

ORI NEWSLETTER

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UNIV. OF FLORIDA AND ORI HOLD WORKSHOP ON RESEARCH INTEGRITY

Fifty-five representatives of fourteen public and private institutions in Florida and Georgia attended a workshop on research integrity issues in Gainesville on April 15 that was jointly organized and presented by the University of Florida and ORI. ORI staff also made a presentation on research integrity to about 35 graduate students on April 14.

Chris Pascal, Acting Director, ORI, said, "This was the first workshop we have done jointly with an institution. This successful experience has us thinking about trying to do more joint workshops . . . with institutions strategically located around the country."

Staff from the University of Florida and ORI each presented three sessions; two other sessions were jointly presented. Representatives from several other institutions served as panel members in two sessions.

Topics covered included the procedural choices institutions must make in developing their policy for responding to allegations of scientific misconduct; the impact of State laws on the maintenance of confidentiality in misconduct cases; the need to establish new standards for recording research data to replace or supplement the bound notebook; the need to develop awareness among faculty and students about research integrity issues; the evolving definition of research misconduct; ORI policies and procedures related to inquiries, investigations, retaliation complaints, policy reviews and institutional compliance; the protection of whistleblowers; and the restoration of reputations of exonerated individuals.

One session took the attendees through the actual handling of a complex misconduct case and asked the attendees what decisions they would have made at certain points in the process. Their responses were compared to the actual decisions.

"The support provided by the University of Florida made the workshop possible," Pascal said. The university handled local arrangements, produced and mailed a promotional brochure, handled advance registration, and provided staff support during the workshop.

INSTITUTIONS OPENED 70 MISCONDUCT CASES IN 1996

Seventy new scientific misconduct cases were opened in 1996 by 54 institutions that conducted 61 inquiries and 25 investigations in response to 127 allegations according to their 1996 Annual Report on Possible Research Misconduct.

A total of 88 institutions were responding to allegations in 1996 because 47 institutions were continuing to investigate allegations received before 1996 while 13 were dealing with allegations made prior to and in 1996.

In their submissions, institutions report the receipt of an allegation of scientific misconduct, the type of misconduct, and the conduct of an inquiry and/or investigation. Reportable activities are limited to alleged misconduct involving PHS-supported research, research training, or other research-related activities.

Of the 54 institutions reporting new allegations in 1996, 41 were institutions of higher education; eight were research organizations; four were independent hospitals; and one was another health, human resources, or environmental services organization.

The 127 new allegations reported in 1996 included 33 of fabrication, 34 of falsification, 19 of plagiarism, and 41 of other serious deviations. The number of new cases opened by the 54 institutions ranged from 1 to 4. Twenty cases involved multiple allegations. Seven institutions did not report the type of misconduct.

ORI CONDUCTING STUDY OF INSTITUTIONAL INQUIRIES

ORI is undertaking a study of inquiries conducted by institutions in 1994 or 1995 that did not proceed to an investigation and did not require submission of the inquiry report to ORI to determine what technical assistance, if any, should be offered to institutions and to fulfill its oversight responsibility related to the implementation of the PHS regulation (42 C.F.R. Part 50, Subpart A).

The review is expected to indicate problem areas in the conduct of inquiries that may need to be addressed by institutions through revised procedures or by the ORI through its publication and workshop programs.

Inquiry reports were received from 16 of the 21 institutions that indicated on their Annual Report on Possible Research Misconduct that they had conducted inquiries in 1994 or 1995 that were not followed by an investigation. Numerous inquiries that did not proceed to an investigation were eliminated from the study because the inquiry was referred to the institution by ORI, which requested an inquiry report.

Institutions were asked to eliminate the names of the institution and individuals involved to protect the confidentiality of the proceedings and the privacy of the individuals involved. The reports were submitted in plain envelopes with no return address. Under separate cover, the institution notified ORI whether it was participating in the study.

The submitted material is being examined to determine whether the process employed by each institution followed the provisions of the Federal regulation. Results will be reported as

aggregate data in an ORI report that will be posted on the ORI Home Page and published in the *ORI Newsletter* and the *ORI Annual Report*. The report will also be available from ORI upon request.

ANGELIDES APPEALS ORI FINDING

ORI has concurred with an institutional investigation finding that Kimon J. Angelides, Ph.D., formerly at the Baylor College of Medicine, has committed scientific misconduct by intentionally falsifying data in the text and figures of five NIH grant applications and five published scientific papers from 1988-92.

ORI has proposed that Dr. Angelides retract the five papers and be prohibited from serving in any advisory capacity to the PHS or as a consultant for a period of five years. The DHHS Debarring Official also has proposed that Dr. Angelides be debarred from applying for, or receiving Federal funds for a five-year period.

The Baylor investigation, upon which ORI primarily based its finding, concluded that Dr. Angelides was solely responsible for the falsifications of data and that he did so with an intent to deceive. Dr. Angelides is accused of falsely reporting data originally generated by five different researchers. Many of the falsifications occurred after the researcher who produced the data had moved to another laboratory, and the data falsification often escalated in successive grant applications and paper submissions. The primary data utilized by Dr. Angelides were left in Dr. Angelides' laboratory after the researchers moved elsewhere.

Dr. Angelides has requested a *de novo* review of the findings and proposed administrative actions, including the debarment, before the DHHS Departmental Appeals Board. He has also sued the Baylor College of Medicine and several of its officials, including the investigation committee and witnesses, in Texas state court. The Texas suit raises several claims, including but not limited to wrongful termination and defamation arising out of the institutional misconduct proceedings.

An *amicus curiae* brief filed by the Federal government in the U.S. Court of Appeals for the Fifth Circuit argues that institutions and individuals should be protected from defamation lawsuits when they provide information on allegations of scientific misconduct to ORI because such actions are privileged by the mandatory notification requirements of Federal law.

SOME WORDS TO THE WISE ABOUT MISCONDUCT INVESTIGATIONS

In 1991, the University of South Florida (USF) developed an 8-page policy for responding to allegations of scientific misconduct. In 1996, USF used the policy for the first time in responding to two allegations: one on plagiarism; the other on falsification of data. At the University of Florida workshop described on page 1 of this issue, Camille A. McWhirter,

Assistant General Counsel for Health Affairs, USF, presented the lessons learned in interpreting the gaps in that policy while applying it to the “incredibly emotional experience that the review process turned out to be.” A summary follows:

The purpose of the review process is to substantiate or refute the allegation. If the alleged facts are true, the motive of the accuser is irrelevant. Each allegation must be considered separately from the character, position or reputation of the person bringing the charge.

An allegation of scientific misconduct may be one of the most stressful events the accused person will ever face. Stress can be alleviated by clearly explaining the procedures that will apply, the confidentiality measures that will be taken, and the expected length of the review. Periodic updates on the progress of the investigation are helpful. Be friendly and cordial but do not become a friend or confidante of the accused or the accuser.

The success of the investigation panel will depend on having the right persons with the right expectations. Include a member from outside the university on the investigation panel for credibility, a member from the department of the accused, and a member from elsewhere in the university. Selection should be based on scholarly achievement and reputations for unquestioned personal integrity. Scholarly achievement without the balance of temperament suitable to this task can scuttle the whole process.

Panel members will have no idea what a stressful, difficult, time-consuming and thankless task they have undertaken. Convey the seriousness of the task, the time it can take, their liability and protections as panel members, the meaning of intent and standards of proof, the importance of being thoughtful and objective, the need for confidentiality, the role of legal counsel, the availability of support staff, the collection of evidence, the requirements of a good and adequate final report, and what will happen to the report after the process ends. A good panel will become righteously indignant if their findings are questioned or changed without the opportunity for input.

Insulate the panel from any administrative influence and *ex parte* communications with the parties. It is crucial to maintain the integrity of the review process and avoid any appearance of institutional influence over the panel’s deliberations or decision-making.

Present a clear charge to the panel and a precise statement of the scope of the review or issues to be resolved. Otherwise the panel will not ask the right questions, will omit relevant avenues of inquiry and may pursue irrelevant ones. The result will be a directionless inquiry with meaningless conclusions.

Have procedures in place for securing original documents, biological specimens, lab notebooks, research and financial records and other items that could be altered, lost, or destroyed. This delicate and intrusive process will be stressful for the respondent and the institution. Explain to the respondent why these steps are necessary for his or her own protection, and allow the respondent to have copies of records needed so that the work is not interrupted.

Discourage or prohibit the use of e-mail for transmitting information concerning the substance of the case and especially drafts of reports.

ORI ACTIVITIES MONITOR INSTITUTIONAL COMPLIANCE IN 1996

ORI closed 12 compliance cases, requested policies for responding to allegations of scientific misconduct from 226 institutions, warned 4 institutions about possible funding cutoffs, and inactivated the assurances of 319 institutions in 1996 as part of its effort to monitor institutional compliance with the PHS regulation.

The compliance cases involved four retaliation complaints, six compliance reviews, and two cases involved both. An institutional investigation found no retaliation in one case; PHS jurisdiction could not be established in the remaining cases. Three compliance reviews resulted in requests for revised policies. The other three were closed because the concerns did not violate the regulation or they were too old to pursue. Six compliance cases—three retaliation complaints and three compliance reviews—were opened in 1996. Ten cases were carried into 1997.

ORI requested policies when: institutions did not appropriately answer the questions in the Annual Report on Possible Research Misconduct about the availability of policies; as part of the 5 percent sample; and when ORI opened a case—misconduct, compliance, retaliation—involving the institution.

By December 31, reviews were completed on 168 policies; 84 were accepted as submitted and 84 were returned to institutions for revision. Fifteen policies were under review in ORI. Receipt of 33 policies was pending. Ten institutions inactivated their assurances instead of submitting policies.

ORI notified four institutions that it would recommend that NIH suspend current support and withhold all future support to them if they failed to establish active assurances by submitting the requested materials within 60 days. These compliance actions were taken after the institutions failed to respond to repeated requests for the required materials. All four institutions subsequently established active assurances.

Assurances were inactivated in 319 cases because the institution failed to submit its Annual Report on Possible Research Misconduct or failed to respond to a request for its institutional policy.

ORI REQUESTS POLICIES FOR REVIEW IN 1997

Two hundred and sixty-nine institutions were asked in April to submit their policies for

responding to allegations of scientific misconduct involving PHS-supported research to ORI within 60 days for review.

One hundred and seventy-nine policies were requested because the institutions indicated in their 1996 Annual Report on Possible Research Misconduct that they did not have such a policy or that they failed to answer the question asking about the availability of a policy. Ninety policies were requested for the 1997 annual sample of policies reviewed by ORI.

Institutions with fewer than 10 employees may submit a small organization policy statement in lieu of an administrative policy. A copy of that policy statement is in the *ORI Handbook for Institutional Research Integrity Officers* or may be requested from ORI.

Besides fulfilling its monitoring responsibility, ORI views these reviews as a mechanism for assisting institutions in developing an administrative policy that complies with the Federal regulation (42 C.F.R. Part 50, Subpart A).

Each institution that submits a policy will receive the review results by the end of the year. Each institution will receive a letter indicating that the policy complies with the regulation or a request for a revised policy within 90 days. The request for a revision will be accompanied by a report indicating the provisions of the regulation not adequately represented in the policy.

ORI will inactivate the assurance of any institution that fails to adopt a policy that complies with the regulation, thereby making that institution ineligible for PHS funds until the requested document is received.

Need a Speaker for an Educational Program?
For information about possible topics and availability of ORI staff speakers,
call Dr. Dustira at (301) 443-5300.

CASE SUMMARIES

James B. Boone, Jr., Ph.D., University of Missouri-Columbia (UMC): Based upon an investigation conducted by UMC, information obtained by ORI during its oversight review, and Dr. Boone's own admission, ORI found that Dr. Boone, former Research Assistant Professor, Department of Veterinary Biomedical Sciences at UMC, engaged in scientific misconduct by fabricating and falsifying data in biomedical research supported by a grant from the National Heart, Lung, and Blood Institute.

Specifically, Dr. Boone fabricated the weights of individual, isolated muscles that, in fact, had not been separated by dissection, and falsely presented unrelated gamma counter results as having been obtained from the same individual muscles. He presented these data to his laboratory director as the results from two experiments that Dr. Boone admitted he did not finish.

Boone committed additional falsifications in conducting research, including presenting: (1) a computer spread sheet that used the above-described sets of the fabricated primary data of muscle weights and the falsified gamma counter results to generate false computations of blood flow in separate muscles; (2) a computer spread sheet for the statistical computations of the data from the two sets of fabricated and falsified reduced data; and (3) a histogram derived from the falsified reduced data that showed significant differences in some of the fabricated experimental measurements on individual muscles.

Dr. Boone has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has agreed, for the three-year period beginning February 10, 1997, to exclude himself from serving in any advisory capacity to the PHS and that any institution that submits an application for PHS support for a research project on which the respondent's participation is proposed or which uses the respondent in any capacity on PHS supported research must concurrently submit to ORI a plan for supervision of his duties. The supervisory plan must be designed to ensure the scientific integrity of the respondent's research contribution.

Ann Marie Huelskamp, M.H.S., The Johns Hopkins University School of Medicine (JHUSM): Based upon a report forwarded to ORI by JHUSM, information obtained by ORI during its oversight review, and Ms. Huelskamp's own admission, ORI found that Ms. Huelskamp, a research program coordinator in the JHUSM Oncology Center engaged in scientific misconduct by fabricating patient interview data for a study of quality of life measures in cancer patients. The research was supported by a grant from the National Cancer Institute.

ORI also found that Ms. Huelskamp engaged in scientific misconduct by falsifying patient status data by failing to update the status of treated breast cancer patients and misrepresenting data from previous contacts as the updated status for a study. These data were reported in an NCI grant application and gave the appearance that some patients' outcomes were more favorable than they actually were.

Ms. Huelskamp cooperated fully with the institution's investigation. The investigation report acknowledged her excessive workload, the difficulties associated with recruiting and following up on patients, and a lack of supervisory oversight.

Ms. Huelskamp has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which she has agreed, for the three-year period beginning April 17, 1997, to exclude herself from serving in any advisory capacity to the PHS and that any institution that submits an application for PHS support for a research project on which Ms. Huelskamp's participation is proposed or which uses her in any capacity on PHS-supported research must concurrently submit a plan to ORI for supervision of her duties. The supervisory plan must be designed to ensure the scientific integrity of Ms. Huelskamp's research contribution. No scientific publications were required to be corrected as part of this Agreement.

William G. McCown, Ph.D., Integra, Inc.: Based upon a report forwarded to the ORI by Compass Information Services, Inc., and information obtained by ORI during its oversight

review, ORI found that Dr. McCown, former Project Director at Integra, Inc. (now Compass Information Services, Inc.), engaged in scientific misconduct by falsifying answer sheets for an “Item Count Substance Abuse Survey” supported by a grant from the National Institute on Drug Abuse.

Dr. McCown has entered into a Voluntary Exclusion Agreement with ORI in which he does not admit to any acts of scientific misconduct but has voluntarily agreed, for the three-year period beginning April 17, 1997, to exclude himself from serving in any advisory capacity to the PHS and that any institution that submits an application for PHS support for a research project on which Dr. McCown’s participation is proposed or which uses him in any capacity on PHS-supported research must concurrently submit a plan to ORI for supervision of his duties. The supervisory plan must be designed to ensure the scientific integrity of Dr. McCown’s research contribution. No scientific publications were required to be corrected as part of this Agreement.

Manoj Misra, Ph.D., Dartmouth College (DC): Based upon the ORI review of a report forwarded to ORI by DC, Dr. Misra’s admission of certain facts in that report, and ORI’s own analysis, ORI found that Dr. Misra, a former postdoctoral research associate in Department of Chemistry, DC, engaged in scientific misconduct by intentionally altering laboratory notebook data entries for research supported by a grant from the National Institute of Environmental Health Sciences.

Specifically, Dr. Misra altered laboratory notebook data entries in two instances in an effort to conceal prior manipulations of that data without disclosure or explanation to the principal investigator or anyone else. The experiment at issue involved an assay of the chemical activity of a carcinogen, and Dr. Misra’s change in the readings of the “control” experiment, in which no carcinogen was present, changed the results.

Dr. Misra has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has agreed, for the three-year period beginning April 7, 1997, to exclude himself from serving in any advisory capacity to the PHS and that any institution that submits an application for PHS support for a research project on which Dr. Misra’s participation is proposed or which uses him in any capacity on PHS-supported research must concurrently submit a plan to ORI for supervision of his duties. The supervisory plan must be designed to ensure the scientific integrity of Dr. Misra’s research contribution. No scientific publications were required to be corrected as part of this Agreement.

Enrico Portuese, University of Pittsburgh (UP): Based upon an investigation conducted by UP, information obtained by the ORI during its oversight review, and Mr. Portuese’s own admission, ORI found that Mr. Portuese, a former graduate student in the Department of Epidemiology, Graduate School of Public Health, UP, engaged in scientific misconduct by fabricating research data in biomedical research supported by two grants from the National Institute of Diabetes and Digestive and Kidney Diseases.

Specifically, Mr. Portuese fabricated data in a study of angiotensin-converting enzyme

polymorphism and complications from insulin-dependent diabetes mellitus. These fabricated data were included in an abstract that was submitted to the American Diabetes Association in January 1996; however, the abstract was not accepted, presented in public, or published.

In addition, Mr. Portuese fabricated genetic data on lipoprotein lipase polymorphisms as related to diabetes complications and risk factors. These fabricated data were included in tables prepared by Mr. Portuese and presented by him to his doctoral committee in October 1996. None of the fabricated data in question has been published, presented at a scientific meeting, or used in any grant applications.

Mr. Portuese has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has agreed, for the three-year period beginning March 25, 1997, to exclude himself from serving in any advisory capacity to the PHS and that any institution that submits an application for PHS support for a research project on which Mr. Portuese's participation is proposed or which uses him in any capacity on PHS supported research must concurrently submit a plan to ORI for supervision of his duties. The supervisory plan must be designed to ensure the scientific integrity of Mr. Portuese's research contribution. No scientific publications were required to be corrected as part of this Agreement.

Weidong Sun, M.D., Ph.D., Medical College of Pennsylvania (MCP) and Hahnemann University (HU): Based upon a report forwarded to the ORI by MCP and HU as well as information obtained by ORI during its oversight review, ORI found that Dr. Sun, a former graduate student in the Department of Neuroscience, MCP and HU, engaged in scientific misconduct by falsifying data in conducting and reporting research supported by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). The research also was reported in applications requesting funding from NIAMS and the National Institute of Diabetes and Digestive and Kidney Diseases.

Specifically, Dr. Sun falsified data by misrepresenting cloned DNA sequences from chicken non-muscle myosin as an isoform of neuronal myosin II from rat brain. The falsified DNA was included in the following publications and nucleotide sequences in GenBank and EMBL databases:

Sun, W.D., & Chantler, P.D. "Cloning of the cDNA encoding a neuronal myosin heavy chain from mammalian brain and its differential expression within the central nervous system." *Journal of Molecular Biology* 224(4):1185-1193, 1992;

Sun, W.D., & Chantler, P.D. "A unique cellular myosin II exhibiting differential expression in the cerebral cortex." *Biochemical and Biophysical Research Communications* 175(1):244-249, 1991;

Sun, W., Chen, X., & Chantler, P.D. "Inhibition of neuritegenesis by antisense arrest of the expression of a specific isoform of brain myosin II." *Journal of Muscle Research and Cell Motility* 15:184-185, 1994;

M64596, "Rat myosin II mRNA, 3' end." [RETMYOSII];

M80591, "Rat neuronal myosin heavy chain mRNA, 3' end." [RATMYOH3E];

M94962, "Rattus rattus neuronal myosin heavy chain gene promoter sequence."
[RATMYOPRO]; and

X62659, S98128, "R.rattus MRNA for brain neuronal myosin heavy chain." [RRNMYOHC].

Dr. Sun has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has agreed, for the three-year period beginning April 17, 1997, to exclude himself from any Federal grants, contracts, or cooperative agreements and to exclude himself from serving in any advisory capacity to the PHS. Retractions of the publications and deletions from the public data banks have been requested.

COURT DENIES FISHER APPEAL AND REQUEST FOR REHEARING

Last year, Dr. Bernard Fisher, former Chair of the National Surgical Adjuvant Breast and Bowel Project, appealed the dismissal of his Privacy Act suit against the government in *Fisher v. NIH*. (See *ORI Newsletter* 4(4), September 1996.) On November 27, 1996, the D.C. Circuit Court of Appeals denied Dr. Fisher's appeal and granted the government's motion for summary affirmance. Subsequently, Dr. Fisher asked that the appeals court rehear his appeal, but this motion was also denied by order dated March 28, 1997, as was his suggestion that the court rehear his appeal *en banc*.

REQUEST FOR INFORMATION

ORI would like to facilitate information exchange among institutions about procedures institutions have developed for responding to scientific misconduct or promoting the responsible conduct of research. Procedures may address such topics as maintaining confidentiality of the proceedings, sequestering data, charging inquiry/investigation committees, identifying and responding to conflicts of interest, role of attorneys, protecting respondents and whistleblowers, managing laboratories, clearance for publications and proposals, mentoring, and authorship. Material submitted by institutions may be published in the *ORI Newsletter*, compiled in a separate publication, and/or posted on the ORI home page.

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

Duplication of this newsletter is encouraged. Copies of this and other ORI publications are available on WWW of the Internet at <http://www.dhhs.gov/phs/ori>

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