Forsyth Street, SW, Atlanta, Georgia 30303–8960, Phone number: (404) 562–8190, Kathy Piselli, Librarian; or The Georgia Department of Natural Resources Environmental Protection Division, 205 Butler Street, Suite 1154, East, Atlanta Georgia 30334-4910, Phone number: 404–656–7802.

FOR FURTHER INFORMATION CONTACT: Narindar Kumar, Chief, RCRA Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303–8960; (404) 562–8440.

SUPPLEMENTARY INFORMATION: For additional information, please see the immediate final rule published in the ''Rules and Regulations'' section of this **Federal Register**.

Dated: October 20, 2000.

A. Stanley Meiburg,

Regional Administrator, Region 4.

[FR Doc. 00–30007 Filed 11–27–00; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 94

RIN 0905–AE71

Public Health Service Standards for the Protection of Research Misconduct Whistleblowers

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department proposes to add a new Subchapter I, Part 94, to Title 42 of the Code of Federal Regulations to implement section 493(e) of the Public Health Service Act. Under this proposed regulation, covered institutions must follow certain requirements for preventing or otherwise responding to occurrences of retaliation against whistleblowers. The purpose of this part is to protect persons who make a good faith allegation that a covered institution or one of its members engaged in or failed to respond adequately to an allegation of research misconduct and persons who cooperate in good faith with an investigation of research misconduct.

DATES: Submit comments on or before January 29, 2001.

ADDRESSES: Address all comments concerning this proposed rule to Chris B. Pascal, J.D., Acting Director, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD, 20852.

You may submit comments and data by sending electronic mail (E-mail) to *whistlereg@osophs.dhhs.gov.*

Submit comments as either a WordPerfect file, version 5.1 or higher, or a Microsoft Word 97 or 2000 file format. Comments can also be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

FOR FURTHER INFORMATION, CONTACT:

Legal Information: Gail L. Gibbons, 301–443–3466 (This is not a toll-free number).

Technical Information: Barbara Bullman, 301–443–5300 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 493(e) of the PHS Act requires the Secretary to establish regulatory standards for preventing and responding to occurrences of retaliation taken against whistleblowers by entities which have a research misconduct assurance under § 493 and by those entities' officials and agents. These entities and their officials and agents are prohibited from retaliating against an employee with respect to the terms and conditions of employment when the employee has in good faith (1) made an allegation that the entity or its officials or agents, has engaged in, or failed to respond adequately to an allegation of, research misconduct, or (2) cooperated with an investigation of such an allegation.

The Commission on Research Integrity (established by section 162 of the NIH Revitalization Act of 1993) recommended that the standards stated in its document, ''Responsible Whistleblowing: A Whistleblower's Bill of Rights'' (Commission Report, Department, 1995), be adopted by regulation. Two of the seven principles in the Whistleblower's Bill of Rights relate directly to the prevention of and response to whistleblower retaliation. These two are: protection from retaliation (''Institutions have a duty not to tolerate or engage in retaliation against good faith whistleblowers.''), and fundamentally fair procedures (''In cases of alleged retaliation * * * whistleblowers should have an opportunity to defend themselves in a proceeding where they can present witnesses and confront those they charge with retaliation against them. * * *''). The substance of those two provisions has been incorporated in this proposed regulation. You may obtain the full text of the Commission's proposed Whistleblower's Bill of Rights upon request at the Office of Research Integrity address above, or on the ORI web page at *http://ori.dhhs.gov/whistle.htm.*

The proposed regulation represents a considered effort by the Department to implement the statutory directive on whistleblower protections in accordance with equitable principles, reason, and sound policy. The Department strongly supports good faith whistleblowers who place themselves at potential risk in disclosing apparent or actual research misconduct involving projects supported by PHS funds. The Department also recognizes that institutions bear a substantial burden in ensuring the fair resolution of good faith allegations that may ultimately prove to be unwarranted. The proposed regulation tries to strike a fair balance among those persons and entities with an interest in the regulation.

This proposed regulation does not apply to Federal agencies. Federal employees are offered separate whistleblower protections under the Federal Whistleblower Protection Act of 1989, 5 U.S.C. 1201, *et seq.*

When an institution receives a retaliation complaint, the proposed regulation allows the whistleblower and the institution up to 30 days to negotiate a settlement. The whistleblower and the institution may agree to extend this period for up to an additional 60 days. During the negotiation period, the parties may agree to use any means of settlement that is legal and consistent with this regulation, including alternative dispute resolution mechanisms such as mediation. However, no settlement under the proposed regulation may prohibit the whistleblower from making allegations of research misconduct or cooperating with an investigation.

If the dispute is not resolved by the end of the negotiation period, the institution must make an administrative proceeding available to the whistleblower to address the retaliation complaint. The proceeding offered by the institution must meet all of the standards in the proposed regulation. A whistleblower may agree to have a retaliation complaint resolved through this proceeding or may elect to pursue any other available remedy provided by law.

Although certain settlement mechanisms such as mediation may be used during the negotiation period, they might not qualify as an acceptable administrative proceeding after the negotiation period has terminated because they do not meet the regulation's requirements. For example, mediation does not constitute an acceptable administrative proceeding because it does not use an ''objective

decisionmaker'' who will make a final determination on whether retaliation occurred, as required by the regulation.

The proposed regulation gives institutions wide latitude in the types of administrative proceedings they may choose to offer. However, the proceeding must meet certain minimum standards such as allowing the whistleblower an opportunity to be represented by counsel and having a qualified, objective decisionmaker. Although the terms ''qualified'' and ''objective'' are not defined in the proposed regulation, the decisionmaker should have significant training, experience, or expertise in adjudicating disputes. Moreover, the decisionmaker must not have any real or apparent conflict of interest in hearing or deciding the case.

One type of administrative proceeding that institutions may make available is binding arbitration. Arbitration is specifically encouraged in the Conference Report recommendations accompanying the NIH Revitalization Act. The Conferees suggested that the regulation should, ''where the whistleblower consents, allow for the possible adjudication of disputes through an arbitration proceeding conducted under the auspices of the American Arbitration Association.'' H.R. Conf. Rep. No. 100, 103d Cong., 1st Sess. 19, 107 (1993).

Another type of administrative proceeding that may be used for resolving retaliation disputes is an institutional fact-finding procedure similar to an option allowed under the ORI ''Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research'' (November 20, 1995) (Whistleblower Guidelines) which will be superseded when this part is issued as a final rule. You may obtain a copy of these interim Whistleblower Guidelines by contacting ORI at the above address, or on the ORI web page at *http://ori.dhhs.gov/whistle.htm.* Unlike the administrative proceedings in the interim Whistleblower Guidelines, an institutional fact-finding procedure under the proposed regulation must satisfy the minimum standards specifically in this part.

Other possible administrative proceedings that an institution may use for resolving a retaliation complaint under this part include an academic or institutional employment hearing, a state statutory whistleblower proceeding, or any other administrative proceeding that resolves the complaint. A proceeding satisfies the requirements of this part only if it meets the minimum standards outlined in the proposed regulation. Some states may have whistleblower statutes that provide recourse for a whistleblower but that may not include every requirement of this part. Therefore, the Department requests comments on whether an institution should be permitted to offer a proceeding, whether administrative or judicial, under a state whistleblower law if the law generally parallels the minimum standards of this part but differs in some details.

Regardless of the type of administrative proceeding used, the decisionmaker's final decision must be based on the standards of proof set forth in the regulation. The decisionmaker must order an institutional remedy if the whistleblower proves by a preponderance of the evidence that the act of good faith whistleblowing was a contributing factor in the alleged adverse action taken by the institution or one of its members against the whistleblower. However, even if the whistleblower meets this burden, the decisionmaker may not order an institutional remedy if the institution then proves by clear and convincing evidence that it would have taken the action at issue even in the absence of the whistleblower's allegation or cooperation with an investigation. The legislative history of the PHS Act § 493(e) shows that the Conferees encouraged adoption of this specific standard. Also, the proposed regulatory standard is the same as that used in the Federal Whistleblower Protection Act of 1989, 5 U.S.C. 1201, *et seq.*

If the decisionmaker determines that the institution or one of its members has retaliated against the whistleblower, the proposed regulation allows the decisionmaker to authorize appropriate remedies. For example, the decisionmaker could order reinstatement, back pay, rehabilitation of reputation, or compensation to the whistleblower for expenses, including attorneys' fees, incurred in the administrative proceeding.

The proposed regulation allows both the institution and whistleblower to appeal an adverse finding or remedy by the decisionmaker only if the administrative proceeding used allows for an appeal or an appeal is otherwise provided by state law. The Department has chosen this approach consistent with the current misconduct regulation, 42 CFR part 50, subpart A, and the Office of Science and Technology Policy's (OSTP) proposed government-wide Federal policy for research misconduct, 64 FR 55722, 55724, Oct. 14, 1999, which do not require offering an opportunity to appeal at the institution to a respondent found to have committed misconduct. This is also consistent with the general approach of this regulation to allow flexibility and to mandate only limited requirements for the institutional administrative proceeding. The Department requests comments on whether the availability of an appeal should be required.

Covered institutions would also be required to establish procedures for preventing retaliation against good faith whistleblowers. For example, under the proposed regulation, an institution's preventive activities must include informing all institutional members of the institution's whistleblower procedures and the importance of compliance. These whistleblower procedures must describe the measures that the institution intends to use to prevent retaliation against good faith whistleblowers. Although not specified in the proposed regulation, these measures may include, for example, cautioning respondents or other institutional members against retaliation, relocating the whistleblower when appropriate, and providing educational materials or group instruction on the topic of whistleblower retaliation. We invite suggestions for other steps institutions may take to prevent retaliation against good faith whistleblowers.

Section 493(e)(2) of the PHS Act requires the Director of ORI to monitor covered institutions' implementation of the proposed regulatory standards. Moreover, § 493(e)(3) requires ORI to establish remedies for noncompliance with this whistleblower retaliation regulation. Therefore, the proposed regulation authorizes ORI to review any covered institution's compliance with the regulation and to impose appropriate administrative actions for retaliation or other regulatory noncompliance. Administrative actions against noncompliant institutions may include, but are not limited to, termination or recovery of PHS funds.

Several of the definitions require brief explanations. The proposed regulation adopts the term ''research misconduct'' instead of ''misconduct in science'' as currently used in PHS' scientific misconduct regulation at 42 CFR 50.102 (1989). Section 493(a)(3)(A) of the PHS Act instructs the Secretary to establish a definition for the new term ''research misconduct.'' As discussed earlier, the OSTP has published a proposed government-wide Federal policy for research misconduct for adoption and implementation by agencies that conduct and support research. This policy includes a new proposed definition of research misconduct. 64

FR 55722, Oct.14, 1999. When the OSTP policy is adopted in final form, the Department will implement the policy, including the new definition of ''research misconduct,'' through rulemaking. In the meantime, the term ''research misconduct'' in this proposed regulation will be defined in the same manner as ''misconduct in science,'' as used in the existing PHS misconduct regulation.

The proposed regulation uses the term ''whistleblower'' despite negative connotations that might be associated with it. The common understanding of the term's meaning strongly supports its continued usage, in keeping with the authorizing statute, PHS Act § 493(e), and consistent with other statutes such as the Whistleblower Protection Act of 1989, 5 U.S.C. 1201, *et seq.* The Department strongly disavows any negative inference that might be drawn from the term ''whistleblower.''

The proposed regulation does not confine the use of the term ''whistleblower'' to those who raise an initial allegation of research misconduct. Rather, it defines a whistleblower as any institutional member, including a non-employee, who makes an allegation that a covered institution or one of its members has engaged in, or failed to respond adequately to an allegation of, research misconduct, or who cooperates with an investigation of the allegation. Although the PHS Act § 493(e) specifically protects an ''employee'' with respect to the terms and conditions of employment, the Department is proposing that the regulation cover all institutional members, i.e., all persons who are employed by, affiliated with under a contract or agreement, or under the control of, a covered institution, including students, fellows, and contractors.

The Department may extend its jurisdiction to protect non-employee whistleblowers based upon its general rulemaking authority as well as its authority to establish the terms and conditions of PHS support. Potential whistleblowers include more than just employees of the covered institution. Students and research fellows at an academic institution, for example, may be in a position to allege research misconduct or cooperate with a misconduct investigation. The proposed regulation's more inclusive definition of whistleblower is consistent with the Department's interpretation of the current scientific misconduct regulation which is not limited to employees of the institution but requires protecting ''those persons who, in good faith, make allegations,'' 42 CFR 50.103(d)(13).

Consistent with the proposed definition of whistleblower, the proposed regulation's definition of ''retaliation'' focuses on adverse actions that negatively affect the terms or conditions of the whistleblower's status at the institution, including employment, academic matriculation, and institutional relationship under a grant, contract, or cooperative agreement.

An ''adverse action'' by an institution or one of its members may also include the *threat* of an adverse action if the threat in and of itself negatively affects the conditions of the whistleblower's institutional status. Whether a threat constitutes an ''adverse action'' under the proposed rule must be determined on a case-by-case basis. However, the Department believes that only objectively credible and imminent threats that substantially and negatively inhibit the whistleblower's normal institutional activities would constitute adverse actions.

The proposed regulation requires each covered institution to submit an assurance that the institution is in compliance with this regulation. This requirement will be incorporated in PHS grant application (PHS Form 398) or any other application for PHS contracts or cooperative agreements. PHS Form 398 and all other pertinent application forms already include a certification of compliance with this part which will be changed to an assurance at the next revision.

The proposed regulation applies only to whistleblower retaliation complaints that are made within 180 days of the alleged adverse action, or its discovery. This time limitation for filing retaliation complaints is consistent with other statutory and regulatory programs that establish a date certain after which complaints may not be filed, and encourages whistleblowers to come forward with a complaint promptly. This improves the opportunity for a rapid resolution of the dispute. *See, e.g.,* 29 U.S.C. 1855(b) (Migrant and Seasonal Agricultural Worker Protection; Discrimination prohibited); 10 CFR 50.7(b) (Nuclear Regulatory Commission; Employee Protection). The 180-day limitation period is also consistent with ORI's interim Whistleblower Guidelines, § IV.C.1.

In addition to cases of whistleblower retaliation that occur after this regulation's promulgation, the Department also proposes that the regulation cover pending cases of retaliation, if the retaliation complaint and the underlying whistleblower activity took place within one year before the effective date of the regulation. The Department has required covered institutions to protect whistleblowers since at least 1989 pursuant to 42 CFR 50.103(d)(13). The proposed regulation merely prescribes new procedural, as opposed to substantive, requirements for implementing an already established duty. Thus, extending the applicability of the proposed regulation to previously filed, pending whistleblower complaints does not violate the principle of impermissible retroactivity. *See Landgraf* v. *USI Film Products,* 511 U.S. 244 (1994); *U.S.* v. *Riddick,* 104 F.3d 1239 (10th Cir. 1997).

Analyses of Impacts

A. Review under Executive Order 12866, sections 202 and 205 of the Unfunded Mandate Reform Act of 1995 (Pub. L. No. 104–4), and the Regulatory Flexibility Act (5 U.S.C. 603–605).

The Department has examined the potential impact of this proposed rule as directed by Executive Order 12866, sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104–4), and the Regulatory Flexibility Act (5 U.S.C. 603–605).

Executive Order 12866 directs agencies to assess the costs and benefits of available regulatory alternatives, and when regulation is necessary, to select regulatory approaches that maximize net benefits. This proposed rule is designed to establish regulatory standards for institutions that apply for or receive grants, contracts, or cooperative agreements under the PHS Act. (The proposal has been reviewed by the Office of Management and Budget (OMB) under the terms of the Executive Order.)

The Unfunded Mandates Reform Act of l995, in sections 202 and 205, requires 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. As any final rule resulting from this proposal would not result in expenditures of this magnitude, such statements are not necessary.

The Regulatory Flexibility Act 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 preventing and responding to whistleblower retaliation in research misconduct cases.

Currently, ORI receives about 125 allegations of research misconduct a year from the 3700 entities which file assurances with ORI. Of these, only five of the allegations were received from the approximately 1000 entities which are considered small. Therefore, the Secretary 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.

B. Impact of Proposed Actions on Family Well-Being

The Department has examined the potential impact of this proposed rule as directed by section 654 of the Treasury and General Government Appropriations Act of 1999 and determined that this proposed rule would not have an impact on Family Well-Being.

C. Estimated Annual Reporting and Record Keeping Burden

Subchapter I, sections 94.215, 94.310, 94.315, 94.320, 94.340, 94.345(b), 94.380, and 94.425 of the proposed rule contain information collection requirements that are subject to review by the OMB under the Paperwork Reduction Act of l995. 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 Standards for the Protection of Research Misconduct Whistleblowers.

Description: This proposed rule implements section 493(e) of the PHS Act (added by section 163 of the NIH Revitalization Act of 1993, Pub. L. No. 103–43). Section 493(e)(1) requires the Secretary to establish standards for preventing and responding to occurrences of whistleblower retaliation by entities, their officials or agents, against an employee in the terms and conditions of employment in response to the employee having made a good faith allegation or cooperated with an investigation of such an allegation. In addition, sections 493(e) (2) and (3) of the PHS Act require that remedies be established for regulatory noncompliance by entities, their officials or agents, and that procedures be established for monitoring implementation of the standards established by the entities.

Description of Respondents: The ''respondents'' for the collection of information described in this regulation are (1) institutions that apply for or receive grants, contracts, or cooperative agreements under the PHS Act for any project or program that involves the conduct of biomedical or behavioral research, and (2) whistleblowers who seek protection from or restitution for retaliation in accordance with the regulation.

Section 94.200

See Section 94.215 for burden statement.

Section 94.205

See Section 94.215 for burden statement.

Section 94.210

See Section 94.215 for burden statement.

Section 94.215(a), (b), and (c)

Number of Respondents—20.

Number of Responses per Respondent—1.

To institute an action for whistleblower protection, a whistleblower must file a retaliation complaint with the responsible official of the covered institution. The retaliation complaint must include (1) a statement containing the required elements listed in this section, and (2) any supporting dates and facts. We estimate that there will be approximately 20 complaints filed by whistleblowers annually. This estimate is based on data that we have compiled from the Annual Report on Possible Research Misconduct (PHS–6349) form submitted by the covered institutions and from the number of actual cases received by ORI.

Annual Average Burden per Response—8 hours

Total Annual Burden—160 hours

Section 305(a) and (b)

See Section 94.320 for statement of burden.

Section 94.310

Number of Respondents—244.

Number of Responses per Respondent—1

Each covered institution that uses subawardees or subcontractors to carry out its PHS funded research must ensure that the subawardees and subcontractors comply with the institution's policies and procedures under this part or obtain assurances from them that will enable the institution to comply with this part.

There are 3700 entities that are currently applying for or receiving PHS research funds, and each of these entities could potentially use a subawardee or subcontractor. We estimate from reviewing the available information that 25% of the covered institutions use a subawardee or subcontractor. In turn, we estimate that only 25% of the subawardees and subcontractors will establish their own policies and procedures for addressing whistleblower retaliation allegations. The other 75% will use the covered institution's compliance procedures.

Annual Average Burden per Response—8 hours.

Total Annual Burden—1848 hours.

Section 94.315

See Section 94.320 for statement of burden.

Section 94.320

Number of Respondents—3700.

Number of Responses per Respondent—1.

Each covered institution that applies for or receives a grant, contract, or cooperative agreement under the PHS Act for any project or program that involves the conduct of biomedical or behavioral research is required to establish written procedures that include (1) specific strategies to prevent whistleblower retaliation by the institution or one of its members, and (2) appropriate administrative actions for verified cases of retaliation.

There are 3700 entities that currently receive or are eligible to receive grants, contracts, or cooperative agreements that would be required to meet this single-time requirement to establish and maintain current policies and procedures designed to prevent whistleblower retaliation and provide a mechanism to respond to a retaliation complaint involving PHS funding or applications therefor.

Annual Average Burden per Response—40 hours.

Total Annual Burden—148,000 hours.

We estimate that it will take between 10–80 hours to establish these

procedures with an average of 40 hours per covered institution. This burden estimate applies only to the first year when all the covered institutions will be required to establish procedures. In subsequent years, the burden will only be for new recipients or applicants of PHS funding or to update a covered entity's procedures.

Section 94.325(a) and (b)

See Section 94.320 for statement of burden.

Section 94.340

Number of Respondents—20.

Number of Responses per Respondent—1.

After receipt of a retaliation complaint, a covered institution is required by this part to provide the whistleblower with a copy of this regulation, 42 CFR Part 94, and the institution's policies and procedures for responding to retaliation complaints. The institution must also provide the whistleblower with written notification of (1) the date the complaint was received by the institution, (2) the date the negotiation period will expire, and (3) the institution's determination regarding the issue of jurisdiction as discussed in § 94.215(b). The institution is also required to process the complaint in accordance with this part.

Annual Average Burden per response—2 hours

Total Burden—40 hours.

Section 94.345(b)

Number of Respondents—1.

Number of Responses per Respondent—1.

The responsible official of the covered institution is required to notify the whistleblower in writing of any decision to provide temporary protection before the final resolution of a retaliation complaint.

This estimate is based on the number of retaliation cases that have been reported to ORI.

Annual Average Burden per response—2 hours.

Total Annual Burden—2 hours.

Section 94.380

Number of Respondents—20.

Number of Responses per Respondent—1.

Covered institutions are required by this part to report to ORI any of the following (1) the receipt of any whistleblower retaliation complaint, (2) the date received, (3) the date the negotiation period under Section 94.365 expires, (4) any temporary protections requested or provided to the whistleblower, (5) the administrative proceedings used or made available to the whistleblower, and how the institution met the standards of Section 94.420, and (6) the final disposition of the complaint, including any settlement.

This reporting estimate is an approximation of the average time expected to be necessary for collection of this information by the covered institution. The estimate is based on past experiences of respondents reporting similar information to ORI.

Annual Average Burden Per Response—2 hours.

Total Annual Burden—40 hours.

Section 94.425

Number of Respondents—20.

Number of Responses per Respondent—1.

At the time a covered institution proposes an administrative proceeding, it must inform the whistleblower of the requirements, rights, procedures, and possible consequences associated with the proceeding.

Annual Average Burden Per Response—1 hour.

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 the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th Street, N.W., Rm 10235, Washington, D.C. 20503, Attn: Allison Eydt. Submit written comments by January 29, 2001.

List of Subjects in 42 CFR Part 94

Administrative practice and procedure, Grant programs-science and technology, Reporting and recordkeeping requirements, Research, Science and technology, Whistleblowing.

Dated: July 17, 2000.

David Satcher,

Assistant Secretary for Health and Surgeon General.

Approved: July 25, 2000.

Donna E. Shalala,

Secretary.

For reasons set out in the preamble, the Public Health Service proposes to add a new subchapter I, part 94, to title 42 of the Code of Federal Regulations as follows:

Subchapter I—Policies Relating to Research Misconduct

PART 94—PUBLIC HEALTH SERVICE STANDARDS FOR THE PROTECTION OF RESEARCH MISCONDUCT WHISTLEBLOWERS

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

Subpart A—General

§ 94.100 What is the purpose of this part?

(a) This part describes the standards used by the Office of Research Integrity (ORI) and covered institutions for preventing and responding to retaliation against whistleblowers who in good faith—

(1) Allege that a covered institution or institutional member has engaged in, or failed to respond adequately to, an allegation of research misconduct.

(2) Cooperate with an investigation of the allegation in paragraph (a)(1) of this section.

(b) These standards apply where the allegation or cooperation regarding an investigation concerns research involving Public Health Service (PHS) grants, contracts, or cooperative agreements, or applications therefor.

§ 94.105 What is covered in this part?

This part explains—

(a) The rights and responsibilities of whistleblowers who seek protection from or remedies for retaliation under this regulation and who comply with the requirements of this part.

(b) Standards for covered institutions and their members for preventing or otherwise responding to retaliation against whistleblowers.

(c) Procedures for ORI to determine whether covered institutions have established the required standards and that those standards are being followed.

(d) Remedial actions that ORI may administer when a covered institution engages in an act of retaliation or otherwise does not comply with this regulation.

§ 94.110 Does this part apply to me?

(a) Portions of this part may apply to you if you are a—

(1) Covered institution;

(2) Decisionmaker of a covered institution;

(3) Institutional member of a covered institution;

(4) ORI;

(5) Responsible official of a covered institution;

(6) Subawardee or subcontractor of a covered institution; or

(7) Whistleblower.

(b) The following table shows the portions of this part that may apply to you:

If you are a—	then the portions that may apply to you are—
(1) Covered institution or subawardee or subcontractor of a covered institution.	Subparts A, C, D, E, and F.
(2) Decisionmaker	Subparts A, D, and F and §§ 94.420 and 94.435–94.450.
(3) Institutional member.	Subparts A, C, and F and §§ 94.410 and 94.445.
(4) ORI	Subparts A, E, and F.
(5) Responsible official.	Subparts A, C, and F and §§ 94.205, 94.210, 94.225, 94.430, 94.505, and 94.520.
(6) Whistleblower	Subparts A, B, D, and F, and §§ 94.360–94.375, and 94.505.

§ 94.115 What provisions of confidentiality apply to this part?

(a) The provisions in this part for filing whistleblower retaliation complaints must not be construed to encourage or allow whistleblowers or covered institutions and their members to disclose publicly information regarding research misconduct cases other than to the person(s) designated in this part, or as otherwise provided by law.

(b) A covered institution may take appropriate administrative actions that are consistent with this part in response to breaches of confidentiality.

Subpart B—Whistleblower Retaliation Complaints

§ 94.200 When must you file your retaliation complaint?

(a) You, as a whistleblower, must file your retaliation complaint within 180 calendar days of the alleged adverse action or your discovery of the alleged adverse action.

(b) The alleged adverse action must have occurred within one calendar year after you made your allegation or cooperated with an investigation of the allegation.

(c) However, if your retaliation complaint was pending on the effective date of this part, ORI will consider your complaint to have been timely filed if—

(1) You have filed it within one calendar year before the effective date of this part;

(2) Your allegation or cooperation with an investigation of the allegation also occurred within that year; and

(3) You refile your pending complaint, using the procedures in this subpart for filing complaints, within 120 calendar days of the date on which the covered institution provides the § 94.325 written information to its members about its whistleblower policies and procedures.

§ 94.205 Where do you file a retaliation complaint?

(a) You must file your whistleblower retaliation complaint with the responsible official at the covered institution where the alleged adverse action occurred.

(b) If the responsible official does not acknowledge receipt of your complaint within 10 business days of receiving it, you may file the complaint with ORI. ORI will review the complaint and decide whether to refer it to the covered institution.

§ 94.210 Must your retaliation complaint be in writing?

Yes, your whistleblower retaliation complaint must be made in writing to the responsible official at the covered institution or to ORI.

§ 94.215 What information must you provide in your retaliation complaint?

To establish jurisdiction under this part, you must include in your whistleblower retaliation complaint a statement containing all the following information, including supporting dates and facts:

(a) That you made an allegation that the covered institution or one of its members committed research misconduct or failed to respond adequately to an allegation of research misconduct, or that you cooperated with an investigation of such an allegation that concerns research involving PHS grants, contracts, cooperative agreements, or applications therefor.

(b) That the covered institution or one of its members committed an adverse action against you within one year after you made your allegation or cooperated with an investigation.

(c) That the adverse action resulted from your allegation or cooperation.

(d) That you are making the complaint within 180 calendar days of the alleged adverse action or your discovery of the adverse action.

§ 94.220 May you revise your retaliation complaint?

Yes, if your whistleblower retaliation complaint does not contain all the information required by § 94.215, you may revise it to supply that information at any time before the complaint is fully resolved, dismissed, or otherwise closed under this part.

§ 94.225 May you ask the covered institution to take temporary actions to protect you?

Yes, you may ask the responsible official to take temporary actions under §§ 94.345 through 94.355 to protect you against an existing or threatened adverse action by the covered institution or one of its members at any time before your whistleblower retaliation complaint is fully resolved, dismissed, or otherwise closed under this part.

§ 94.230 May you negotiate or settle your retaliation complaint?

Yes, you may negotiate or settle your whistleblower retaliation complaint with the covered institution by using the procedures described in §§ 94.360 through 94.375.

Subpart C—Responsibilities of Covered Institutions

Responsibilities and Procedures

§ 94.300 What institutions are covered by this part?

This part applies to any institution that applies for or receives grants, contracts, or cooperative agreements under PHS Act, as amended (42 U.S.C. 201, *et seq.*) for any project or program that involves biomedical or behavioral research, research training, or research related activities.

§ 94.305 What responsibilities does a covered institution have?

(a) Covered institutions have primary responsibility for preventing and otherwise responding to occurrences of whistleblower retaliation.

(b) A covered institution and its members must—

(1) Comply with the standards in this part for preventing or otherwise responding to retaliation against whistleblowers if the underlying research misconduct allegation or act of cooperation with an investigation concerns research involving PHS grants, contracts, cooperative agreements, or applications therefor;

(2) Not retaliate against good faith whistleblowers as defined by this part; and

(3) Take all reasonable and necessary steps to prevent or otherwise respond to instances of whistleblower retaliation within the institution.

§ 94.310 Are subawardees and subcontractors of a covered institution included in this part?

(a) Yes, if a covered institution carries out PHS funded research through subawardees or subcontractors, the institution must take reasonable steps to ensure that subawardees and subcontractors and their members comply with this part.

(b) An institution may either require its subawardees and subcontractors to comply with its whistleblower policies and procedures or obtain assurances from them sufficient to allow compliance.

§ 94.315 Must a covered institution establish procedures for whistleblowers?

Yes, a covered institution must establish whistleblower protection procedures and remedies consistent with this part.

§ 94.320 What procedures must a covered institution establish?

A covered institution must establish written procedures for whistleblowers that—

(a) Include specific strategies aimed at preventing whistleblower retaliation by the covered institution or its members;

(b) Provide a mechanism for processing whistleblower complaints;

(c) Authorize appropriate administrative actions for verified cases of retaliation; and

(d) Ensure to a reasonable extent that its institutional members do not retaliate against whistleblowers, including whistleblowers who are not institutional members, such as persons who are located at other institutions or who are members of the general public.

§ 94.325 Who must a covered institution inform of these procedures?

(a) Each covered institution must provide written information informing all of its members about the content of this part and the institution's procedures to implement its requirements and must emphasize the importance of compliance with those procedures.

(b) A covered institution must provide its procedures to ORI and other authorized representatives of the Secretary upon request.

§ 94.330 What is an assurance of compliance?

(a) Effective on [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER] each institution, as a condition for receiving PHS funding, is required to provide in its application for that funding an assurance of compliance with this part which is satisfactory to the Secretary.

(b) The institution must assure that it—

(1) Has established written whistleblower protection procedures consistent with this part;

(2) Will comply with and enforce these procedures; and

(3) Will comply with all other requirements of this part.

§ 94.335 Who designates the responsible official, and what are the responsible official's duties?

(a) Each covered institution must—

(1) Appoint one person as the official responsible for overseeing the institution's whistleblower protection procedures;

(2) Authorize and direct the responsible official to execute or coordinate the implementation of the institution's policies and procedures in compliance with this part; and

(3) Authorize the responsible official to oversee each whistleblower retaliation case that arises at the institution, to oversee the negotiation and settlement process described in §§ 94.360 through 94.375, including implementing and enforcing appropriate institutional remedies as part of any agreement with the whistleblower, and to serve as a liaison between the covered institution and ORI.

(b) If involvement of the responsible official in a particular case creates a real or apparent conflict of interest with the covered institution's obligation to protect good faith whistleblowers, or with a fair process for adjudicating the retaliation proceeding, the institution must appoint a substitute official to oversee the case. If the institution is unable to appoint a suitable substitute from within the institution, it must designate a person outside the institution who has no real or apparent conflict of interest.

§ 94.340 How does a covered institution process whistleblower complaints?

(a) A covered institution must process all whistleblower retaliation complaints that are made to the responsible official pursuant to this part.

(b) Within 20 calendar days of receiving a whistleblower retaliation complaint, the institution must provide the whistleblower with copies of this part, the institution's policies and procedures implementing this part, including its administrative procedures under § 94.415, and a written notification, which includes—

(1) The dates the institution received the retaliation complaint and on which it believes the 30 day negotiation period of § 94.365(a) expires; and

(2) The institution's determination of whether the retaliation complaint satisfies the jurisdictional elements required by § 94.215 and, if the jurisdictional elements are not satisfied, the specific basis for that determination.

§ 94.345 Must a covered institution provide temporary protections to whistleblowers?

(a) Consistent with § 94.350, a covered institution must provide reasonable and necessary temporary protections to whistleblowers before the final resolution of a retaliation complaint under this part if, based on the evidence, the responsible official reasonably determines that protection is warranted.

(b) The responsible official must notify the whistleblower in writing of the decision on whether to provide temporary protections.

§ 94.350 What temporary protections may a covered institution offer?

A covered institution must authorize the responsible official to provide any reasonable and necessary temporary protection(s), including but not limited to—

(a) Ensuring the confidentiality of an ongoing research misconduct investigation or retaliation proceeding;

(b) Protecting the whistleblower's institutional status; and

(c) Taking disciplinary actions against institutional members who fail to comply with the responsible official's orders.

§ 94.355 How long do temporary protections last?

When a covered institution and a whistleblower have fully resolved the retaliation complaint, any temporary protection(s) taken to protect the whistleblower may be discontinued or replaced with permanent remedies.

Negotiations and Settlements

§ 94.360 How may a covered institution negotiate and settle a retaliation complaint?

(a) A covered institution and a whistleblower may negotiate and settle a retaliation complaint through any legal means not inconsistent with this part at any time after the institution receives the complaint.

(b) If an institution and a whistleblower agree, any alternative dispute resolution mechanism, such as mediation, may be used to facilitate a resolution during the negotiation period.

(c) Consistent with § 94.335(a)(3), a covered institution must authorize its responsible official to implement any remedies as part of any agreement with a whistleblower.

(d) However, any agreement to settle the complaint must not restrict a whistleblower's right or opportunity to make disclosures or to otherwise cooperate with institutional officials, ORI, or other Federal agencies with respect to the underlying research misconduct allegation(s).

§ 94.365 How long may a covered institution conduct negotiations on a retaliation complaint?

(a) Except as modified by paragraph (b) of this section, a covered institution has 30 calendar days after the responsible official receives a written whistleblower retaliation complaint in which to negotiate a settlement with a whistleblower.

(b) If an institution and a whistleblower have not fully resolved the retaliation complaint within the 30 day period of paragraph (a) of this section, they may mutually agree in writing to extend that period for up to an additional 60 calendar days.

(c) If an institution and a whistleblower fully resolve the complaint during the negotiation period, ORI considers the complaint closed for purposes of this part. The head of the institution, or designee, and the whistleblower must sign an agreement that the complaint has been resolved, and the institution must notify ORI of the agreement within 30 calendar days of its execution, as required by § 94.380(d)(5).

§ 94.370 What must a covered institution do if it questions jurisdiction during negotiations?

If a covered institution provided the § 94.340(b)(2) notice to a whistleblower that the retaliation complaint does not contain the jurisdictional information required by § 94.215, the whistleblower has not adequately revised the complaint, and the institution and the whistleblower continue to dispute whether the complaint falls within the jurisdiction of this part, the institution may, at its discretion, either—

(a) Continue settlement discussions during the 30 to 90 day negotiation period allowed under § 94.365 and move to dismiss the complaint for lack of jurisdiction during any administrative proceeding under subpart D of this part; or

(b) Immediately end the negotiation period, offer the whistleblower an administrative proceeding under subpart D of this part, and in that proceeding, make a preliminary motion to dismiss the complaint for lack of jurisdiction.

§ 94.375 What happens if negotiations do not resolve a retaliation complaint?

(a) If a covered institution and a whistleblower have not fully resolved the retaliation complaint by the end of the 30 to 90 day negotiation period, or if they mutually agree to end negotiations without a settlement, the

institution must immediately offer the whistleblower an administrative proceeding under subpart D of this part.

(b) The administrative proceeding must begin no later than 90 calendar days after the negotiations have ended unless the parties mutually agree otherwise.

Compliance

§ 94.380 What information must a covered institution report to ORI regarding retaliation complaints?

A covered institution must report and submit the following information and items to ORI no later than 30 calendar days after each of the following events occur:

(a) *Complaint filed.* A copy of the whistleblower retaliation complaint, the date the institution received it, and the expected expiration date of the negotiation period under § 94.365.

(b) *Temporary protection requested.* A description of any temporary protection either provided to or requested by the whistleblower and the responsible official's written decision regarding the request.

(c) *Proceeding held or offered.* A description of the administrative proceeding used or made available to resolve the complaint under subpart D of this part, including an explanation of how the institution met the procedural standards of § 94.420.

(d) *Final disposition of complaint.* A copy or description of the final disposition of the retaliation complaint including, where applicable—

(1) The dismissal of the complaint for jurisdictional inadequacy;

(2) The whistleblower's failure to timely file any supporting documentation required by the proposed administrative proceeding;

(3) The whistleblower's election of a remedy other than that made available by the institution;

(4) The outcome of the administrative proceeding under subpart D of this part, including any remedies imposed; and

(5) Any mutual settlement agreement of the complaint including a statement to that effect signed by the head of the institution or designee and the whistleblower. The terms of the settlement agreement need not be disclosed, but the agreement must comply with § 94.360.

§ 94.385 Must a covered institution cooperate with ORI compliance reviews?

Yes, a covered institution and its members must cooperate with any ORI compliance review conducted under § 94.510, including requests for information, on-site visits, inspection of relevant records, and interview of institutional members.

§ 94.390 What happens if a covered institution retaliates or fails to comply with this part?

A covered institution that engages in whistleblower retaliation or otherwise fails to comply with any provision of this part may be subject to any of the PHS administrative actions provided under § 94.520.

Subpart D—Administrative Proceedings

Election of Remedies

§ 94.400 May a whistleblower elect remedies other than an administrative proceeding?

(a) Yes, a whistleblower may choose to resolve a retaliation complaint either through the administrative proceeding made available by the covered institution under this subpart or through any other available remedy provided by law, including remedies under any applicable Federal or State law or other institutional policy or employment agreement.

(b) If the whistleblower elects a remedy other than settlement or the administrative proceeding made available by the covered institution, the whistleblower must provide the institution with written notice of that election.

(c) If the whistleblower does not make an election of remedies under paragraph (b) of this section before the final disposition of the retaliation complaint, whether by settlement, dismissal, or final decision, ORI will consider that the institution has fully satisfied the requirements of this part.

§ 94.405 What actions may a covered institution take if a whistleblower elects a remedy other than an administrative proceeding?

ORI will not require a covered institution to complete any administrative proceeding or otherwise pursue a final resolution of the complaint if a whistleblower elects a remedy for the retaliation complaint other than the administrative proceeding made available under this part.

Administrative Proceedings

§ 94.410 Must a covered institution offer a whistleblower an administrative proceeding?

Yes, for each case of possible whistleblower retaliation to which this part applies and which is not settled, a covered institution must make available and comply with an administrative proceeding that meets the standards in this part for resolving retaliation complaints.

§ 94.415 What types of administrative proceedings may a covered institution offer?

A covered institution may resolve a whistleblower retaliation complaint by any of the following types of administrative proceedings, if the proceeding satisfies all of the elements of § 94.420:

(a) An independent and binding arbitration.

(b) An institutional fact-finding.

(c) An academic or institutional employment hearing.

(d) A state statutory whistleblower proceeding.

(e) Any other administrative proceeding that addresses and resolves the retaliation complaint.

§ 94.420 What elements must a covered institution include in its administrative proceeding?

A covered institution must have written procedures for administrative proceedings to resolve whistleblower retaliation complaints. These procedures must include all of the following elements:

(a) A procedure for appointing a qualified and objective decisionmaker.

(b) The opportunity for the whistleblower and the institution to be represented by counsel. The institution may, but is not required by this part to, provide counsel for the whistleblower.

(c) An equal opportunity for the institution and the whistleblower to present evidence in support of their respective positions or in response to contrary evidence, including having an attorney present and cross-examining witnesses.

(d) A presumption that the whistleblower's research misconduct allegation or cooperation with an investigation of the allegation was made in good faith. If the institution rebuts that presumption in a timely manner by submitting *prima facie* evidence of a lack of good faith, the whistleblower then has the burden to prove good faith by a preponderance of the evidence.

(e) A final written decision made according to the following standards of proof:

(1) Subject to paragraph (e)(2) of this section, the decisionmaker must order a binding institutional remedy according to § 94.445 if the whistleblower proves by a preponderance of the evidence that the whistleblower's research misconduct allegation or cooperation with an investigation of the allegation was a contributing factor in an adverse

action taken by the institution or one of its members.

(2) Even if the whistleblower meets the burden of proof required by paragraph (e)(1) of this section, the decisionmaker must not order an institutional remedy if the institution proves by clear and convincing evidence that the institution or one of its members would have taken the action at issue in the absence of the whistleblower's research misconduct allegation or cooperation with an investigation of the allegation.

§ 94.425 What information must a covered institution provide to a whistleblower?

At the time a covered institution proposes an administrative proceeding, it must provide the whistleblower with a copy of the procedures for the proceeding, and it must fully inform the whistleblower of the requirements, rights, procedures, and possible consequences associated with that proceeding.

§ 94.430 What happens if a whistleblower fails to timely file supporting documentation for the administrative proceeding?

(a) A whistleblower must timely file any supporting documentation required by the proposed administrative proceeding, or the decisionmaker may dismiss the retaliation complaint for purposes of this part. The applicable filing period will be 60 calendar days from the day the covered institution proposed the proceeding if the institution has not specified a filing date or if the specified date is less than 10 calendar days.

(b) However, the whistleblower's failure to timely file will not be grounds for dismissal of the retaliation complaint if either—

(1) The institution failed to inform the whistleblower of the proposed administrative proceeding and its procedures, requirements, rights, and possible consequences in a full and timely manner; or

(2) If the decisionmaker determines there is good cause for the whistleblower's failure to timely file.

§ 94.435 May a covered institution or whistleblower challenge the decisionmaker's qualifications?

(a) Either the whistleblower or the covered institution may challenge the qualifications or objectivity of the administrative proceeding's decisionmaker.

(b) Any challenge must be made within 30 calendar days of the notice of the appointment of the decisionmaker.

(c) If either party challenges the decisionmaker's qualifications or objectivity, the challenge must be made part of the record, and may be subject to any ORI compliance review under § 94.510.

§ 94.440 May the decisionmaker be replaced?

The covered institution may replace the decisionmaker for good cause before final resolution of the retaliation complaint. Good cause includes—

(a) The decisionmaker dies or becomes incapacitated;

(b) The decisionmaker is determined to have a conflict of interest under § 94.435;

(c) The parties mutually agree to a replacement; or

(d) The administrative proceedings' procedures otherwise allow replacement.

Remedies

§ 94.445 What remedies may a decisionmaker impose?

(a) If the decisionmaker in an administrative proceeding determines that the covered institution or one of its members retaliated against the whistleblower, the decisionmaker must order one or more remedies based on the findings. The decisionmaker has broad discretion in determining whether all or any of the following remedies are appropriate and warranted:

(1) Reinstate the terms and conditions of the whistleblower's status at the institution that existed before the retaliatory action, including but not limited to employment (including tenure eligibility and promotion potential), academic matriculation, awarding of degree, or relationship established by grant, contract, or cooperative agreement.

(2) Offer a position within the institution that is comparable financially, vocationally, and otherwise to the position the whistleblower held before the retaliatory action.

(3) Compensate the whistleblower for any financial or other loss incurred between the retaliatory action and the provision of a remedy or remedies under this part.

(4) Restore the whistleblower's reputation, to the greatest extent feasible, within the institution and the broader scientific community. If the whistleblower agrees, this may include an official retraction of negative references or the publication of an exoneration.

(5) Protect the whistleblower against further potential retaliation. This may include monitoring the retaliator for a period of time.

(6) Compensate the whistleblower for part or all expenses, if any, incurred pursuant to the administrative proceeding.

(7) Take any other action allowed under law that reasonably restores the whistleblower's status and reputation.

(b) The institution must implement in a timely manner the remedy(s) ordered by the decisionmaker unless the order is revoked or otherwise modified by an appeal under § 94.450.

Appeals

§ 94.450 May a covered institution or whistleblower appeal an adverse decision or remedy?

Either the covered institution or the whistleblower may appeal an adverse finding or remedy by the decisionmaker only if the administrative proceeding allows an appeal or an appeal is provided by state or other applicable law.

Subpart E—Responsibilities of the Office of Research Integrity

General Provisions

§ 94.500 What are ORI's responsibilities?

(a) ORI is responsible for monitoring covered institutions to determine whether they have established administrative procedures and are following them in accordance with this part and the institution's certification of compliance under § 94.330.

(b) ORI may take the remedial administrative actions, specified in § 94.520, against covered institutions that retaliate against good faith whistleblowers or that otherwise do not comply with the standards and procedures of this part.

§ 94.505 What does ORI do when it receives a whistleblower retaliation complaint?

Consistent with § 94.205, if a whistleblower brings a retaliation complaint directly to ORI, ORI reviews the complaint to determine if, on its face, it meets the requirements of this part. If so, ORI will instruct the whistleblower to send the complaint to the covered institution's responsible official or notify the responsible official directly.

Compliance Reviews

§ 94.510 When does ORI do an institutional compliance review?

(a) ORI may review a covered institution's compliance with the provisions of this part at any time. ORI's decision to begin a compliance review may be based on the institution's written whistleblower procedures, its certification of compliance, its submissions to ORI regarding whistleblower retaliation complaints, or

any other information ORI considers relevant to the institution's compliance with this part.

(b) ORI's review may include, but is not limited to, requests for information, on-site visits, inspection of relevant records, and interviews with institutional members.

§ 94.515 What factors does ORI consider in a compliance review?

(a) If a covered institution complies with each provision of this part, ORI will consider the institution to be in compliance with the institution's certification of compliance and this part.

(b) ORI may consider a covered institution's failure to comply with the provisions of this part to be a material failure to comply with the institution's certification of compliance and with the terms and conditions of any PHS funding provided under an application in which that certification is made.

§ 94.520 What administrative actions may ORI take pursuant to a compliance review?

If ORI determines that a covered institution has engaged in whistleblower retaliation or has failed to comply with any provision of this part, ORI may impose, or recommend to the appropriate authorized Department official, imposition of one or more of the following administrative actions:

(a) A corrective action plan including, where applicable, oversight of the institution's responsible official and its whistleblower protection procedures.

(b) Probationary status under which the noncompliant institution could be subject to cumulative administrative actions if future incidents of institutional noncompliance occur including loss of PHS funding.

(c) Special conditions imposed upon any future PHS awards of grants, contracts, or cooperative agreements to the institution.

(d) Recovery of PHS funds misspent in connection with a retaliatory action or other institutional noncompliance with this part.

(e) Termination of PHS current or future funding to the institution or any part thereof.

(f) Public notice of the determination.

(g) Any other action that ORI finds reasonable and appropriate to correct the noncompliance.

§ 94.525 May a covered institution appeal administrative actions imposed by ORI or the Department?

A covered institution may appeal any administrative actions imposed by ORI or the Department under § 94.520 only if an appeal is specifically allowed by an existing Departmental regulation. The institution must appeal under the terms of the applicable regulation.

Subpart F—Definitions

§ 94.600 Administrative proceeding.

Administrative proceeding means the procedure that a covered institution employs or offers to employ to resolve a whistleblower retaliation complaint in compliance with the provisions of this part.

§ 94.605 Adverse action.

Adverse action means any action taken or threatened by a covered institution or its member(s) that negatively affects the terms or conditions of the whistleblower's status at the institution, including but not limited to employment, promotion, academic matriculation, awarding of a degree, financial aid, or relationship established by grant, contract, or cooperative agreement.

§ 94.610 Allegation.

Allegation means any disclosure, whether by written or oral statement, or other communication, to an institutional or Departmental official, that a covered institution or one of its members has engaged in, or failed to respond adequately to an allegation of, research misconduct as defined by this part and that involves the use of PHS funds or the application for PHS funds.

§ 94.615 Contributing factor.

Contributing factor means any whistleblower activity protected under this part that alone or in combination with other factors results in an adverse action against the whistleblower.

§ 94.620 Covered institution.

Covered institution means any entity, whether individual or corporate, that applies for or receives grants, contracts, or cooperative agreements under the PHS Act, as amended (42 U.S.C. 201, *et seq.*), for any program that involves the conduct of biomedical or behavioral research, research training or research related activity. Covered institutions do not include Federal agencies.

§ 94.625 Decisionmaker.

Decisionmaker means the person(s) designated by the covered institution, according to the rules of the administrative proceeding made available under this part, to preside over the proceeding, to make preliminary decisions of jurisdictional adequacy, to make a final determination of whether retaliation against the whistleblower occurred based on the evidence presented, and to order appropriate remedies consistent with this part.

§ 94.630 Good faith.

(a) *Good faith* means having a belief in the truth of one's allegation or testimony that a reasonable person in the whistleblower's position could have based upon the information known to the whistleblower at the time the allegation was made.

(b) An allegation or cooperation with an investigation is not in good faith if made with knowing or reckless disregard of information that would negate the allegation or testimony.

§ 94.635 Institutional member or member.

(a) *Institutional member* or *member* means a person who is employed by, is affiliated with under a contract or agreement, or is under the control of a covered institution.

(b) *Institutional members* include, but are not limited to, teaching and support staff, researchers, clinicians, technicians, fellows, students, volunteers, and contractors, subcontractors, and subawardees and their employees.

§ 94.640 Investigation.

Investigation, solely for the purpose of this part, means—

(a) An initial assessment by ORI, the Department, or a covered institution.

(b) An inquiry or investigation by the Department or a covered institution.

(c) Any institutional appeal of an allegation of research misconduct involving PHS funds or applications therefor, including preparation for and conduct of any research misconduct hearing.

(d) A review, recommendation, or decision regarding an assessment, inquiry, or investigation by ORI or the Department.

(e) An appeal to the Departmental Appeals Board.

(f) An investigation of an alleged inadequate response to an allegation of research misconduct.

§ 94.645 Office of Research Integrity or ORI.

Office of Research Integrity or *ORI* means the office to which the Secretary has delegated responsibility for addressing research misconduct issues related to PHS activities, including the protection of whistleblowers.

§ 94.650 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, the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrator.

§ 94.655 PHS funds or PHS funding.

PHS funds or *PHS funding* means Public Health Service grants, contracts, or cooperative agreements.

§ 94.660 Research misconduct.

Research misconduct means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

§ 94.665 Responsible official.

Responsible official means the official designated by a covered institution to establish and implement the institution's whistleblower protection procedures as required by this part.

§ 94.670 Retaliation.

Retaliation for the purpose of this part means an adverse action taken against a whistleblower by a covered institution or one of its members in response to—

(a) A good faith allegation that the covered institution or one of its members has engaged in, or failed to respond adequately to an allegation of, research misconduct; or

(b) A good faith cooperation with an investigation of an allegation in paragraph (a) of this section.

§ 94.675 Secretary.

Secretary means the Secretary of the Department of Health and Human Services or any other officer or employee of the Department of Health and Human Services to whom the Secretary has delegated authority.

§ 94.680 Whistleblower.

Whistleblower means an institutional member who in good faith—

(a) Makes an allegation that the covered institution or one of its members has engaged in, or failed to respond adequately to an allegation of, research misconduct; or

(b) Cooperates with an investigation of an allegation in paragraph (a) of this section.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 697

[I.D. 112100A]

American Lobster Fishery Management

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings; request for comments.

SUMMARY: NMFS has prepared a draft supplemental environmental impact statement (DSEIS) which identifies several preferred management actions and alternatives for the American lobster fishery in Federal waters. These measures are based upon recommendations in Addendum 1 to Amendment 3 of the Interstate Fishery Management Plan for American Lobster (ISFMP) made by the Atlantic States Marine Fisheries Commission (Commission) for management of the American lobster resource in Federal waters. NMFS will hold public meetings to receive comments on the biological, economic, and social impacts addressed in the DSEIS.

DATES: Written comments on the preferred lobster management measures and alternatives discussed in the DSEIS must be received at the appropriate address or facsimile (fax) number (see **ADDRESSES**), no later than 5 p.m., eastern standard time, on Tuesday, January 9, 2001. Also, verbal comments may be presented at public meetings which are scheduled to be held from Tuesday, December 12 through Friday, December 15, 2000, in Maine, Rhode Island, New York and New Jersey. See **SUPPLEMENTARY INFORMATION** for times and locations of the meetings and special accommodations.

ADDRESSES: Written comments and direct requests for copies of the lobster public meeting document and DSEIS should be sent to the State, Federal and Constituent Programs Office, National Marine Fisheries Service, Northeast Region, One Blackburn Drive, Gloucester, MA 01930-2298. Comments may also be sent via fax to (978) 281-9117. Comments submitted via email or Internet will not be accepted.

FOR FURTHER INFORMATION CONTACT: Peter Burns, NMFS, Northeast Region, telephone (978) 281-9144, fax (978) 281-9117.

SUPPLEMENTARY INFORMATION: NMFS is considering several new management measures for the American lobster fishery in Federal waters in response to the Commission's recommendations in Addendum 1 to Amendment 3 of the ISFMP. Specifically, NMFS is considering a preferred alternative to control fishing effort in the lobster trap fishery in LCMAs 3, 4 and 5 by limiting access to only those Federal permit holders who can substantiate a history of trap fishing in these areas. The eligibility criteria for access to these management areas would be based upon industry advice developed by the ISFMP's lobster conservation management teams. In LCMA 3, eligible permit holders would have to meet all of the following criteria:

1. Possession of a current Federal limited access lobster permit.

2. Provision of documentation to demonstrate a history of 2 consecutive calendar-months of active lobster trap fishing in LCMA 3 in any calendar year during the March 25, 1991 through September 1, 1999 qualification period (qualification period). A history of active trap fishing is defined as the fishing of at least 200 traps set in LCMA 3 for the duration of the 2-month qualifying period. Documentation may include copies of vessel logbooks, state or Federal Fishing Trip Reports, permit applications, or any other form of certification that denotes area fished and harvest information.

3. Provision of sales receipts or records showing the landing of at least 25,000 lb (11,370 km) of lobster from any area throughout the range of the resource during the year used as the qualifying year referenced in the preceding paragraph (Criterion number 2).

Under the preferred alternative Federal permit holders who qualify for participation in LCMA 3 based on the preceding criteria would be required to submit a signed affidavit to NMFS certifying the number of traps they have historically fished in LCMA 3. Qualifying permit holders would be restricted to the number of traps they have historically fished in that area, but limited to no more than 3,250 traps, and would be required to comply with annual trap reductions over a 5-year period.

In LCMA 4 and LCMA 5, the preferred alternative would require eligible permit holders to meet all of the following criteria to participate in the trap fishery in either of these areas:

1. Possession of a current Federal limited access lobster permit.

2. Provision of documentation to demonstrate a history of 2 consecutive