

**ANONYMITY AND PSEUDONYMITY IN
WHISTLEBLOWING TO THE U.S.
OFFICE OF RESEARCH INTEGRITY**

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SPECIAL ARTICLE

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Anonymity and Pseudonymity in Whistleblowing to the U.S. Office of Research Integrity

ABSTRACT

Given the concerns expressed by members of the academic and legal community about whether (and how) to handle anonymous and pseudonymous allegations of scientific misconduct, this paper summarizes the experiences of the Office of Research Integrity and its predecessor from 1989 through 1997. Although the record shows that research institutions and the ORI have treated such allega-

tions seriously, the fraction of complainants to the ORI who remain anonymous is small (8% of 986 allegations); few anonymous complaints are sufficiently substantive to be pursued (4% of the 357 formal cases opened in the ORI); and only 1 of these 13 cases resulted in an ORI finding of scientific misconduct (Acad. Med. 1998;73-467-472).

The Office of Research Integrity (ORI) was created in June 1992 within the U.S. Public Health Service (PHS), a part of the U.S. Department of Health and Human Services, to handle allegations and reports of inquiries and investigations of scientific misconduct in biomedical research related to applications and awards for PHS grants, fellowships, and cooperative agreements. (The predecessor to the ORI, created in the PHS in 1989, was called the Office of Scientific Integrity [OSI].) Scientific misconduct is defined by the 1989 PHS regulations as

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.

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(For a related article, see page 534)*

While most allegations of scientific misconduct have come to the ORI from complainants whose identity is known to it, a small percentage of the allegations have been made anonymously or under pseudonyms.

Members of the academic and legal community have expressed concerns about whether (and how) to treat anonymous and pseudonymous allegations. Although some complainants may legitimately fear retaliation by an angry respondent or institutional official, others may try to bring forward unfounded or unfair complaints-without being required to document the allegations or to defend their accuracy-in an attempt to damage the accused person's reputation. Thus, a discussion of the ORI's experiences with the small number of anonymous or pseudonymous complaints may help to put the issue into perspective and may allay some of the academic community's fears about the handling of such complaints.

The ORI's records show that, of the 986 allegations made in letters and telephone calls to the ORI from 1993 through 1997, approximately 8% were anonymous (Table 1). In addition, the records show that anonymous complainants raised the allegations in only 4% of the 357 cases that were formally opened by the ORI or the OSI from May 1989 through 1997. These cases involved inquiries or investigations that were conducted by the institutions that employed the accused (Table 2). It is important to understand the terminology used by the ORI. "Anonymous" complainants are

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Table 1

<u>Year</u>	<u>Total</u>	<u>Anonymous</u>	
		<u>No.</u>	<u>%</u>
1993	197	9	5
1994	185	5	3
1995	244	29	12
1996	197	26	13
1997	163	13	8
TOTAL	986	82*	8

*Only three of the 82 anonymous allegations become formal cases. Of the remainder, 53 were allegations that involved credit or authorship disputes between collaborators or other concerns that did not fall under ORI's policy and the Public Health Service (PHS) definition of scientific misconduct. Of these 53 allegations, 24 were referred to other federal offices or agencies (these were allegations of Fiscal abuses, mistreatment of human or animal subjects, and criminal matters or were issues under the jurisdiction of agencies outside the PHS). Of the remaining 29 allegations, four involved issues that did not fall under PHS or other federal funding jurisdiction, and 22 were not adequately documented and/or the ORI found no evidence to warrant further review.

those whose identities are unknown both to the ORI and to the research institution. Some "anonymous" persons may use names that are clearly pseudonyms. In addition, the term "confidential status" is used for those whose identities are known to their research institutions but not to the ORI. The purpose of this article is to analyze the types of allegations and formal cases in which the complainants were

Table 2

<u>Year</u>	<u>Anonymous</u>		
	<u>Total</u>	<u>No.</u>	<u>%</u>
1989	72	6	8
1990	45	0	0
1991	30	0	0
1992	29	4	14
1993	35	1	3
1994	38	0	0
1995	49	2	4
1996	39	0	0
1997	20	0	0
TOTAL	357	13	4

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anonymous or pseudonymous to the ORI and to compare the outcomes from such cases with those in which the complainants were known to the institution and/or the ORI. This analysis suggests that the ORI and the research institutions to which it has referred such cases have taken anonymous allegations as seriously as those from known complainants. However, it is more difficult-impossible when there is no follow-up by the complainants to their anonymous letters and anonymous telephone calls-to obtain further information from or to provide feedback on ORI outcomes to, anonymous complainants. Their allegations often either have too few factual details to pursue in depth or do not fall under PHS/ORI authority (see the footnote to Table 1). Although the numbers are small, the formal cases in which complainants remained anonymous appeared to result in a smaller proportion of the institutional conclusions being misconduct than was the case when the complainants' identities were known.

ORI FORMAL CASES-ANONYMOUS COMPLAINANTS

The following are summaries of the seven formal cases based on allegations made by anonymous complainants to the ORI

and the National Institutes of Health (NIH) that the ORI opened from 1992 through 1991.

Case 1. The ORI received a copy of an anonymous letter of allegation that had been sent to an NIH institute that was funding a research grant at an eastern university. The complainant alleged that the principal investigator and staff on the grant had falsified records for case studies of mental patients that were summarized in a progress report to the NIH. The complainant wrote

Please look into this situation immediately. If I do not hear about an investigation soon, I will have no choice but to bring this to the attention of the media. The only reason I do not sign this letter is because DL has a habit of getting rid of personnel who challenge his authority.

This letter was followed by a newspaper article several months later; the article quoted a person identified as an administrative staff member, who may or may not have been the original complainant. In the interim, the ORI had re-ferred the original allegations to the university, which conducted an inquiry and found no evidence of falsification of data. The patients were found to exist, and their case studies were found to have been accurately reported to the NIH. Also, the principal investigator had informed the NIH about the difficulty in recruiting such patients for the study. The ORI accepted the institution's finding that no further investigation was warranted. The respondent and the university

also made public the results of the inquiry, in order to correct the negative information printed previously in the press.

Case 2. In a case involving a professor at an eastern university, an anonymous reviewer who had received a grant application for a federal agency (which application had also been submitted to the NIH) alleged that the professor had plagiarized the words of a previously published paper by others and had failed in his grant applications to give credit to others for the research materials they had developed. The university investigation found that the accused professor had committed plagiarism amounting to scientific misconduct. The respondent admitted that he had intentionally used language and pictures from the paper without attribution in order to improve his grant application. The ORI concurred with the university report, which formed the basis for a voluntary agreement between him and the ORI; under the agreement, the professor was required to certify to the ORI for three years the accuracy of attribution of all sources of information in any PHS grant application. The ORI published the misconduct finding and his name in the Federal Register, The *NIH Guide to Grants and Contracts*, and the *ORI Newsletter* to inform the scientific and research administrative community.

Case 3. In a case involving professors at an eastern college, an anonymous letter was sent to the ORI and to the press alleging that there were conflicts of interest and possible falsification of research reports by a new "spin-off" company involving university faculty and university investment. The college president established an inquiry committee composed of outside scientists and lawyers. When the inquiry committee and staff wanted to obtain further information about the basis for the allegations from the anonymous complainants, the president published a letter in the local press, asking the complainants to come forward to give testimony, but none did so. However, one of the complainants, identifying himself as "B. Wissel" ("whistle"-which he said was a pseudonym for a group of complainants), called the ORI and tried to obtain the confidential college report. He declined to identify himself, and in accord with ORI policy the report was not provided to him. The college found insufficient evidence to warrant an investigation, and the ORI accepted that finding.

Case 4. In a case involving a department chairman at a midwestern research institute, the ORI received a detailed, anonymous letter alleging "irregularities" amounting to falsification of data (laboratory assay results) in five papers published during the previous decade. The ORI referred the allegations to the institute, which did not make a finding of scientific misconduct. In its investigation, the data were

identified for some experiments, and the shared method was confirmed for other experiments; no evidence of falsification was found. The ORI accepted the institute's conclusion and made no finding of scientific misconduct. An institute official also noted to the ORI that, although the complainant had remained anonymous, there were two groups of staff members who were hostile to each other and to the new department chairman, and one group might have used anonymous allegations, among several other approaches, in an attempt to discredit him.

Case 5. In a case involving professors at a southern university, the ORI received an anonymous letter stating, "I have recently heard about misrepresentation in a large study . . . I cannot identify myself for fear of reprisal." The complainant alleged that numerous subjects admitted to a drug abuse study did not meet protocol requirements. The ORI referred the allegation to the university for inquiry. The inquiry committee found that the complainant had apparently been uninformed: because of the difficulty in enrolling the target group of subjects, the protocol had been revised with the approval of the funding agency. The research subjects had been appropriately classified, and the university found no evidence to warrant further investigation of scientific misconduct. The ORI concurred with the institution's report.

Case 6. In a case involving a professor at an eastern university, the OSI and the NIH Office for Protection from Research Risks (OPRR) received a detailed, anonymous letter alleging violations of the study protocol and of standards for maintenance of the data in a cancer drug study, which resulted in some deaths from drug toxicity. The anonymous letter alleged that the problems were being suppressed and stated: "A full investigation is needed to prevent further patient mistreatment. Faculty participating in deception are likely to blame low-level employees." The ORI referred the allegations to the university for an inquiry, which found no evidence to warrant an investigation. The deaths had been reported to the institutional review office, which was then to report them to OPRR and the Food and Drug Administration (FDA). There was no evidence of suppression of the adverse results by the investigators. The ORI reviewed the report (as did the FDA and the OPRR) and concurred with the university's finding.

Case 7. In a case involving faculty at a midwestern university, a detailed, anonymous letter to the Federal Bureau of Investigation (FBI) was referred to the ORI. The author of the letter alleged falsification of results in two publications involving clinical work among female patients. The ORI referred the allegations to the university, where an inquiry

found no evidence to warrant further investigation. The ORI reviewed the medical and statistical issues and concurred with the university's finding that the complainant either had misunderstood the data presented or had an honest disagreement with its interpretation, which was not scientific misconduct.

Thus, of the seven allegations received by the ORI in six years from anonymous complainants that became formal cases, five of these cases ended at the institutional inquiry stage with findings of insufficient evidence to warrant further investigation. The remaining two anonymous-complainant cases led to formal investigations at the institutions. One found no evidence of scientific misconduct. The other (the case involving the reviewer of a grant application for another federal agency) led to an investigation that resulted in a finding, by both the university and the ORI, of scientific misconduct on the part of the accused professor-in this case for plagiarism of material used in a PHS grant application.

OSI FORMAL CASES-ANONYMOUS COMPLAINANTS

During the first year of its operation (1989), the OSI (the predecessor of the ORI) reviewed anonymous allegations in six cases, which were handled primarily by administrative review at the NIH. Most of the allegations fell outside the ORI's jurisdiction (except for Cases C and F) and would not have been formally opened as cases by the ORI (which succeeded the OSI in mid-1992).

Case A. An anonymous caller to the NIH alleged, without providing any specifics or documentation, that there were fabricated experiments in a certain grant application from a western university. While investigating related allegations of fiscal misconduct, the NIH auditors and a scientific expert from the funding institute reviewed the original data for one of three papers reported in the application. They found no evidence of scientific misconduct. On the basis of their report, the OSI closed the case.

Case B. In an anonymous letter sent simultaneously to the director of the NIH, an official of an eastern university, the mayor of the nearby city, and the local press, a complainant alleged that there were improprieties involving an NIH grant to the university and relating to a faculty member's connections to a local company. The university conducted an inquiry, which found no evidence of misconduct. The OSI closed the case for lack of an allegation that fell under the PHS definition of scientific misconduct.

Case C. An anonymous letter sent to the NIH alleged various irregularities under an NIH grant awarded to an east-

ern university, including improper manipulation of data by a faculty member, specifically, the biasing of the randomization of human subjects to an experimental group. Following the NIH's referral of the allegations to the university, the affiliated medical school conducted an inquiry that included interviews of the involved staff members. No evidence of scientific misconduct was found. The OSI concurred with the university's determination that no further investigation was warranted in this case.

Case D. In a telephone call to the NIH, a complainant who remained anonymous alleged that a faculty member at a midwestern university had committed various improprieties related to a grant application, including not having performed the work described. The caller could not identify the title or number of the grant application, but he claimed that death threats had been made against him and that the university was involved in a cover-up. OSI staff found no record in the NIH's IMPAC database that the accused faculty members had submitted any grant applications to the NIH. Consequently, the case was closed for lack of PHS jurisdiction.

Case E. In an anonymous letter to the NIH, the complainant made various allegations about a research program at an eastern medical school. The complainant identified no NIH grant, and OSI staff found no relevant grant applications. Furthermore, the allegations appeared to be that the research was sloppy in ensuring a representative sampling of the entire patient population. The OSI closed the case because the allegation lacked adequate documentation and appeared to fall outside the PHS definition.

Case F. In two anonymous letters to the OSI involving a PHS intramural research program, the writer alleged that some assays had not been carried out as described in one publication and that measurements of an enzyme activity had not been performed as claimed in another paper. The OSI referred the allegations to the institution for inquiry. Some data were found, but other data were reported to have been discarded. An error was found in the citation to the method, which became the subject of a published correction in the journal. Later that year, the HHS Office of the Inspector General (OIG) received a follow-up letter reiterating the allegations. The anonymous letter claimed that the (unnamed) employee who had originally reported the allegation had been forced to leave the institution and that no action had been taken after the investigation. OSI staff checked the available original data and concluded that they could have been obtained with the modified assay described in the paper. The OSI accepted the conclusion in the institution's inquiry report that no further investigation was war-

board asking whether anyone had information about a certain type of research. The ORI declined to do so. Although the ORI uses the Internet to disseminate general information, it is ORI policy not to discuss sensitive information or confidential cases on the Internet, in order to avoid possible breaches of confidentiality. Because the anonymous complainant did not contact the ORI again, the file was closed for lack of an allegation.

Case III. An anonymous person called the ORI and identified himself as a scientist who was working as a consultant to a law firm. The firm represented a group of faculty members at an eastern university who were preparing allegations against their new division chief. This call was followed by a conference call with the anonymous group of complainants, who discussed their general concerns with ORI staff. However, they did not bring forward allegations that the ORI could pursue under the PHS definition of scientific misconduct. The file was closed.

Case IV. A caller to the ORI used a pseudonym in his first calls. The complainant asked how to make allegations to the institution or to the ORI about questionable data for papers. Only some time later did the complainant identify himself/herself, seek protection as a whistleblower, and file specific allegations of falsification of data, which the ORI later confirmed.

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CONCLUSIONS

First, many of the allegations made anonymously to the ORI either have contained too little detail to pursue or did not fall under the PHS definition of scientific misconduct or under the grant application and award authority of the PHS (see the footnote to Table 1). Furthermore, when letters or calls are totally anonymous, with no return call or contact point provided by the complainant, there is no way for the ORI to get more information. Also, there is no way for the ORI to inform such a complainant about the outcome of an ORI or institutional review of the allegations.

Second, it is clear that the percentage of anonymous complainants to the ORI has been small: only 8% of the 986 allegations received in five years (Table 1), and only 4% of the 357 formal cases opened in nine years by the ORI and the OSI (Table 2).

Third, the outcomes of ORI-OSI formal cases in which the complainants remained anonymous have a lower propor-

tion of findings of scientific misconduct-1 of 13 cases (8%)-than do the outcomes of formal cases in which the complainants were known-91 of 315 cases (29%) (Table 3). This difference may be partially a result of the fact that when the complainant is known, more information, documentation, and testimony can be obtained from the complainant to help prove that scientific misconduct has occurred.

It is noteworthy that in most instances in which the complainants were anonymous or used pseudonyms in their initial calls, they later identified themselves to ORI staff.

Therefore, the ORI could collect more information from them. In a few cases, however, callers to the ORI have used pseudonyms while giving telephone numbers or mailing addresses where they could be contacted; others have used attorneys, other scientists, or a whistleblowers' organization as a liaison. These can be useful communication routes when complainants insist on remaining anonymous or pseudonymous. In a few ORI cases, the complainant has requested confidential status so that the ORI will not disclose his or her name outside the ORI. The ORI generally accepts that condition and continues with its review of the allegation. In some cases, however, the ORI informs such complainants that pursuing their allegations will depend heavily on their testimony as witnesses and that their ongoing participation in the inquiry or investigation may be essential; if such complainants are not willing to testify, the cognizant institutions and/or ORI may be unable to resolve the cases.

In summary, the experiences of the ORI and OSI from 1989 through 1997 in handling allegations of scientific misconduct show few complainants to the ORI have been anonymous; such complaints have been taken seriously by the ORI and institutions; however, very few anonymous complaints have been sufficiently substantive to be pursued in formal inquiries or investigations, and only one case stemming from an anonymous allegation has led to a finding of scientific misconduct.

The author thanks Mr. Gary Lipschultz, ORI Program Analyst, who conducted the ORI database searches and provided the numerical summaries of cases, and Mrs. Karen Gorirossi, ORI Editor, who edited the manuscript.