

ORI Guidelines for Institutions and Whistleblowers:

Responding to Possible Retaliation Against Whistleblowers in Extramural Research

(November 20, 1995)

I. INTRODUCTION

The Office of Research Integrity (ORI), Department of Health and Human Services (DHHS), strongly believes in the importance of protecting whistleblowers who make good faith allegations of scientific misconduct to ORI or appropriate institutional authorities. In particular, ORI is committed to protecting good faith whistleblowers from retaliation by covered institutions and their members.

By regulation, each extramural entity that applies for a biomedical or behavioral research, research-training, or research-related grant or cooperative agreement under the Public Health Service (PHS) Act must establish policies and procedures that provide for "undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations." 42 C.F.R. Part 50.103(d)(13).

Although the regulation does not provide specific direction on how to protect whistleblowers, ORI has determined that adherence to the policies and procedures set forth in these Guidelines is one method of satisfying the requirements of the regulation. ORI will recognize an institution's substantial conformity with these Guidelines as meeting the whistleblower protection requirement of 42 C.F.R. Part 50.103(d)(13). Specifically, each institution which substantially adheres to Sections IV and V of these Guidelines in responding to whistleblower retaliation complaints will be considered in compliance with the regulatory whistleblower protection requirement for resolution of retaliation complaints. However, institutions are free to disregard these Guidelines and adopt other procedures that conform to the regulatory requirement.

If an institution elects to adopt these Guidelines, it must abide by each provision that uses the operative word "shall." On the other hand, provisions which employ the words "should" or "may" are merely practical suggestions. An institution will not be out of conformity with the Guidelines if it fails to carry out these recommendations. Rather, an institution may substitute for these suggested provisions alternative procedures that are consistent with the mandatory provisions of these Guidelines and the regulatory whistleblower protection provisions.

In addition to the requirements of 42 C.F.R. Part 50.103(d)(13), ORI encourages covered institutions to adopt policies and procedures that conform to PHS Act Part 493(e), a whistleblower protection statute enacted by Part 163 of the National Institutes of Health Revitalization Act of 1993, although Part 493 has not been implemented by regulation at the time of issuance of these Guidelines. Besides protecting good faith allegations of scientific misconduct, PHS Act Part 493(e) mandates the protection of whistleblowers for (1) good faith allegations of an inadequate institutional response to scientific misconduct allegations and (2) good faith cooperation with investigations of such allegations. The statute covers allegations of misconduct which involve research or research related grants, contracts or cooperative agreements under the PHS Act.

ORI also encourages institutions to adopt principles consistent with the Whistleblower Bill of Rights (Appendix A) recommended by the Commission on Research Integrity and to foster

institutional commitment to those principles. The specific principles of the Whistleblower Bill of Rights are as follows:

- (1) whistleblowers are free to disclose lawfully whatever information supports a reasonable belief of research misconduct as it is defined by PHS policy,
- (2) institutions have a duty not to tolerate or engage in retaliation against good-faith whistleblowers,
- (3) institutions have a duty to provide fair and objective procedures for examining and resolving complaints, disputes and allegations of research misconduct,
- (4) institutions have a duty to follow procedures that are not tainted by partiality arising from personal or institutional conflict of interest or other sources of bias,
- (5) institutions have a duty to elicit and evaluate fully and objectively information about concerns raised by whistleblower,
- (6) institutions have a duty to handle cases involving alleged research misconduct as expeditiously as possible without compromising responsible resolutions, and
- (7) at the conclusion of proceedings, institutions have a responsibility to credit promptly, in public or private as appropriate, those whose allegations are substantiated.

These Guidelines are consistent with the rights and responsibilities enumerated in the **Whistleblower Bill of Rights**.

While compliance with these Guidelines will satisfy the existing regulatory requirements at 42 C.F.R. Part 50.103 (d)(13), this publication does not bind the Department in any way as to the substantive provisions of the forthcoming new regulation implementing the whistleblower protection statute, PHS Act Part 493(e).

II. PURPOSE

The purpose of these Guidelines is to set forth ORI's suggested approach for handling whistleblower retaliation cases which arise at covered institutions. Substantial adherence to the Guidelines in each whistleblower case affords a "safe harbor" in which conforming institutions will be deemed in compliance with Part 50.103(d)(13) of the scientific misconduct regulation. For those institutions which adopt alternative procedures to comply with the regulation, ORI may review those cases which do not abide by these Guidelines to determine whether an institution has taken diligent efforts to protect the positions and reputations of good faith whistleblowers.

These Guidelines also provide information to whistleblowers on an appropriate method of submitting retaliation complaints and subsequent procedures for resolving the complaints. ORI encourages whistleblowers to refer institutions to these Guidelines when making specific complaints of retaliation.

These Guidelines apply to all instances of possible retaliation against whistleblowers whose allegation of scientific misconduct is covered by 42 C.F.R. Part 50, Subpart A.

III. DEFINITIONS

"Adverse action" means any action taken by a covered institution or its members which negatively affects the terms or conditions of the whistleblower's status at the institution, including but not limited to his or her employment, academic matriculation, awarding of degree, or institutional relationship established by grant, contract or cooperative agreement.

"Allegation" means any disclosure, whether by written or oral statement, or any other communication, to an institutional, a Department of Justice (DOJ), or a DHHS official who receives the allegation while acting in their official capacity, that a covered institution or member thereof has engaged in scientific misconduct. Allegations made to any of the above officials may be in conjunction with communications to Congress ¹.

"Arbitration" means the process described in this Part through which an unresolved dispute regarding whistleblower retaliation is submitted to an arbitrator for a final and binding decision.

"Arbitrator" means one or more impartial persons selected according to the rules of a designated arbitration association who shall hear and decide whistleblower retaliation complaints under this Part.

"Covered institution" means any entity, whether individual or corporate, which applies for or receives funds under a research, research-training, or research-related grant or cooperative agreement under the PHS Act.

"Deciding official" means the official designated by the administrative head of a covered institution to make a final institutional determination as to whether retaliation occurred.

"Good faith allegation" means an allegation of scientific misconduct made with a belief in the truth of the allegation which a reasonable person in the whistleblower's position could hold based upon the facts. An allegation is not in good faith if made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

"Institutional member, or member" means a person who is employed by, affiliated with under a contract or agreement, or under the control of a covered institution. Institutional members include but are not limited to administrative, teaching and support staff, researchers, clinicians, technicians, fellows, students, and contractors and their employees.

"Office of Research Integrity (ORI)" means the office to which the Secretary has delegated responsibility for addressing scientific misconduct issues related to PHS activities, including the protection of good faith whistleblowers.

"Responsible official" means the official designated by and reporting to the administrative head of a covered institution to establish and implement the institution's whistleblower policies.

"Retaliation" means any adverse action or credible threat of an adverse action taken by a covered institution, or member thereof, in response to a whistleblower's good faith allegation of scientific misconduct. It does not include an institution's decision to investigate a good faith allegation of scientific misconduct.

"Scientific 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.

"Whistleblower" means an individual who makes an allegation or demonstrates an intent to make an allegation (or what is perceived to be an allegation) while a member of the institution at which the alleged scientific misconduct occurred.

IV. PROCESSING WHISTLEBLOWER RETALIATION COMPLAINTS

A. Responsible Official

1. Covered institutions shall designate a "responsible official" to establish and implement the institution's whistleblower policies according to 42 C.F.R. Part 50.103(d)(13) and these Guidelines. The responsible official also serves as a liaison between the institution and ORI for transmitting such information as ORI may require.
2. The responsible official shall be free of any real or apparent conflicts of interest in any particular case.
3. If involvement of the responsible official in a particular case creates a real or apparent conflict of interest with the institution's obligation to protect good faith whistleblowers, and the conflict cannot be satisfactorily resolved for that case, the administrative head of the institution shall appoint a substitute responsible official who has no conflict of interest.

B. Notice of Institutional Policy

The institution shall provide to all its members notice of its whistleblower policies and these Guidelines with Appendices. The notice shall include the requirement set forth below regarding a whistleblower's deadline for filing a retaliation complaint. The institution's policies and these Guidelines shall be either disseminated or be publicized and made readily available to all institutional members.

C. Filing Complaints

1. A whistleblower who wishes to receive the procedural protections described by these Guidelines shall file his or her retaliation complaint with the responsible official at the appropriate institution within 180 days ² from the date the whistleblower became aware or should have become aware of the alleged adverse action. Covered institutions shall review and resolve all whistleblower retaliation complaints and should do so within 180 days after receipt of the complaint. If the whistleblower fails to receive an institutional response to the complaint in accordance with these

Guidelines within ten (10) working days³, the whistleblower may file the retaliation complaint directly with ORI at the following address:

Office of Research Integrity
Division of Policy and Education
5515 Security Lane, Suite 700
Rockville, MD 20852
Telephone: (301) 443-5300
Fax: (301) 594-0042

ORI will forward such complaints to the institution's responsible official for appropriate action.

2. In addition to prospective complaints, institutions may apply these Guidelines to complaints of retaliation made prior to the effective date of the institution's adoption of these Guidelines.
3. The retaliation complaint must include a description of the whistleblower's scientific misconduct allegation and the asserted adverse action, or threat thereof, against the whistleblower, by the institution or its members in response to the allegation. If the retaliation complaint is incomplete, the responsible official shall describe to the whistleblower what additional information is needed in order to meet the minimum requirements of a complaint under this Part.

D. Responding to Complaints

1. Upon receipt of a whistleblower retaliation complaint, the responsible official shall notify the whistleblower of receipt within ten (10) working days⁴ after receipt. The notice shall also inform the whistleblower of which process under Section V of the Guidelines the institution proposes to follow in resolving the retaliation complaint and the necessary actions by the whistleblower required under that process. The notice shall also notify the whistleblower of his or her choice of responses listed below.
2. The whistleblower may raise any concerns about the proposed process with the responsible official and the institution may modify the process in response to the whistleblower's concerns.
3. The whistleblower has five working days from the date of receipt of the initial notification in Part 1 above to:
 - a. accept the proposed process, although the whistleblower may also submit documentation for the official record about any concerns he or she may have about the proposed process; or
 - b. not accept the proposed process. If the whistleblower rejects the proposed process, he or she may pursue other remedies as provided by law.

4. If the whistleblower does not accept the proposed process, the institution may, but is not required to, propose the alternative option under Section V of the Guidelines.

5. The institution shall notify ORI of any whistleblower retaliation complaint it receives within ten (10) working days ⁵ after receipt of the complaint.

E. Interim Protections

1. At any time before the merits of a whistleblower retaliation complaint have been fully resolved, the whistleblower may submit a written request to the responsible official to take interim actions to protect the whistleblower against an existing adverse action or credible threat of an adverse action by the institution or member.

2. Based on the available evidence, the responsible official shall make a determination of whether to provide interim protections and shall advise the whistleblower of his or her decision in writing. Documentation underlying the decision whether to provide interim protections shall become part of the record of the complaint. When the whistleblower retaliation complaint is fully resolved, any temporary measure taken to protect the whistleblower shall be discontinued or replaced with permanent remedies.

V. RESOLUTION OF COMPLAINTS

1. For each whistleblower retaliation complaint received, a covered institution shall adhere to one of the two alternative processes for resolving the whistleblower retaliation complaint, or settle the complaint, as described below.

2. Whichever process is elected shall be implemented in a timely fashion. The process should be completed within 180 days of the date the complaint is filed, unless the whistleblower agrees to an extension of time. The institution shall promptly report the final outcome of either process or any settlement to ORI.

3. If the whistleblower declines the institution's proposed process according to these Guidelines, he or she may pursue any other legal rights available to the whistleblower for resolution of the retaliation complaint. However, ORI will deem the institution to have met its obligation under 42 C.F.R. Part 50.103(d)(13) and will not pursue the whistleblower complaint further.

Option A: Institutional Investigation

1. If the institution elects Option A, the institution shall conduct an investigation of the whistleblower retaliation complaint according to these Guidelines and implement appropriate

administrative remedies consistent with the investigation's finding and institutional decision thereon.

2. An investigation of whistleblower retaliation shall be timely, objective, thorough, and competent. The investigation should be conducted by a panel of at least three (3) individuals appointed by the responsible official. The members of the investigation panel, who may be from outside the institution, shall have no personal or professional relationship or other conflict of interest with the whistleblower or the alleged individual retaliator(s), and shall be qualified to conduct a thorough and competent investigation.

3. The investigation shall include the collection and examination of all relevant evidence, including interviews with the whistleblower, the alleged retaliator(s), and any other individual who can provide relevant and material information regarding the claimed retaliation.

4. The institution shall fully cooperate with the investigation and use all available administrative means to secure testimony, documents, and other materials relevant to the investigation.

5. The confidentiality of all participants in the investigation shall be maintained to the maximum extent possible throughout the investigation.

6. The Panel members shall evaluate and respond objectively to any concerns raised by the whistleblower about the process, including concerns regarding the selection of the deciding official, responsible official and specific panel members, which are raised prior to resolution of the complaint.

7. The conclusions of the investigation shall be documented in a written report and made available to the whistleblower. The report shall include findings of fact, a list of witnesses interviewed, an analysis of the evidence, and a detailed description of the investigative process.

8. The deciding official shall make a final institutional determination as to whether retaliation occurred. This decision shall be based on the report, the record of the investigation, and a preponderance of evidence standard.

9. If there is a determination that retaliation has occurred, the deciding official shall determine what remedies are appropriate to satisfy the institution's regulatory obligation to protect whistleblowers. The deciding official shall, in consultation with the whistleblower, take measures to protect or restore the whistleblower's position and reputation, including making any public or private statements, as appropriate. In addition, the deciding official may provide protection against further retaliation by monitoring or disciplining the retaliator.

10. The institution shall promptly notify ORI of its conclusions and remedies, if any, and forward the underlying investigation report to ORI.

11. The ORI will review the institutional report to determine whether the institution has substantially followed the process described herein. If the institution has substantially conformed to the process, ORI will not review the merits of the institutional determination under Paragraphs 8 and 9.

12. Institutional compliance with Option A does not bar the whistleblower from seeking redress against the institution's decision under Paragraph 8 and 9, under State law, institutional procedure, policy or agreement, or as otherwise provided by law.

Option B: Arbitration

1. If the institution elects Option B, the institution shall offer the whistleblower the opportunity to submit the retaliation dispute to binding arbitration. The parties shall sign a written agreement that the retaliation dispute will be decided by final and binding arbitration, identifying the person who shall conduct the arbitration.

2. The arbitration agreement shall specify that the institution and the whistleblower abrogate all other rights under Federal, State and local law, and other institutional policies or employment agreements pertinent to the resolution of the whistleblower retaliation complaint, other than enforcement of the arbitration award. However, the parties may enter into any legally enforceable settlement agreement before a final arbitration award is made. A sample arbitration agreement is attached at Appendix B.

3. Any retaliation complaint submitted to arbitration shall be arbitrated according to the rules and procedures of the presiding arbitrator and designated arbitration association.

4. An arbitration under these Guidelines shall be conducted by an arbitrator who has no personal or professional relationship or conflict of interest with the whistleblower, the institution, the alleged retaliator(s), or any person who is the subject of the underlying scientific misconduct allegation. The institution and the whistleblower shall agree on the choice of arbitrator. The arbitration should be facilitated by the American Arbitration Association or any other recognized non-profit arbitration association.

5. The institution and the whistleblower shall share equally the administrative costs of the arbitration. Each party is responsible for the cost of presenting its own case.

6. The arbitration agreement shall specify that the arbitrator shall require the institution to compensate the whistleblower for part or all of his or her arbitration costs, including attorney fees, if the arbitrator finds that the institution, or its members, retaliated against the whistleblower.

7. The arbitration agreement shall also specify that the arbitrator shall require the whistleblower to

compensate the institution for part or all of any filing fees and arbitrator's costs if the arbitrator finds that the whistleblower's allegation of scientific misconduct was not made in good faith. If an institution seeks compensation on this basis, it shall make a preliminary motion to dismiss the retaliation complaint prior to commencement of a hearing. The arbitrator shall, if possible, make a threshold decision on the question of good faith based on written submissions prior to commencement of a hearing on the merits of the retaliation dispute. The institution has the burden of proving by a preponderance of the evidence that the allegation of scientific misconduct was not made in good faith.

8. The arbitration agreement shall specify a preponderance of the evidence standard in determining whether retaliation occurred or any other standard mutually agreed to by the parties.

9. The arbitration agreement shall state that the arbitrator's award is final and binding on all parties, and enforceable as provided by law.

10. If the arbitrator finds that the institution, or its members, retaliated against the whistleblower, the arbitrator may order any relief necessary to make the whistleblower whole for the direct or indirect consequences of retaliation, including protection against further retaliation through imposing a system to monitor or discipline the retaliator. The institution shall abide by the arbitrator's final award and shall implement any additional administrative actions it determines is necessary to correct the retaliation.

11. The institution shall promptly forward a copy of the final arbitration award to ORI.

C. Settlement

In lieu of the two options described above, an institution and whistleblower may, at any time after the retaliation complaint is made, enter into any binding settlement agreement which finally resolves the retaliation complaint. If both parties agree, the responsible official shall facilitate negotiation of such settlements. If such an agreement is reached, the institution and the whistleblower shall sign a statement indicating that the retaliation complaint has been resolved. The institution shall within 30 days send a copy of the signed statement to ORI. ORI does not require a copy of the actual terms of the settlement. The settlement may not restrict the whistleblower from cooperating with any investigation of an allegation covered by 42 C.F.R. Part 50, Subpart A. ORI shall consider a settlement meeting these requirements as fulfilling the institution's regulatory obligation under 42 C.F.R. Part 50.103(d)(13).

VI. INSTITUTIONAL COMPLIANCE

At any time ORI may review a covered institution's compliance with 42 C.F.R. Part 50.103(d)(13) and these Guidelines to the extent that the institution relies on these Guidelines for regulatory compliance. Covered institutions and their members shall cooperate with any such review and provide ORI access to all relevant records. If a covered institution's procedures and implementation

thereof substantially conforms to Sections IV and V above, it shall be deemed to have met its whistleblower protection obligation under 42 C.F.R. Part 50.103(d)(13).

¹ Communications to Congress must be made in a way that affords "affected individual(s) confidential treatment to the maximum extent possible" consistent with 42 C.F.R. 50.103 (d)(3).

² The institution may establish a longer period of time.

³The institution may establish a shorter period of time.

⁴The institution may establish a shorter period of time consistent with footnote 2.

⁵The institution may establish a shorter period of time.