ORI Handbook for Institutional Research Integrity Officers

Introduction

The ORI Handbook for Institutional Research Integrity Officers is designed as a reference work for institutional officials who have responsibilities related to the handling of allegations of scientific misconduct involving biomedical or behavioral research or research training supported by the Public Health Service (PHS) including Research Integrity Officers, institutional administrators, inquiry/investigation committee members, and general counsel. The PHS regulation (42 C.F.R. Part 50, Subpart A) defines scientific misconduct 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 interpretation or judgments of data." (See Appendix B).

This guide is non-binding and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, officers or employees.

The Office of Research Integrity (ORI) developed the handbook to facilitate the partnership established between itself and institutions to pursue allegations of scientific misconduct efficiently and effectively. Institutions have the primary responsibility for responding to scientific misconduct. ORI primarily has a monitoring and oversight role to ensure that applicant and awardee institutions are complying with the PHS regulation and that the resolution of scientific misconduct allegations adequately protects PHS funds and the integrity of PHS-supported research.

ORI realizes that institutions must respond to various types of misconduct and must comply with regulations promulgated by various government offices. However, the authority and responsibility of ORI are limited by the PHS regulation, and therefore, this handbook is focused on the respective roles of institutions and the ORI in implementing that regulation. Nevertheless, ORI produced this handbook to support and facilitate a step taken by many institutions to address the problems encountered in handling allegations of scientific misconduct the appointment of a Research Integrity Officer (RIO) to coordinate all related activities. ORI designed the handbook to make the coordination task easier by clearly describing the responsibilities of institutions and the ORI in the text and providing the various documents related to the handling of allegations of scientific misconduct in PHS-supported research and research training in the appendices:

Appendix A - Public Health Service Act § 493

Section 493 establishes ORI and describes its various authorities, including requirements that each entity receiving PHS research funds establish an administrative process for responding to allegations of scientific misconduct and report to ORI any investigation of alleged scientific misconduct that appears substantial and (2) requires the Secretary of Health and Human Services to establish standards for the protection of whistleblowers.

Appendix B - PHS Regulation on Handling Allegations of Scientific Misconduct (42 C.F.R. Part 50, Subpart A)

This regulation places responsibilities for dealing with and reporting possible misconduct in science on institutions applying for or receiving PHS support for research or research training in the biomedical or behavioral sciences. The regulation also states the authorities of ORI. The regulation was published in the Federal Register on August 8, 1989.

Appendix C - ORI Model Policy for Responding to Allegations of Scientific Misconduct

ORI issued the Model Policy in April 1995 to assist institutions to develop the policy required by the PHS regulation. The Model Policy is advisory; it is not mandatory. The Model Policy may be modified or partially or wholly adopted. The Model Policy may also serve as a source of provisions that an institution may want to incorporate into its existing policy. The Model Policy exceeds the minimal requirements for a policy; portions of the model that specifically address regulatory requirements reference the section number from the PHS regulation.

Appendix D - ORI Model Procedures for Responding to Allegations of Scientific Misconduct

ORI also issued the Model Procedures in April 1995 to assist institutions to develop detailed procedures for handling allegations of scientific misconduct. The Model Procedures cover the preliminary assessment of an allegation, the conduct of inquiries and investigations, and the preparation of reports on the inquiry and investigation. The Model Procedures also are advisory; they are not mandatory. The Model Procedures may be modified or partially or wholly adopted.

Appendix E - Responsibilities of Deciding Official and Research Integrity Officer

This document compiles the responsibilities assigned to the Deciding Official and Research Integrity Officer in the Model Policy and Model Procedures. The lists may be used to design the respective roles.

Appendix F - ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliations Against Whistleblowers in Extramural Research

ORI issued these guidelines in November 1995 to assist institutions to meet their obligation to undertake diligent efforts to protect the reputation and position of good faith whistleblowers. The guidelines offer institutions three options for handling retaliation complaints: settlement, investigation, and arbitration.

Appendix G - Guidelines for Hearings before the Research Integrity Adjudications Panel, Departmental Appeals Board, Department of Health and Human Services

Respondents receiving a formal charge letter of scientific misconduct from ORI may request a hearing before the Research Integrity Adjudications Panel, Departmental Appeals Board. The guidelines describe the procedures for requesting and conducting a hearing.

Appendix H - Administrative Actions

This document describes seven administrative actions that have been imposed on individuals found to have committed scientific misconduct. The role of the employing institution in implementing each action is described.

Appendix I - Legal Decisions and Rulings

This appendix presents court decisions, either Federal District Court or various Federal Courts of Appeal, and rulings by the Departmental Appeals Board that address significant issues related to scientific misconduct and ORI.

Appendix J - Annual Report on Possible Research Misconduct

Institutions are required to submit this report annually. The report asks about the availability of policies and procedures for responding to allegations of scientific misconduct, the number of allegations received and inquiries /investigations conducted, the restoration of reputations of exonerated individuals, the protection of whistleblowers, the name of the official responsible for implementing the PHS regulation, and the name and address of the institution. Information gathered through the report is used to maintain the assurance database and to provide feedback to institutions through the ORI Newsletter.

Appendix K - Review Report Form on Institutional Policies

ORI uses this report form to guide its review of institutional policies and to inform institutions about the provisions of the PHS regulation that are not adequately represented in the institutional policy. The institution is asked to submit a revised policy that corrects the deficiencies within 90 days of the date of the accompanying letter. Institutions also may use the report form to review their policy.

Appendix L - Small Organization Policy Statement

This statement may be submitted to ORI in lieu of an institutional policy by an organization that has fewer than 10 employees.

Appendix M - Initial Assurance Form

This is the form that institutions used to establish their initial assurance between 1989-1995. Beginning in 1996, institutions submitted their initial assurance by signing the face page of the grant application. However, the initial assurance form is still used in special circumstances by ORI.

Research Integrity Officers may direct their calls as follows:

Office of the Director, Phone: (301) 443-3400, Fax: (301) 443-5351, Subject: Overall management and direction of the office.

Division of Research Investigations, Phone: (301) 443-5330, Fax: (301) 594-0039, Subject: Allegations, inquiries, investigations, Model Procedures.

Division of Policy and Education, Phone: (301) 443-5300, Fax: (301) 443-5351, Subject: Assurances, annual reports, compliance reviews, retaliation complaints, institutional policy reviews, regulations, Freedom of Information Act (FOIA) requests, Model Policy, ORI Whistleblower Guidelines, publications, conferences, and workshops.

Research Integrity Branch, Office of the General Counsel, Phone: (301) 443-3466, Fax: (301) 594-0041, Subject: Legal matters, voluntary exclusion agreements, hearings.

Research Integrity Officers may also find it useful to regularly consult the ORI Home Page: http://www.ori.hhs.gov.

Return to Table of Contents

Institutional Responsibilities

Introduction

The PHS Regulation (Appendix B) places several requirements on institutions applying for or receiving research funds under the PHS Service Act § 4931 (Appendix A), because by applying for or accepting PHS funds, an institution assumes legal and financial accountability for the awarded funds and for the performance of the supported activities. These requirements are described below in the following sections: (1) Developing an Administrative Process; (2) Submitting an Assurance; (3) Keeping an Assurance Active; (4) Responding to Allegations of Scientific Misconduct; (5) Restoring Reputations; (6) Protecting Whistleblowers; (7) Cooperating with ORI; (8) Fostering Research Integrity; and (9) Informing Scientific and Administrative Staffs. Six of these requirements (1, 2, 3, 7, 8, 9) apply to institutions even if they have not received any allegations of scientific misconduct. As the result of a finding of scientific misconduct, an institution may also be obligated to assist in implementing administrative actions imposed on individuals.

Developing an Administrative Process

To become eligible for funding in compliance with the PHS Act, an institution must develop policies and procedures that establish an administrative process for reviewing, investigating, and reporting allegations of scientific misconduct involving biomedical or behavioral research supported by PHS or for which support has been requested. This process must comply with the provisions of the PHS Regulation (42 C.F.R. § 50.103 and § 50.104). An administrative process that complies with the PHS Regulation is presented in the Model Policy. (Appendix C). This document may be used freely in developing the administrative process for your institution. Detailed procedures for conducting inquiries and investigations are presented in Appendix D.

If an institution is very small (typically fewer than 10 employees), the institution may be unable to conduct inquiries or investigations without encountering real or apparent conflicts of interest. Under this circumstance, the institution may submit a Small Organization Policy Statement to ORI (Appendix L). The Small Organization Policy Statement indicates that the institution will contact ORI regarding all scientific misconduct allegations received so ORI may assist the institution in conducting inquiries and investigations involving PHS-related research. The institution also agrees, under the signature of a responsible official, to inform all of its employees involved in PHS-related research of this policy.

Submitting an Assurance

An institution submits its assurance each time an official signs the face page of an application for a research or research training grant or cooperative agreement. In some cases, the institution may be asked to submit an initial assurance form (PHS 6315, Appendix M) to ORI (42 C.F.R. § 50.103(a)). In submitting the assurance, the institution declares that:

it has an administrative process for handling allegations of scientific misconduct that complies with the PHS Regulation; and

it will follow its administrative process and the regulatory requirements when responding to allegations of misconduct in science.

The names of institutions submitting an assurance are placed in the ORI Assurance Database. Incoming applications and pending awards are checked automatically against this database to ensure that PHS research funding is awarded only to institutions that have an active assurance on file.

Keeping an Assurance Active

Institutions keep their assurance active by (1) filing their Annual Report on Possible Research Misconduct, (2) submitting their policies and procedures to ORI upon request; (3) maintaining policies and procedures that comply with the PHS regulation; and (4) complying with the provisions of the PHS Regulation.

Annual Report on Possible Research Misconduct

Each institution must submit an Annual Report on Possible Research Misconduct2 (PHS form 6349, Appendix J) to ORI (42 C.F.R. § 50.103(b)). This annual report requests: (1) the name and address of the institutional official responsible for implementing the PHS Regulation; (2) the availability of an administrative process for responding to allegations of scientific misconduct; (3) aggregate information on allegations received and inquiries and investigations conducted; and (4) other activities the institution took to meet the requirements of the PHS Regulation during the previous calendar year. ORI mails this form to institutions in January of each year and institutions must respond by the designated deadline, usually March 1. Data from the Annual Report from each institution is used to update the ORI Assurance Database. Other information provided in the Annual Report may be reported in the aggregate in the ORI Newsletter. If an institution does not submit the required Annual Report, its institutional assurance lapses, and the institution is ineligible to apply for or receive PHS research funds.

Policies and Procedures

ORI may request a copy of the policies and procedures an institution is required to establish by the PHS regulation (42 C.F.R. § 50.103(c)(1)) for the following reasons: (1) the institution is included in the annual 5 percent review sample; (2) the institution did not adequately respond to the pertinent questions in its Annual Report; or (3) the institution is involved in a scientific misconduct case, compliance review, or retaliation complaint.

The institutional policies and procedures are reviewed to determine whether they adequately reflect the provisions of the PHS regulation. If deficiencies are noted, a report (Appendix K) listing the deficiencies is sent to the institution with a request that a revised policy correcting the deficiencies be submitted within a stipulated time period (usually 90 days of the date of the transmittal letter). Otherwise, a letter accepting the policies and procedures is sent to the institution.

Responding to Allegations of Scientific Misconduct

Institutions have the primary responsibility for responding to allegations of scientific misconduct involving biomedical or behavioral research supported under the PHS Act or for which support has been requested. Detailed procedures for implementing the administrative process suggested in the Model Policy are presented in the Model Procedures. These procedures may be used freely in developing the procedures your institution will follow in implementing its administrative process for responding to allegations of scientific misconduct.

Restoring Reputations

The PHS Regulation requires institutions to undertake "diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed" (42 C.F.R. § 50.103(d)(13)). These efforts should be undertaken in consultation with the individual against whom allegations were made. Institutions are asked to report in the Annual Report the efforts they have undertaken to restore reputations of exonerated individuals. Past reports have indicated that institutions primarily take three steps to protect/restore reputations: (1) maintain confidentiality of proceedings; (2) inform all persons involved in the proceedings of the outcome; and (3) remove materials concerning the allegation from the personnel file of the exonerated individual. Some institutions also reported publishing an article in the campus newspaper or issuing an all-hands memorandum, particularly if the allegation became public.

Protecting Whistleblowers

The PHS Regulation also requires institutions to undertake "diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations" (42 C.F.R. § 50.103 (d)(13)). A regulation to protect good faith whistleblowers in scientific misconduct cases is under development. In the meantime, ORI has developed interim guidelines for institutions that have received allegations of retaliation from whistleblowers (Appendix F). Several institutions have used the guidelines in responding to retaliation complaints. Institutions have reported in their Annual Reports that they have taken the following actions to protect whistleblowers: (1) establishing a policy prohibiting retaliation; (2) creating procedures for investigating retaliation complaints; (3) maintaining confidentiality of the proceedings; (4) cautioning respondents against retaliating; (5) reminding department chairs and deans about the protections afforded to good faith whistleblowers; (6) monitoring for possible retaliation; (7) imposing sanctions on retaliators; (8) relocating the whistleblowers; (9) informing appropriate officials if a scientific misconduct allegation was made in good faith; and (10) publicly acknowledging that the whistleblower did the "right thing."

Several institutions include a provision in their policies and procedures authorizing disciplinary actions against "bad faith" whistleblowers.

Cooperating with ORI

ORI is responsible for reviewing institutional investigations involving PHS funding to determine "whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness, and competence" (42 C.F.R. § 50.104(a)(6)). ORI also has the right "to perform its own investigation at any time prior to, during, or following an institution's investigation" (42 C.F.R. § 50.104(a)(6)). In addition, if a hearing is requested by the respondent, ORI must present its misconduct findings (which are frequently based on an institutional investigation) before the Departmental Appeals Board (DAB) (Appendix G). Consequently, ORI relies on institutions to inform and cooperate with ORI "with regard to each investigation of possible misconduct" (42 C.F.R. § 50.103(c)(4)). Specific requirements for reporting to ORI are noted in the PHS Regulation.

In addition, an institution is required to provide its policies and procedures to ORI, upon request, and the documentation for any institutional inquiry which concludes that an investigation was not warranted. ORI will provide the institution with a copy of its final oversight report on each investigation (or inquiry if ORI has requested submission of the report) conducted by the institution and its final report on investigations conducted at the institution by ORI.

Fostering Research Integrity

Although the PHS Regulation primarily addresses institutional responsibilities for responding to allegations of scientific misconduct, it also requires institutions to "foster a research environment that

discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested" (42 C.F.R. § 50.105).

Informing Scientific and Administrative Staff

Finally, the PHS Regulation requires institutions to inform their scientific and administrative staffs about the policies and procedures they have adopted for responding to allegations of scientific misconduct and "the importance of compliance with those policies and procedures" (42 C.F.R. § 50.103(c)(2)). Institutions have employed various methods to comply with this requirement including publishing their policies and procedures in faculty and staff handbooks, posting them on electronic bulletin boards, disseminating them in all-hands memoranda, and discussing them in seminars or courses.

Implementing Administrative Actions

Institutions may be required to assist in implementing administrative actions where, for example, the administrative action affects the submission of grant applications involving an employee who has committed scientific misconduct. The Department of Health and Human Services (HHS) and/or PHS has imposed one or more of the following administrative actions on individuals when scientific misconduct has been found: (1) debarment from receiving Federal grant and contract funds; (2) prohibition from PHS advisory service; (3) certification of sources; (4) certification of data; (5) plan of supervision; (6) retraction of articles; and (7) correction of articles (Appendix H). Institutions may have implementation responsibilities in six actions: 1, 3, 4, 5, 6, and 7.

Return to Table of Contents

ORI Oversight

Introduction

The Office of Research Integrity (ORI) is responsible for implementing the PHS Regulation requiring institutions to respond to allegations of scientific misconduct in biomedical and behavioral research supported by PHS or for which support is requested. The Assistant Secretary for Health established ORI3 in May 1992 to oversee and direct the PHS research integrity effort.4 In June 1993, ORI became an independent entity within HHS with the Director, ORI, reporting directly to the Secretary of HHS when President Clinton signed the NIH Revitalization Act of 1993.

ORI Mission

ORI is responsible5 for:

assuring that all institutions applying for or receiving PHS funds have appropriate mechanisms for dealing with allegations of scientific misconduct and the protection of whistleblowers, conducting reviews of institutional programs to determine whether they comply with Federal requirements, and investigating and resolving problems of institutional compliance;

overseeing the conduct of institutional investigations of scientific misconduct allegations through the review of the reports of these investigations and the imposition of administrative actions when misconduct is found;

conducting inquiries and investigations into scientific misconduct allegations at institutions when necessary and conducting all investigations of such allegations in PHS intramural programs;

developing and presenting findings of scientific misconduct in hearings before the DAB;

developing regulations and policies to assure full and fair investigations of scientific misconduct allegations, establishing appropriate due process protections for those accused of misconduct, and protecting against institutional cover-up of misconduct or retaliation against whistleblowers; and

promoting research integrity through collaborative efforts with colleges and universities, scientific and professional organizations, and other Federal agencies.

ORI Structure

ORI is composed of the Office of the Director (OD), the Division of Research Investigations (DRI), and the Division of Policy and Education (DPE). In addition, ORI receives legal services from the Research Integrity Branch, Office of the General Counsel (OGC), HHS.

OD provides overall management and administrative support for the office. DRI assesses allegations, monitors and reviews institutional inquiries and investigations, conducts inquiries and investigations at extramural institutions, and conducts investigations in PHS intramural programs. DPE develops regulations, policies, and procedures, manages the assurance program, conducts institutional compliance reviews, oversees institutional responses to complaints of retaliation against whistleblowers, monitors the implementation of administrative actions, responds to FOIA and Privacy Act requests, produces publications, and organizes conferences and workshops. OGC provides legal advice on all ORI activities, represents ORI before the DAB, and assists the Department of Justice in litigation involving scientific misconduct.

Return to Table of Contents

PHS Offices that Handle Research Abuses

In addition to ORI, four other offices within PHS handle abuses of the research process: (1) the Office for Protection from Research Risks handles misuse of human and animal research subjects; (2) the Office of Management Assessment handles financial mismanagement; (3) the Office of Extramural Research handles conflicts-of-interest; and (4) the Office of Regulatory Affairs handles misconduct in specifically regulated research. The first three offices are located within NIH; the fourth office is located within FDA.

National Institutes of Health (NIH)

Office for Protection from Research Risks (OPRR)--This office is responsible for responding to allegations of misuse of human and animal subjects in PHS-supported research. Allegations in this area involve improper care of research animals, the failure to obtain informed consent from human subjects, mistreatment of human and animal subjects in research, and the failure to obtain approval from an institutional review board or animal care committee. Contact OPRR at (301) 496-7005.

Office of Management Assessment (OMA)--This office, through its Division of Program Integrity, handles allegations of financial waste, fraud, and abuse of NIH research funding. Contact OMA at (301) 496-1361.

Office of Extramural Research (OER)--This office is responsible for the implementation of the Objectivity in Research (conflict-of-interest) regulation. Contact OER at (301) 435-0949.

Food and Drug Administration (FDA)

Office of Regulatory Affairs (ORA)--This office handles allegations of misconduct in regulated research under FDA jurisdiction that focuses on testing and evaluating human and animal drugs, food and feed additives, and human biological products and medical devices through its Division of Compliance Policy, Bioresearch Program Coordination at (301) 827-0420.

ORI, OPRR, OMA, OER, and ORA only deal with applications or awards for research supported by the one or all PHS agencies. Other Federal agencies such as the National Science Foundation, the Veterans Administration, the Department of the Navy, and the Department of Agriculture also have offices to handle abuses of the research process under their jurisdiction.

These abuses do not cover all the problem areas associated with the research process. Other areas--authorship responsibilities, collaboration agreements, data sharing, duplicate publication, laboratory management, and quality control--are largely an institution's responsibility.

Return to Table of Contents

Investigative Program

The investigative program at ORI focuses on institutional referrals and the oversight of institutional inquiries and investigations. ORI is authorized to conduct institutional inquiries and investigations by the PHS Regulation, but it does so only under limited circumstances. Individuals may request an independent hearing before the DAB if a finding of scientific misconduct is made against them by ORI.

Institutional Referrals

ORI advises whistleblowers to make their allegations of scientific misconduct to the appropriate institutional official because institutions have the primary responsibility for responding to such allegations under the PHS Regulation. However, whistleblowers may make their allegations directly to ORI rather than to their institution. ORI routinely refers those allegations to the institution for action.

Oversight of Institutional Inquiries and Investigations

When ORI receives a report of an institutional inquiry or investigation into allegations of scientific misconduct, it reviews the report for timeliness, objectivity, thoroughness, and competence. During its review, ORI staff examine the institution's report and conclusions to determine whether the institutional findings are defensible, well supported by the evidence, and acceptable as a final resolution of the allegations. Also, when there is a finding of scientific misconduct, ORI determines whether it can carry its burden of proof during any hearing before the DAB if it accepts the institution's findings as a basis for PHS action.

During the oversight process, ORI may need to review all substantial documentation used or prepared by the institution during the inquiry or investigation. This includes grant applications, publications, computer files, research data, slides, letters, memoranda, transcripts, summaries of interviews, etc. ORI reviews the appropriateness and sufficiency of any analysis the institution conducted. If the institution has not provided an adequate justification of how it reached its conclusions, ORI may reanalyze or perform a new analysis of the research data, publications, or other source documents to determine whether to accept the institution's conclusions. ORI frequently asks institutions to provide additional information, consider additional questions, or provide further analysis.

The oversight review usually results in agreement on the findings between the institution and ORI. Occasionally, ORI concludes that it is unable to base the PHS finding on the institutional finding because of differences in the definition of scientific misconduct, the standard of proof, or other pertinent factors. Under these circumstances, ORI may decline to pursue the allegation or it may open its own investigation.

When ORI completes an oversight review of an institutional inquiry or investigation, it usually prepares an ORI oversight report that describes the institutional process and, in the case of an inquiry, concludes whether an investigation is warranted or, in the case of an investigation, concludes whether misconduct has occurred. When ORI does not make a finding of scientific misconduct following an investigation, it sends a copy of the report to the institution and requests that the institution notify the respondent and whistleblower directly of the outcome of the investigation. When ORI makes a proposed finding of scientific misconduct, it notifies the respondent and the institution and advises the respondent of his or her opportunity to request a hearing on the ORI decision.

During the oversight review of an institutional inquiry or investigation, ORI does not seek comments from the whistleblower or the respondent on the ORI report. When it conducts its own investigation, ORI seeks comments from the respondent and the whistleblower as discussed below.

Conduct of Inquiries and Investigations at Institutions

Although ORI normally expects the institution to conduct inquiries and investigations involving allegations of scientific misconduct affecting research conducted by the institution's faculty, staff, and students, ORI is authorized by regulation to conduct its own inquiry or investigation prior to, during, or following the institution's inquiry or investigation. ORI exercises its authority only in unusual circumstances, such as

when a multi-site clinical trial is involved, when the institution is unable to conduct a competent investigation itself, or when other special circumstances exist.

In conducting a direct inquiry or investigation, ORI generally:

notifies the institution, the whistleblower, and the respondent that an inquiry or investigation is being conducted;

advises the respondent of the nature of the allegations, ORI's authority to take action, the respondent's right to seek counsel, and other procedural matters;

requests that the institution sequester the evidence relevant to the allegation;

appoints one or more scientific experts to advise ORI during the inquiry or investigation;

interviews all relevant witnesses, including the whistleblower and the respondent;

reviews and analyzes the relevant evidence; and,

prepares an ORI report on the inquiry or investigation.

When ORI completes the inquiry or investigation, it sends a draft report to the respondent for comment. If comments are received, ORI considers those comments and incorporates appropriate changes into the final report. Generally, the whistleblower's comments are also sought and considered when the whistleblower has cooperated with ORI in providing evidence relevant to the investigation and has complied with ORI procedures regarding confidentiality.

When ORI has issued a final report on an inquiry or investigation, it notifies the institution, the whistleblower, and the respondent. If ORI does not find misconduct, it closes its file on the matter. When misconduct is found, additional actions follow as discussed below.

Determinations of Misconduct, Administrative Actions, and Hearing Process

When ORI makes a finding of scientific misconduct, ORI sends the respondent a copy of the final ORI report and a notification letter that describes the proposed administrative actions to be taken against the respondent. ORI also provides notice of the respondent's opportunity to request a hearing before the DAB on the scientific misconduct findings and administrative actions. The administrative actions that HHS may take against the respondent include, but are not limited to: (1) debarment from eligibility to receive Federal funds for grants and contracts; (2) prohibition from service on PHS advisory committees, peer review committees, or as a consultant; (3) implementation of special procedures for supervising the respondent and certifying data and sources; and (4) correction or retraction of published scientific articles. ORI generally relies on the cooperation of the institution where the respondent is currently employed to assist in implementing these administrative actions.

The respondent has an opportunity to present his or her case to the DAB and to be represented by counsel by requesting a hearing (Appendix G). During the hearing process, the respondent may file

motions and pleadings, make legal arguments, request discovery, present and cross examine witnesses, submit evidence, and participate in the hearing. ORI relies heavily on the cooperation of the involved institutions in obtaining witnesses, documents, and other assistance in presenting its case before the DAB.

If the DAB rules in favor of the respondent, the finding of misconduct will be overturned and the proposed administrative actions will not take effect. DAB rulings on proposed debarments are subject to final approval by the Deputy Assistant Secretary for Grants and Acquisition Management (DASGAM), HHS' debarring official.

If the respondent does not request a hearing or the findings of scientific misconduct and proposed administrative actions are affirmed by the DAB (and DASGAM in cases of debarment), these findings and administrative actions are published in the Federal Register, the NIH Guide for Grants and Contracts, the ORI Newsletter, and the ORI Annual Report. A copy of the final notification letter containing the finding and administrative actions is sent to the institution where the investigation was conducted and to the current employing institution if the respondent has relocated. In addition, PHS findings and administrative actions are posted on the PHS Administrative Action Bulletin Board. Debarments are also published in the General Services Administration's List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

Defining Plagiarism

Although there is widespread agreement on including plagiarism as a major element of the definition of scientific misconduct, there remains considerable uncertainty about the definition of plagiarism itself. As the first step in clarifying the meaning of plagiarism, ORI has developed the following operational definition:

Plagiarism includes the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work. It does not include authorship or credit disputes.

The theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained via a privileged communication, such as a grant or manuscript review.

Substantial unattributed textual copying of another's work is defined as the unattributed verbatim or nearly verbatim copying of sentences and paragraphs which materially misleads the ordinary reader regarding the contributions of the author. It does not include the limited use of identical or nearly-identical phrases which describe a commonly-used methodology or previous research.

Many allegations of 'plagiarism' involve disputes among former collaborators who participated jointly in the development or conduct of a research project but subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of legitimate use of the products of the collaboration by any of the former collaborators. For this reason, ORI considers many such disputes to be authorship or credit disputes rather than 'plagiarism.' Such disputes are referred to PHS agencies and extramural institutions for resolution and are not considered by ORI under the PHS definition of scientific misconduct.

Return to Table of Contents

Compliance Program

The PHS Regulation places several requirements on institutions receiving funds under the PHS Act. ORI monitors institutional compliance with these requirements through the following activities: (1) Assurance Program; (2) Annual Report on Possible Research Misconduct; (3) Institutional Compliance Reviews; (4) Complaints of Retaliation Against Whistleblowers; (5) Implementation of Administrative Actions, and (6) PHS ALERT System.

Assurance Program

ORI is responsible for ensuring that all institutions that apply for or receive funding under the PHS Act have an active assurance with ORI stating that the institution has and will follow an administrative process for handling allegations of scientific misconduct that complies with the PHS Regulation. ORI maintains an assurance database which contains the names and addresses of all institutions that have an active assurance and the name of the official responsible for implementing the scientific misconduct policy. Grants management officers are automatically notified electronically to contact ORI before they continue processing an award to an institution that is not listed in the assurance database. ORI also audits awards to determine whether any have been made to institutions that do not have an active assurance. ORI inactivates an assurance when the institution fails to (1) file its Annual Report on Possible Research Misconduct, (2) submit its policies and procedures for responding to allegations of research misconduct to ORI upon request, (3) maintain policies and procedures that comply with the PHS Regulation, or (4) otherwise comply with the provisions of the PHS Regulation. ORI always provides an institution with advance notice before it proceeds to inactivate an assurance. An institution may reactivate its assurance by taking the actions required by the PHS Regulation. If the assurance of an institution receiving funding is inactivated, the institution is informed that ORI will recommend that the appropriate PHS agency suspend current support and withhold all future support to the institution until an active assurance is established.

Annual Report on Possible Research Misconduct

ORI maintains the assurance database by processing the Annual Reports on Possible Research Misconduct, which institutions are required to submit to maintain an active assurance. The Annual Report also serves as a mechanism for collecting aggregate data on common problems faced by institutions in meeting the requirements of the PHS Regulation, i.e., the availability of policies and procedures, the restoration of reputations, the protection of respondents, and the dissemination of the policies and procedures to staff. This aggregate information is reported to institutions in the ORI Newsletter, the ORI Annual Report, and the ORI Home Page.

Institutional Compliance Reviews

Institutional compliance reviews are designed to monitor institutions' compliance with their own administrative processes and the PHS Regulation in responding to allegations of scientific misconduct in PHS-supported research.

Institutional compliance reviews are conducted by ORI staff and may contain one or two components, depending on whether the review is limited to the administrative policy and procedures or extends to the conduct of an actual inquiry and/or investigation. The first component examines the institution's policy and

procedures for adherence to the provisions of the PHS Regulation. The second component examines the actual conduct of an inquiry and/or investigation of scientific misconduct to determine if the process used was consistent with the institution's own policy and procedures and the Federal Regulation. A final report containing the results of the review is sent to the institution. The report may require actions by the institution to bring its written policy and procedures or actual handling of allegations of scientific misconduct into compliance with the PHS Regulation.

Most compliance reviews only involve a review of the policy and procedures established by an institution for responding to allegations of scientific misconduct. ORI reviews the policy and procedures when ORI refers an allegation to an institution for action, when the institution responds negatively to the question on the Annual Report asking about the availability of such a policy, or as part of its annual five percent sample. Complete compliance reviews usually originate from problems noted during ORI's oversight of institutional inquiries and investigations or receipt of an allegation of institutional non-compliance.

Complaints of Retaliation Against Whistleblowers

ORI responds to complaints of retaliation against whistleblowers under the PHS Regulation which requires institutions to undertake "diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations" (42 C.F.R. § 50.103(d)(13)). In seeking compliance with this provision of the PHS Regulation, ORI consults with whistleblowers about their situation or concerns, reminds institutions about their obligations to protect whistleblowers, requests institutions to respond to or investigate the retaliation complaints, and monitors the steps taken by institutions to prevent or redress retaliatory actions. ORI has developed interim guidelines for institutions to respond to retaliation complaints against whistleblowers (Appendix F) and is drafting a regulation on the protection of whistleblowers.

Implementation of Administrative Actions

ORI monitors the implementation of administration actions imposed by HHS and/or PHS on individuals found guilty of scientific misconduct. These actions are in addition to any sanctions imposed by an institution. Institutions are required to submit materials to ORI in compliance with some of the imposed administrative actions. To assist institutions in implementing administrative actions, ORI established the Administrative Actions Bulletin Board, an electronic bulletin board that provides current information on administrative actions imposed on individuals for scientific misconduct or violation of FDA regulations governing research.

Each entry on the bulletin board for scientific misconduct includes the name of the respondent, the name of the institution where the misconduct was investigated, the type of misconduct found, the administrative actions imposed, and the starting and ending dates for the administrative actions. Relevant information on FDA violations is also provided.

The information included in the bulletin board is meant to be used by PHS program officials, scientific review officials, committee management officials, and grant and contract officials as well as administrators at PHS applicant or awardee institutions to assist in the enforcement of administrative actions. The new bulletin board was developed in collaboration with the Division of Research Grants, NIH.

The bulletin board may be accessed directly through the Internet at the following address: http://silk.nih.gov/public/cbz1bje.@www.orilist.html. Please note that the character after cbz is the numeral 1, not the lower case letter "L" and note the . (dot) before the @. The bulletin board may also be

accessed through the DRG home page (http://www.drg.nih.gov) by clicking on "referral and review" and going to "ORI Listing".

PHS ALERT System

ORI also maintains a Privacy Act System of records called the PHS ALERT System to monitor individuals against whom scientific misconduct or violation of FDA regulations governing research has been confirmed. In addition to the names of individuals against whom the PHS has imposed administrative actions for committing scientific misconduct, the PHS ALERT also contains the names of individuals who have been found guilty of scientific misconduct by an institution or ORI, but are still subject to a review and/or a hearing before the DAB. Entries are removed from the system if ORI or DAB does not support the finding of misconduct or when the term of the administrative action expires.

Information on each individual in the PHS ALERT is limited to name, social security number, date of birth, type of misconduct, name of the institution that conducted the investigation, a summary of the administrative actions imposed as a result of the misconduct, and effective and expiration dates of the administrative actions.

Information in the PHS ALERT is generally held confidential; the information is shared with PHS officials only on a need-to-know basis. The information is not publicly available. The PHS ALERT is checked against incoming applications, pending awards, and proposed appointments to PHS advisory committees, boards, and peer review groups.

Return to Table of Contents

ORI Outreach

Introduction

ORI uses several mechanisms to keep institutions, the scientific community, and the public informed about PHS efforts to handle scientific misconduct and promote research integrity, including: (1) Publications; (2) Conferences and Workshops; (3) Speakers; (4) Responses to FOIA Requests; (5) Federal Register Notices; (6) Public Notices; (7) Notification to Journal Editors; (8) Press Releases; and (9) ORI Home Page.

Publications

ORI publishes a quarterly newsletter, an annual report, conference and workshop proceedings, position papers, and other publications to facilitate institutions' and PHS agencies' responses to allegations of scientific misconduct and pursuit of research integrity. The newsletter and annual report are sent to all institutions that have an active assurance on file with ORI and to PHS agencies. A current ORI publication list is available on the ORI Home Page.

Conferences and Workshops

ORI conferences and workshops are designed to assist institutions in implementing the PHS Regulation. ORI also holds conferences and workshops on topics related to research integrity, e.g., data

management and plagiarism. Conferences and workshops are presented when funding permits. They are announced in the ORI Newsletter.

Speakers

ORI staff make presentations at scientific and professional meetings, workshops, conferences, universities, colleges, and medical schools. Travel funds or workload may limit the availability of speakers.

Freedom of Information Act Requests

The Freedom of Information Act (FOIA), 5 U.S.C. § 552, provides public access to ORI records except to the extent that the records are protected from disclosure by one or more of FOIA's nine exemptions.

ORI records are primarily within the scope of Exemptions 5, 6, and 7. Exemption 5 covers intra- and inter-agency memoranda and documents. Exemption 6 provides protection for personal privacy interests and permits withholding, if disclosure would constitute a clearly unwarranted invasion of personal privacy. Exemption 7 protects records that the government has compiled for law enforcement purposes.

A FOIA request for ORI records should be made to the PHS FOIA Officer, 5600 Fishers Lane, Room 13C24, Rockville, MD 20857. The request must reasonably describe the records sought so that the agency official is able to locate the record with a reasonable amount of effort. Some requests may be subject to review, search, and duplication costs. Records and reports may be redacted to protect the privacy of individuals involved.

Federal Register Notices

ORI publishes a variety of notices in the Federal Register, including notices of proposed rule making, modifications of existing regulations, and findings of scientific misconduct. These notices also appear in the ORI Newsletter and the ORI Annual Report.

Public Notices

ORI publishes notices on closed investigations that have resulted in findings of scientific misconduct. The notices identify the respondent, the institution at which the misconduct occurred, the type of misconduct, the scientific literature involved, and the administrative actions either imposed by HHS or agreed upon in a voluntary settlement. The notices are published in the Federal Register, the NIH Guide for Grants and Contracts, the ORI Newsletter, and the ORI Annual Report.

Notification to Journal Editors

ORI notifies the editors of scientific journals containing publications that might require correction or retraction as a result of confirmed scientific misconduct. Such notification is made at the time of publication of the Federal Register notice announcing the ORI findings and administrative actions. The notification to journal editors comprises a cover letter transmitting a copy of the Federal Register notice, the ORI report or Voluntary Agreement, and the DAB report, if applicable. The ORI report is provided unedited pursuant to the Office of Research Integrity Privacy Act system of records, 09-37-0021, "Public Health Service Records Related to Inquiries and Investigations of Scientific Misconduct, HHS/OASH/ORI" 60 FR 2140 (Jan. 6, 1995).

Press Releases

ORI issues press releases on some investigations. A press release may be issued while an investigation is still underway if there are public health implications, i.e., a clinical trial. This would normally be done without identifying the individuals involved. Press releases may also be prepared on closed investigations if a misconduct case has achieved public notoriety or if an exonerated researcher requests such a release.

ORI Home Page

ORI has established a Home Page on the World Wide Web on INTERNET. The Home Page contains a description of the office's functions, phone numbers, copies of publications (such as the ORI Newsletter and the ORI Annual Report, and general information and announcements. The ORI Home Page address is: http://ori.hhs.gov.