ORI NEWSLETTER

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ADMINISTRATIVE ACTIONS AVAILABLE ON ELECTRONIC BULLETIN BOARD

An administrative actions bulletin board was established in February to assist PHS agencies and extramural institutions in implementing administrative actions imposed on individuals for scientific misconduct or violations of FDA regulations governing research.

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

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

Access to the bulletin board can be obtained through a modem, NIHnet, or Internet. The information can be viewed and/or downloaded. Specific instructions on accessing and downloading information on the bulletin board were published in the NIH Guide for Grants and Contracts, Volume 24, Number 7, on February 24, 1995. Technical questions on accessing the bulletin board should be directed to Ms. Jo Ann Wingard of the NIH Division of Research Grants by phone at (301) 435-0922 or by Email at cja@drgpo.drg.nih.gov.***

GUIDELINES DEVELOPED ON WHISTLEBLOWER PROTECTION

ORI has drafted advisory guidelines to assist institutions in responding to retaliation complaints from good faith whistleblowers. The existing PHS regulation requires institutions to "undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations." [42 C.F.R. 50.103(d)(13)] However, the existing regulation does not provide a procedure for responding to retaliation complaints.

The NIH Revitalization Act of 1993 mandated the development of a regulation on whistleblower protection that will contain procedures for handling retaliation complaints. However, since it will take some time before any proposed regulation becomes

effective, ORI developed these guidelines to assist institutions in complying with the existing regulation.

ORI is not mandating the adoption of the whistleblower guidelines. An institution may adopt other procedures that would adequately comply with the current regulation. However, if an institution adheres to the guidelines in handling a complaint, ORI will consider it in compliance with the existing regulation.

At press time, the draft guidelines were being reviewed by 40 extramural institutions, the PHS, and the Commission on Research Integrity. ORI is also seeking comments from whistleblowers.

Copies are available from the Division of Policy and Education at (301) 443-5300.***

ORI ANNUAL REPORT PUBLISHED FOR 1994

Nine of the eleven respondents found guilty of scientific misconduct in 1994 were debarred from receiving Federal research funds for periods ranging from three to five years. Allegations of fabrication and/or falsification provided the basis for 24 of the 26 investigations closed in 1994 and 10 of the 11 findings of misconduct.

Only one of the 26 investigations involved an allegation of "other practices" and it was combined with plagiarism. That investigation found no misconduct.

ORI closed 50 cases in 1994, the highest number completed in a single year, and reduced its backlog, cases opened from 1989 to 1992, by 69 percent.

In the only hearing decision issued in 1994, the Departmental Appeals Board affirmed the finding of scientific misconduct and the administrative actions imposed on the respondent.

These are some of the facts presented in the ORI Annual Report 1994 along with summaries and descriptive statistics on closed investigations, information on legal issues, institutional compliance reviews, retaliation complaints, the PHS research integrity program, and policy and procedural development.

A copy of the 1994 report may be obtained from the Division of Policy and Education, ORI. Copies of the 1993 and the 1991-92 reports are also available.***

EDITORS LIST AUTHORSHIP CRITERIA

Authorship must be acquired the old-fashioned way; it must be earned, not bestowed, according to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals developed by the International Committee of Medical Journal Editors and followed by over 500 journals.

Authorship may be earned only by substantially contributing to: "a) the conception and design, or analysis and interpretation of data; and to, b) drafting the article or revising it critically for important intellectual content; and on c) final approval of the version to be published. Conditions a), b), and c) must all be met."

Authorship should not be bestowed for:

- participation solely in the acquisition of funding or the collection of data, or the
- general supervision of the research group.

The Uniform Requirements further assert that "each author should have participated sufficiently in the work to take public responsibility for the content" and "any part of an article critical to its main conclusion must be the responsibility of at least one author."

A supplemental statement from the International Committee of Medical Journal Editors stipulated that "the order of authorship should be a joint decision of the coauthors." However, authors may want to explain the order in a footnote because the "different ways" in which authorship is assigned makes it difficult to accurately interpret the significance of the order.

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CASE SUMMARY RESIDENT FALSIFIED RESULTS

James T. Kurtzman, M.D., University of California at San Francisco. An investigation conducted by the University found that Dr. Kurtzman, a former Resident/Fellow in the Department of Obstetrics, Gynecology, and Reproductive Sciences, falsified results of research on the kinetics of nitric oxide synthase in cells and homogenates of human myometrial tissue in pregnant women. Dr. Kurtzman admitted that he had altered data in eight experiments that he performed during December 1993 and January 1994. Dr. Kurtzman reported that he had conducted the enzyme

assays and entered the data into a computer-based spreadsheet, but then changed the data to generate graphs that would reproduce the type of results that he had submitted earlier to the Journal of Clinical Investigation. The paper was not published. Dr. Kurtzman executed a Voluntary Exclusion and Settlement Agreement in which he has agreed not to apply for Federal grant or contract funds and will not serve on PHS advisory committees, boards or peer review groups for a three-year period beginning March 18, 1995. The voluntary exclusion, however, shall not apply to Dr. Kurtzman's future training or practice of clinical medicine whether as a resident, fellow, or licensed practitioner, as the case may be, unless that practice involves federally funded research or the direct receipt of an award for federally funded research training.

CASE SUMMARY CLINIC COORDINATOR FALSIFIED AND FABRICATED DATA

Vivian N. Tanner, Cleveland Clinic Foundation. ORI conducted an investigation into possible scientific misconduct on the part of Vivian N. Tanner while she was a clinic coordinator for the Collaborative Ocular Melanoma Study (COMS) at the Cleveland Clinic Foundation (CCF). ORI concluded that Ms. Tanner committed scientific misconduct by falsifying and fabricating clinical trial data on research data forms related to a multicenter study on the treatment of choroidal melanoma, a rare form of eye cancer. Due to these falsifications and fabrications, inaccurate clinical data were entered into the clinical trial database. These acts were committed over a period of several years, were material, and, therefore, were potentially detrimental to the study. The CCF COMS project received PHS support from 1985 to the present through subcontract funds from a National Eye Institute cooperative agreement award to the COMS Coordinating Center, The Wilmer Ophthalmological Institute, The Johns Hopkins Medical Institutions, Baltimore, Maryland. Because the COMS is an ongoing study, no publications were affected by the falsfified or fabricated data, and no clinical treatment has been based on the results of the study. Ms. Tanner has been debarred for three years beginning February 21, 1995.***

COMMISSION DELIBERATIONS TURN TO RECOMMENDATIONS AND REPORT

The Commission on Research Integrity will focus its next three meetings on the development of its recommendations and report.

The meetings will be held at the Washington Dulles Airport Marriott on June 26-27; the Belmont House near Baltimore on July 30-August 1, and at the Washington Dulles Airport Marriott on

September 18-19. The final report is expected to be available in the fall of this year.

The Commission concluded its data collection with regional meetings at the University of Alabama-Birmingham on May 4-5, at Harvard Medical School on April 10-11, at De Paul University in Chicago on March 9-10, and at the University of California-San Francisco on February 9-10.

All meetings are open to the public and announced in the Federal Register. Information on the meetings may be obtained by contacting Henrietta Hyatt-Knorr at (301) 443-5300 or through Internet at hhyatt@oash.ssw.dhhs.gov.***

MEDICAL SCHOOL POLICIES REFLECT REGULATION; DEFICIENCIES NOTED

A review of the administrative processes established by 32 medical schools for responding to allegations of scientific misconduct found that more than 90 percent of the institutions have incorporated the basic process outlined in the Federal regulation into their policies and procedures.

The deficiencies found in the administrative processes are related to the applicability of the process to all persons involved in PHS-supported research, the composition of committees, the rights of the respondent to comment on the inquiry and investigative reports, the protection of whistleblowers, notifications to ORI, and the maintenance of documentation.

The provisions of the Federal regulation that are incorporated into the administrative processes of more than 90 percent of the sampled medical schools are:

- an impartial process for receiving allegations,
- confidential treatment afforded to affected individuals,
- completion of an inquiry within 60 days,
- preparation of an inquiry report,
- initiation of an investigation within 30 days of the completion of an inquiry recommending an investigation,

- notification to ORI that an investigation will be conducted,
- selection of appropriate experts to conduct a thorough investigation,
- completion of the investigation within 120 days,
- diligent efforts to restore reputation of persons against whom allegations are not confirmed, and
- imposition of sanctions on individual against whom allegations are confirmed.

The most notable deficiency found in the administrative processes is the failure to explicitly state that the process covers all individuals involved in research supported by PHS funds. The majority of medical schools explicitly state that their policies and procedures apply to faculty (75 percent) and staff (56.2 percent). Other categories of individuals supported by PHS research funds are rarely cited specifically: post-doctoral students (12.5 percent), graduate students (15.6 percent), and technicians (3.12 percent).

Another notable deficiency is the failure to recognize that several provisions apply to both inquiries and investigations. Although 91 percent of the medical schools cite the need for expertise to conduct an investigation, only 81 percent cite a comparable need for conducting an inquiry. Affected individuals are afforded an opportunity to comment on the investigative report (88 percent) more frequently than they are afforded an opportunity to comment on the inquiry report (72 percent). The need to take precautions against real or apparent conflicts of interest is inadequately cited for inquiries and investigations (81 percent).

The provisions related to the protection of respondents and whistleblowers were differentially included. More medical schools cite the provision requiring a diligent effort to restore the reputation of an individual against whom the allegation was unsubstantiated (91 percent) than cite the provision requiring a diligent effort to protect the reputation and position of good faith whistleblowers (72 percent).

The least cited provisions pertained to notification to ORI, the protection of Federal funds, and retention of documentation. Only 66 percent of the medical schools require submission of an investigative report to ORI in 120 days. Other provisions with

low citation rates were notification within 24 hours of possible criminal violations (75 percent), promptly advising ORI about developments that may affect funding for the respondent (69 percent), taking appropriate interim actions to protect Federal funds (69 percent), submitting a report on the premature termination of an inquiry or investigation (59 percent) and requesting an extension of time to complete an investigation (53 percent). The retention of documentation of an inquiry for at least three years is cited by 59 percent of the medical schools.

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LETTER TO THE EDITOR:
UCSF Investigators' Handbook Available on Internet

During discussions that occurred at a workshop on research misconduct recently, I was struck by the need among many institutions for written materials to promote good research practices. While most large, research-intensive institutions seem to have developed and distributed materials tailored to their individual needs, many smaller institutions may lack the resources, experience, or expertise to produce de novo their own detailed materials. Here at the University of California, San Francisco (UCSF), we have just completed revising our Investigators' Handbook.* It is a compilation of UCSF policies and practices related principally to pre-award research administration, but it includes matters related to research integrity. To the degree that some of this material is generally applicable in promoting good research practices, it may be of interest to institutions of any size.

The following topics related to good research practices and the maintenance and protection of research integrity are addressed: (1) Relations with Industry, including disclosure of financial interests and management of intellectual property; (2) Meeting Regulatory Requirements for Conducting Research, including biosafety, the use of human and animal subjects, chemical safety, radiation safety, and the use of radioactive drugs; and (3) Research Integrity, including integrity in science, scientific misconduct, whistleblower policy, data ownership and management, authorship responsibilities, and freedom of information.

Readers will find the UCSF Investigators' Handbook on the Internet, and are welcome to use those parts of it they find useful. It can be found by pointing a WWW browser to http://www.library.ucsf.edu/ih/. Consistent with the principles of academic integrity, UCSF would appreciate acknowledgement, as appropriate, by those who choose to use materials from the Handbook. Comments and suggestions are also welcome, and may be

sent to the address cited in the on-line Handbook.

Karl J. Hittelman, Ph.D.
Associate Vice Chancellor
Academic Affairs, UCSF, and
Member, Commission on Research Integrity

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TWO TEXTBOOKS AVAILABLE ON SCIENTIFIC INTEGRITY

Scientific Integrity: An Introductory Text with Cases* is a new textbook published by the American Society for Microbiology, which was written by Francis L. Macrina, Ph.D., Chair, Department of Microbiology and Immunology, Virginia Commonwealth University.

The text provides a full range of areas in the field of scientific integrity, and each chapter ends with 10-20 case studies for use in classroom discussion or writing assignments. The text covers the practical, regulatory, and ethical issues related to the use of both animals and humans in biomedical research, and includes the complete text of Helsinki II.

Copies may be ordered by calling the American Society for Microbiology, 1-800-546-2416.

Research Ethics: Cases and Materials* is a new textbook that provides teaching materials focussed on ethical issues in research.

Edited by Robin Levin Penslar, the topics covered in this book include theory and pedagogy, cases in the natural sciences, cases in the behavioral sciences, and cases in the humanities.

Copies may be ordered from Richard Gilbert, Indiana University Press, 601 North Morton Street, Bloomington, IN 47404; Telephone (812) 855-5429; FAX: (812) 855-7931 or E-mail: rgilber@indiana.edu.***

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.**

NIH CREATES COMMITTEE ON SCIENTIFIC CONDUCT

A Committee on Scientific Conduct and Ethics (CSCE) will be established by the Office of Intramural Research, NIH, to handle cases involving misconduct in science and other ethical issues.

In addition to the proposed committee, the Office of Intramural Research has created a "Science Ethics Forum" in its bimonthly publication, The NIH Catalyst.

According to an article in the November - December 1994 issue of The NIH Catalyst, the CSCE will include members from each NIH institute, center and division to ensure a broad representation of scientific disciplines.

Each allegation of misconduct in science or dispute concerning authorship or publication practices, record keeping, sharing of materials and data, and mentoring and supervision will be addressed by a subcommittee of CSCE. Some cases may be settled through arbitration, the article said.

Besides responding to allegations and disputes, the committee is expected to develop procedures for protecting the rights of complainants and respondents in scientific misconduct cases. The committee may also review the Guidelines for the Conduct of Research in the Intramural Research Program at NIH and the Instructions for Assessing Allegations and Conducting Inquiries in Cases of Scientific Misconduct in PHS Intramural Programs.

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EUROPE, AUSTRALIA ADDRESS SCIENTIFIC DISHONESTY

Efforts to address scientific dishonesty are underway in Europe and Australia according to the 1993 Annual Report of the Danish Committee on Scientific Dishonesty (DCSD).

The DCSD was appointed in November 1992 to handle all allegations of scientific dishonesty in Denmark. In 1993, the Committee handled 15 cases, none of which resulted in a finding of scientific dishonesty. However, the cases did reveal "the existence of serious conflicts in certain research environments," the need for a neutral body to clear "researchers of baseless accusations" and the necessity of developing "standards and norms for good scientific conduct."

In Norway, a committee appointed by the Council for Medical Research in 1992 has prepared a briefing that discusses the concept of scientific dishonesty, preventive measures, and a permanent procedure for investigating allegations of scientific dishonesty. The briefing is under review.

A conference on research fraud held in October 1993 by the Swedish Medical Research Council concluded that a Swedish initiative was needed.

Guidelines on research practice prepared by the Finnish National Research Ethics Committee were accepted by all universities and major research institutions in Finland in March 1994.

In 1990, the European Medical Research Council, a subdivision of the European Science Foundation, cited scientific dishonesty as a national problem requiring national solutions. In June 1992, the Council established a Panel on Medical Ethics, which in May 1993, recommended the establishment of good practice guidelines for use in member countries.

In Australia, the National Health and Medical Research Council in 1990 published guidelines for good scientific practices that applicant institutions are required to follow. The Council has also published guidelines for dealing with charges of scientific dishonesty.***

PASCAL AND MACFARLANE NAMED TO RESEARCH INVESTIGATION POSTS

ORI integrated the legal and scientific perspectives into investigations of scientific misconduct by naming a lawyer and a medical doctor to top administrative posts in the Division of Research Investigations.

Chris B. Pascal, J.D., Chief, Research Integrity Branch, Office of the General Counsel, was named Director, DRI, and Dorothy K. Macfarlane, M.D., Senior Medical Officer, DRI, was named Deputy Director, DRI.

The appointments of Mr. Pascal and Dr. Macfarlane gives the DRI management team expertise in law, clinical research and basic research. Both branch chiefs within DRI hold Ph.Ds.

Mr. Pascal served as Chief Counsel, ORI, since the office was established in May 1992. He also served as legal advisor to the former Office of Scientific Integrity Review (OSIR) from 1989-1992 when OSIR was merged with the former Office of Scientific Integrity (OSI) to form ORI.

Mr. Pascal spent most of his Federal service (1977-1992) with the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). As Chief Counsel for ADAMHA he participated in investigations of scientific misconduct.

Mr. Pascal holds a law degree from Duke University (1974) and a bachelor's degree from Auburn University (1971). He also did postdoctoral work in psychology and law at Duke University.

Dr. Macfarlane served as Acting Director, DRI, for 19 months (August 1993 to February 1995) before assuming her new position. She joined OSI in February 1992 as Senior Medical Officer.

Dr. Macfarlane worked for the National Cancer Institute for 15 years before joining OSI. Among the positions she held were Assistant Program Director, Clinical Oncology Program, 1977-78; Executive Secretary, Cancer Clinical Investigation Review Committee, 1979-83; Program Director, Community Oncology and Rehabilitation Program, 1983-84; and Head, Quality Assurance and Compliance Section, Regulatory Affairs Branch, Cancer Therapy Evaluation Program, 1985-92. She also served as a research assistant in the Department of Biology at Georgetown University from 1967-72.

Dr. Macfarlane holds a medical degree from University of Maryland (1976) and a bachelor's degree from Chestnut Hill College, Philadelphia (1967).***

ACTING CHIEF COUNSEL NAMED FOR ORI

Marcus H. Christ, Jr., has been appointed Acting Chief, Research Integrity Branch, Office of the General Counsel. He replaces Chris B. Pascal, who was appointed Director, DRI.

Mr. Christ joined ORI in 1992 from the Health Care Financing Division of the HHS Office of the General Counsel where he was a litigator. He received his law degree from Pepperdine University; his bachelor's degree is from the University of Arizona.***

RESOURCE MATERIALS*

Teaching the Responsible Conduct of Research Through a Case Study Approach: A Handbook for Instructors. AAMC Publications Sales, 2450 N St., N.W., Washington, DC 20037. Phone (202) 828-0416.

On Being A Scientist: Responsible Conduct in Research. Updated in 1995. National Academy Press. Phone: (800) 624-6242.

Honor in Science. Sigma Xi, The Scientific Research Society. Phone (800) 243-6534.***

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ORI PUBLICATIONS ON OASH BULLETIN BOARD

Copies of this newsletter and other ORI publications are available through the Office of the Assistant Secretary for Health's Electronic Bulletin Board System.

Access is available by dialing (202) 690-5423 for up to 14.4. Four outside the DC area, dial (800) 841-4593. The system requires the caller's communication package settings to be: n (no parity), 8 (8 data bits), 1 (1 stop bit) and full duplex. The system contains text files compressed by PKZIP. For technical assistance, call Ted Foor (202) 401-8646.***

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

Office of the Director.....(301) 443-3400
FAX.....(301) 443-5351
Division of Policy and Education...(301) 443-5300
FAX.....(301) 443-5351
Assurances Program.....(301) 443-5300
FAX.....(301) 443-0042
Div. of Research Investigations....(301) 443-5330
FAX.....(301) 443-0039
Research Integrity Branch/OGC.....(301) 443-3466
FAX.....(301) 443-0041

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