ORI NEWSLETTER

Volume 2, No. 2, Office of Research Integrity, U.S. Public Health Service, March 1994

***

Please Duplicate and Circulate this Newsletter to Offices, Departments, Committees, and Labs. Thank You.

***

Impact of Sharma and Popovic Decisions On Institutional Investigations

Recent Departmental Appeals Board (DAB) decisions have caused some concern within the university community about the ability of extramural institutions to enforce their own sanctions or remedial actions in response to incidents of scientific misconduct. These decisions were Dr. Rameshwar K. Sharma, DAB Decision 1431 (Aug. 6, 1993) and Dr. Mikulas Popovic, DAB Decision 1446 (Nov. 3, 1993).

ORI wants to respond to those concerns, and to reiterate its continuing support for scientific misconduct investigations conducted by institutions receiving PHS research funds.

Awardee institutions still have the primary responsibility for preventing, detecting, investigating, reporting, and resolving allegations of scientific misconduct. The Public Health Service (PHS) statutory mandate and regulations complement, but do not replace, the authority that extramural institutions always have had to establish scientific and other standards for employees, contractors, and other individuals who perform research under institutional auspices.

Therefore, the institution should continue to rely on its own authorities to redress the violation of its standards, even if the DAB interpretation of scientific misconduct falls below the scientific standards expected by a particular institution.

In some cases, an institution will find that particular conduct violates both institutional requirements and the PHS definition of misconduct. An explicit finding that the institutional requirement has been violated may enable the institution to sustain its own sanctions even if the violation under the PHS definition is appealed.

However, ORI is requesting that institutions conduct their investigations and prepare their reports to ORI to meet the scientific and legal standards articulated by the DAB in the Popovic and Sharma decisions.

Reports on investigations should specifically address the materiality or significance of the misconduct, identify evidence that shows the respondent had a deliberate intent, and explain why the conduct constitutes a serious deviation from accepted scientific practices under institutional or general scientific standards at the time and place they occurred.

Institutions should continue to apply the preponderance of the evidence standard of proof when making a finding of misconduct, but should place greater emphasis on confirmatory evidence. For example, confirmatory evidence could include forensic analysis of relevant documents, expert statistical analysis demonstrating that the research was not done as reported, and documentary evidence from sources other than the questioned research records (such as medical charts or records of other laboratory members) demonstrating that the reported research data are false or fabricated.

ORI wants to encourage institutions to work closely with their attorneys in conducting the investigation and preparing the report so that misconduct findings based on the PHS definition will be sustainable. Institutions and their counsel should feel free to consult with ORI and its legal branch (Research Integrity Branch/OGC, 301-443-3466) on any matters that arise during the course of investigations.

Finally, DAB rulings have noted that standards for scientific conduct may vary by location and have emphasized the importance of notice to the researcher that specific conduct constitutes scientific misconduct. Therefore, the written policies of the institution provide critical evidence of standards of conduct and notice of misconduct. This emphasizes once again the need for institutions to state their standards for the responsible conduct of research, in addition to policies and procedures for dealing with allegations of misconduct.

***

NAS/NAE/IOM Research Integrity Needs More Attention

The research community was urged to "renew its commitment to strengthening the professional climate of the research system" in a statement issued by the Councils of the National Academy of Sciences and the Institute of Medicine and the Executive Committee of the Council of the National Academy of Engineering.

The statement on scientific conduct issued on February 2 asserts that "maintenance of high standards for the scientific enterprise is the responsibility of all who participate" and all involved "must continue to work with vigor to reduce the occurrence of practices that undermine the integrity of the scientific process and its results."

It affirms that individual researchers are the best "safeguard of appropriate scientific conduct" and "[i]ndividual scientists must share in the collective responsibility for ensuring the integrity of the research enterprise. They also need to take action when they become aware of inappropriate scientific conduct, and to support and protect those individuals who, in good conscience, report suspected misconduct."
It mentions recent decisions in specific cases by the Department of Health and Human Services "that have been interpreted by some

scientists as limiting the activities that are defined as misconduct in science. These decisions must not be taken to mean that the scientific community can reduce its efforts on ethical issues. As members of the professional research community, we should strive to develop and uphold standards that are broader than those addressed by the governmental regulatory and legal framework for dealing with misconduct in science" [emphasis in statement].

The statement calls for a uniform Federal definition of misconduct and standard of proof to be developed, coordinated by the Office of Science and Technology Policy. It also encourages the research community to develop common policies and procedures for handling allegations to "aid the scientific community as it attempts to develop better methods for policing itself."

The statement declares that "the research community should adopt a common framework of definitions, distinguishing among misconduct in science, questionable research practices, and other forms of misconduct. Each research institution should also have policies and procedures that ensure appropriate and prompt responses to allegations of misconduct in science. Clear instances of falsification, fabrication or plagiarism deserve the full condemnation of the scientific community as well as whatever sanctions that legal procedures may decide. Institutions should also act to discourage questionable research practices through a broad range of formal and informal methods in the research environment. They should accept responsibility for determining which questionable research practices are serious enough to warrant institutional action."

The statement goes on to recommend that "[u]niversities and other research institutions should integrate into their curricula educational programs that foster faculty, staff, and student awareness of obligations related to the integrity of the research process." It also notes that "[p]rofessional and scientific societies also have an important role in upholding scientific standards, including the development and dissemination of training materials related to scientific conduct in their specific fields."

The statement announced that the Academy is planning a major national convocation this spring to examine the ways in which various research institutions have been educating their faculty, staff, and students on the practice and ethics of research.

***

Study Reports Widespread Misconduct

An article in the November-December 1993 issue of *American Scientist* reported that misconduct and other ethical problems in university-based research may be more widespread than previously thought.

"Ethical Problems in Academic Research," by J.P. Swazey, M.S. Anderson, and K.S. Lewis, reports on the results of a survey of

"2,000 doctoral candidates and 2,000 of their faculty about their experiences with 15 types of ethically questionable behavior." They "sampled doctoral students and faculty from 99 of the largest graduate departments in chemistry, civil engineering, microbiology and sociology."

The article stated that "between six and nine percent of both students and faculty report that they have direct knowledge of faculty who have plagiarized or falsified data," and "nearly a third of faculty claim to have observed student plagiarism."

"Twenty-two percent of faculty reported instances of their colleagues overlooking sloppy use of data" and "almost one-third know of inappropriate assignment of authorship of research papers."

In addition, a majority of the students do not feel safe reporting misconduct of a faculty member. "Fifty-three percent of the students compared to 26 percent of the faculty said they probably or definitely could not report a faculty member without expecting retaliation" if they did so.

***

ORI Conducting Compliance Reviews

The Office of Research Integrity (ORI) recently added formal institutional compliance reviews to its oversight of inquiries and investigations. This function, previously handled informally by the Division of Research Investigations within ORI, has been placed in the ORI Division of Policy and Education.

Initially, these reviews will concentrate on cases where problems of compliance have come to light during ORI*s oversight of institutional inquiries and investigations. Ultimately, all intramural and extramural cases will be reviewed for compliance. In addition, review of institutional actions against whistleblowers are now part of the compliance review process.

Each of these institutional compliance reviews will contain two major components.

The first component will compare the institution*s policies and procedures with the provisions of the PHS Final Rule (42 CFR Part 50 Subpart A). The process developed by each institution for dealing with allegations of research misconduct must incorporate all the specific provisions of the Final Rule, and their policies and procedures will be examined for adherence to these specific provisions.

The second component will examine the actual process used by the institution in an inquiry and/or investigation of research misconduct to determine if the process utilized during that review was consistent with the institution*s own policies and procedures. Since the Final Rule requires that the institutional process include protection of the positions and reputations of those who in

good faith make allegations of research misconduct, alleged retaliation against whistleblowers also will be examined as part of this process.

At the conclusion of each review, a final report will be prepared assessing the institution*s

compliance with both the Final Rule and its own administrative process, and this report will be provided to officials at the institution reviewed. Any recommendation for corrective actions will be provided to the institution.

***

ORI Settles Michigan State Case

The ORI and Michigan State University (MSU) settled their case of scientific misconduct against Maie Elkassaby, who was accused of sequestering data from a principal investigator for 15 months. Ms. Elkassaby had appealed ORI*s finding of misconduct to the DAB for an administrative hearing.

As part of the settlement, ORI and MSU jointly withdrew the finding of scientific misconduct. In turn, Ms. Elkassaby agreed to admit that her conduct was improper, acknowledge PHS* authority over any PHS-funded research in which she engages, submit to close MSU supervision of her research activities, and comply with all institutional and Federal requirements for the retention and provision within the laboratory of data, research materials, and analyses. The latter provision essentially implements the administrative action that ORI originally proposed in conjunction with its finding of misconduct.

Given the respondent*s agreement to comply with the above conditions, and in light of recent DAB decisions further defining the standards for finding scientific misconduct, ORI believes that this resolution of the case is equitable, is in the best interests of all parties, and achieves ORI*s objective of protecting the integrity of PHS research in this matter.

ORI wishes to acknowledge the efforts of the complainant, Dr. Jeffrey F. Williams, in reporting the allegations to MSU and ORI officials in accordance with the regulations, and to recognize the serious attention given by the MSU investigative committee. It is through the complainant's and committee's efforts, and many others in similar situations, that PHS funded research is protected and the integrity of science is maintained.

***

Research Misconduct Receives International Attention

The Committee on Scientific Dishonesty of the Danish Research Council sponsored an "International Conference on Scientific Dishonesty and Good Scientific Practice" in Copenhagen last November. The conference included invited representatives from

Denmark, Norway, Sweden, Great Britain, Germany, Austria and the U.S. Dr. Dorothy Macfarlane, Acting Director of the Division of Research Investigations, represented the Office of Research Integrity.

The purpose of the meeting was to exchange information on how scientific misconduct allegations are handled in the represented countries, to share experiences in dealing with cases, and to foster international cooperation in promoting scientific integrity and investigating misconduct.

The Danish Committee on Scientific Dishonesty reported its experiences in dealing with scientific misconduct. It had received an unexpectedly large number of allegations in its initial year of operation. Twelve cases were opened, with allegations ranging from authorship disputes to data fabrication and falsification.

Dr. Stephen Lock (former chief editor of the British Medical Journal) discussed the "History and Epidemiology of Scientific Misconduct," and later spoke on the role of the journal editor in preventing misconduct. Dr. Albin Eser (former vice president of the German Research Foundation) reviewed the judicial bases for investigating and sanctioning misconduct. A member of the Danish Committee on Scientific Dishonesty, Dr. Povl Riis, discussed the scope of scientific dishonesty. His colleague, Dr. Steen Walter, commented on the role of the educator in preventing misconduct. Invited speakers reported on what measures have been taken to deal with scientific misconduct and promote scientific integrity in each country represented. They also described the problems encountered in defining, identifying, and investigating alleged misconduct, and appropriate sanctions for those found to have committed misconduct.

***

Board Rules on Legal Issues

Besides addressing the substantive merit of misconduct cases, the Research Integrity Adjudications Panel of the Departmental Appeals Board (DAB) issued several important rulings related to ORI policies and procedures during 1993.

The rulings stemmed from issues raised by respondents who had filed appeals before the DAB. The ORI was required to provide the DAB with considerable legal argument on existing policy and procedure.

These briefings resulted in determinations that:

(1) the Department*s authority to investigate and take action against scientific misconduct predates the specific scientific misconduct statute and its implementing regulations, and the exercise of that authority is not retroactive rulemaking;

(2) the Equal Access to Justice Act is not applicable to the ORI

hearing process, and, thus, respondents may not be reimbursed by the government for their legal fees;

(3) ORI jurisdiction to investigate scientific misconduct extends to unfunded PHS grant applications; and

(4) the current ORI policies and procedures for handling scientific misconduct cases are not legislative rules and, thus, are not subject to the requirements of the Administrative Procedure Act.

For further information on these rulings, you may contact Gail Gibbons, Esq., at (301)443-3466.

***

PHS Research Integrity Program Focuses on PHS Agencies

After its initial focus on extramural research, the ORI has shifted the development of the PHS Research Integrity Program to the creation of administrative processes within PHS agencies for handling allegations of research misconduct and promoting research integrity.

These administrative processes must span the extramural and intramural research programs and perform the following functions: (1) Respond to allegations of research misconduct in intramural research programs by conducting inquiries and cooperating with ORI investigations; (2) report allegations of research misconduct received or identified by extramural program officers and scientific review administrators; (3) cooperate with ORI reviews or investigations of extramural allegations; (4) implement administrative actions imposed on researchers found to have committed research misconduct; (5) verify the eligibility of institutions to receive funding under the PHS Act; and (6) promote research integrity.

The performance of these functions involve
(1) research integrity officers, (2) intramural research directors, (3) extramural research directors, (4) research program officers, (5) scientific review administrators, (6) committee management officers, and (7) grant and contract management officers.

In response to a memorandum from Dr. Philip R. Lee, Assistant Secretary for Health, each PHS agency head has named an Agency Research Integrity Liaison Officer to implement the Research Integrity Program within the agency. Some agency heads have also named Agency Intramural Research Integrity Liaison Officers, Agency Extramural Research Integrity Liaison Officers, and Research Integrity Liaison Officers for components of the agency.

The ORI will hold a training workshop for all PHS research integrity liaison officers this spring.

ORI is developing instructions for handling allegations of research misconduct made against researchers in PHS intramural

programs. The instructions largely parallel the process outlined in the PHS regulation for extramural institutions (42 CFR Part 50 Subpart A).

The instructions require PHS employees to report suspected or apparent research misconduct and cooperate in the conduct of inquiries and investigation. Instances of apparent retaliation are to be reported to the agency for appropriate action. Bad faith allegations are subject to disciplinary action.

The instructions also establish a two-step process. Each agency has the responsibility for completing an inquiry within 30 working days. The agency must submit a report to ORI on all inquiries. ORI has the responsibility for conducting all investigations, completing them within 120 days. Misconduct must be proved by "a preponderance of the evidence." Misconduct proceedings are considered confidential.

In an intramural inquiry, the respondent and the complainant may comment on the allegation. Original data and other documents and materials are taken into custody when the respondent is notified about the allegation. The respondent also may comment on the draft report. The respondent is given a copy of the final report; the complainant is notified of the inquiry outcome by letter. In an investigation the respondent may be represented by counsel and may propose witnesses; be interviewed; have reasonable access to copies of any research data under review by ORI; submit information and evidence; rebut issues and evidence identified by ORI; and comment on the draft report of the investigation. The respondent will be given a copy of the final report; the complainant will be notified of the outcome by letter.

***

Nomination Package Submitted;Commission Chartered

A nomination package containing the names of 24 candidates for the twelve positions on the Commission on Research Integrity has been submitted to the Assistant Secretary for Health (ASH). The nomination package also must be approved by the Secretary of Health and Human Services before Commission membership may be established.

The Secretary signed the charter establishing the Commission on November 4, 1993. The Commission replaces the PHS Advisory Committee on Research Integrity which was terminated on September 21, 1993. The ORI has tentatively scheduled the initial Commission meeting for spring 1994.

The Commission is mandated by Section 162 of the National Institutes of Health Revitalization Act of 1993 (Pub. L. 103-43) to "develop recommendations for the Secretary of Health and Human Services on the administration of section 493 of the Public Health Service Act" as amended by provisions of the 1993 Act. Section 493 requires the Department of Health and Human Services to develop a process for responding to allegations of misconduct in research

activities funded under the PHS Act and to establish protections for whistleblowers.

***

Which Office Handles What Type of Research Abuse

The emergence of several abuses of the research process has generated some confusion about which PHS office handles what abuse.

The abuses are (1) scientific misconduct, (2) misuse of human and animal research subjects, and (3) financial mismanagement. Each of these areas is the subject of Federal regulations. Another emerging area is financial conflict of interest. A PHS regulation is being drafted in this area by the Office of Extramural Research at the National Institutes of Health (NIH).

The ORI handles allegations of scientific misconduct that involve PHS-supported research and that fit within the following definition: "Misconduct or misconduct in science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data." Contact the ORI Division of Research Investigations at (301)443-5330.

The ORI does not handle allegations of misconduct in regulated research monitored by the Food and Drug Administration (FDA). This research focuses on testing and evaluating human and animal drugs, food and feed additives, and human biological products and medical devices. Investigations of those allegations are coordinated by the Office of Regulatory Affairs, Division of Compliance Policy, Bioresearch Program Coordination, FDA, at (301) 443-2390.

The Office for Protection from Research Risks (OPRR) at the NIH 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 get approval from an institutional review board or animal care committee. Contact OPRR at (301)496-7005.

The Office of Management Assessment and Internal Control (OMAIC) at NIH handles allegations of financial mismanagement of NIH research funding. Allegations in this area involve using research funds for unauthorized purposes and the submission of false expenditure claims. Contact OMAIC at (301)496-1361.

The ORI, OPRR, and OMAIC only deal with applications or awards for research supported by the PHS agencies.

Other Federal agencies such as the National Science Foundation, the Veterans Administration, and the Department of Agriculture also have offices to handle these abuses of the research process.

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 - fall largely within the responsibility of institutions and scientific and professional associations.

***

Upcoming Meetings*

May 27 - "Scientific (Mis)Conduct and Social (Ir)Responsibility." One day conference on research ethics will be held on the Indiana University-Bloomington campus. Registration deadline: April 15. Contact: Poynter Center, 410 North Park Avenue, Bloomington, IN 47405. Telephone (812) 855-0261, Fax: (812) 855-0261.

June 11-15 - The second annual faculty workshop on "Teaching Ethics in the Biomedical and Biological Sciences" will be held in Bar Harbor, Maine. The workshop will deal with content areas and teaching methods including the use of case studies. Registration deadline: May 1. Contact: Dr. Judith P. Swazey, The Acadia Institute, 118 West Street, Bar Harbor, ME 04609. Telephone and Fax: (207) 288-4082.

*The list of upcoming meetings is 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.

***

Office of Research Integrity
U.S. Public Health Service
5515 Security Lane, Suite 700
Rockville, Maryland 20852

Office of the Director	(301) 443-3400
Executive Office	(301) 443-4210
Division of Policy and Education	(301) 443-5300
Assurances Program	(301) 443-5377
Division of Research Investigations	(301) 443-5330
Research Integrity Branch/OGC	(301) 443-3466

ORI NEWSLETTER

The ORI Newsletter is published quarterly by the Office of Research Integrity, U.S. Public Health Service, and distributed to applicant or awardee institutions to facilitate pursuit of a common interest in handling allegations of misconduct and promoting integrity in PHS-supported research.