

Complainant Issues in Research Misconduct: The Office of Research Integrity Experience

CHRIS B. PASCAL¹

Office of Research Integrity, U.S. Department of Health & Human Services, Rockville, Maryland 20852

This paper discusses the experiences of the Office of Research Integrity (ORI) with issues involving complainants who make allegations of research misconduct. The paper describes the legal framework for complainant issues, the various roles of the complainant as the allegation of misconduct proceeds through the steps of investigation and resolution, how allegations of retaliation against the complainant are handled, the responsibilities of ORI and of the research institution where the alleged misconduct occurred, and ORI's experience with several cases of alleged retaliation. In each of these areas, the paper attempts to provide guidance to prospective complainants, research institutions, and other interested persons on effective ways to approach the various problems and concerns that arise, while maintaining a balance between the needs of the complainant, the accused, the research institution handling the allegation, and ORI. *Exp Biol Med* 231:1264–1270, 2006

Key words: Office of Research Integrity; research misconduct; complainant; retaliation; confidentiality; allegation of misconduct

Introduction and Overview

The Office of Research Integrity (ORI) is assigned responsibility within the U.S. Department of Health and Human Services (HHS) to carry out the research misconduct and integrity programs related to biomedical and behavioral research funded by the Public Health Service (PHS) (1). Two key components of this program involve institutional investigations of research misconduct that are reported to ORI, and ORI's responsibilities for overseeing reports of institutional inquiries and investigations into research misconduct that are forwarded to ORI under the institutions' regulatory responsi-

bilities. Institutional and ORI responses to alleged research misconduct are highly dependent upon the willing initiative of individual scientists and other members of the scientific community to come forward with such allegations and their willingness to serve as witnesses in a subsequent inquiry or investigation. It is rare that an institution or ORI identifies possible research misconduct on its own. The term "complainant" has been commonly used to refer to such individuals.

In this article, the author describes the various issues that affect ORI, the extramural institutions that receive PHS research funds, and the complainants themselves. These include:

- the legal framework for ORI's involvement in complainant issues;
- the various roles that the complainant adopts in bringing forward cases of possible misconduct—that of a complainant or charging party and that of a witness;
- retaliation issues that occur when institutions or others take an adverse action or other negative response against the complainant;
- the institutional and ORI responsibilities related to these issues; and
- ORI's experience in dealing with several complainant retaliation cases.

ORI Authorities Related to the Complainant

The existing regulations that institutions are required to follow in making reports of alleged research misconduct acknowledge the special role of the complainant by stating that the institution must protect the privacy of those who in good faith report apparent misconduct and undertake diligent efforts to protect the positions and reputations of such persons (2). The regulations also provide, at the election of the institution, an opportunity for the complainant to comment on the findings of the inquiry and investigation and to receive a copy of those portions of the investigation report that address the role and opinions of the complainant (3). Subsequent to issuance of the original regulations published in 1989 at 42 CFR Part 50, Subpart D, ORI's statutory authority was amended in 1993 to provide explicitly for complainant protections. As amended, the

The views expressed herein are those of the author and do not necessarily reflect the position of ORI, the Department of Health and Human Services, or any component thereof.

¹ To whom correspondence should be addressed at Office of Research Integrity, U.S. Department of Health & Human Services, Suite 750, Tower Building, 1101 Wootton Parkway, Rockville, MD 20852. E-mail: cpascal@osophs.dhhs.gov

1535-3702/06/2317-1264\$15.00

Copyright © 2006 by the Society for Experimental Biology and Medicine

statute requires the Secretary of HHS to issue regulations establishing standards that protect individuals who, in good faith, make allegations of research misconduct, allege failure to respond adequately to such allegations, or cooperate with an investigation of alleged research misconduct, that is, act as a witness (4). ORI is planning to develop recommendations for such standards in the next year or two for approval by the Secretary to implement the statutory requirement for protections for the complainant, prior to publication for public comment.

In the meantime, ORI has adopted a detailed set of voluntary guidelines to guide institutions and complainants in resolving complaints of retaliation taken in response to allegations of research misconduct (5). These guidelines are an attempt by ORI to suggest specific interim measures for complying with the current regulatory provision that requires institutions to undertake diligent efforts to protect the reputation and position of those who make allegations in good faith. In general, the guidelines provide for resolution of the complainant's retaliation complaint by the institution through settlement, institutional investigation, or binding arbitration. ORI's experience with these guidelines is discussed later in the article.

The Role of the Complainant in Reporting Misconduct

Perhaps the most important role of the complainant is to be the complaining party who brings forward the initial allegations of research misconduct to the institution or to ORI. This role has proven essential to the efforts of institutions and the government to respond adequately to research misconduct issues. Such allegations are often not readily apparent without having a knowledgeable individual identify the issue for the proper authorities to review. The role of the complaining party is a difficult and exacting one that deserves clear explanation at the government and institutional level in order to assist the complainant to carry it out properly and to protect himself or herself at the same time.

Prior to bringing forward an allegation, the complainant should make responsible inquiries concerning the research in question to ensure that an allegation is well grounded in fact. ORI's definition of a "good faith" allegation of research misconduct requires that the complainant have a reasonable basis for believing that the incident falls within the definition of research misconduct and that the allegation is not brought forward with knowing or reckless disregard of information that would disprove the allegation or testimony (6). In other words, "mere suspicion" does not constitute a good faith basis for making an allegation of research misconduct.

In determining whether there is a reasonable factual basis for the allegation, one must refer to the PHS definition of "research misconduct." It is defined in the regulations as "fabrication, falsification, or plagiarism in proposing,

performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences in opinion" (7). Certain types of authorship disputes, such as disputes between collaborators, are specifically not covered by the PHS definition as discussed in a prior ORI publication (8).

When an individual has intimate knowledge of the research in question, he or she may have a sufficient basis for making an allegation without further inquiry. In other circumstances, the researcher or other individual who suspects that research misconduct may have occurred in a publication, grant application, or other activity may need to consult with disinterested and knowledgeable colleagues to determine that there is a "reasonable" basis for the individual's suspicions before going forward with an allegation.

If the individual is unsure whether the factual situation warrants a charge of research misconduct, he or she should inquire among the responsible officials at the institution whether it is possible to discuss the concerns privately with an institutional official before making a formal allegation. ORI strongly encourages all research institutions to provide for such confidential discussions of potential misconduct allegations. The institutional research integrity officer (RIO) is usually the best place to start. Individuals who wish to report an allegation of research misconduct may also call 240-453-8800 to speak with ORI staff who are experienced in receiving such allegations and obtain guidance on whether the allegations appear to fall within the research misconduct definition and ORI jurisdiction. The individual may also want to consult an ombudsperson, trusted colleague, or other responsible person who can be trusted with confidential information.

Once an individual has identified a factual situation that reasonably appears to fall within the definition of research misconduct, he or she should disclose that information to the responsible official at the individual's institution. The responsible official for receiving allegations of research misconduct is often the RIO or some other senior official in the Office of the Vice President for Research. The complainant may also review the institutional policy on research misconduct (often posted on the institution's website), which should identify the individual to whom the allegation should be reported. The complainant may also contact ORI directly (240-453-8800) to obtain the name and phone number of the institutional official who handles misconduct. Under no circumstances should this information be discussed casually in the laboratory, department, or clinic or with the individual's friends or colleagues or the individual suspected of misconduct.

Disclosures of alleged misconduct should be made directly to ORI if the complainant believes that the institution has failed to respond to the individual's allegations or guidance is needed regarding how or to whom the allegations should be reported. ORI can also

provide the complainant with the name of the responsible official at the institution.

In order to receive complainant protection under the regulation, it is necessary for the allegation to be made in "good faith" as discussed above. Furthermore, the questioned research must involve PHS biomedical or behavioral research funds or applications for such funds. This protection for the complainant also applies to PHS intramural researchers who receive PHS funds to conduct research, receive research training, or are engaged in other intramural activities related to biomedical or behavioral research or research training; see 42 CFR 93.102 (b). If there is no PHS jurisdiction over the allegation, ORI cannot protect the complainant under its regulation. Nevertheless, other institutional or state laws may offer protection to complainants who bring forward allegations of misconduct even if the PHS rules do not apply (9).

The Complainant as Witness

Once the complainant has brought forward an allegation of possible research misconduct, he or she assumes the role of a possible witness in any subsequent inquiry or investigation. The parameters of this "witness" role are sometimes misunderstood.

ORI finds in its experience with individual complainants that sometimes the complainant believes that he or she is a "party" to the investigation because the complainant brought forward the allegation. As a party, the complainant assumes that he or she can control or direct the investigation, may have access to all evidence, and may even be a decision-maker on the investigation's outcome. This is definitely not the approach taken by ORI.

The PHS regulations may be the cause of some of this confusion because they acknowledge the important role of the complaining individual in bringing forward allegations, particularly with respect to the need for protection of that individual, but also by addressing the need for confidentiality for the complainant and providing for comment by the individual, at the election of the institution, on the findings of the inquiry and investigation. However, this does not amount to making the complainant a party to the investigation. ORI and the institution receiving the allegation are obligated by fundamental fairness to the accused to be objective in any inquiry or investigation that arises out of the allegation. Accordingly, it is not appropriate for the complainant to become a party who conducts or directs the conduct of the investigation.

The most important thing that the complainant can do in his or her role as a witness is to cooperate with the institution or ORI in providing evidence, identifying other possible witnesses, and responding to questions. If there is a formal proceeding related to the investigation, the complainant may be asked to serve as a witness in such proceeding just as he or she would in a court of law. In some cases, of course, the complainant turns out to be a key witness in the

investigation, and therefore the institution or ORI may rely on that witness very heavily in presenting evidence in the case. In other instances, however, the complainant is a minor witness or perhaps not needed further once the original allegation is raised. An example might be a case of plagiarism where the existence of the copied material is not in dispute.

Being a complainant can be very difficult in some circumstances because the complainant may have been involved in the research under question and feel that his or her reputation is also at stake. Nevertheless, it is extremely important that the complainant understand the obligation of the institution and ORI to maintain objectivity during the investigation and to accept the complainant's role as that of a witness and not someone who controls or directs the investigation.

Complainant Retaliation

One of the most important issues involving complainants is that concerning retaliation by the institution or others because of the complainant's allegation of research misconduct. In a study conducted by ORI and the Research Triangle Institute, 69% of complainants in research misconduct cases reported at least one negative outcome and 25% reported serious consequences, such as loss of position, promotion, or salary increase and denial of tenure (10). These results are consistent with ORI's experience that complainants are at risk when they come forward with allegations. In response to this risk, ORI has taken steps to prevent or ameliorate acts of retaliation.

The regulations protect those individuals who make good faith allegations of research misconduct by requiring institutions to undertake diligent efforts to protect their positions and reputations. However, the regulations do not prescribe any particular process. ORI guidelines issued in 1995 provide instructions to institutions and complainants on how to respond to an allegation of retaliation against a complainant. These guidelines generally apply when a good faith allegation results in an institutional adverse action such as loss of job, promotion, or degree. Under the guidelines, the complainant is instructed to report the alleged retaliation to the responsible institutional official, who may be the same individual who accepts allegations of research misconduct. If the institution does not respond to the alleged retaliation, the complainant may report it directly to ORI.

While the guidelines are voluntary, if an institution decides to follow them, ORI will deem it in compliance with the regulations. However, in order to earn such compliance, the institution must follow certain provisions of the guidelines. These provisions are described below.

The guidelines provide the following options for resolving retaliation disputes: settlement, institutional investigation, or binding arbitration. At any time following the retaliation complaint, the complainant and the institution may try to settle the alleged retaliation in lieu of more

formal procedures. This settlement can be fostered by direct discussions between the complainant and the institution, by other techniques such as use of an ombudsperson or a mediator, by use of legal representatives, or by any other appropriate means in order to reach resolution of the case. If a settlement is reached, ORI requests that documentation that a settlement has occurred be sent to ORI, but there is no requirement that the terms of settlement be disclosed.

Under the guidelines, if there is no settlement the institution is required to offer either binding arbitration to the complainant or an investigation conducted by an impartial panel of institutional or outside individuals to review the retaliation complaint. If arbitration is the selected option, the complainant and the institution would have to agree to make it binding. A model arbitration agreement is provided with the ORI guidelines.

If the institution offers an investigation to the complainant instead of arbitration, the institution must make efforts to ensure that the panel which conducts the investigation is impartial and unbiased. Once the investigation has been completed, the institutional decision-maker must decide whether retaliation occurred, and if so, what remedy will be offered to the complainant. If the institution has followed the procedural guidelines laid out by ORI, ORI will accept the institution's findings as the final resolution of the retaliation dispute under the regulation.

However, the complainant retains any rights she or he may have under state law to challenge the results of the investigation. Furthermore, if the complainant is not satisfied with the investigation option offered by the institution, she or he could opt out of the process at the time of the offer and pursue any other legal remedy. However, ORI would deem the institution's regulatory obligation for protection of the complainant to have been satisfied.

ORI has had experience with several cases in which either the arbitration or investigation model has been followed, although some of these began before the guidelines were adopted. In one case an institution conducted an investigation, found retaliation, and implemented some remedial actions. ORI was satisfied with the result and the case was closed. In another case where there had been prior litigation between the institution and the complainant, ORI took the initiative to facilitate an arbitration between the parties. The parties agreed to the arbitration but before the arbitration was completed they settled the retaliation claim. ORI was notified of the settlement and closed its file.

Following adoption of the guidelines, ORI has had experience with several other institutional investigations into retaliation complaints. In one case, a large university conducted a thorough and lengthy investigation, the report was reviewed and accepted by ORI, and the case was closed. In that case, the university found no retaliation.

Complainant Responsibilities

Being a complainant is not easy. Being an effective and responsible complainant while protecting one's own self-interest is even more difficult. However, in order to do an effective job of protecting the public trust by bringing forward allegations of research misconduct and assisting in their fair resolution, complainants must strive to be responsible and disciplined.

As discussed earlier, complainants have an obligation to make a reasonable and responsible inquiry into the facts prior to making an allegation of research misconduct and not rely solely on their suspicions. The complainant should also follow the rules that are established for making such complaints.

One important rule that the complainant should be aware of when he or she begins the process is the need to maintain confidentiality. Federal regulations require institutions to take steps to protect the confidentiality of all affected parties, including that of the accused (11). ORI policies provide for the same. ORI is also separately obligated under the federal Privacy Act to protect information in its possession regarding an accused scientist except under limited circumstances (12). Failure of the complainant to maintain confidentiality for the accused individual could expose the complainant to possible litigation and damages for defamation if the complaint does not result in a finding of research misconduct (13). Furthermore, the institution may take actions against the complainant for disclosing confidential information in violation of the institution's policies and the federal misconduct regulation.

In addition to protecting confidentiality, the complainant has an obligation to cooperate with the investigating body and provide it with information that he or she may have that is relevant to the allegation. However, the complainant is not responsible for ensuring that the allegation is thoroughly and completely investigated to resolution. That is the obligation of the institution and ORI. The complainant should continue to perform his or her assigned duties in a responsible and competent manner and let the institutional officials assume responsibility for the outcome of the investigation. If the complainant allows distractions caused by the investigation of the misconduct allegations to result in neglect of his or her primary job responsibilities, it may be difficult to distinguish between an adverse action against the complainant based on just cause and one based on retaliation.

Being a complainant often exacts an emotional toll on the individual. If the individual has been involved in the research project under question, the complainant may feel discomfort from the questions being raised about the research and be concerned about preserving his or her own reputation. The complainant may also have legitimate concerns that colleagues and others do not understand why the allegations were made. Making a complaint can generate

fear, anger, or concerns about one's future in a chosen profession. While many complainants successfully navigate these concerns, some have great difficulty with them.

ORI encourages complainants to come forward with good faith allegations of misconduct but advises them to let the responsible institutional and ORI officials assume the responsibility for the proper outcome of the process and not to put that burden on themselves. In this regard, ORI notes that, in its experience, less than 10% of all allegations brought forward to ORI result in a finding of research misconduct. Thus, when an allegation is made, the complainant should be prepared to accept a resolution of the case that does not result in a finding of misconduct. The fact that misconduct is not found does not mean that the complainant has not acted in good faith, and does not mean that making the allegation was not the right thing to do. Complainant protections are available for good faith complainants regardless of the final outcome.

By being prepared to deal with the difficulties of being a complainant and not assuming full responsibility for the outcome of the investigation, the complainant can help ameliorate the potential negative effects of being a complainant.

Institutional Responsibilities

The institution has a regulatory responsibility to establish policies and procedures for receiving allegations, investigating them, and reporting findings to the Office of Research Integrity (14). These policies and procedures should provide guidance to institutional employees and others about how to make allegations of research misconduct and to whom these should be disclosed. ORI strongly recommends that institutions offer potential complainants opportunities to seek confidential advice and counseling on scientific disputes if they are unsure about whether to make an allegation.

It is vitally important that institutional policies indicate how institutions plan to protect the reputation and positions of good faith complainants. Sound, well-developed policies in this area that are communicated to all staff will create a climate in which the complainant feels confident that he or she can come forward with a good faith allegation of research misconduct and be treated fairly. It should also diminish the likelihood that institutional staff may attempt retaliatory actions against complainants if the institutional commitment to enforce their policies and procedures and provide fair protections for complainants is communicated properly.

After the institution has established adequate policies and procedures, it must implement those policies in an effective way. This requires the institution to investigate fully good faith allegations of research misconduct. A full and thorough investigation will go a long way toward persuading complainants that the process is fair, encourage them to follow the institutional rules that are laid out for

making research misconduct allegations, and help them accept the outcome of the investigation even if their allegations are not substantiated.

The institutions also must maintain objectivity. The institution must strive to keep a balance between the rights of the complainant and the rights of the accused. Both should be treated fairly and with respect. In addition to the right of the accused to confidentiality, mentioned previously, there are a number of other protections for the accused, who sometimes is also referred to as the respondent. These protections include: the opportunity to review and comment on the institutional inquiry and investigation reports and the supporting evidence; the opportunity to challenge investigation committee members who may have conflicts of interest with the accused; the right to have scientists with the appropriate expertise conduct the investigation; the opportunity to retain counsel to assist in his or her defense, which is available but not addressed specifically in the ORI regulation; if misconduct is not found, the right to have his or her reputation restored by the institution; and perhaps most importantly the right to contest any findings of research misconduct in an administrative hearing conducted by an administrative law judge (15).

The complainant may not have the same due process considerations involved as the accused, but his or her reputation may also be placed at risk by coming forward with an allegation. Even though the complainant may not always be completely objective about the allegation, the institution has an obligation to assess the facts objectively. It is the institution's responsibility, and not the complainant's, to investigate fully the allegations and to reach a fair resolution of them.

It is not enough for the institution to merely address retaliation if it occurs. The institution should take affirmative steps to try to prevent retaliation whenever possible. This includes having policies and procedures in effect that are communicated and explained to staff to foster an environment in which good faith allegations are respected and not discouraged. Whenever an allegation is made, the institution can inform all appropriate parties who have a need to know, orally or in writing, including the supervisor of the complainant, the accused, the lab chief, the department chair, and others as appropriate, that retaliation will not be tolerated and that good faith allegations of misconduct are protected under the federal regulations and institutional policy. Furthermore, the institution can make clear to the complainant and any other appropriate person that complaints of retaliation may be reported to an identified official. If a retaliation complaint is made to the institution, the institution should respond promptly, assess the complaint fairly, and reach a resolution. In doing so, the institution can follow the ORI guidelines or any other policy or procedure that reflects diligent efforts by the institution to protect the reputation and position of the complainant.

ORI Responsibilities

ORI has a responsibility to conduct oversight reviews of institutional inquiries and investigations thoroughly, promptly, and fairly. When needed, this can include requesting all documents and data supporting the institutional findings and an independent analysis by ORI staff.

ORI has the additional obligation of providing fair and reasonable guidance to complainants, institutions, and other concerned parties about its procedures. It does this through its annual reports, quarterly newsletter, position papers, and other mechanisms, such as this article. ORI will provide further guidance in this area as needed.

ORI must review allegations of possible research misconduct received from the complainant in an objective fashion. One way in which ORI maintains its objectivity is by not considering the complainant to be a party to the investigation. ORI also assigns dedicated staff to handle any retaliation complaints and seeks formal legal advice from the HHS Office of General Counsel as needed.

If ORI receives a retaliation complaint from a complainant, ORI usually refers that complaint to the institution to handle as part of its duty to protect the position and reputation of the complainant. ORI asks the institution to follow the regulatory requirements and ORI guidelines or other appropriate process to resolve the complaint. ORI then monitors the institutional process until the case is resolved. When it is determined that the institution has adequately responded to the complaint, ORI closes the case.

Although comprehensive regulations have not yet been adopted to protect complainants from retaliation, ORI is actively attempting to resolve any retaliation complaints by relying on the existing regulations to protect complainants and facilitating that process through its complainant guidelines.

Case Studies

ORI has experience with a number of cases where complainants have alleged that they suffered retaliation after making an allegation of research misconduct. Several issues keep reoccurring in these cases; they are discussed below.

ORI's jurisdiction is the first issue that must be considered. ORI has had several cases in which the initial misconduct allegation did not fall within the PHS definition of research misconduct or did not involve PHS funding or applications, and therefore it did not accept jurisdiction over the subsequent complaint.

Another issue that has arisen in some of the ORI cases involves the need for early intervention or resolution of the alleged retaliation. ORI has found that if the time between the alleged incident of retaliation and its resolution is lengthy, the prospects for a nonadversarial resolution of the retaliation complaint are greatly diminished. In many of these cases, litigation is the ultimate result. In others, the harm to the complainant has become permanent and there is no way to remedy the retaliation effectively. However, ORI

has had several cases in which an early communication of the alleged retaliation to the proper institutional official has led to corrective action being taken to diminish or rectify the retaliatory conduct. For these reasons, ORI believes that complainants should report alleged retaliation promptly and that institutions should respond as soon as possible.

Another issue that has come up in some cases is the adequacy of the nexus between the complainant's misconduct allegations and a perceived adverse action. The complainant may allege misconduct just before he or she is fired or some other job-related action takes place, and the complainant may perceive the action as retaliation for the misconduct complaint. However, a prior institutional decision could have been made that the complainant's position would not be maintained based on discontinuance of PHS funding or some other legitimate reason.

Depending on the timing of the allegation of research misconduct and the institutional decision, it may be possible to determine clearly that adverse action was due to other factors. If the case is clear-cut, ORI may decide not to refer a retaliation complaint to the institution. This has occurred in several cases. In other cases, where the facts are ambiguous, ORI will ask the institution to determine whether the adverse action occurred as a result of the complainant alleging misconduct and provide to ORI specific facts supporting the institutional determination.

Another important feature in retaliation cases is the need for an impartial review and decision by the institution. In the ORI guidelines discussed earlier, ORI has offered two options, other than settlement, to the institution: binding arbitration or an investigation by the institution. In the case of binding arbitration, a neutral, independent arbitrator will make the decision based on the facts presented by the institution and the complainant, and the decision should be entirely objective. Where the institution conducts an investigation, however, questions often arise as to whether the institutional process can be objective. In the ORI guidelines, ORI has asked the institutions to take steps to ensure that there is no conflict of interest between those conducting the investigation and the parties involved in the alleged retaliation. Although not required under the guidelines, one step that may increase objectivity is to appoint one or more individuals from outside the institution to conduct the investigation. Both the reality and the perception of impartiality are important if the complainant is to have confidence in the institution's investigation and is willing to accept the result of the process as final.

ORI has been involved in several cases where the retaliation complaint has ultimately resulted in a lawsuit between the complainant and the institution. Successful resolution of the retaliation complaint by the institution under the ORI guidelines or other procedures could prevent such litigation. ORI has taken the position that it will not require the institution to resolve the retaliation dispute under the guidelines or the regulatory provision for protecting complainants if, at the same time, the institution is litigating

a suit brought by the complainant based on the same claim. ORI views the complainant's decision to go forward with litigation against the institution as an election of remedies and does not believe it is appropriate to require the institution to address the same issue through an ORI process at the same time.

Conclusion

The involvement and cooperation of complainants who come forward with allegations of research misconduct is essential to the successful protection of research integrity by institutions and the ORI. The role of the complainant in research misconduct issues is a difficult and complex one. The personal views of the complainant on the merits of the allegations must be balanced against the need to be objective and fair and to act in a responsible manner. This serves best the interests of the institution and ORI and ultimately that of the complainant as well. When the complainant is retaliated against based on a good faith misconduct allegation, the institution and ORI must take assertive action to protect the complainant. Only then will the process of identifying and resolving research misconduct work well and be fair to all. However, in assessing the merits of the allegation of misconduct, ORI and the institution must remain objective and be fair to the accused. This careful balance is important to the process and is something that the complainant needs to understand when he or she goes forward with an allegation of misconduct.

1. 42 USC 289b establishes ORI's authority to respond to allegations of research misconduct involving research funded by the Public Health Service or applications for such funds. In 2000, HHS delegated additional authorities to ORI to undertake programs in education, responsible research, evaluation, research, promotion of research integrity, and prevention of research misconduct. Office of the Secretary. Statement of organization, functions, and delegations of authority. Federal Register 61:30600-30601, 2000.

2. All of the cases discussed in this paper involving complainants and acts

of alleged retaliation were handled under the original regulations adopted in 1989 at 42 CFR Part 50, Subpart D. A new regulation was published on May 17, 2005, and became effective on June 16, 2005. It will be codified at 42 CFR Part 93 and is available on the ORI website at http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf. Although the terminology has changed somewhat in 42 CFR Part 93, the basic principles of providing confidentiality for individuals making good faith allegations of research misconduct and protecting them from retaliation are the same. See 42 CFR 93.210 and 93.300(d) and (e).

3. 42 CFR 93.308(b) and 93.312(b).

4. 42 USC 289b(e). ORI has also added protections against retaliation for committee members who act in good faith in investigating allegations of research misconduct on behalf of the research institution. 42 CFR 93.210.

5. Office of Research Integrity: Guidelines for Institutions and Complainants: Responding to Possible Retaliation Against Complainants in Extramural Research. 1995 http://ori.dhhs.gov/misconduct/Guidelines_whistleblower.shtml

6. 42 CFR 93.210

7. 42 CFR 93.103

8. Office of Research Integrity. ORI provides working definition of plagiarism. ORI Newsletter. 1994; December: 3. <http://ori.dhhs.gov/policies/plagiarism.shtml>

9. ORI Position Paper: The Whistleblower's Conditional Privilege to Report Allegations of Scientific Misconduct. http://ori.dhhs.gov/documents/whistleblower_conditional.pdf

10. Research Triangle Institute. Consequences of whistleblowing for the complainant in misconduct in science cases. 1995. <http://ori.dhhs.gov/documents/consequences.pdf>

11. 42 CFR 93.108

12. 5 USC 552a

13. *Arroyo v. Rosen*, 102 Md.App.101, 648 A.2d 1074 (Md. Ct. App. 1994). In this case, a scientist who was accused of research misconduct successfully sued the complainant for defamation and invasion of privacy and was awarded a jury verdict of \$75,001. The court ruled that the complainant had a qualified privilege to report her allegations of misconduct, but violated that privilege by publicly disclosing the allegations after the institution exonerated the accused of all charges of misconduct.

14. 42 CFR 93.300

15. 42 CFR 93.304(e) and (f); 42 CFR 93.305(b); 42 CFR 93.304(b); 42 CFR 93.310(f); 42 CFR 93.304(k); 42 CFR 93.500.