

ORI NEWSLETTER

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COMMISSION ON RESEARCH INTEGRITY IDENTIFIES PROBLEM AREAS

The Commission on Research Integrity identified three problem areas which may produce recommendations aimed at ensuring the responsible conduct of research supported by the PHS, according to its interim report to the Secretary for Health and Human Services and Congress.

These areas are (1) the definition of research misconduct, (2) the lack of institutional standards for good research practices, and (3) retaliation against witnesses (whistleblowers).

The Commission will hold its third regional meeting in Boston on April 10-11. Other meetings are scheduled for Washington, D.C. on May 4-5, June 15, and September 18. A three-day retreat will be held from July 30 to August 1 at a location to be determined to develop recommendations for the final report of the Commission.

According to the interim report, the Commission is attempting to develop a definition of research misconduct that includes more than fabrication, falsification, and plagiarism but less than the broad universe implied under the current "other practices" clause.

The Commission may address the lack of standards for good research practices by recommending that each institution be required to give the PHS an assurance that it will develop standards for the responsible conduct of research and disseminate them to their staffs. Among the areas to be addressed by these proposed standards are data recording and retention, supervisory responsibility, authorship, and the protection of witnesses.

According to the interim report, the Commission may address the concerns of whistleblowers by developing a "witness 'bill of rights' and procedures for its implementation." Testimony from witnesses has demonstrated that "reprisals against witnesses are not uncommon in the current culture, and rewards for or appreciation of a witness' action is a rare exception, even for those ultimately vindicated by the findings." The report states that the "Commission believes that any environment offering potential witnesses the choice between reprisal and silence is unacceptable, because the public-policy stakes for research integrity are too high."

OUTSTANDING SCIENTISTS URGED TO PROMOTE RESEARCH INTEGRITY

Presidents of two national honorific scientific organizations have issued a clarion call to "our most outstanding scientists" to enlist in a grass roots movement to protect the scientific enterprise by actively promoting the high ethical standards within the scientific community that will ward off increased external control.

In an article in *Science* on December 9, 1994, Bruce Alberts, President of the National Academy of Sciences, and Kenneth Shine, President of the Institute of Medicine, reported on the activities of their organizations and called upon every scientist and national scientific organization to become involved in the grass roots movement in these efforts.

Alberts and Shine believe "the involvement of our most outstanding scientists is critical" because "they play key roles in departmental and university governance and serve as the role models for students and young scientists. If we are to be effective in maintaining high standards for the scientific community, this issue cannot be left to deans and administrators alone."

They continued, "The involvement of the most respected scientists at an institution is necessary for setting standards of conduct, designing educational programs, and responding to alleged violations of ethical norms."

The presidents also called upon national organizations to "provide a framework for grass roots efforts and facilitate the spread of model programs designed elsewhere. They can also help define standards for education programs and methods to evaluate the effectiveness of such programs."

They reported that the "Academy complex is working with other organizations to organize a series of regional projects designed to help local institutions and departments improve how they handle allegations of misconduct, address questionable research practices, educate their communities about research ethics, and share resources."

Alberts and Shine concluded, "Every scientist has a stake in contributing to the ethical standards of scientific conduct. If we do not police ourselves, others may step in to do so. The result could be a scientific enterprise that is increasingly constrained by legal strictures, financial oversight, and bureaucratic provisions."

ORI ADDRESSES MORE ISSUES RAISED BY INSTITUTIONS

This article continues the discussion of important issues that have arisen in the course of inquiries and investigations conducted by extramural institutions under their PHS scientific integrity assurance programs. The following responses represent ORI's position with respect to PHS-supported research and are not necessarily applicable to independent determinations of an institution's own professional norms on the responsible conduct of research.

È Provision of counsel—Many institutions have asked ORI about whether and to whom to provide counsel during an inquiry or investigation. ORI permits, but neither requires nor provides counsel for respondents, complainants, and other participants in misconduct proceedings. An institution must decide who it should provide counsel to and when such counsel should be provided. Some institutions routinely provide counsel for all or some parties, and others provide none. If counsel is provided, care should be taken to prevent any potential conflicts of interest between the needs of the institution and that of the individual being provided with representation. For example, if an institution does decide to provide a respondent with counsel, the institution's obligation to comply with the regulation and to cooperate with ORI investigations must not be compromised. ORI strongly recommends that outside counsel be provided in this instance. While parties may arrange for their own counsel, reimbursement is not available under the Equal Access to Justice Act.

È Training foreign students—Occasionally, foreign national students and postdoctoral fellows will tell ORI that certain research policies in the U.S. are different from those in their home countries. They have noted that no one ever discussed these differences with them or told them that they were performing research in what was considered to be an inappropriate manner. It is possible that some allegations of misconduct could be avoided if these individuals received training in biomedical research ethics, and if their mentors and fellow researchers made a point of helping them to understand the research methods and practices that are appropriate.

WHISTLEBLOWER RETALIATION COMPLAINT SETTLED

ORI's first attempt at resolving a whistleblower retaliation complaint through arbitration has reached a successful conclusion through a settlement of the dispute by the parties. The complainant in this case had made an allegation of scientific misconduct against his supervisor, a medical researcher. Soon thereafter, the complainant was dismissed from his employment at the medical institution.

The institution conducted an inquiry into the scientific misconduct allegation against the supervisor and found that further investigation was not warranted based on the evidence. ORI subsequently reviewed the inquiry report and concurred with the institution's conclusion. Nonetheless, ORI maintains a policy of protecting good faith whistleblowers, regardless of whether the misconduct allegation is proven to be true. Therefore, ORI responded to the complainant's claim of retaliation.

ORI intervened in this case by proposing a binding arbitration process for resolving the retaliation claim through the American Arbitration Association (AAA) and offering to underwrite partially the administrative expenses of the arbitration as a test case. The complainant and the institution agreed to arbitrate the retaliation dispute and mutually selected a neutral arbitrator through the AAA. After a pre-hearing conference with the arbitrator but prior to the actual hearing, the parties agreed to settle the dispute. The terms of this agreement are confidential.

ORI reviews and seeks to resolve whistleblower retaliation complaints on a case-by-case basis. The arbitration proposal described above represents one example of ORI's continuing effort to implement its whistleblower protection policy in the most constructive and effective manner possible. A sample arbitration agreement is available upon request.

CASE SUMMARIES

Gerald Leisman, Ph.D., New York Chiropractic College. ORI reviewed an investigation conducted by the New York Chiropractic College (NYCC) into possible scientific misconduct on the part of Dr. Leisman, formerly Director of Research and Institutes at NYCC. ORI found that Dr. Leisman committed scientific misconduct by misrepresenting his academic credentials and professional experience and awards in a grant application for PHS research funds. Based upon information obtained during its oversight

review, the ORI found that Dr. Leisman falsely claimed: A) to have earned a M.D. degree from the University of Manchester (England) in 1972; B) to have held the position of Professor, Neurology and Biomedical Engineering, Harvard University Medical School (June 1982 to January 1987); and C) to have been awarded inventorship or co-inventorship of 13 U.S. Patents. He accepted the ORI findings and agreed to a Voluntary Exclusion Agreement under which he is not eligible to apply for or receive any grants and co-operative agreements and is not eligible to contract or subcontract with any Federal Agency for a three-year period. Dr. Leisman is also prohibited from serving on PHS advisory committees, boards, or peer review groups for three years.

David F. Eierman, Ph.D., University of North Carolina at Chapel Hill. ORI reviewed an investigation conducted by the University of North Carolina at Chapel Hill into possible scientific misconduct on the part of Dr. Eierman while a research assistant at the university. Based in part on Dr. Eierman's admission, the university concluded that he committed scientific misconduct by falsifying or fabricating data in biomedical research supported by two PHS grants. The ORI accepted the university's conclusions and found that Dr. Eierman engaged in scientific misconduct.

Dr. Eierman has fully cooperated with the university and ORI in this matter and has signed a Voluntary Exclusion Agreement under which he has agreed to be excluded from support under Federal grants, contracts, and cooperative agreements for a three-year period, and from service on PHS advisory committees, boards, or peer review groups for the same period. ORI notes that Dr. Eierman's cooperation in resolving this matter indicates that he has accepted responsibility for his actions, and this is regarded as a positive factor that was taken into consideration in negotiating the Voluntary Exclusion Agreement.

Celia Ryan, R.N., University of Pittsburgh. ORI reviewed an investigation conducted by the University of Pittsburgh into possible scientific misconduct on the part of Ms. Ryan while an employee of the university. ORI concurred with the factual findings as set forth in the university report, and finds that Ms. Ryan committed scientific misconduct by falsifying and fabricating interview data in a research project, "Assessment of the Variation and Outcomes of Pneumonia" supported by a grant from the Agency for Health Care Policy and Research. Ms. Ryan accepted the misconduct finding and agreed to a Voluntary Exclusion Agreement under which Ms. Ryan will not apply for, nor permit her name to be used on any application for Federal grant

or contract funds, will not receive nor be supported by such funds, and will not serve on PHS advisory committees, boards, or peer review groups for a three-year period.

Aaron Apte, Stanford University. ORI reviewed an investigation conducted by Stanford University into possible scientific misconduct on the part of Mr. Apte, a former technician in the Division of Cardiovascular Medicine. Mr. Apte and his research were supported by PHS grants. ORI concluded that Mr. Apte fabricated data for research by cutting a scintillation counter printout from a former coworker's notebook, pasting it into his own notebook, and representing it as his own results from a different experiment on the binding of angiotensin to transfected cells. Mr. Apte has been debarred from eligibility for, and involvement in, grants as well as other assistance awards and contracts from the Federal Government for a period of three years. The fabricated research did not appear in any publications.

DANES DEPLORE PUBLICATION PRACTICE

An American communications company was found to have encouraged a dishonest act by the Danish Committee on Scientific Dishonesty (DCSD) for offering the authorship of a finished manuscript to a Danish researcher who did not participate in preparing the manuscript.

The DCSD came to that conclusion for the following reasons:

"The company wanted to convey the false impression that the review article which recommends the product of a particular company had been written by an independent and impartial expert, whereas it had in fact been written by authors associated with the company.

The company encouraged a violation of international regulations of authorship which state that authorship may only be claimed if considerable and independent efforts have been expended in the preparation of the article."

In its response to the DCSD, the American company asserted it had not committed a dishonest act because the content of the review

article was true and the researcher could make corrections to the article, which contained no original data.

The DCSD commended the researcher for submitting the case and concluded that "it would be very deplorable, if the practise were to spread where experts lend their authority to articles which have been written by other persons at the instigation of the pharmaceutical manufacturer which persons cannot be considered above rendering a biased presentation. The medical profession should not be tempted by comfortable authorships to participate in such misleading conduct. . ."

CANADIANS DEVELOPING MISCONDUCT POLICIES

The Canadian government is requiring its research universities to develop guidelines for handling alleged cases of misconduct before June 30 or they risk losing Canadian research funds, according to the December 9 issue of Science magazine. Increased competition among Canadian researchers for funds prompted three Canadian agencies that fund research to demand that institutions develop policies for handling misconduct allegations, according to Science. Recent high profile misconduct cases in Canada probably also provided the impetus for the requirement.

The requirement is outlined in "Integrity in Research and Scholarship." It has been adopted by three of Canada's agencies that sponsor research: National Sciences and Engineering Research Council, Medical Research Council, and Social Sciences and Humanities Research Council. The document includes a statement of basic principles and responsibilities applying to all researchers and scholars receiving funds from these organizations, as well as a set of procedures for "promoting integrity and for preventing and addressing misconduct in research."

To obtain a copy, contact the Social Sciences and Humanities Research Council, P.O. Box 1610, Ottawa, Ontario, Canada, K1P 6G4; (613) 992-0691.

ORI APPEARS IN BBC PROGRAM

BBC is scheduled to broadcast a program on the British approach to handling allegations of misconduct in science as part of the Horizons television series on March 13. Part of the program compares how the U.S. and Britain handle these issues differently and portions of interviews with ORI staff are expected to be

included.

INSTITUTIONS ELABORATE PHS DEFINITION OF SCIENTIFIC MISCONDUCT

An analysis of the definitions of scientific misconduct adopted by 46 institutions shows that the vast majority of institutions either incorporated the provisions of PHS definition of scientific misconduct into their definitions or adopted a more elaborate one.

Seventeen institutions adopted the PHS definition verbatim. Sixteen of the 29 unique definitions were more elaborate than the PHS definition but included the core PHS elements: fabrication, falsification, plagiarism, and "other practices that seriously deviate from those that are commonly accepted within the scientific community" in proposing, conducting, and reporting research. The core elements most often missing in the remaining 13 definitions were "other practices" and proposing and reporting research.

Besides the core elements of the PHS definition, institutions specified numerous other behaviors in their definitions: (1) grossly negligent data collection or analysis, (2) wrongful manipulation of data or results, (3) arbitrary or biased selection of data, (4) improprieties of authorship, (5) unauthorized use of confidential information, (6) forging of academic documents, (7) intentional misrepresentation of credentials, (8) intentionally or knowingly helping another to commit an act of academic misconduct or otherwise facilitating such acts, (9) deliberate interference with the integrity of the work of others, (10) failure to comply with the guidelines for handling misconduct in research, (11) material failure to comply with applicable requirements, whether governmental and/or institutional, affecting specific aspects of the conduct of research (e.g., protection of human subjects and ensuring the welfare of laboratory animals), and (12) failure to meet other professional standards or legal requirements governing research. The ORI has, in individual cases, found that some of these same practices fell under the PHS definition.

Some definitions attempted to define the core terms--plagiarism, falsification, and fabrication. Plagiarism was defined as (1) "intentionally or knowingly representing their words or ideas as one's own"; (2) "failure to provide appropriate citations"; (3) "appropriating the data of another individual and presenting it as one's own", and (4) "representation of another's work as one's own."

Many institutions limited their definitions of falsification and fabrication to the falsification and fabrication of data. Other institutions adopted broader specifications: (1) "falsifying or fabricating data, citations, or information", (2) "fabricating data to selective reporting"; (3) "ranging from fabrication to deceptively selective reporting, including the purposeful omission of conflicting data with the intent to falsify results", and (4) "fabrication or falsification of data including misleading selective reporting and the falsification of academically related information, such as degrees earned or works published." The PHS definition applies falsification and fabrication to the range of activities involved in proposing, conducting, and reporting research.

Some institutional definitions require a demonstration of intent through the use of such words as "intentionally or knowingly", "deliberate", "purposeful", and "willful deception." A few institutions base their definitions, wholly or in part, on the existence of ethical or professional standards. The Departmental Appeals Board has held that ORI must show intent to prove falsification or fabrication.

Besides the "other practices" clause, institutions inserted ambiguity into their definitions by using broad statements such as (1) "Academic misconduct includes any act that violates the standards of integrity in the conduct of scholarly and scientific research and communications."; (2) "Academic fraud can take many forms, including. . ."; (3) "Academic misconduct involves any form of behavior which entails an act of deception whereby. . ."; (4) "A failure to maintain a high level of integrity in. . .", and (5) "Research misconduct is defined as actions which cast doubt on the integrity of research and research results, such as. . ." Another source of ambiguity is the phrase "including, but not limited to. . ."

ORI ISSUES REVISED NOTICE ON PRIVACY ACT SYSTEM OF RECORDS

On January 6, 1995, ORI published in the Federal Register a notice revising a Privacy Act System of Records for ORI investigative files that was first published on July 19, 1994. Establishment of these files under the Privacy Act permits ORI to retrieve files by individual identifier.

Following the July 19 announcement, some organizations raised concerns that certain routine uses identified in the system of records would allow for release of information before a finding of scientific misconduct was made. Concern was also expressed

about language in the notice suggesting that ORI would provide information about inaccurate or misleading research. In response to these concerns, revisions and clarifications were made in the statement of purpose for the system of records and in six of the routine uses for information in the system.

The revised notice appears in the Federal Register, Volume 60, No. 4, Friday, January 6, 1995. Copies of the notice may be obtained by calling Barbara Bullman, Esq., Division of Policy and Education, ORI, (301) 443-5300.

IMAGE PROCESSING USEFUL IN MISCONDUCT INVESTIGATIONS

ORI has found that image processing software can be a useful tool in the forensic examination and extraction of information from contested figures and images. For example, a test of the authenticity of a gray scale image (a photomicrograph or an autoradiogram) is sometimes central to resolving an allegation of scientific misconduct. Also, features in a black and white figure can be measured to compare separate representations of the same data or to determine whether a geometric distortion exists that might indicate how a figure was reproduced. Often the original numerical data that was used to construct plots may be missing, making any associated statistical claim difficult to evaluate. Both parties to an allegation should insist on objective and reproducible forensic measurements.

A useful image processing program in the public domain is the well known NIH Image,[®] written by Wayne Rasband. A Macintosh[®] (II series) Computer is required. The software will drive most scanners for the Macintosh; an image scanned separately by a DOS-computer system can be converted by the Apple File Exchange[®] and imported by NIH Image.[®] The Image file can, in turn, be exported to other computers to take advantage of high resolution printers.

ORI's experience to date indicates the potential of image processing in scientific misconduct investigations to assist in visualization of otherwise hidden or "random" features of the background to compare the origin of two figures; reconstruction of a source Northern blot from regions of overlap, when the trimmed components had been presented separately; determination of whether two images represent different intensity exposures of the same experimental result; precise measurement of geometric distortions; and reassembling numerical data from point plots and from continuous line plots.

A copy of the compressed version of NIH Image® v1.52 for the Macintosh is available to any institution conducting an investigation. Contact Dr. John Krueger at (301) 443-5330, or by Internet: jkrueger@oash.ssw.dhhs.gov.

NAS UPDATES "ON BEING A SCIENTIST"

The National Academy of Sciences (NAS), National Academy of Engineering, and the Institute of Medicine have jointly issued a second edition of the NAS booklet on the ethical obligations of being a scientist. This updated version includes a series of case examples and incorporates important developments in science ethics over the past six years. It also incorporates material from the 1992 NAS volume Responsible Science. It retains discussions from the first edition on the social and historical context of science, the allocation of credit for discovery, the scientist's role in society, the role of publication, and other aspects of scientific and engineering research. For further information or to order copies of this 40-page booklet, contact the National Academy Press, telephone: (800) 624-6242.

RTI CONDUCTS STUDY OF RESPONDENTS

The ORI has contracted with the Research Triangle Institute (RTI) to conduct a study of the consequences of being accused of scientific misconduct.

Little information exists on the impact an allegation of scientific misconduct has on the employment, career, professional activities, and personal life of the accused. Some researchers who have been subjected to unconfirmed allegations of research misconduct have claimed that their reputations have been seriously damaged by such allegations. Data on the impact of supported allegations are also minimal.

This project intends to collect information systematically from respondents involved in closed PHS scientific misconduct cases to determine what has happened to them since they were accused of misconduct. The study population should range between 100 and 150 individuals. A self-administered questionnaire will be used to collect the data. The ORI expects the final study results in 1995.

MISCONDUCT ISSUES PAPER AVAILABLE

The second ORI position paper, "ORI Addresses Ten Issues in Inquiries and Investigations," is now available. Based on a series of articles published in the ORI Newsletter, the paper summarizes the PHS position on ten different issues in inquiries and investigations into allegations of misconduct in PHS-supported research.

Please send requests for copies to the ORI Division of Policy and Education.

UPCOMING MEETINGS:*

May 26, 1995 - "Mentoring and Teaching Research Ethics" Seminar at Indiana University in Bloomington. Pre-registration required by April 15. Contact: Kenneth D. Pimple, TRE Project Director, The Poynter Center, 410 N. Park Ave., Bloomington, IN 47405, telephone: (812) 855-0261; FAX: (812) 855-3315, Internet: pimple@indiana.edu.

The Commission on Research Integrity:

April 10-11	Meeting	Boston, MA
May 4-5	Meeting	Birmingham, AL
June 26-27	Meeting	Washington, DC
July 30 to Aug. 1	Retreat	Location to be determined
Sept. 18-19	Meeting	Washington, DC

Meetings subject to availability of funds. Call 301 443-5300.

*Lists are neither exhaustive nor all inclusive. Nor should any of the items listed or described be even remotely construed as being favored or endorsed by the Government.

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