Volume 5, No. 1, Office of Research Integrity, December 1996.

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**GOVERNMENT SUPPORTS INSTITUTION, INDIVIDUALS IN MISCONDUCT SUIT**

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, according to an *amicus curiae* brief filed in the U.S. Court of Appeals for the Fifth Circuit by the federal government.

The brief supports an appeal filed by the Baylor College of Medicine and others of a decision by the U.S. District Court for the Southern District of Texas that rejected claims of governmental immunity for the defendants and federal jurisdiction. The suit, originally filed in State court, was removed to federal court on the governmental immunity question but was later remanded to State court for trial when the district court rejected Baylor's argument.

Kimon J. Angelides, Ph.D., filed the lawsuit against Baylor, two administrators, members of the investigation committee, and witnesses who testified as part of the institutional misconduct investigation. He raised various claims including breach of contract, wrongful termination, libel and slander, interference with contracts and business relations, and blacklisting, arising out of Baylor's finding of scientific misconduct and his subsequent dismissal from the college.

In its brief, the federal government asserted that the preemptive requirements of federal law, which mandate the reporting of misconduct investigations to ORI, provide no basis for State tort liability in defamation: "These federal requirements preempt state tort liability for such actions since compliance with state and federal requirements is a practical impossibility and state tort liability stands as an obstacle to the accomplishment of the full purposes and objectives of Congress."

The brief continued, "The conflicting state and federal requirements give rise to an absolute privilege of defendants from liability for reporting scientific misconduct since private parties carrying out federally-mandated duties should not be put in an untenable position between such requirements. Alternatively, individual defendants who report on matters of scientific misconduct have a qualified privilege from state law claims."

However, the government acknowledged that the privilege does not protect defendants from all lawsuits. "To the extent that

plaintiff's claims arise out of the manner by which the investigation in this case was conducted, defendants are not entitled to immunity from such claims (although the guidelines for investigations contained in federal regulations would certainly inform any decision as to the reasonableness of defendants' conduct, see 42 C.F.R. 50.103(d))."

**INSTITUTIONS WARNED ABOUT FUNDING CUTOFF**

ORI notified three institutions in October 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.

Two institutions may establish active assurances by submitting initial assurance forms; the third institution must file revised policies and procedures for responding to allegations of scientific misconduct.

ORI took these compliance actions after the institutions failed to respond to repeated requests for the required materials. In the usual situation, ORI will undertake this compliance action after institutions have failed to respond to two requests.

The PHS regulation requires institutions to establish and maintain an active assurance pertaining to misconduct in science with ORI to be eligible to receive PHS research or research training support. Institutions establish an active assurance by filing a form with ORI or signing the face page of the revised PHS grant application form and establishing an administrative process for responding to allegations of scientific misconduct that complies with the Federal regulation. Institutions maintain their assurance by submitting the Annual Report on Possible Research Misconduct and complying with the provisions of the Federal regulation.

**INFORMING STAFF ABOUT POLICIES AND PROCEDURES**

Three methods are primarily used to inform faculty, staff, technicians, fellows and graduate students about institutional policies and procedures for responding to allegations of scientific misconduct. More than half of the institutions rely on a single method to reach each target population, according to the 1995 Annual Report on Possible Research Misconduct.

The handbook/manual option is the predominant method used. The all hands memo is a distant second; the orientation session is third. The question concerning the dissemination of policies and

procedures was answered by 2613 institutions.

About a quarter of the institutions reported using two methods to reach each of the target populations; about a tenth reported using three. Five percent or less of the institutions reported using four methods or more. The mode and median number of methods used for each target population was one.

The use of other methods varied by target population. The rank order of methods used for faculty, staff, and technicians differed from those used for fellows and graduate students. Pamphlets, brochures, and newsletter articles were more frequently used to communicate with faculty, staff, and technicians than with fellows and graduate students. Courses, seminars, and electronic bulletin boards were more frequently used to reach fellows and graduate students than faculty, staff, and technicians. A lecture series was the least frequently used general method across all populations.

Popular choices among those who wrote in answers were "oral discussion" and "staff meetings." A common theme among the write-ins seemed to be face-to-face discussion of the issues and the institutional policies. A growing number of institutions also indicated that their policies are available on their respective home pages on the World Wide Web.

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## 1996 ANNUAL REPORT FORMS DUE BY MARCH 3

Institutional officials can save time and effort and eliminate the aggravation associated with an inactivated assurance by submitting a completed and signed 1996 Annual Report on Possible Research Misconduct by the March 3, 1997, deadline.

The 1996 Annual Report on Possible Research Misconduct forms will be mailed to institutions on January 17, 1997. Assurances will be inactivated for all institutions that have not returned the form by the deadline. Last year, 396 institutions became ineligible for PHS funding because their 1995 Annual Reports were not returned by the deadline.

The 1996 form is essentially the same as the 1995 report. One question has been deleted.

ORI hopes the substantial improvement noted in the submission of the 1995 Annual Report will continue with the 1996 reports. The number of unsigned reports decreased by one-third. The number of institutions that did not respond to the questions on the

availability of policies and procedures and the methods used to disseminate them to institutional members declined 56 and 54 percent respectively.

Only 111 institutions were asked to submit their policies and procedures as a result of their response to the question in the 1995 report concerning the availability of policies and procedures. The previous year, 184 institutions were asked for their policies because of an inadequate response to the question.

Institutional officials are asked to check whether their institution has filed policies and procedures or a small organization agreement with ORI before answering the availability question. For 1995, 93 institutions that had policies on file with ORI indicated that they did not have them or failed to answer the question. Small businesses should respond positively if they have submitted a small organization statement.

Report on the 1995 Annual Report on Possible Research Misconduct is available on the ORI Home Page or in hard copy.

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## INSTITUTIONS ADOPTING ORI MODEL POLICY

ORI routinely reviews institutional policies and procedures for responding to allegations of scientific misconduct to ensure that the policies established by extramural institutions comply with the PHS regulation (42 C.F.R. Part 50, Subpart A). ORI also developed the ORI Model Policy and Procedures for Responding to Allegations of Scientific Misconduct (ORI model) in 1995 to respond to the numerous requests it receives every year for a sample policy that would meet the regulatory requirements.

Since it began reviewing policies last year, ORI has accepted a total of 133 institutional policies. Thirty-three of those institutional policies were based on the ORI model, nearly 25% of the total accepted.

The review consists of examining existing institutional policies and procedures for adherence to specific provisions of the PHS regulation. Some policies are accepted after the initial review if they are found to address adequately all the relevant components of the regulation. To date, 38 policies have been accepted after the initial review, with 14 policies (37%) using the ORI model.

If the review determines that some provisions of the PHS regulation are not adequately represented, a report on the

deficiencies is sent to the institution with a request for revisions. If numerous deficiencies are noted, the ORI models are also forwarded as guidance. To date, 95 revised policies have been accepted, with 19 policies (20%) closely following the ORI model.

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## RETALIATION COMPLAINTS ILLUSTRATE DIFFICULTIES OF PROTECTING WHISTLEBLOWERS

Summaries of three selected retaliation complaints are provided below to illustrate how institutions and ORI have responded to these difficult situations.

**Case 1**

The complainant claimed that his reputation was severely damaged and he was forced to resign his position as chairman of his department as a result of his bringing allegations of scientific misconduct against a faculty member at his institution. At ORI's request, the institution appointed an investigative committee to review the matter. The committee conducted an extensive review and concluded that the institution was responsible for many of the adverse actions suffered by the complainant as a result of his making allegations. The committee suggested a number of remedies, including developmental leave for a full year, start-up research funds, and a written announcement to the faculty stating that the complainant acted properly in making the allegation. The committee also recommended that as a way to prevent future retaliation, an official was to meet with the complainant on a semiannual basis to monitor his reintegration into his department. The institution implemented several of the actions recommended by the committee.

**Case 2**

The complainant claimed that the keys to his lab and a personal file cabinet were confiscated and he was sent a "lay off" notification because he made allegations of scientific misconduct against his supervisor. His supervisor also wrote to the complainant's former employer stating that the complainant falsified documents, sabotaged experiments, and breached patient confidentiality in an attempt to terminate the complainant's pension privileges. ORI contacted the institution and asked officials to explain the actions they intended to take in response to these retaliatory actions, and how they intended to prevent it from happening again.

The institution directed the respondent to cease such actions, and filed a formal complaint against the respondent for violation of the institution's policies and procedures, as well as the Faculty Code of Conduct. In terms of protecting the complainant, institutional officials extended his appointment for an additional year while the misconduct investigation was ongoing, and moved him twice to avoid interaction with the respondent. This protection was provided despite the complainant also being named as a respondent in the misconduct case he initially reported. The complainant's employment was terminated at the conclusion of the misconduct investigation, based on his admitted misconduct, but this action was not considered to be retaliatory.

**Case 3**

The complainant claimed that officials at the university where he received his doctorate were providing negative or false letters of recommendation in retaliation for his raising allegations of scientific misconduct. ORI staff contacted recipients of the letters, and they indicated that they did not perceive the contents as negative. The recipients also indicated that their hiring decisions were based on personal impressions developed during interviews and presentations; the letters had little or no impact on their hiring decision. There was insufficient evidence to pursue this allegation and the case was closed with no referral to the institution.

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*Need Misconduct Case Summaries for Classes?*
**Request back issues of the ORI Annual Report.**

*Interested in the Results of the Institutional Annual Reports?*
**Ask for the "Report on the 1995 Annual Report"**

Call ORI at (301) 443-5300

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## CASE SUMMARIES

**Melissa A. Harrington, Ph.D., University of Texas Southwestern Medical Center (UTSMC)**. Based upon an investigation conducted by the UTSMC, information obtained by ORI during its oversight review, and Dr. Harrington's own admission, ORI found that Dr. Harrington, former postdoctoral research fellow, Department of Pharmacology at the UTSMC, engaged in scientific misconduct by falsifying the methodology and figures in a manuscript that was accepted for publication in the *Journal of Neuroscience* ("Gáq and

Gâa open two Bradykinin-gated potassium channels via a membrane-delimited pathway"). The research was supported by a National Institute of General Medical Sciences grant.

Specifically, ORI found that Dr. Harrington had (1) falsely described the addition of GDP to a G-protein subunit buffer when she had omitted it from some of the experiments; (2) falsified three figures (a) by falsely depicting the course of an electro-physiological response as being due to a combination of two substances that had not been combined and (b) by falsely representing a single channel current record as being an example of a distinct channel type that was elicited by the substance Gáq, which had not been added prior to the recording; and (3) intentionally incorporated the falsified data from the experiments in which GDP had been omitted in her statistical descriptions.

The *Journal of Neuroscience* manuscript was withdrawn and was never published.

Dr. Harrington 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 October 23, 1996, to exclude herself from serving on any PHS advisory committee, board, and/or as a consultant; and that any institution that submits an application for PHS support for a research project on which her participation is proposed or which uses her in any capacity on PHS-supported research must concurrently submit a plan for supervision of her duties. The supervisory plan must be designed to ensure the scientific integrity of Dr. Harrington's research contribution. The institution must submit a copy of the supervisory plan to ORI.

**Eric Whitters, Ph.D., University of Oregon (UO)**. Based upon a UO investigation as well as his own admission, ORI found that Dr. Whitters, a former postdoctoral fellow at the Institute of Molecular Biology at UO, engaged in scientific misconduct by fabricating experimental results that involved the selective growth of yeast strains that he represented as having temperature-sensitive phenotypes. The research was supported in part by a grant from NIH's National Institute of General Medical Sciences.

Dr. Whitters has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has agreed to exclude himself from any Federal grants and cooperative agreements and from service on any PHS advisory committee, board,

and/or peer review committee or as a consultant for the three-year period beginning November 6, 1996.

The research at issue did not affect any published research and was not included in any grant application.

**Gang Yuan, Fox Chase Cancer Center (FCCC)**. ORI has entered into a Voluntary Exclusion Agreement with Mr. Yuan, a former laboratory technician at FCCC. The agreement resolved ORI's proposed administrative actions against Mr. Yuan which were based on allegations concerning research data he generated at FCCC. The data became the subject of an investigation conducted by FCCC and an ORI oversight review. The data at issue were included in a grant application submitted to the National Institute of General Medical Sciences of NIH and in a manuscript submitted to, but not published by, the journal *Biochemistry*.

Mr. Yuan disagreed with the allegations, but to settle the matter he has voluntarily agreed, without admitting to guilt, to exclude himself from any Federal grants, contracts, and cooperative agreements, and from service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for the two-year period beginning October 25, 1996.

## ORI CLARIFIES ASPECTS OF ITS PROCEDURES AND 0PERATIONS

Several recent news articles and opinion pieces have discussed ORI procedures and operations and the need for improvement. Many of the questions have centered on the process of pursuing complaints and the rights and recourse of scientists being investigated. In order to promote more informed discussion of these issues, ORI is providing the following information:

### What opportunities exist for accused scientists to defend themselves?

The investigating entity (whether ORI or the institution) informs the respondent about the allegations when an inquiry begins. During an inquiry a respondent is interviewed, confronts and presents evidence, and suggests witnesses. A draft inquiry report is presented to the respondent for comment. If the inquiry shows evidence that misconduct may have occurred, a formal investigation follows. At this stage, the respondent is re-interviewed, sometimes more than once, confronts and presents additional evidence, and suggests additional witnesses. The draft investigation report is presented to the respondent for comment. If ORI proposes a finding of misconduct, the respondent

may request a hearing before the HHS Departmental Appeals Board. Throughout this process the respondent may have counsel.

**What steps has ORI taken to reduce the duration of cases?**

ORI acknowledges that the resolution of allegations has taken far too long in some cases and has put enormous effort into shortening the processing time for allegations and cases. ORI inherited several hundred unresolved allegations of misconduct and a caseload of about 70 formal cases from the former Office of Scientific Integrity in 1992. Since that time, ORI has closed over 1,000 allegations and 194 formal cases, reducing its current caseload to 50, a record low. ORI's goal over the next few years is to turn over its caseload approximately every 12 months, except for a few complex and difficult cases which will necessarily take longer. These 50 cases have been open in ORI an average of 12 months, suggesting that this is a reasonable goal.

**Does ORI have qualified investigators to handle its misconduct cases?**

A well-trained staff with relevant professional experience is essential to protecting the integrity of research supported by the Public Health Service. Since its establishment, ORI has adopted detailed internal procedures to guide its professional staff in the conduct of investigations. Each ORI investigator has a Ph.D. or M.D. and has attended courses at the Federal Law Enforcement Training Center which provides initial and advanced training for federal investigators. After auditing 40 ORI case files, the General Accounting Office recently concluded that ORI has "developed and implemented procedures for handling misconduct cases, which we believe conforms to established federal standards for investigations . . ." and found "few concerns about the [ORI] techniques used in handling cases."

**Is ORI objective when it investigates alleged misconduct?**

ORI believes that objectivity is essential to the integrity of any investigative office. ORI has found misconduct 66 times since 1992, which represents less than 7 percent of the over 1,000 allegations reviewed. This record demonstrates a principled effort to balance the need to protect the integrity of PHS-supported research with the need to respect the rights and reputations of scientists who have not engaged in misconduct. This winnowing process results from the careful review ORI conducts of each allegation to determine whether it falls within the PHS definition of misconduct, involves federal funds, and is substantive enough to warrant pursuit. Each year, about 200

allegations lead to 40 to 50 formal inquiries or investigations which result in about 12 findings of misconduct a year. Almost all of these inquiries or investigations are conducted by institutions; ORI opened only one extramural investigation in 1995 and 1996.

Since 1992, ORI has declined to go forward with eight institutional findings of misconduct. While institutions, as employers, have authority to establish broader standards of conduct and to impose additional sanctions for violations beyond those contemplated by ORI, ORI's exercise of discretion not to pursue institutional findings in certain cases represents a clear sign that ORI recognizes and abides by the limits of the PHS definition of scientific misconduct.

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## EDITORS REQUIRED TO PURSUE MISCONDUCT, PUBLISH RETRACTIONS

Journal editors have an affirmative responsibility to appropriately pursue possible scientific fraud in manuscripts submitted to or published in their journals and publish a retraction of any fraudulent paper published in their journals according to a 1987 supplemental statement to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals issued by the International Committee of Medical Journal Editors and adopted by over 500 journals.

"If substantial doubts arise about the honesty of a work, either submitted or published, it is the editor's responsibility to ensure that the question is appropriately pursued (including possible consultations with the authors)," the statement declares.

Editors, however, are not responsible for conducting a full investigation or deciding whether scientific fraud occurred. Those responsibilities rests with the institution where the work was done or the agency that supported the research.

The statement continues, "The editor should be promptly informed of the final decision, and, if a fraudulent paper has been published, the journal must print a retraction." ORI notifies the relevant editors when a finding of scientific misconduct involves a published work. Administrative actions imposed by the PHS may require authors to retract or correct published manuscripts.

"The retraction, so labeled," the statement declares, "should appear in a prominent section of the journal, be listed in the

contents page, and include in its heading the title of the original article. It should not simply be a letter to the editor."

The statement also addresses the authorship and content of retractions: "Ideally, the first author should be the same in the retraction as in the article, although under certain circumstances the editor may accept retractions by other responsible persons. The text of the retraction should explain why the article is being retracted and include a bibliographic reference to it."

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## SUBAWARDEE ARRANGEMENTS NEEDED

Did you know that institutions are held responsible for the compliance of any organization that receives PHS support through your institution, such as other institutions in a consortium where your institution is the grantee? You must ensure that entities with which your institution has such consortium or contractual relationships have an assurance on file with ORI, or have agreed to be subject to the policies of your institution with respect to the research supported through the consortium or contractual arrangement.

Call the Assurance Program staff if you have questions or need assistance.

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## PUBLICATIONS*

"Federal Actions Against Plagiarism in Research" by Alan R. Price. *Journal of Information Ethics*, Spring 1996: 34-51. Reviews policies and specific cases involving plagiarism in federally funded research, focusing on the findings and administrative actions of ORI and NSF concerning confirmed or admitted plagiarists.

"Advice to Individuals Involved in Misconduct Accusations" by Paul Friedman. *Academic Medicine*, 71 (7): 716-723.

*Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case* is a new book by Marcia Angell, M.D., W.W. Norton & Co.: New York, 1996.

"Scientific Misconduct in Epidemiologic Research" by C. Soskolne and D. Macfarlane, in *Ethics and Epidemiology* (S. Coughlin and T. Beauchamp, editors), Oxford University Press, 1996.

"Scientific Reasoning and Due Process" by Louis Guenin and Bernard Davis. *Science and Engineering Ethics* Vol. 2(1): 47-54, 1996.

*Limits: The Role of the Law in Bioethical Decision Making* by Roger B. Dworkin, Indiana University Press, 1996.

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**MEETINGS***

March 6-8, 1997. Sixth Annual Meeting of the Association for Practical and Professional Ethics (APPE), Washington, DC. Contact APPE, 410 North Park Ave., Bloomington, IN 47405; (812) 855-6450; FAX (812) 855-3315; appe@ indiana.edu; http://ezinfo.ucs.indiana.edu/~appe/home.html.

March 8-9, 1997. Mini-conference on Practicing and Teaching Ethics in Engineering and Computing, Washington, DC. Contact same as above.

June 25-28, 1997. Fourth Annual Workshop on Teaching Research Ethics, Bloomington, IN. Contact Kenneth Pimple, Poynter Center, Indiana University, 410 North Park Ave., Bloomington, IN 47405; (812) 855-0261; FAX (812) 855-3315.

**Lists of Publications and Meetings 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.*

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## ORI NEWSLETTER

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.