

ORI NEWSLETTER, Volume 1, No. 1
Office of Research Integrity, U.S. Public Health Service
January 1993

Department of Health and Human Services, Public Health Service,
Office of Research Integrity, Rockwall II Building, Suite 700,
5515 Security Lane, Rockville, Maryland 20852, (301) 443-3400

Dear Colleague:

With this letter, I am pleased to share with you both the first issue of the ORI Newsletter and the announcement of Dr. Lyle Bivens to lead the Office of Research Integrity (ORI). In June 1992, the U.S. Public Health Service created the Office of Research Integrity in an effort to elevate, augment, and revise its activities and policies related to scientific integrity. We feel that a great deal has been accomplished in the intervening period. Major developments include: enhancement of ORI investigations staff; codification of investigative procedures in a three-volume ORI manual; development of a formal proposal to revise research integrity policies in a way that will clarify the definition of scientific misconduct, increase accountability of institutions for followup to allegations, and streamline investigations by both universities and the government; implementation of an adjudicated appeals process for scientists who disagree with ORI determinations; expansion of the Advisory Committee on Research Integrity; and introduction of an initiative on education and outreach. In addition, substantial progress has been made on the existing caseload. During the last six months of 1992, final decisions and notices went out to approximately 15 respondents accused of scientific misconduct, including certain of the most visible cases.

The ORI Newsletter offers an important vehicle to contribute to the education and outreach effort. It will be published quarterly and distributed free to organizations and individuals with an interest in the field of research integrity. It is not copyrighted, and we hope you will maximize exposure to the newsletter within your organization by freely duplicating and distributing it to appropriate offices, departments, committees, and laboratories. If you have any comments or suggestions for the newsletter, please send them to Dr. Lawrence J. Rhoades, Division of Policy and Education, Office of Research Integrity, U.S. Public Health Service, 5515 Security Lane, Suite 700, Rockville, MD 20852. Your comments will be greatly appreciated, and will help us make the newsletter useful and informative to the broadest possible audience.

Sincerely, J. Michael McGinnis, M.D.
Deputy Assistant Secretary for Health
and Assistant Surgeon General

Enclosure

TO: ORI Newsletter Readers

FROM: Acting Director, Office of Research Integrity

We in the Office of Research Integrity are pleased to provide you with a copy of this first edition of the ORI Newsletter. As its columns indicate, the Public Health Service (PHS) is in the process of a major restructuring of its efforts to handle allegations of research misconduct, consolidating responsibility in a single office within the Office of the Assistant Secretary for Health.

Several policy changes are also underway, including revision of the definition of research misconduct, streamlining of the process for pursuing allegations of misconduct, creation of an appeals process for all individuals found to have committed misconduct, and amending the criteria and stage for listing individuals in the PHS ALERT system. In addition, the changes in progress are intended to place a greater emphasis on the prevention of research misconduct through the promotion of research integrity.

It is our hope that the ORI Newsletter will help facilitate the communication that is so vital to joint pursuit of these issues by researchers, awardee and applicant institutions, scientific and professional societies, and the PHS. We welcome comments as we seek ways to improve our collaborative efforts to protect and promote research integrity for the sake of science and the American public.

Lyle W. Bivens, Ph.D

PHS REORGANIZES EFFORT TO HANDLE RESEARCH MISCONDUCT

Under a reorganization announced in June 1992, the Office of Research Integrity (ORI) is now responsible for promoting research integrity and investigating misconduct in research supported by the Public Health Service (PHS).

The ORI is a consolidation of the Office of Scientific Integrity (OSI) at the National Institutes of Health (NIH) and the Office of Scientific Integrity Review (OSIR) in the Office of the Assistant Secretary for Health (OASH). The ORI is in OASH and the Director reports directly to the Assistant Secretary for Health. In conjunction with this reorganization, ORI now offers scientists found to have committed scientific misconduct an opportunity to request an administrative hearing by a Research Integrity Adjudications Panel under the auspices of the Department of Health and Human Services (HHS) Appeals Board.

The ORI is composed of the Office of the Director, the Division of Policy and Education (DPE), the Division of Research Investigations (DRI), and the Division of Legal Counsel (DLC).

DLC is staffed by the Office of the General Counsel, HHS.

Lyle W. Bivens, Ph.D., is Acting Director, ORI.

Lawrence J. Rhoades, Ph.D., is Acting Director, DPE. This Division is responsible for developing policies, procedures, rules and regulations, generating education and prevention activities, providing support for the PHS Advisory Committee on Research Integrity, responding to Privacy Act and Freedom of Information Act requests, and managing the Assurances Program. John Butler heads the Assurances Program.

Clyde A. Watkins, Ph.D., is Acting Director, DRI. This Division is responsible for reviewing investigations conducted by grantee institutions, conducting extramural investigations when necessary, and investigating allegations of misconduct in PHS intramural programs.

Chris B. Pascal, Esq., is Chief, DLC. This Division provides legal advice on ORI activities and represents ORI in during administrative hearings conducted by the Research Integrity Adjudication Panels.

PHS ESTABLISHES INTERIM PROCEDURES FOR HEARING PROCESS

Under interim procedures established by the Public Health Service (PHS), an individual against whom the Office of Research Integrity (ORI) makes a finding of scientific misconduct may now request a hearing before the Departmental Appeals Board.

An opportunity for a hearing is available, and applies to cases not closed as of May 29, 1992. A case is closed when the PHS has communicated its final decision on misconduct findings and administrative actions to the respondent. The opportunity for a hearing was announced in the Federal Register on November 6, 1992.

During a hearing, the respondent will have an opportunity to be represented by counsel, to question any evidence and witnesses presented by PHS, and to present evidence and witnesses in rebuttal to the findings and proposed administrative actions. The Panel decision will be the final decision on findings and PHS administrative actions and the recommended final decision on debarment.

To activate the hearing process, a respondent must submit a written request for a hearing within 30 days of receipt of the ORI notice of findings and proposed administrative actions.

The written request must be sent to the Research Integrity Adjudications Panel, Departmental Appeals Board, Room 637-D, Humphrey Building, 200 Independence Avenue, S.W., Washington, DC 20201.

ANNUAL REPORT FORM REVISED

The Annual Report of Activities (PHS Form 6349) now required of institutions will no longer request information on misconduct occurring in research not supported by the PHS.

The 1992 annual report form will be mailed to institutions in January 1993. Submission deadline to ORI/DPE is March 1, 1993.

ADVISORY COMMITTEE IMPACTS RESEARCH INTEGRITY PROGRAM

Since its first meeting in July 1991, the PHS Advisory Committee on Research Integrity has made major contributions to the reorganization of the PHS research integrity program.

The Advisory Committee focused on revising the definition of misconduct in science, offering hearings, protecting complainants, instituting a statute of limitations period on undertaking investigations, limiting the ALERT system to individuals found to have committed misconduct in science, and other issues. With the acceptance of these recommendations, the Advisory Committee will give some of its attention to fostering research integrity.

Committee members are Nicholas H. Steneck, Ph.D., Director, Historical Center for the Health Sciences, University of Michigan, Chair; Stuart Bondurant, M.D. Dean, University of North Carolina Medical School; Roger Bulger, M.D., President, Association of Academic Health Centers; Estelle A. Fishbein, Esq., Vice President and General Counsel, The Johns Hopkins University; Paul J. Friedman, M.D., Dean of Academic Affairs, School of Medicine, University of California, San Diego; Karl A. Piez, Ph.D., Professor of Biochemistry and Molecular Biology, Jefferson Medical College, Thomas Jefferson University; Frances Degen Horowitz, Ph.D., President, Graduate School and University Center, City University of New York; Thomas E. Malone, Ph.D., Vice President for Biomedical Research, Association of American Medical Colleges; Drummond Rennie, M.D., Deputy Editor (West), Journal of American Medical Association, and Adjunct Professor, Institute for Health Policy Studies, University of California, San Francisco; and Eleanor G. Shore, M.D., Dean for Faculty Affairs, Harvard Medical School. One vacancy is being filled following the resignation of Daniel Callahan, Ph.D., Director, The Hastings Center, and two new members are being added.

Dr. Steneck urged the scientific community to bring its concerns and suggestions to the attention of the committee: "Although sometimes seen as opposing forces, PHS and academic scientists clearly have a shared common interest in fostering the greatest possible integrity in health-science research. The Advisory Committee on Research Integrity is committed to seeing that this shared interest is achieved."

DISCLOSURE RULING BEING APPEALED

The Department of Justice is appealing a D.C. District Court decision that would require ORI to disclose the names of all individuals accused of scientific misconduct even those found not to have committed misconduct.

The decision was made in a suit filed by Dr. Charles McCutchen, NIH, under the Freedom of Information Act, that also requested disclosure of the names of complainants. ORI does not voluntarily release the names of individuals found not to have committed misconduct or the names of complainants.

The court ruled that ORI must disclose the identities of individuals accused of scientific misconduct because the accused's privacy interest is professional, not personal, and there is a strong public interest in disclosure of such names, i.e., there is a substantial public interest in oversight of the scientific integrity investigation process. However, the court denied access to complainants' names finding that complainants have a substantial interest in maintaining their privacy and there is little public need for the information.

ORI recommended that the Department of Justice appeal the court's ruling. Several academic associations have indicated they are interested in filing amici curiae briefs in the case.

PHS ALERT SYSTEM LISTING CHANGED

The Public Health Service now lists an individual in the PHS ALERT system only after an investigation concludes that the individual engaged in research misconduct in proposing, conducting, or reporting PHS-supported research.

Under this new procedure, an individual is listed in the PHS ALERT system when the Office of Research Integrity (ORI) receives an investigative report from an institution containing a finding of misconduct in PHS-supported research or when an investigation conducted by ORI finds misconduct.

CASE REPORT: REVIEW ARTICLES PLAGIARIZED IN BOOK CHAPTER

Editor's Note: This newsletter will regularly feature reports on closed cases to broadly disseminate descriptive data on incidents of alleged research misconduct. The reports will cover cases in which misconduct or no misconduct was found. Cases will be selected based on their informational value to institutions and scientists.

An allegation of plagiarism was brought against a full professor by a junior colleague in the Department. The inquiry panel concluded that there was sufficient evidence to warrant an investigation.

The investigative committee found the respondent had used large portions of several review articles, without source acknowledgement, in the preparation of an invited book chapter. The respondent was not a co-author of some of the review articles from which portions were plagiarized. The respondent argued that his role in commissioning the reviews and editing the journal issue in which they appeared justified his use of the material without citation of the original authors.

The committee concluded, and ORI concurred, that the respondent had committed plagiarism and, therefore, scientific misconduct. Administrative actions taken by PHS were (1) prohibiting the respondent from serving on PHS advisory committees, (2) requiring the respondent to certify to his institution and the PHS that he has properly acknowledged the work of others in any application he submits to PHS, and (3) notifying the PHS advisory council or board of the administrative actions in force when an application submitted by the respondent is presented for funding. All actions are in effect for three years. Independently, the university applied additional sanctions, including revocation of the respondent's tenure.

ORI OFFERS ASSISTANCE TO SMALL ORGANIZATIONS

Since 1990, PHS has offered a voluntary policy statement, as an amendment to the Initial Assurance form, for very "small" organizations (typically fewer than 20 employees involved in research or research administration) because these organizations are often unable to conduct inquiries or investigations themselves without encountering real or apparent conflicts of interest.

The voluntary policy statement indicates that the organization will transmit to the ORI all scientific misconduct allegations received, so that the ORI may assist in the conduct of all inquiries and investigations involving PHS-related research at that organization. The organization also agrees, under the signature of a responsible official, to inform all of its employees involved in PHS-related research of this policy.

If your organization is small and you wish to consider such a policy statement to amend your Initial Assurance, please contact the Assurances Program, Division of Policy and Education, ORI.

ORI ALLOTTED MORE PERSONNEL

Additional personnel resources have been assigned to the Office of Research Integrity (ORI) to implement the reorganization of the Public Health Service effort to investigate research misconduct and promote research integrity.

The increased staff will provide more investigators to handle the review and conduct of investigations, more lawyers to assist with investigations and the implementation of the hearing process, and

staffing for the newly created Office of the Director, ORI. Recruitment actions are underway to fill these positions.

PUBLICATIONS

Guidelines for the Conduct of Research within the Public Health Service - States general principles for supervision of trainees, data management, publication practices, authorship, privileged information obtained through peer review, and the special requirements of clinical and epidemiologic research. Free. Office of Research Integrity, U.S. Public Health Service, 5515 Security Lane, Suite 700, Rockville, MD 20852.

Data Management in Biomedical Research: Report of a Workshop, April 1990 - Explores data ownership, retention, and sharing. Free. Office of Research Integrity, U.S. Public Health Service, 5515 Security Lane, Suite 700, Rockville, MD 20852.

Misconduct in Science - Recurring Issues, Fresh Perspectives - Conference executive summary that addresses definition of misconduct, misconduct investigations, and risks, rights, and responsibilities of whistleblowers. Photo copies available. Cost \$4.00, includes postage and handling. Alex Fowler, Directorate for Science and Policy Programs, American Association for the Advancement of Science, 1333 H Street, N.W., Washington, DC 20005.

Honor in Science - Practical advice to individuals beginning careers in scientific research. Single copy: \$2.50. Publications Office, Sigma Xi, The Scientific Research Society, P. O. Box 13975, Research Triangle Park, NC 27709.

Responsible Science: Ensuring the Integrity of the Research Process, Volume 1 - Reports a two-year study by the National Academy of Sciences that comprehensively reviewed the factors that influence the integrity of the research process. Paperback copy: \$24.95 plus \$4.00 shipping and handling. National Academy Press, 2101 Constitution Avenue, N.W., Washington, DC 20418.

Good Science and Responsible Scientists: Meeting the Challenge of Fraud and Misconduct in Science - Albert H. Teich and Mark S. Frankel for the AAAS-ABA National Conference of Lawyers and Scientists. Single copies are free. Directorate for Science and Policy Programs, American Association for the Advancement of Science, 1333 H Street, N.W., Washington, DC 20005.

ORI ESTABLISHES LIAISON GROUP

The Office of Research Integrity (ORI) has established an intra-Departmental Research Integrity Liaison Group (RILG) to solicit advice from each PHS agency on policies, procedures, programs, plans, and issues related to research integrity and research misconduct. The RILG also will review recommendations from the PHS Advisory Committee on Research Integrity.

Chaired by the Director, ORI, members of RILG include Richard J. Greene, M.D., Director, Center for Medical Effectiveness Research, Agency for Health Care Policy and Research; Claire V. Broome, M.D., Associate Director for Science, Centers for Disease Control; Mary K. Pendergast, Senior Advisor to the Commissioner, Food and Drug Administration; William Freeman, M.D., Chairman, National IHS Institution Review Board, Indian Health Service; Lyman Van Nostrand, Deputy Associate Administrator for Planning, Evaluation, and Legislation, Health Resources and Services Administration; Michele W. Applegate, Associate Administrator for Extramural Programs, Substance Abuse and Mental Health Services Administration; John W. Diggs, Ph.D., Deputy Director for Extramural Research, National Institutes of Health; Richard J. Riseberg, Esq., Chief Counsel, Public Health Service, Office of General Counsel, Department of Health and Human Services; and Roger McClung, Associate Director (Health), Office of the Deputy Assistant Secretary for Legislation (Health).

MEETINGS

February 25-26 - Ethics, Values, and the Promise of Science. Sigma Xi Forum. Westin St. Francis Hotel, San Francisco. Contact: Lynn Giesmann at (800) 243-6534.

February 27-28 - PHS Advisory Committee on Research Integrity. San Francisco. Westin St. Francis Hotel, San Francisco. Contact: Henrietta Hyatt-Knorr at (301) 443-5300.

April 1-2 - Conference on Teaching Ethics to Science Students. Sponsored by Public Responsibility in Medicine and Research. Park Plaza Hotel, Boston. Contact: Joan Rachlin at (617) 423-4112.

June 21-22 - Conference on Plagiarism and Theft of Intellectual Property. Cosponsored by ORI and AAAS. Lister Hill Auditorium, National Institutes of Health, Bethesda. Contact: Dr. Alan Price at (301) 443-5330.

PROSPECTUS

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.

Communications should be addressed to ORI Newsletter, Office of Research Integrity, U.S. Public Health Service, 5515 Security Lane, Suite 700, Rockville, MD 20852. Phone: (301) 443-5300.

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