

ORI NEWSLETTER

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ORI PAPER: PROTECTION FOR WHISTLEBLOWERS IN DEFAMATION SUITS

A paper describing protection for whistleblowers in defamation suits is now available from ORI. Prepared by ORI lawyers, the document discusses the whistleblower's conditional privilege to report allegations of scientific misconduct.

In ORI's opinion, if a respondent accused of misconduct files a defamation suit against the whistleblower, the whistleblower may assert a conditional privilege, thereby defeating the respondent's claim.

The whistleblower, however, must adhere to certain requirements. These include reporting the misconduct to appropriate institutional or ORI authorities, avoiding intentional public disclosure of the allegation, and making the allegation in good faith. These conditions and other aspects of the whistleblower's conditional privilege are covered in ORI's paper. For copies of the paper, please address requests to the Division of Policy and Education at the address listed at the back of this newsletter.

ORI WITHDRAWS FROM GALLO CASE

The Office of Research Integrity (ORI) withdrew its Dec. 29, 1992, legal determination that Dr. Robert C. Gallo had committed scientific misconduct. The announcement made on November 12 ended an appeal brought by Dr. Gallo.

ORI took this action in light of recent Research Integrity Adjudications Panel decisions, including the related Popovic decision issued on November 3, five days before the Gallo hearing was to begin. These decisions established a new definition of scientific misconduct as well as a new and extremely difficult standard for proving misconduct. (See related story on page.....)

"After analyzing the panel's November 3 decision, it is clear that the panel now applies different standards from those applied by ORI to review findings of scientific misconduct," Dr. Bivens stated.

"The scientific community has a low threshold of tolerance for false statements, and this view is reflected in the regulatory definition of scientific misconduct. ORI maintains that the standards applied by the panel reflect a fundamental disagreement with ORI as to the importance of clarity, accuracy and honesty in science. However, because ORI is bound by the panel's decisions, it will not continue its proceeding against Dr. Gallo. As a

practical matter, the panel's recent decisions have made it extraordinarily difficult for ORI to defend its legal determination of scientific misconduct."

Under the regulatory definition, scientific misconduct includes "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted in the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data."

In its Popovic decision and others, the panel announced its standard for finding misconduct based on false statements. The panel ruled that ORI must prove deliberate intent to deceive, that a false statement have a material or significant effect on the research conclusions of the paper, and that there be no possibility of honest error.

"Although ORI is not proceeding with the Gallo case, it remains committed to applying the scientific community's standards for integrity, and will vigorously investigate allegations of scientific misconduct," Dr. Bivens said.

Dr. Bivens also noted that the Department of Health and Human Services (HHS) is moving quickly to implement new statutory mandates in the misconduct area. These mandates include establishing a Commission on Research Integrity to enhance ORI's ability to address wrongdoing by scientists.

In commenting on the panel's recent decisions, Dr. Bivens stated: "We believe that ORI's approach to determining scientific misconduct is the correct course of action. We are confident that the new Commission will reinvigorate our efforts to maintain the highest scientific standards and to deal effectively with misconduct. While dismayed by the scientific and legal standards established by the Research Integrity Adjudications Panel's decisions, we remain committed to protecting the integrity of Public Health Service research."

DAB REJECTS REQUEST FOR ATTORNEY'S FEES

The Departmental Appeals Board (DAB) decided on November 9 that the Equal Access to Justice Act (EAJA) did not apply to scientific misconduct hearings held before the DAB.

Following a decision by the DAB that he did not commit misconduct, Dr. Rameshwar K. Sharma asked the DAB to grant him attorney's fees and expenses under EAJA. The ORI argued that EAJA only applied when a hearing was required by statute and the DAB hearing process was established by agency discretion.

The DAB agreed with ORI's analysis of EAJA and denied Dr. Sharma's request for attorney's fees. In response to another issue by Dr. Sharma, the DAB also ruled that there was no constitutional right to the DAB hearing because no property interest of Dr. Sharma's was at issue.

RTI CONDUCTS WHISTLEBLOWER STUDY

The ORI has contracted with the Research Triangle Institute to conduct a study of the consequences of whistleblowing for the whistleblower in cases of research misconduct.

Anecdotal information indicates that some whistleblowers risk their careers by making allegations of misconduct. This project intends to systematically collect information from all known whistleblowers involved in PHS misconduct in science cases to determine what has happened to them since they made their allegations.

The study population is expected to include 100-135 individuals from closed cases in ORI's files. The contractor will collect the data using a questionnaire mailed to the whistleblower. The ORI expects to receive the final study report in August 1994.

BIVENS NAMED DIRECTOR, ORI

Lyle W. Bivens, Ph.D., has been appointed Director of the Office of Research Integrity by the Secretary of Health and Human Services. Dr. Bivens has been serving as Acting Director of ORI since January 1993.

Previously, Dr. Bivens served as the Director of the Division of Policy and Education, ORI, since the office was created in May 1992. From 1989 to 1992, he served as Director of the Office of Scientific Integrity Review (OSIR). He received a PHS Special Recognition Award (1991) for his leadership in establishing the PHS research integrity program.

Dr. Bivens spent most of his Federal career with the National Institute of Mental Health (NIMH), 1968-89. Beginning as Chief, Neuropsychology Section of the Behavioral Sciences Research Branch, 1968-75, he also served as Assistant Chief, Behavioral Sciences Research Branch, 1970-75; Deputy Director, Division of Extramural Research Programs, 1975-85; and Director, Division of Basic Sciences, 1985-92. He was appointed to the Senior Executive Service in 1985.

Prior to joining the PHS, Dr. Bivens was Chief of the Psychology Research Laboratories at the Veterans Administration Hospital in Denver. From 1964-67, he was a research psychologist at the

Veterans Administration Hospital in Pittsburgh and an instructor in the Department of Psychology at the University of Pittsburgh.

Dr. Bivens holds a Ph.D. in experimental psychology (1963) from the University of Colorado and a post-doctoral degree in clinical psychology from the George Washington University (1983). He also has a B.A. in geology from the University of Colorado (1957).

RESEARCH MISCONDUCT ACTIVITIES REPORTED BY INSTITUTIONS

Seventy-two institutions reported activities related to allegations of research misconduct in 1991 and/or 1992, according to their Annual Reports on Possible Misconduct in Science.

Thirty-five institutions reported activity in 1991; 55 institutions reported activity in 1992. Eighteen of these institutions reported activity in both years.

The activities include receipt of an allegation and the conduct of an inquiry and/or investigation. Reportable activities are limited to alleged misconduct involving Public Health Service-supported research, research training, or other research-related activities.

Fifty-five institutions received 108 allegations during the two-year period. The number of allegations received by the institutions ranged from one to 10. The median number of allegations received was one. Thirty-one institutions received one allegation; 13 received two; five received three; two received four; and one institution received five, six, seven, and 10 allegations respectively.

The allegations contained 150 charges of research misconduct including 25 of fabrication; 41 of falsification; 38 of plagiarism, and 46 of "other practices".

Sixty-five institutions conducted 121 inquiries. Some of the inquiries were based on allegations made prior to 1991. The number of inquiries conducted by the institutions ranged from one to 11. The median number of inquiries conducted was one. Thirty-nine institutions conducted one inquiry; 14 conducted two; seven conducted three; and one institution conducted four, five, six, seven, and 11 inquiries respectively.

Thirty-three institutions conducted 51 investigations. The number of investigations ranged from one to four. The median number of investigations conducted was one. Twenty institutions conducted one investigation; nine conducted two; three conducted three; and one conducted four.

The Annual Report forms for calendar year 1993 are scheduled to

be mailed to institutions on January 14, 1994.

WHISTLEBLOWER AWARDED DAMAGES IN RETALIATION CASE

A judge awarded a research scientist \$1.2 million in damages after a jury determined that her work had been plagiarized by one supervisor and she had been retaliated against by another supervisor at the University of Michigan, according to recent press reports.

The plaintiff, Dr. Carolyn Phinney, a research psychologist at the Institute of Gerontology, sued her former supervisor Dr. Marion Perlmutter, Dr. Richard Adelman, Director of Michigan's Gerontology Institute, and the University of Michigan. Dr. Phinney alleged that Dr. Perlmutter had plagiarized her work by taking credit for her research materials and using her materials in applying for a Federal grant without naming her as a principal investigator. Dr. Phinney also claimed that the University's investigation was insufficient and that Dr. Adelman had retaliated against her by discrediting her and not renewing her contract after she had filed an allegation of scientific misconduct.

This case was not handled by the Office of Research Integrity. The allegation was brought in 1989 and Dr. Phinney filed suit in 1990. In 1992, Phinney's contract with the university was not renewed and she is currently unemployed.

The court found that the Michigan investigation was flawed in its composition and conclusions. Dr. Richard Adelman had appointed colleagues of Dr. Perlmutter to investigate the allegations and the investigation was terminated without findings. Instead, the investigative panel ordered the scientists to negotiate an agreement. Both sides refused.

The court also found that Dr. Perlmutter had committed fraud in taking credit for Dr. Phinney's work and that Dr. Adelman had violated a Michigan law in retaliating against Dr. Phinney. The university is appealing the ruling.

According to a news item in Science, the university is paying for Adelman's lawyers and will pay damages Adelman owes Phinney if the award is not reversed on appeal, but not Perlmutter's. A university spokesman was quoted as saying this is because Adelman was acting as an agent of the university in overseeing the investigations, but Perlmutter was acting as an individual.

According to Science, attorneys specializing in scientific misconduct say the case is the first in which a whistleblower has won a financial award as a result of a suit charging retaliation.

STATUS OF ORI HEARINGS

To date, nine ORI findings of misconduct and/or administrative actions have been appealed. Three of these appeals have been resolved in the pre-hearing conference process. The DAB affirmed the three-year debarment of Dr. Paul Langlois. Dr. James Freisheim and Dr. Raphael Stricker withdrew their appeals and accepted a three-year debarment and three-year voluntary exclusion, respectively. The Departmental Appeals Board overturned the ORI findings in two cases.

The DAB ruled that ORI did not prove that Dr. Mikulas Popovic, formerly of the National Cancer Institute, committed scientific misconduct in a 1984 article on the isolation of the AIDS virus.

The DAB also cleared Dr. Rameshwar K. Sharma, formerly of the Cleveland Clinic Foundation, by ruling that "ORI did not prove that negligent inclusion of a false statement in a grant application in the circumstances involved in this case would so seriously deviate from accepted practice at the time as to constitute scientific misconduct. Thus, ORI could establish scientific misconduct in this case only if it proved by a preponderance of the evidence that Dr. Sharma intentionally falsified material statements in his grant applications."

In that decision, the DAB declared that ORI would be required to show (1) intent, (2) materiality, and (3) lack of honest error.

The ORI withdrew from two cases because of the standards enunciated by the Board for proving scientific misconduct. Based on the new DAB standards developed in Dr. Sharma's and Dr. Popovic's cases, ORI declined to pursue its findings against Dr. Margit Hamosh of Georgetown University and Dr. Gallo.

At press time, decisions were outstanding in one DAB case, and another was scheduled for hearing in February.

To date, ORI has issued findings of misconduct in 22 cases. Thirteen of these findings have not been appealed. With the recent DAB rulings and the withdrawal of two cases by ORI, ORI findings and administrative actions have been upheld in 16 of 20 cases.

CALL FOR PAPERS*

April 7-9 - "Diversity in Mentoring." International Mentoring Association and Western Michigan University. Atlanta Hilton and Towers Hotel, Atlanta, GA. Contact: Office of Conferences and Institutes, Western Michigan University, Kalamazoo, MI 49008-5161. Phone: (616) 387-4174.

PHS ALERT SYSTEM TRANSFERRED TO DPE

Responsibility for the PHS ALERT system, which contains information on individuals found to have committed scientific misconduct by an institution or the ORI has been internally transferred from the Division of Research Investigations to the Division of Policy and Education (DPE) within ORI. The new system manager is John J. Butler at (301) 443-5300.

The DPE also recently was assigned the responsibility for reviewing institutional compliance with PHS regulations and ensuring implementation of PHS administrative actions.

Each ALERT file includes the subject of the investigation, affected institutions, the misconduct findings, and administrative actions imposed by PHS and HHS as well as duration of these actions.

Individuals are notified by the system manager when they are placed in the system and when they are removed from the system. An individual is placed in the PHS ALERT system when he/she has been found to have committed research misconduct by an institutional or an ORI investigation. An individual is removed from the system when (1) the ORI does not accept a finding of misconduct reached in an institutional investigation; (2) the Departmental Appeals Board reverses a misconduct finding; or (3) the administrative actions imposed against the individual have expired.

Information in the PHS ALERT system is periodically checked against appointments to PHS advisory committees and boards, new applications, and active and pending awards. When a match occurs, PHS personnel are informed on a need-to-know basis. The ORI also responds to queries from PHS personnel on a need-to-know basis.

MAKING FREEDOM OF INFORMATION ACT REQUESTS

The Freedom of Information Act (FOIA) grants any individual access to records of a Federal agency, except to the extent that the records are in whole or in part protected from disclosure by one or more of the FOIA exemptions.

It is the policy of the ORI to disclose the following information on closed cases where there has been a finding of research misconduct: the final decision of the ORI and the final report of the institution's investigation. The final reports will be released in response to a FOIA request for the information. The ORI policy is not to release information on cases where no misconduct has been found.

Requests for ORI records may be made to the ORI, Attention: Barbara Bullman, Esq., 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443-5300; or you may write directly to the PHS FOIA Officer, 5600 Fishers Lane, Rockville, MD 20857.

ASSURANCES PROGRAM PARTICIPATION

About 3200 institutions, including 175 in other countries, have filed assurances with the ORI that they have an administrative process for handling allegations of research misconduct that complies with PHS regulations.

Institutions must file an assurance with ORI to be eligible to receive funding from the Public Health Service. Filing of an assurance was mandated by Congress in the 1985 Health Extension Act.

Once the initial assurance is filed, an institution is required to submit an annual report to keep the assurance active. Since November 1992, more than 500 new assurances have been received. Since the assurance program began in 1989, more than 650 organizations have allowed their assurances to expire.

The calendar year 1993 Annual Report on Possible Research Misconduct (PHS 6349) will be mailed on January 14, 1994, to institutions that have an active assurance. The Annual Report must be completed and returned to the ORI no later than March 1, 1994. (An active assurance is required for the awarding of all PHS research grants, fellowships and cooperative agreements.) If you have questions regarding the Annual Report, contact ORI's Assurances Program at (301) 443-5377.

UPCOMING MEETINGS*

February 24-26 - Association for Practical and Professional Ethics. Annual meeting. Stouffer Tower City Plaza Hotel, Cleveland, OH. Contact: Kenneth D. Pimple, Assistant to the Executive Secretary, APPE, 410 North Park Ave., Bloomington, IN 47405. Phone: (812) 855-0261.

May 22-27 - Teaching Research Ethics: A Workshop at Indiana University, Bloomington, IN. Contact: Kenneth D. Pimple, Assistant to the Executive Secretary, APPE, 410 North Park Ave., Bloomington, IN 47405. Phone: (812) 855-0261.

June 16-17 - Data Collection and Management. Johns Hopkins Center for Clinical Trials. Contact: Office of Continuing Education, Johns Hopkins Medical Institutions, Turner 20, 720 Rutland Avenue, Baltimore, MD 21205-2195 Phone: (410) 955-2959.

PUBLICATIONS*

Fraud and Misconduct in Medical Research. Edited by Stephen Lock and Frank Wells. Provides information on efforts to handle misconduct in medical research in England, France, Denmark, Australia, and the United States. Published by the BMJ Publishing Group, Tavistock Square, London WC1H 9JR England, UK.

Integrity in Biomedical Research. Supplement to September 1993 issue of Academic Medicine. Edited by Paul Friedman, M.D. To order copies of the supplement, contact the AAMC Publications Order Department, Association of American Medical Colleges, 2450 N Street N.W., Washington, DC 20037-1123. Phone: (202) 828-0548.

Ethics, Values, and the Promise of Science. Proceedings from a forum held on February 25-26, 1993 in San Francisco, CA. Copies may be purchased from Sigma Xi, P.O. Box 13975, Research Triangle Park, NC 27709. Contact Dee Windley at 1-800-243-6534.

Intellectual Property Rights and Industry-Sponsored University Research. A Guide to Alternatives for Research Agreements. Copies are available from the Government-University-Industry Research Roundtable, 2101 Constitution Avenue NW (NAS340), Washington, DC 20418. Phone: (202) 334-3486.

ORI BIENNIAL REPORT PUBLISHED

In 1991-1992, the ORI opened 57 misconduct cases and closed 55 cases, ending the two-year period with 71 cases, a net gain of two.

Of the 55 closed cases, 20 investigations resulted in 10 findings of misconduct, and 10 findings of no misconduct. The other 35 cases were inquiries which did not progress to investigations.

In addition, the ORI responded to 314 queries concerning possible research misconduct, including 40 related to intramural research and 274 related to extramural research.

These are some of the facts reported in the Office of Research Integrity Biennial Report: 1991-1992 which has been distributed to readers of this newsletter.

The biennial report provides summaries of the 20 closed investigations as well as a descriptive statistical analysis of those investigations. The analysis presents case outcome by PHS research program, type of investigation, allegations, institutional actions, government actions, academic rank of complainant/respondent, highest degree of complainant/respondent, gender of complainant/respondent, complainant/respondent relationship, institutional setting, funding mechanisms, length

of inquiries/investigations, and size of inquiry/investigation panels.

In addition, the report contains listings of ORI conferences and workshops, project support, Federal Register notices, publications, and presentations.

A copy of the report may be obtained from the Division of Policy and Education, ORI.

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

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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.

*Lists of Upcoming Meetings, Papers, and Publications 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.