide oversight of these intramural investigations just as it does for extramural programs. Additional instructions for PHS officials on intramural investigations may be issued via internal policies, as needed.

2. *Inclusion of Contracts:* The existing Final Rule does not include contracts involving PHS funds, but is limited to research grants, training grants, and cooperative agreements. The proposed rule expands the scope of coverage to include procurement contracts as required by the PHS Act and consistent with the OSTP policy and current PHS practice.

B. Definition of Research Misconduct

1. *The Definition:* The regulatory definition of "scientific misconduct'' in the existing Final Rule has been the subject of considerable discussion over the years since its introduction, and we have considered the comments and concerns expressed by Congress, the research community, and other interested organizations. Now, as noted above, OSTP has adopted a final new governmentwide Federal definition and guidelines on research misconduct.

As an initial matter, the existing Final Rule refers to "Misconduct or Misconduct in Science,'' 42 CFR 50.102, whereas, the proposed regulation refers to "Research Misconduct.'' This change would be consistent with the statutory amendments and the OSTP governmentwide definition.

In addition, the existing Final Rule defines "scientific misconduct'' as "fabrication, falsification, plagiarism, or other practices * * * for proposing, *conducting,* or reporting research.'' (Emphasis added.) In contrast, OSTP and section 93.103 of the proposed regulation define "research misconduct'' in relation to "proposing, *performing, or reviewing* research, or in reporting research results.'' (Emphasis added.) The proposed regulation would use the term "performing'' instead of "conducting'' research and would

change the scope of the covered activity to include misconduct occurring in connection with the "reviewing'' of research. The inclusion of "reviewing'' in section 93.102 is consistent with the addition of "reviewing'' in the proposed definition. This is also consistent with the intent of the HHS Review Group and the OSTP policy to include the process of submitting an application for research support (proposing), and the peer review of an application or a journal article (reviewing). We propose to retain the definition of research misconduct as "fabrication, falsification or plagiarism'' (commonly called FFP), but would augment it to include OSTP's description for each of these terms. The "other practices'' clause of the existing final rule would be dropped.

We propose to interpret the phrase "data or results'' in section 93.226 broadly to encompass all forms of scientific information about the research at issue without regard to the type of recording or storage media involved. The phrase would include, but not be limited to, raw numbers, field notes, interviews, notebooks and folders, laboratory observations, computers and other scientific equipment, CD–ROMs, hard drives, floppy disks, Zip disks, back-up tapes, machine counter tapes, research interpretations and analyses, tables, slides, photographs, charts, gels, individual facts, statistics, tissue samples, reagents, and statements by individuals. The phrase "statements by individuals'' refers to documented oral representations of research results made by scientists and, therefore, would also be considered to be "data.''

2. *Burden of Proof:* We propose to revise slightly the burden for establishing research misconduct in three ways: First, in keeping with the OSTP policy, the proposed regulation would require that the FFP be a "significant departure'' from accepted practices as opposed to ORI's current standard of "serious deviation.'' As discussed in the OSTP policy statement, the phrase "significant departure'' intends to make clear that behavior alleged to invoke research misconduct should be assessed in the context of practices generally accepted by the relevant research community. As the current definition requires a serious deviation from practices generally accepted in the particular scientific community, we do not anticipate that this change in phraseology would alter the burden of proving or disproving research misconduct in any significant way. However, we specifically ask for comments on this issue.

Second, the proposed regulation is consistent with the OSTP position on who has the burden of proving honest error or a difference of opinion. Proposed sections 93.106(a) and 93.516(c) provide that the respondent bears the burden of proving any affirmative defenses raised, including honest error and differences of opinion and any mitigating factors that the respondent wants the institution or HHS to consider in imposing administrative actions. Section 93.106(a) provides that once the institution or HHS makes a *prima facie* showing of research misconduct the burden of going forward to prove that the conduct was the result of an honest error or difference of opinion shifts to the respondent. Under section 93.106(a), the absence of, or a respondent's failure to provide, research records adequately documenting the questioned research establishes a rebuttable presumption of research misconduct, specifically falsification. Credible evidence corroborating the research or providing a reasonable explanation for the absence of, or respondent's failure to provide, these research records may be used by the respondent to rebut the presumption of research misconduct. Third, consistent with the OSTP policy, the level of intent would be expanded beyond an intentional and knowing standard to include recklessness.

3. *Plagiarism and the Definition of Research Misconduct:* Section 93.102 of the proposed regulation would be applicable to PHS supported research "including any research proposed, performed, *reviewed,* or reported * * * *regardless of whether the user or reviewer receives PHS support* * * *.'' (Emphasis added.) Thus, the proposed regulation would expressly cover research misconduct involving plagiarism of PHS supported research. Neither the respondent nor the respondent's research needs to be PHS supported for jurisdiction to attach. The misconduct regulation would cover plagiarism where the respondent has copied or appropriated ideas or data from another's PHS supported research, for example, where the respondent is a reviewer in the PHS grants review process or where the respondent is a reviewer for a scientific journal.

The collective experience of the PHS and extramural institutions in dealing with alleged research misconduct has revealed the use of varying interpretations or definitions of the term "plagiarism.'' For purposes of the existing final rule and proposed regulation, we consider plagiarism to include both the copying of words of another and the appropriation of ideas, findings, or methods of another without giving full and proper credit for those words, ideas, or methods. Under the proposed regulation we would continue to limit our interpretation of the term plagiarism to exclude those acts that involve limited use of identical or nearly identical phrases (1) to describe a commonly used method, (2) to describe previous research in a scientific article, grant application, or contract proposal, and (3) where the use does not materially inflate the contribution of the author as perceived by the reader or reviewer in a manner which would be a significant departure from accepted standards.

In keeping with the PHS and OSTP policies, we would also continue to exclude disputes involving authorship or credit among collaborators unless they involve plagiarism. Past allegations have often involved disputes among former or current collaborators who participated jointly in the development or conduct of a research project, but who subsequently made independent use of the jointly developed concepts, methods, descriptive language, or other products of the joint effort. The ownership of the intellectual property in many of these situations is seldom clear, and the collaborative history among the scientists may support a presumption of implied consent for each of the collaborators to use their joint efforts. Although these disputes involve very important principles, we believe that these matters are best handled by the researchers and their institutions. *See* "ORI Provides Working Definition of Plagiarism,'' *ORI Newsletter,* Vol. 3, No. 1 (Dec. 1994), available at *http://ori.dhhs.gov/html/publications/newsletters.asp.* Therefore, we propose to continue to consider them outside the PHS regulatory definition of plagiarism. As these issues are of long-term continuing interest, we invite comments on the PHS interpretation.

C. Institutional and Federal Responsibilities

1. *Clarifying the Institutional and Federal Roles:* In general, the sections of the proposed regulation addressing the respective responsibilities of institutions and HHS contain more detail than the corresponding provisions of the existing final rule. Over the years, institutions have often requested guidance in these matters, but the existing final rule contained little in the way of explanation. In most instances, the increased detail would require minor, if any, changes to the current process used by the institutions and PHS for handling research misconduct allegations. Rather, the proposed regulation would memorialize current

practices, as developed through experience and contact with institutions, and recommendations already contained in ORI's guidance documents and model policies.

Codifying these practices and policies should be helpful to institutions and, in some instances, may provide them with legal protection. First, setting out the steps to be taken in a research misconduct proceeding would level the playing field by providing the accused researcher with much needed notice of the required process to be used and protections offered in addressing the allegations. Also as noted, many institutions have requested a more specific road map to follow in responding to allegations of research misconduct. Finally, formalizing the specific process for institutional responses to research misconduct allegations provides a mechanism by which all players in the process, *e.g.*, respondents, institutions, and complainants, may be held accountable.

2. *Institutions' Primary Responsibility:* Research institutions' responsibilities for handling allegations of research misconduct would remain substantially the same under the proposed regulation, in keeping with ORI's pre-existing conformity with the OSTP policy. Institutions would continue to have primary responsibility for conducting inquiries and investigations. In this regard, institutions have conducted over 95% of the PHS misconduct investigations since 1995 and all of them since 2000. Furthermore, as recommended by the HHS Review Group, we also propose at section 93.306 to increase institutional flexibility by specifically providing that institutions which are too small, or otherwise unable to respond adequately to allegations of research misconduct, would be able to use the services of a consortium or other entity to handle a research misconduct proceeding.

3. *Providing a Clear Road Map:* In conducting inquiries and investigations of research misconduct, institutions assume an important responsibility, made all the more important by the fact that the Federal government relies largely on the institution's work in taking action against an accused researcher. If an institution does not conduct a thorough and fair investigation, the case may be forever compromised, either failing to prove misconduct where it actually exists or not properly considering evidence that would exonerate the accused researcher. Therefore, we propose to modify the existing final rule in certain areas where it would assist in clarifying institutional responsibilities and PHS expectations. For example, the proposed rule has several new definitions to aid in interpreting the regulation. Perhaps most importantly, the proposed rule would clarify the steps institutions should take to ensure a fair and thorough investigation, such as securing the evidence and giving the respondent a reasonable opportunity to comment on the investigational report. In addition, we propose more explicit guidance regarding what information and evidence institutions should provide to enable ORI to perform its oversight function.

4. *Institutional Standards:* Section 93.319 of the proposed regulation would formalize the current policy that institutions may, and many do, have different definitions and standards for research misconduct than those in the Federal regulation. For example, an institution may treat certain authorship disputes as plagiarism under its own internal standards for research misconduct while the PHS would not. Although an institution must apply the PHS regulatory definition, standards, and requirements in evaluating an allegation of research misconduct reported to ORI, it may also apply its internal definition or standards in determining whether research misconduct or other misconduct occurred at the institutional level. Thus, an institution may find misconduct under its internal standards and impose administrative actions based on that finding, regardless of whether it or PHS makes a finding of research misconduct under the PHS standards.

D. Retention of the Inquiry Stage

The existing final rule defines a two-stage process that takes place when an institution receives allegations of research misconduct: (1) An inquiry, or preliminary fact-finding, to determine if the allegation involves PHS supported research and has sufficient substance to warrant an investigation; and (2) an investigation, which is a thorough review and analysis of all relevant facts to reach a conclusion as to whether research misconduct has occurred, who was responsible, and how serious any misconduct was.

Institutions treat the inquiry phase in a widely varying manner, and the distinction between an inquiry and an investigation has caused much confusion. Some inquiries conducted by institutions are largely indistinguishable from investigations. As the OSTP policy adopts a two-stage process, we have retained the current two-stage process but propose to sharpen the distinction between inquiries and investigations by clarifying that the inquiry is only an initial review of the allegations to see if they warrant an investigation.

E. Safeguards

1. *Confidentiality:* Section 93.108 of the proposed regulation would retain the goal of affording confidentiality, to the extent possible, for respondents and complainants in research misconduct proceedings, except for PHS administrative hearings, which must be open to the public in accordance with section 93.517(g). Section 93.108 uses the qualifying phrase, "to the extent possible,'' because research misconduct cases are often subject to unpredictable factors beyond institutional or agency control, and it is not always possible to ensure complete confidentiality for respondents and complainants in these proceedings. Except as otherwise required by law, records or evidence which could identify research subjects must be maintained confidentially. Parties must limit disclosure of this data to those who have a need to know to carry out a misconduct proceeding. Note that the regulation, Standards for Privacy of Individually Identifiable Health Information, 45 CFR parts 160 and 164, permits entities covered by that regulation to disclose individually identifiable health information to ORI for the oversight functions authorized by the Public Health Service Act and the implementing regulation.

2. *Access to Data:* Following the OSTP policy, the proposed regulation would provide an additional safeguard for respondents. Specifically, and in conformance with ORI's current practice, section 93.305(b) of the proposed regulation would require institutions, where appropriate, to give the respondent copies of or reasonable, supervised access to, the research records.

F. Proposed Findings of Research Misconduct

1. *Separation of Fact-finding and Decision Making:* We propose to adopt the current separation of the fact-finding and decision-making processes in research misconduct cases within HHS. The proposed regulation would codify the PHS practice since 1999, in which the decision to find research misconduct is made by the Assistant Secretary for Health (ASH) or the official designated by the ASH. OSTP policy also supports this separation. ORI would continue to be responsible for overseeing institutional inquiries and investigations and making recommendations for proposed research misconduct findings, settlements, and administrative actions to the ASH in cases where ORI believes misconduct

has occurred. Also, as under current practice, if ORI were to propose debarment as an administrative action, that decision would be made by the HHS Debarring Official, the Deputy Assistant Secretary for Grants and Acquisition Management.

2. *HHS Administrative Actions:* As recommended by OSTP, we propose in section 93.408 to include consideration of aggravating and mitigating factors in determining which HHS administrative actions are appropriate to protect the PHS and the research process. Historically, PHS has incorporated an aggravating and mitigating factor analysis in its assessment, but the proposed regulation would memorialize this policy and provide guidance to all parties.

G. HHS Inquiries and Investigations

HHS would continue to have ultimate oversight authority for PHS supported research. As part of this organizational scheme, PHS has assigned to ORI the responsibility of conducting oversight reviews of these investigations, recommending to the ASH findings and appropriate administrative actions necessary to protect the interests of the PHS, and supporting these findings before the HHS Departmental Appeals Board (DAB). However, infrequent circumstances may arise where it becomes necessary for HHS itself to investigate the allegations of research misconduct at an extramural or intramural institution. Section 93.400(a)(4) would codify the HHS Review Group's recommendation that the investigatory function for these cases be handled at the Departmental level. The HHS Office of Inspector General (OIG) will conduct such investigations.

H. Role of Complainants, Witnesses, and Others

1. *Good Faith:* The PHS Act requires the Secretary to establish regulations for preventing and responding to institutional retaliation against employees who raise *good faith* allegations that an individual has committed research misconduct, or that an institution has failed to respond adequately to an allegation of research misconduct. 42 U.S.C. 289b(e)(1). The existing final rule requires institutions to undertake "diligent efforts to protect the positions and reputations of those persons who, in *good faith,* make allegations.'' (Emphasis added.) 42 CFR 50.103(d)(13). Because the attachment of whistleblower protections is contingent upon the making of *good faith* allegations, section 93.210 of the proposed regulation would define what it means to make an allegation in "good faith'' and, conversely, when an allegation is not brought in good faith. With this provision, PHS seeks to clarify a common misunderstanding about the nature of whistleblower protection. Namely, even if an allegation is wrong, the person bringing that allegation is still entitled to protection against retaliation as long as the whistleblower made the allegation in good faith. However, if a complainant does not make an allegation in good faith, (*e.g.* makes an allegation with knowledge that the factual basis for the allegation is untrue), an institution may take reasonable action to redress any harm caused by the allegation. In the academic community, these are commonly known as "bad faith'' allegations, and some institutions currently have policies and procedures for responding to them.

2. *Complainants and Witnesses in Research Misconduct Proceedings:* We recognize the critical role of complainants and other witnesses in research misconduct proceedings. The vast majority of cases that result in misconduct inquiries or investigations result from a complaint brought to the attention of appropriate institutional officials. However, the responsibility for addressing allegations should not fall on those who raise them. In conformance with the OSTP policy, the HHS Review Group, and current agency practice, this proposed rule would make clear that an institution has an obligation to pursue allegations of misconduct independent of the complainant's role. Once the complainant has made a formal allegation that research misconduct has occurred, that person does not participate in the research misconduct proceeding other than as a witness. A complainant is not the equivalent of a "party'' in a private dispute. Complainants are witnesses in that they do not control or direct the process, do not have special access to evidence except as determined by ORI or the investigative body, and do not act as decision makers.

The proposed regulation would employ a new term, "complainant,'' defined at section 93.203 as a person who in good faith makes an allegation of research misconduct. The role of complainants is limited by the proposed provisions governing the conduct of inquiries and investigations. Under the proposed regulation, the institution may, but would no longer be required, to give the complainant an opportunity to comment on the inquiry and investigation reports.

I. Compliance

1. *Assurances for Small Institutions:* Since 1990, ORI has permitted institutions determined to be too small to conduct research misconduct proceedings effectively or without any appearance of a conflict of interest to submit a "Small Organization Statement'' under which they agree to work with ORI to develop an alternative mechanism to handle research misconduct allegations. Proposed section 93.303 would codify this option. Because we want to retain the flexibility these small institutions need, we have not explicitly defined the upward limit of what is considered a small institution. In the past, this alternative for small institutions has been applied to institutions with no more than 10 employees.

2. *Using a consortium or other entity to conduct research misconduct proceedings.* The HHS Review Group suggested that institutions that were unable to conduct their own research misconduct proceedings use the services of a consortium or other entity qualified by practice and experience to conduct research misconduct proceedings. Section 93.306 would allow institutions that are too small, have real or apparent conflicts of interest, lack the capacity, or otherwise prefer not to conduct misconduct proceedings to elect this alternative. Our experience to date with this process has been positive, but we ask for comments as to whether there should be any limitations on an institution's ability to choose this option.

3. *Noncompliance with the Regulation:* The proposed regulation would provide more information on institutional compliance obligations and the potential actions we may take in response to compliance concerns. The existing final rule provides that an institution's failure to comply with its assurance and the applicable regulations may result in an enforcement action against the institution. However, that rule does not spell out what type of institutional action constitutes a failure to comply. Nor does it explain what type of enforcement action an institution may face for noncompliance other than revocation of its assurance and the loss of PHS funding.

Over the past several years, ORI has needed to take a number of compliance actions but has had to do so without any clear regulatory guidance in place for either the institution or ORI. We propose to rectify this problem and take some of the guesswork out of compliance enforcement. First, section 93.412 of the proposed regulation would

establish the circumstances under which ORI could find an institution out of compliance. These circumstances would include, among other things, a failure to establish and comply with policies and procedures required by the regulation or a failure to cooperate with review of institutional research misconduct proceedings. As we already view all of the factors listed in the proposed regulation as examples of potential institutional noncompliance, the regulation would essentially codify current policy and practice. To that end, like some of the other changes in the proposed regulation, we believe it is helpful to spell out existing practice.

A second way in which the proposed regulation would lend clarity to the compliance process would be the addition in section 93.413 of a more complete explanation of the potential enforcement actions that HHS may impose in response to institutional noncompliance. This clarification serves several functions. First, it introduces a graduated scheme of actions that ORI could take itself or propose to other PHS agencies or HHS, as appropriate, in response to a given instance of noncompliance. These actions, most of which are already in effect through other PHS regulations, range from issuance of a warning letter (which could also require an institution to take corrective actions) to revocation of an assurance. A graduated scheme of compliance actions responds both to the needs of HHS and the institutions. The proposed regulation would answer institutional concerns that the current compliance system provides only for the revocation of an assurance.

J. Maintenance and Custody of Records.

Responsibility for maintenance and custody of research records and evidence: We propose to codify current policy regarding ongoing institutional responsibilities for obtaining and maintaining custody of the research records of the accused researcher and other evidence relevant to the misconduct allegations. To protect respondents, the OSTP policy recommends that institutions provide accused researchers with reasonable access to the evidence supporting the allegations. It cautions that misconduct policies should ensure that the mere filing of an allegation does not bring research to a halt nor provide a basis for other disciplinary or adverse action absent other compelling reasons. Accordingly, section 93.305(b) of the proposed regulation would provide that, where appropriate, institutions must "give the respondent copies of or reasonable, supervised access to the research record.'' However, we do not propose to limit an institution's control over its employees and the research conducted under its auspices. The proposed regulation would not give a respondent any rights to continue research in the face of reasonable institutional objections.

K. Hearing Process

We propose to add the HHS hearing process for reviewing PHS findings of research misconduct, as the existing final rule did not include provisions for a hearing. Since 1992, when we began to offer hearings, we have not had clear-cut procedures for research misconduct adjudications. Complainants, parties, witnesses, and others have commented that the current informal hearing procedures, published at 59 FR 29809 (1994), lack the consistency and clarity provided by binding rules of procedure for other types of cases. Accordingly, we believe that adding a hearing regulation applicable only to research misconduct cases is advisable to codify a fair, efficient, and timely process for accused researchers.

We have modeled the proposed hearing regulation in subpart E primarily on the current regulations, at 42 CFR part 1005, governing the hearing process for the exclusion of health care providers used by the OIG, while modifying them to reflect current practice, knowledge, and experience in research misconduct proceedings. The proposed regulation also retains several key features from the current informal procedures.

The current *ad hoc* hearing process involves a trial-like evidentiary hearing on the PHS findings of scientific misconduct and proposed HHS administrative actions by a three-person panel of the DAB. The panel, which may include one or two outside scientists, in addition to the DAB Board Member(s), conducts a *de novo* review in which the merits of the case are heard as if for the first time, without any reference to or reliance on any previous decision making or review process. In other words, both the PHS and the accused scientist have an opportunity to present their side of the case to the DAB. The DAB conducts this *de novo* hearing pursuant to the above noted informal guidelines and determines whether the respondent committed scientific misconduct and whether the proposed administrative actions should be imposed. In reaching its decision, the panel does not rely on the administrative record developed by the institution or ORI during its oversight review but instead relies solely upon testimony and other evidence presented by the parties at the hearing.

Because proposed subpart E is new, we have described it in greater detail than the other subparts and request comment, especially on the following issues.

1. *Administrative Law Judges (ALJ):* We believe that the proposal in section 93.502 to change from the current system of using a panel of three decision makers to using a single ALJ appointed from the DAB Administrative Law Judges would substantially improve and simplify the process for all parties. This change would provide a process similar to program exclusion cases brought by the OIG, cases which have similar impact on the subjects' reputations and livelihood. In fact, for many other HHS programs, including those conducted under the OIG regulation, a single decision maker conducts the hearings. Section 93. 506, Authority of the Administrative Law Judge (ALJ) , closely follows the OIG regulations at 42 CFR 1005.4. Under the OIG regulations, the ALJ must follow all Federal laws, regulations, and Secretarial delegations of authority. Proposed section 93.506(a) adds applicable HHS policies to this list, because certain policies and guidelines apply to PHS biomedical and behavioral research and research training grants.

2. *Recommended decision:* The ALJ's final ruling on the merits of the PHS misconduct findings and the HHS administrative actions will now constitute a recommended decision to the Assistant Secretary for Health. Under current practice, the DAB's decision on the merits of PHS findings of misconduct and HHS administrative actions, other than debarment, constitutes final agency action as to these matters. In 2000, the Secretary redelegated the authority to propose findings of research misconduct and administrative actions from the Director, ORI, to the Assistant Secretary for Health. The Assistant Secretary for Health will now take final agency action on PHS research misconduct appeals, exercising the office's delegated authority to affirm, reverse, or modify the ALJ's recommended decision. In accordance with 45 CFR part 76, the ALJ's final ruling constitutes proposed findings of fact to the HHS Debarring Official. The respondent may continue to have access to a final review in Federal court under the standards of the Administrative Procedure Act.

3. *Scientist Advisors and Experts:* Substituting a single ALJ for the current three-person panel would alter, to some extent, the role of the scientist in the proceeding. Although the current

system theoretically permits the panel to have up to two scientist members, most panels to date have had either one or no scientist member. However, to ensure that the necessary scientific expertise is available, section 93.502(b) would authorize the ALJ to engage an expert in the relevant area of science to advise the ALJ on scientific or technical issues, and require the employment of such an expert, if requested by either party. This is consistent with recent developments in the Federal judicial system in which judges may select their own outside experts to help them understand cases involving complex scientific, medical, or technological issues. The proposed regulation contemplates that the ALJ would consult informally with the scientific expert, similar to the way experts are used by the Office of Special Masters, United States Court of Federal Claims in the National Vaccine Injury Compensation Program, rather than following the more formal procedures in Federal Rules of Evidence 706. Thus, we do not contemplate that the ALJ's expert advisor would provide testimony for the record, but either party to the hearing (*e.g.*, the accused researcher and PHS) could offer its own experts as witnesses. Therefore, the proposed new process should simplify the proceedings while providing ample and necessary input from the scientific community.

4. *Real or Apparent Conflicts of Interest*. Consistent with current DAB and Federal court practice, section 93.502 (c) would prohibit the appointment of any ALJs or outside science advisors with any real or apparent conflict of interest that might reasonably impair their objectivity in the proceeding. Section 93.502(d) would establish a process for the disqualification of an ALJ or appointed scientist or expert and, consistent with Federal court practice, would also permit the ALJ to rule on a motion to disqualify. If the ALJ rules, either party could appeal the decision directly to the Chief ALJ . This process would permit the ALJ and Chief ALJ to address potential conflicts of interest while maintaining a fair and objective hearing process.

5. *Relation to HHS Debarment Regulations:* The HHS Debarring Official refers disputed material facts related to a proposed debarment in PHS research misconduct proceedings to the DAB for determination. *See* 45 CFR 76.314(b)(2). Subpart E of the proposed regulation would be consistent with this practice and would not supersede or otherwise alter the existing HHS Debarment regulations or procedures for contesting proposed debarments.

6. *Amendment to the PHS Charge Letter:* Consistent with current DAB practice, section 93.514 would permit the PHS to amend its findings of research misconduct up to 30 days before the scheduled hearing. We anticipate that this would occur only in rare circumstances where we learned of additional acts of research misconduct after the DAB process had begun (*e.g.*, the acquisition of new information during the discovery process). In addition, the Assistant Secretary for Health and the HHS Debarring Official (if debarment were proposed) would have to approve any amendments. In this instance, the respondent could request a postponement of the hearing to prepare a response to the new charge.

7. *De Novo Proceedings:* Consistent with current policy, section 93.517(b) would codify the current practice of providing a *de novo* hearing to consider challenges to any PHS findings of research misconduct and proposed PHS administrative actions. We also propose in section 93.503(d) to incorporate the current practice that permits a respondent to waive an in-person hearing and have the case decided on the basis of the administrative record.

8. *Standardization of Requirements:* We believe that the proposed regulation would level the playing field by letting respondents know up front how the hearing process works. For example, the regulation sets up requirements for the content of the hearing request (sections 93.503–504), time frames for conducting preliminary conferences (section 93.511), discovery (section 93.512), submission of witness lists and exhibits (section 93.513), and the post-hearing process (sections 93.520 through 523). Knowledge of these standards by the accused researchers would help promote a fair, timely, efficient, and less costly process for all parties.

9. *Limited Discovery:* Generally, discovery is not required to be made available in administrative proceedings. Under the Administrative Procedure Act, agencies may decide the extent of available discovery. We propose to follow the standard Federal administrative practice of limiting discovery to an exchange of documents. Thus, like other HHS procedures, the proposed regulation would not permit other forms of discovery available in Federal court litigation, such as requests for admissions, written interrogatories, and deposition. *See* section 93.512(a). Limited discovery results in a faster and more efficient process that reduces litigation costs for all parties. Following discussion at a prehearing conference, the ALJ could order the parties to develop stipulations and admissions of fact. See section 93.511(b)(2). In past hearings, however, these mechanisms have not resulted in narrowing the issues or improving the efficiency of the hearing, because the parties had to prepare, but failed to agree on, any stipulations or admissions.

10. *Written Direct Testimony and Use of Telephone and Audio-Visual Communication:* Section 93.518(b) of the proposed regulation would permit the ALJ to admit written witness testimony, including prior sworn testimony, if the person is available for cross-examination. Section 93.518(c)) would permit testimony by telephonic or audio-visual communication. Past experience has shown that these features help foster an efficient and streamlined hearing process and reduce the risk of unfair surprise and increased cost and inconvenience to the parties and witnesses.

11. *Evidentiary Standards:* We also propose to clarify the standards for admitting evidence at the hearing. Section 93.519(c) addresses the standard Federal administrative practice of admitting relevant and material evidence and excluding unreliable or unfairly prejudicial evidence. To avoid ambiguity, the proposed regulation also incorporates several provisions of the Federal Rules of Evidence. *See* sections 93.519(f)–(i). Similarly, section 93.519(e) would permit the ALJ to take judicial notice of established scientific and technical facts, which would reduce the need for expert testimony and, thereby, provide a cost savings to the parties.

12. *Other Federal Laws or Regulations:* With respect to the hearing process, the proposed regulation would not supersede or otherwise alter existing Federal laws or regulations that may provide additional procedures for Federal employees.

13. *Recordkeeping for Inquiries and Research Misconduct Proceedings:* The OIG has raised 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. Accordingly, the new NPRM proposes extending the period for retaining records on inquiries and misconduct proceedings to 7 years. See proposed sections 93.309(c) and 93.317(a).

L. Other Features of the Proposed Rule

1. *Coordination with Federal Agencies:* Federal agencies try to coordinate when allegations arise that affect more than one funding agency. For example, NIH and the Department

of Energy might be jointly funding a particular project which is the subject of research misconduct allegations. Failure to coordinate may result in overlooking important government policies, adversely impacting other agencies' missions and interests, and duplicating or wasting resources. Therefore, the NPRM proposes to codify current practice to recognize that, in these instances, the agencies may coordinate responses with other Federal agencies. The PHS has coordinated with other interested Federal agencies in a number of cases and will continue to do so.

2. *Limitations period:* Because of the problems that may occur in investigating older allegations and the potential unfairness to accused researchers in defending against them, we propose to limit the scope of the misconduct regulations to cases in which the alleged misconduct occurred within 6 years before the allegation. The proposed rule models this limitation period after the one used in the *qui tam* provision of the False Claims Act, 31 U.S.C. 3731(b), and after the procedures used by the OIG in its Medicare and Medicaid exclusion cases. Thus, with a few exceptions, we would be barred from going forward with cases where the alleged misconduct occurred outside this 6 year window.

3. *Person:* Section 93.219 of the proposed regulation would define "person'' to include individuals as well as institutions and other organizations. This approach to the definition of "person'' is consistent with many regulatory schemes including the governmentwide nonprocurement debarment regulation which is cross-referenced with the proposed misconduct regulation.

4. *Investigation time limits:* The OSTP policy recommends that the Federal agencies establish reasonable time lines to balance expeditious completion of an institutional research misconduct process against fairness and thoroughness. Consistent with the existing final rule, sections 93.307(g) and 93.311 would maintain the 60-day time limit for institutional inquiries and the 120-day time limit for investigations, subject to extensions. As experience has shown that institutions often need extensions of time, we seek comments on whether these time limits are realistic and provide sufficient time to conduct inquiries and investigations.

5. *Institutional Appeals:* Although not required under the existing Final Rule, some institutions provide respondents with an internal process by which to appeal the institutional finding of misconduct. Our experience has shown that often these appeals may result in substantial delays in completing the institutional process and any subsequent review. Therefore, in section 93.314, we have proposed a 120-day deadline for completion of institutional appeals. This section would provide that any appeals must be completed within 120 days of filing the appeal, unless extended by ORI for good cause. The 120-day time limit would apply only to a respondent's appeal of the merits of an institutional finding of research misconduct, if such a process is provided by an institution's research misconduct policy. The 120-day time frame would not apply to any other procedures that an institution may have, such as tenure proceedings, disciplinary proceedings, or honor committee proceedings, that do not go to the merits of a research misconduct finding. It also would not apply to any civil law suits filed by a respondent challenging a finding of research misconduct. We ask for comment on whether this proposed time limit is appropriate and would ameliorate the problems caused by delays in completing proceedings, and, if so, whether the proposed 120 day deadline is sufficient.

6. *Settlements:* In making findings of research misconduct, ORI has relied on settlement agreements with the accused scientist the great majority of the time. These settlements can occur at any stage of the investigative process, from the allegation to completion of the investigation. Consistent with ORI's prior practice, ORI has expressly provided in proposed section 93.409 that ORI may settle a research misconduct proceeding at any time in the best interests of the Federal government and the public health or welfare. ORI has also participated in three-way agreements with the research institution, ORI, and the accused scientist. We encourage institutions or respondents (or counsel) to contact ORI directly when a settlement agreement appears feasible. Finally, we caution institutions about entering into settlement agreements with the respondent without consulting with ORI in advance. In some cases, the institution has purported to enter into a binding agreement with the respondent that seeks to restrict the scope of an investigation or otherwise limits ORI's or the institution's authority under the regulation. Any such attempt would have no binding effect on ORI and would not abrogate the institution's regulatory obligations. Accordingly, we request that any institution considering such action consult with ORI staff and counsel before agreeing to any settlement. However, no regulatory language requires that institutions do so.

M. Structure and Format

We propose to adopt a different approach to the structure and format from the existing final rule based on the Presidential Memorandum on Plain Language issued on June 1, 1998. This memorandum directed Federal agencies to ensure that all of their documents are clear and easy to read. We organized the proposed rule so that matters common to a particular subject appear together. We also grouped related sections within subparts and placed them under unnumbered, centered headings. This allows readers easy access to information of particular importance to them. We have used fewer legal terms and more commonly understood words along with shorter sentences and have tried to make each section easy to understand by using clear and simple language rather than jargon. We would like your comments on how effectively we have used plain language, the organization and format of the proposed rule, and whether the document is clear and easy to read.

III. Analysis of Impacts

As discussed in greater detail below, we have examined the potential impact of this proposed 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 proposed rule would 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 proposed 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 proposed 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 proposed 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 proposal 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 total annual burden is 18,279.5 hours. The U.S Department of Labor, Bureau of Labor Statistics, sets the mean hourly wage for Educational Administrators, Postsecondary at $31.14. The mean hourly wage for lawyers is $43.90. The average hourly cost of benefits for all civilian workers would add $6.41 to these amounts. In order to ensure that all possible costs are included and to account for potential 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 $1,827,950.

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 proposing 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. As any final rule resulting from this proposal would not result in expenditures of this magnitude, 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 proposed rule on small entities, but also permits agency heads to certify that a proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The primary effect of this rule would be to require covered institutions to implement policies and procedures for responding to research misconduct cases. The Department certifies that this proposed rule would 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 NPRM 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 proposed 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, the Department concludes that the regulations proposed in the NPRM will not impose a significant burden on a substantial number of small entities. However, we will carefully consider comments on the analysis and conclusion.

D. Executive Order 13132: Federalism

This proposed rule, if published as a final rule, would 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 proposed rule contain information collection requirements that are subject to review by the OMB under the Paperwork Reduction Act of l995 (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. With respect to the following information collection description, PHS invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of PHS functions, including whether the information will have practical utility; (2) the accuracy of the PHS estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of collection of information on respondents, including the use of automatic collection techniques or other forms of information technology.

Title: Public Health Service Policies on Research Misconduct.

Description: This proposed 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, governmentwide 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 section 93.214).

Subpart C—Responsibilities of Institutions

Compliance and Assurances

Section 93.300(a)

See section 93.304 for burden statement.

Section 93.300(c)

See section 93.320 for burden statement.

Section 93.300(i)

See section 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)

See section 93.301(a) for burden statement.

Section 93.302(a)(2)

See section 93.320 for burden statement.

Section 93.302(a)(3)

Each applicant institution must inform its scientific and administrative staff 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 section 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 hours.

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), (b), (d), and (e)

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 section 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(c)

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 section 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: 16.

Number of Responses per Respondent: 1.

Annual Average Burden per Response: 16 hours.

Total Annual Burden: 256 hours.

Section 93.309(b)

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 section 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: 16.

Number of Responses per Respondent: 1.

Annual Average Burden per Response: 1.

Total Annual Burden: 16 hours.

Section 93.310(d)

See section 93.305(a), (b), (d) and (e) 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: 16.

Number of Responses per Respondent: 1.

Annual Average Burden per Response: 15 hours.

Total Annual Burden: 240 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.

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: 16.

Number of Responses per Respondent: 1.

Annual Average Burden per Response: 80 hours.

Total Annual Burden: 1280 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 section 93.305(a), (b), (d), and (e) for burden statement.

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 will submit a copy of this proposed rule to OMB for its review and approval of this information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the agency official designated for this purpose whose name appears in this preamble and to fax number (202) 395–6974, Attn: Fumie Yokota. Submit written comments by June 15, 2004.

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: December 29, 2003.

Cristina V. Beato,

Acting Assistant Secretary for Health.

Approved: December 31, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

Editorial Note: This document was received in the Office of the Federal Register on April 13, 2004.

Accordingly, under the authority of 42 U.S.C. 289b, HHS proposes to amend 42 CFR parts 50 and 93 to read as follows:

PART 50—POLICIES OF GENERAL APPLICABILITY

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

Authority: Sec. 493, Public Health Service Act, as amended, 99 Stat. 874–875 (42 U.S.C. 289b); Sec. 501(f), Public Health Service Act, as amended, 102 Stat. 4213 (42 U.S.C. 290aa(f)).

Subpart A [Removed]

2. Part 50, Subpart A is removed and reserved.

PART 93 [ADDED]

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.

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 PHS 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) The U.S. Department of Health and Human Services (HHS) and institutions, including individual researchers who 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 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 have primary responsibility for reporting and responding to allegations of research misconduct.

(b) Under this regulation and Section 493 of the PHS Act, 42 U.S.C. 289b, each institution that applies for or receives PHS support for any biomedical or behavioral research or research training activity must comply with this part in responding to allegations of research misconduct occurring at or involving research or research training projects or staff of the institution.

(c) 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 the public fisc.

(d) Institutions that apply for or receive PHS support and persons who work on PHS supported biomedical or behavioral research, biomedical or behavioral research training or activities related to that research or research training have an affirmative duty to protect those funds from misuse by ensuring the integrity of any research or research training activities related to the PHS support and by responding to 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 in connection with PHS supported research;

(2) Providing ORI 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 the public fisc.

§ 93.102 Applicability.

(a) This part applies to allegations of research misconduct and research misconduct involving PHS supported biomedical or behavioral extramural and intramural research, biomedical or behavioral research training programs, or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether the user or reviewer receives PHS support or whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.

(b) 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.

(c) 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 before 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 use or republication of the fabricated, falsified, or plagiarized research record.

(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 had the allegation of research misconduct under review or investigation on the effective date of this regulation.

§ 93.106 Evidentiary standards.

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

(a) *Burden of proof.* (1) The institution or HHS has the burden of proof for making a finding of research misconduct. The absence of, or respondent's failure to provide, research records adequately documenting the questioned research establishes a rebuttable presumption of research misconduct that may be relied upon by the institution or HHS in proving research misconduct. Credible evidence corroborating the research or providing a reasonable explanation for the absence of, or respondent's failure to provide, the research records may be used by the respondent to rebut this presumption.

(2) 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 any honest error or differences of opinion and of proving any mitigating factors that the respondent wants the institution or HHS to consider in imposing administrative actions following research misconduct proceedings.

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

§ 93.107 Rule of interpretation.

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

§ 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, under section 93.517(g), PHS 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, the agencies may coordinate responses to the allegation.

(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 research or research training, and to conserve the public fisc; 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 PHS deciding official's 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 deciding and debarring officials.

§ 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 Governmentwide 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 Deciding official.

Deciding official means an official authorized to make PHS findings of research misconduct and to impose HHS administrative actions. The deciding official is either—

(a) The Secretary; or

(b) An official designated by the Secretary.

§ 93.208 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.

§ 93.209 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.

§ 93.210 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 or research training, *e.g.*, agencies, bureaus, centers, institutes, divisions, or offices and other awarding units within the PHS.

§ 93.211 Good faith.

Good faith 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.

§ 93.212 Hearing.

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

§ 93.213 Inquiry.

Inquiry means preliminary information-gathering and preliminary fact-finding to determine whether an allegation or apparent instance of research misconduct has substance and if an investigation is warranted.

§ 93.214 Institution.

Institution means any individual or entity 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.

§ 93.215 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, teaching and support staff, researchers, clinical technicians, fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

§ 93.216 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 or other appropriate remedies, including administrative actions.

§ 93.217 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 have special notice requirements.

§ 93.218 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 activities.

§ 93.219 Person.

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

§ 93.220 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.

§ 93.221 Prima facie showing.

Prima facie showing means evidence that on its face is sufficient to establish research misconduct in the absence of respondent's presentation of substantial contradictory evidence.

§ 93.222 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.

§ 93.223 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; grants, cooperative agreements, or contracts; or subgrants, subcontracts, or other payments under grants, cooperative agreements, or contracts.

§ 93.224 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.

§ 93.225 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.

§ 93.226 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 response to questions about the research at issue.

§ 93.227 Respondent.

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

§ 93.228 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.

§ 93.229 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 conducting and reporting inquiries and investigations of alleged research misconduct in compliance with this part;

(b) Respond to each allegation of research misconduct at the institution involving PHS supported research in compliance with this part;

(c) Foster a research environment that promotes the responsible conduct of research and 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, biomedical or behavioral research training or activities related to that research or 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, and related activities 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 and to other authorized HHS personnel;

(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 related activities, 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 other aggregated information on research misconduct proceedings and compliance with the requirements of this part that ORI may request.

§ 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.

(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;

(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 either within 30 days of the decision or before the date the investigation begins, whichever happens first;

(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 and material 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 efforts 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;

(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 are discovered during the course of a research misconduct proceeding; and

(d) Maintain the research records and evidence until ORI requests them, HHS takes final action, or as required by § 93.317, as applicable.

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

(a) If an institution is too small, is otherwise unable to respond to allegations of research misconduct because of real or apparent conflicts of interest, lacks the capacity, or otherwise prefers not to conduct its own research misconduct proceeding, it may use the services of a consortium or other entity 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 entity 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) Involves PHS supported research; and

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

(b) *Notice.* 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.

(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 involves PHS supported research and falls within the PHS definition of research misconduct; 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 § 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 or refer to a copy of 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 any 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, complainant, or a witness.

(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 section 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 § 93.309.

(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.* Take custody of and sequester any relevant research records and evidence needed to conduct the investigation not taken into custody at the allegation or inquiry stage. 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 may have substantive information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and maintain detailed records. 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, 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, giving the draft report to the respondent for comment, 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) 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 for review and comment within 30 days of the respondent's receipt of the draft report; and

(b) The institution may provide relevant portions of the report to complainants for comment within 30 days of their receipt of the relevant portions of the report.

§ 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, 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 appeal by the respondent, the institution must complete any appeals within 120 days of filing the appeal.

(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. If an institution plans to end an inquiry or investigation before completion for any reason, including an admission of misconduct by the respondent, it must contact ORI before closing the case and submitting its final report.

(b) After review of an institution's decision to end an inquiry or investigation before completion, ORI may direct the institution to complete its process or refer the matter for further investigation by HHS.

Other Institutional Responsibilities

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

(a) *Maintenance of record.* Institutions must maintain records of research misconduct proceedings in a secure manner for 7 years after their completion or the completion of any PHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later.

(b) *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 PHS 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 section 93.225, 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 PHS 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 PHS or HHS 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; and

(7) Making recommendations to the HHS deciding or debarring officials.

(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 HHS administrative actions against any person to the HHS deciding official and 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 Communications with other offices and interim actions.

(a) ORI may notify and consult with other Federal agencies at any time if it has a reason to believe that a research misconduct proceeding may involve that agency. If ORI believes that a criminal or civil fraud violation may have occurred, it shall promptly refer the matter to the Department of Justice, the HHS Inspector General, or other appropriate investigative body.

(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 the public fisc.

(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 research, 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 may close the case.

(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 PHS 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 manner with sufficient objectivity, thoroughness, 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) Recommend appropriate research misconduct findings and administrative actions; and

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

§ 93.404 HHS findings on research misconduct proceedings.

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

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

(b) Accept a proposed settlement.

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

(a) When the PHS makes a finding of research misconduct or seeks to impose or enforce HHS administrative actions, it notifies the respondent in a charge letter. This letter includes the PHS 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 PHS 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.

(c) In cases involving a debarment or suspension action, the HHS debarring official notifies the respondent. At the discretion of the debarring official, this notice may be combined with the charge letter in paragraph (a) of this section.

§ 93.406 Final HHS actions.

Unless the respondent seeks to contest the charge letter under subpart E of this part, the deciding official's decision is HHS' final action on the PHS research misconduct issues and the HHS administrative actions, 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 funds spent on PHS supported biomedical or behavioral research, research training or related activities.

(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 the public fisc. PHS considers aggravating and mitigating factors in determining appropriate HHS administrative actions and their terms. PHS 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 PHS 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 PHS 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 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 PHS Findings of Research Misconduct and HHS Administrative Actions

General Information

§ 93.500 General policy.

(a) This subpart provides a respondent an opportunity to contest PHS findings of research misconduct and HHS administrative actions 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 PHS research misconduct findings and HHS administrative actions made under this part by requesting an administrative hearing before an Administrative Law Judge (ALJ) affiliated with the HHS DAB, when the PHS has—

(1) Made a finding of research misconduct against a respondent; or

(2) Proposed HHS administrative actions other than debarment or suspension against a respondent.

(c) A respondent has an opportunity to contest a debarment or suspension action related to this part under the HHS debarment and suspension regulations. However, nothing in this subpart modifies, alters, or changes any rights provided under the HHS debarment and suspension regulations at 45 CFR Part 76, subpart C and 48 CFR Parts 9.4 and 309.4.

(d) The ALJ's ruling on the merits of the PHS research misconduct findings and the HHS administrative actions constitutes a recommended decision to the Assistant Secretary for Health. The Assistant Secretary for Health may modify, affirm, or reject the ALJ's ruling in whole or in part. The Assistant Secretary for Health's decision is final and becomes binding on the date the final decision is issued.

(e) The decision of the ALJ constitutes a recommendation to the HHS debarring official in a debarment or suspension action. The debarring official may reject any resultant findings in whole or in part, only after specifically determining them to be arbitrary, capricious, or clearly erroneous.

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

(a) *Opportunity to contest.* A respondent may contest PHS findings of research misconduct and any HHS administrative actions, including any debarment or suspension action related to this part, 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 served on ORI.

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

(1) Admit or deny each PHS finding of research misconduct and each factual assertion made by PHS 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) For good cause shown, the ALJ may grant an additional period of no more than 60 days from the respondent's receipt of the charge letter or other written notice provided under § 93.405 to permit the respondent to supplement the hearing request to comply fully with the requirements of subsection (c).

(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 to conduct the hearing.

(b) The ALJ may retain one or more persons with appropriate scientific or technical expertise to assist the ALJ in evaluating scientific issues related to the PHS findings of research misconduct. At the request of either party, the ALJ must retain such an expert.

(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 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 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 hearing officer 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 PHS findings of research misconduct or HHS administrative actions, including any debarment or suspension action, if the debarring official has referred the matter to the hearing officer. The respondent's general denial or assertion of error for each PHS finding of research misconduct, and any basis for the finding, or for any HHS administrative actions in the charge letter, is not sufficient to establish a genuine dispute.

(b) The hearing request must specifically deny each PHS 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, the PHS finding(s) and any HHS administrative action(s), including any debarment or suspension actions, become final agency actions at the expiration of the 30-day period.

(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 PHS findings of research misconduct and any HHS 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 hearing officer;

(6) Present evidence relevant and material 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 hearing officer 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 laws and regulations. In conducting the proceeding, the ALJ must comply with all Secretarial delegations of authority and applicable HHS policies. 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 hearing officer 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; or

(3) Enjoin any act of the Secretary.

§ 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 PHS 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 hearing officer, the ALJ may take corrective action, including but not limited to, ordering the non-compliant 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 PHS 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) Taking a negative inference from the absence of research records, documents, or other information.

§ 93.516 Standard and burden of proof.

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

(b) Subject to the rebuttable presumption described in section 93.106(b)(1), ORI bears the burden of proving the PHS findings of research misconduct and the need for any HHS administrative actions, including any debarment or suspension actions.

(c) Once ORI makes a *prima facie* showing of research misconduct, the respondent bears the burden of proving any affirmative defenses raised, including honest error or differences of opinion, and of proving any mitigating factors that the respondent wants the ALJ to consider with respect to the HHS administrative actions.

§ 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 PHS findings of research misconduct and HHS administrative actions. The ALJ does not review the procedures or findings of the institution's 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 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 hearing officer 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 the Assistant Secretary for Health's decision becomes final, 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 final 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. The ALJ shall serve a copy of the final ruling upon all parties, the Assistant Secretary for Health and the HHS Debarring Official if debarment or suspension is under review.

(b) If unable to meet the 60-day deadline, the ALJ must set a new deadline and promptly notify all parties, the Assistant Secretary for Health, and the HHS Debarring Official if debarment or suspension is under review.

(c) The final ruling of the ALJ constitutes a recommended decision to the Assistant Secretary for Health, as set forth in section 93.500(d). The final ruling of the ALJ shall constitute proposed findings of fact to the HHS Debarring Official in accordance with section 93.500(e) and 45 CFR part 76.

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