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### **ORI REDUCES CASELOAD; SHORTENS PROCESSING TIME**

ORI began this calendar year with the smallest caseload (48) in its history, having closed 49 cases, opened 39 cases and assessed 196 new allegations in 1996 while significantly reducing the pre-1995 case backlog.

Of the 49 closed cases, 17 resulted in findings of scientific misconduct or PHS administrative actions and one was overturned by the HHS Departmental Appeals Board following a request for a hearing by the accused scientist. Since ORI began operation in 1992, ORI has made findings of scientific misconduct or imposed administrative actions in 68 cases; 3 findings were overturned on appeal; and 1 was withdrawn. Two other cases were settled without a finding of misconduct following an appeal. Overall, 92 percent of ORI's misconduct findings and administrative actions became final.

Of the 196 new allegations, 65 were assessed for a possible inquiry or investigation, 39 were referred to other agencies, and 92 were closed without further action. Eighty percent of the 65 allegations which required in-depth review by ORI staff were resolved with an average processing time of 29 days (time from assignment to closure or the opening of a formal case). The other 20 percent are still under review. The average length of time for assessing allegations has been dramatically reduced by ORI from over 200 days in 1992.

At the end of 1996, ORI had 48 formal cases and 13 allegations under review. In 1992, ORI started with a backlog of 70 plus cases and over 600 unresolved allegations. Currently, ORI's formal cases are open an average of 10-12 months (counting from the time an institution has completed its investigation and reporting activities to ORI resolution).

While ORI has significantly reduced its case backlog, ORI is also acutely focused on the quality of its case investigations, oversight, and resolution. Since June 1992 when ORI began operations, it has closed over 200 cases and well over 1,000 allegations of scientific misconduct. Of the 200 cases closed, 68 have resulted in findings of misconduct and PHS administrative activities, approximately one-third of the total. However, this is well under 10 percent of the total allegations reviewed by ORI.

Where ORI has made a finding or taken action, it has been successful 92 percent of the time. In addition, based on its review of the facts, ORI has declined to make a PHS finding in an additional 10 cases where an institution conducted an investigation and recommended misconduct. This is consistent with ORI's careful efforts to apply the applicable PHS legal standard for misconduct and to protect the rights of the accused.

Of the 68 misconduct findings and administrative actions, 44 were based on cases opened after June 1992 and fully developed by ORI under its own standards and procedures. None of these findings has been reversed. One case was appealed, but following an initial legal decision in ORI's favor, the accused scientist withdrew the appeal and ORI's proposed findings and administrative actions became final.

ORI has taken special efforts the past several years to expedite its resolution of misconduct cases and allegations, while maintaining high quality in its case analysis and assessment. This effort requires a careful balance between efforts to protect the integrity of PHS-sponsored research and the rights of the accused. ORI will continue to monitor its efforts to maintain this delicate balance in its future efforts and take corrective actions as appropriate.

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#### **ORI PRESENTS WORKSHOP FOR INSTITUTIONAL MISCONDUCT OFFICIALS**

ORI is holding an introductory workshop June 6 in the Natcher Center at NIH for institutional misconduct officials who are responsible for ensuring institutional compliance with the PHS regulation related to scientific misconduct (42 C.F.R. Part 50, Subpart A).

This workshop will provide basic information on how the regulatory requirements placed on institutions may be met by such institutional officials as institutional research integrity officers, inquiry/investigation committee members, administrators, and counsel.

Besides presentations by ORI staff, the workshop will include a panel discussion moderated by Barbara Mishkin, an attorney at Hogan & Hartson; Julie Gross Adelson, counsel at Georgetown University Medical Center; Barbara Starklauf, Assistant Dean, The Johns Hopkins University; Frederick Savage, Associate General Counsel, The Johns Hopkins University, and Thomas Silber, Director of Ethics, Children's Hospital National Medical Center. This instructional workshop will review the general

responsibilities of institutional misconduct officials and will highlight the specific requirements that institutions need to fulfill in investigating allegations of misconduct involving research supported by Public Health Service funds. It will cover the inquiry and investigation stages of the process, as well as the role of Federal oversight and resolution of cases. Specific sessions will focus on protecting both whistleblowers and respondents, and handling complaints of retaliation against whistleblowers. The workshop also will discuss institutional and Federal experiences and perspectives on responding to allegations and avoiding possible pitfalls in resolving cases.

A variety of materials will be available at the workshop, including the recently released ORI Handbook for Institutional Research Integrity Officers.

Registration fees are \$80 if received by May 1, or \$95 after May 1. For more information or to register for the workshop contact Circle Solutions, Inc. at (703) 902-1205.

#### **AGENDA**

8:30 a.m. Welcoming Remarks  
9:00 a.m. What is a Research Integrity Officer?  
9:30 a.m. Developing Policies and Procedures  
9:45 a.m. Keeping an Assurance Active  
  
10:00 a.m. Break  
  
10:15 a.m. Responding to Allegations of Scientific Misconduct:  
Inquiries and Investigations  
11:15 a.m. Institutional Experiences & Perspectives-Open  
Discussion  
  
12:00p.m. Lunch  
  
1:00 p.m. Federal Oversight and Resolution  
1:30 p.m. Protecting Whistleblowers & Respondents  
  
2:30 p.m. Break  
  
2:45 p.m. Responding to Retaliation Complaints  
3:00 p.m. PHS and Institutional Sanctions  
3:15 p.m. Approaches and Experiences in Resolving Cases  
3:45 p.m. Avoiding Problems in Disclosing Case Information  
4:00 p.m. Panel Discussion  
5:00 p.m. Adjourn

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**ADMINISTRATIVE ACTIONS BULLETIN BOARD HAS NEW ADDRESS ON WWW**

The PHS Administrative Actions Bulletin Board, which contains information on administrative actions imposed on individuals against whom there is a finding of scientific misconduct or a violation of FDA regulations governing research, has a new address on the WWW:

<http://silk.nih.gov/public/cbz1bje.@www.orilist.html>. Please note that the character after cbz is the numeral 1, not the lower case letter L. Also note the . (dot) before the @.

The bulletin board may also be accessed through the DRG home page (<http://www.drg.nih.gov>) by clicking on "referral and review" and going to "ORI Listing."

Each scientific misconduct entry on the bulletin board includes the name of the respondent, 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 on the bulletin board is meant to be used by PHS program officials, scientific review officials, committee management officials, and grant and contract officials, as well as administrators at PHS applicant or awardee institutions in providing assistance in the implementation of PHS administrative actions. Institutions are required to submit materials with grant applications by some administrative actions. Institutions are also required to send a copy of the required materials to ORI.

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**INACTIVATING ASSURANCES**

If you have not submitted your 1996 Annual Report on Possible Research Misconduct by the time you read this issue of the *ORI Newsletter*, the research misconduct assurance for your institution has been inactivated.

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**WHEN IS AN INSTITUTION REQUIRED TO REPORT TO ORI?**

Extramural institutions are required to notify ORI of scientific misconduct cases if an institution concludes that an investigation is warranted (42 C.F.R. § 50.103(d)(4) and § 50.104(a)(1)). However many institutions remain confused about when a misconduct proceeding may be stopped at the inquiry stage

without notification and when it must proceed to a conclusion. Below are some examples that demonstrate the types of problems that institutions have encountered:

**Case #1:**

An institution convened an inquiry committee to review allegations that a researcher had fabricated data in a draft manuscript presented to his laboratory chief for review. The research was purportedly conducted under the laboratory chief's PHS grant award. When confronted, the researcher admitted that he had fabricated the data and volunteered his resignation. The inquiry committee concluded that the fabrication of data represented scientific misconduct, but noted that the paper was never published and the data were never reported in a grant application. They concluded that the matter was "resolved" at the inquiry stage with the researcher's resignation and recommended that the ORI not be notified. Fortunately, the institutional official questioned that recommendation and called ORI to clarify the reporting requirements.

**ORI Comment:**

In the usual situation, the inquiry committee's responsibility is to determine whether there was sufficient reason to believe misconduct may have taken place to warrant an investigation, not to make a finding of misconduct and "resolve" the issue. However, if the respondent admits to misconduct at the inquiry stage and the institution determines that no further investigation is warranted, the institution should nevertheless report its misconduct finding to ORI and state why it believes further investigation is unnecessary. See 42 C.F.R. § 50.104(a)(3).

The only time the ORI need not be notified is when an inquiry committee finds insufficient evidence of possible misconduct to warrant further investigation. While the resignation of the individual who has admitted misconduct may protect the institution, it does not protect public funds, since this individual may move on to another position where he is engaged in research supported by the PHS. Deciding whether to recommend actions to protect PHS funds when scientific misconduct is confirmed is one of ORI's major responsibilities.

**Case #2:**

An inquiry committee completed its assessment of allegations of possible scientific misconduct on the part of a graduate student

whose research was supported by a PHS grant to his mentor. However, the institution decided to handle the allegations through its student disciplinary process rather than opening an investigation into possible scientific misconduct under its assurance with ORI. Because they followed their student disciplinary procedures rather than their scientific misconduct procedures, institution officials decided that ORI need not be notified.

**ORI Comment:**

As long as the research that is questioned was supported in part by a PHS award, the institution is obliged to notify ORI that it is opening an investigation. ORI counsel may be consulted to determine whether the requirements for a student disciplinary hearing and for a misconduct investigation can be satisfied by a single process.

**Case #3:**

An inquiry committee found that it was likely that an assistant professor had committed scientific misconduct by falsifying experimental data. However, when the assistant professor threatened to sue the university, the committee decided to allow her to repeat the experiments, agreeing that they would not proceed with a misconduct investigation if the repeated experiments supported the earlier results. Therefore, the institution decided not to report to ORI unless the new experiments failed to confirm the results that there was reason to believe were falsified.

**ORI Comment:**

It is ORI's position that a finding of falsification cannot be voided even if further research proves that the respondent "guessed" the right answer. Thus, the institution should proceed to an investigation to determine if the original data were falsified. If the investigation determines that there is not sufficient evidence to find that misconduct has occurred, the matter is settled. Allowing the researcher to repeat her experiments may leave unanswered the question of whether she falsified the original experiments. Her reputation may be harmed more by the lingering questions about her research than by a formal proceeding that arrives at a definitive finding.

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**QUI TAM SUIT VERDICT REVERSED ON APPEAL**

A jury verdict in a *qui tam* suit that resulted in a \$1.9 million

judgment against the University of Alabama-Birmingham (UAB) and four researchers was reversed by the U. S. Court of Appeals for the Fourth Circuit in Baltimore on January 22 because "it is abundantly clear that substantial evidence upon which the jury could have found for Berge is lacking." (*U.S. ex rel. Berge v. Univ. Alabama, et al.*, No. 95-2811, ...F.3d ... (4th Cir., January 22, 1997)).

The reversal cleared Charles A. Afford, M.D., Robert F. Pass, M.D., Sergio B. Stagno, M.D., and Karen Fowler, Ph.D. of submitting false statements to NIH in grant applications seeking support for research on the transmission of cytomegalovirus from pregnant women to their children. The lawsuit was filed by Pamela A. Berge, Ph.D., who conducted her dissertation research on cytomegalovirus at UAB while she was a graduate student at Cornell University.

In rendering its decision the court also responded to jurisdictional issues concerning the constitutionality of the False Claims Act raised by UAB in its appeal and by other institutions and professional associations in *amicus curiae* briefs. The court did not consider the constitutionality of the Act itself because the case was decided on the facts, but it determined that the United States is the real party in interest under the False Claims Act, even where it permits a *qui tam* relator to pursue the action on its behalf. The court also concluded that states do not have Eleventh Amendment immunity from lawsuits brought by the United States. However, the court ruled that the United States, as the real party in interest under the False Claims Act, must have suffered an injury in fact.

In reaching its decision, the court held that Dr. Berge had not met the burden of proof in showing that the United States had suffered an injury. The court concluded that there was insufficient evidence that the alleged false statements were false. Also, the statements were not material to the NIH funding decisions, that is, the statements were not capable of influencing the funding decisions. The funding program officer for the grants at issue testified that the relator's contributions were not central to the project and that the progress reported by UAB was satisfactory for a recommendation of continued funding without her contribution. The court further noted that: (1) UAB did not mislead NIH about the extent of computerization; the project was actually focused on data collection; (2) the relator did not have to be identified as a co-author of an abstract submitted with a progress report because NIH does not require the authors of such abstracts to be identified, and another co-owner of the copyright has an

undivided, independent right to use the work; (3) the relator's work was not submerged in two of the progress reports; there was considerable discussion of her work with appropriate attribution; (4) the mistaken reference to the relator in one report as a "postdoctoral graduate student from the Department of Biostatistics" rather than a doctoral graduate student in nutritional sciences was trivial; (5) the work of the relator was not plagiarized in an abstract because none of the ideas used in the abstract were original to her; and (6) the reasons that UAB's 15-year review had to be performed three times was completely unrelated to the alleged false statements.

In considering Dr. Berge's plagiarism claims, the court noted that ORI has determined that plagiarism does not include credit disputes. See *ORI Newsletter*, Vol. 3, No. 1 (Office of Research Integrity, U.S. Public Health Service, December 1994).

The court also reversed her claim of conversion of intellectual property under state law ruling that her claim was completely preempted by Federal copyright law.

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#### **ORI UPDATE WORKSHOP HELD FOR PHS MISCONDUCT OFFICIALS**

More than thirty PHS agency representatives attended the ORI annual update workshop held on January 14. Participants were briefed on the status of various reports that may affect ORI and heard the latest information on hearings, the ORI caseload, and the changing role of ORI in misconduct cases.

Other subjects discussed in the half-day session included the protection of good faith whistleblowers, new assurance and compliance activities, and a reminder on the general procedures for handling requests for information or inquiries from the press.

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#### **CASE SUMMARY**

**Yi Li, University of Illinois, Urbana-Champaign (UI-UC).** Based upon an investigation conducted by the UI-UC, information obtained during ORI's oversight review, and Mr. Li's own admission, ORI found that Yi Li, while a candidate for a Ph.D. degree in the Neuroscience Program at UI-UC, engaged in scientific misconduct by fabricating an experimental study and results for research represented in an abstract prepared for submission for presentation at a national meeting. The research

was supported by a grant from the National Institute on Aging at NIH. The fabricated abstract and results addressed an electrophysiological study of the behavioral correlates for long-term potentiation in the motor cortex of the central nervous system of freely moving rats.

Mr. Li has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for the three-year period beginning November 18, 1996, to exclude himself from serving in any advisory capacity to PHS and that any institution that submits an application for PHS support for a research project on which his participation is proposed or which uses him 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 Mr. Li's research contribution. The fabricated abstract was not submitted and has not been published or used in any grant applications.

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#### **POLICY DEFICIENCIES CENTER ON ELEMENTS COMMON TO INQUIRIES & INVESTIGATIONS**

Institutions could significantly reduce the number of deficiencies in their institutional policies for responding to allegations of scientific misconduct by recognizing that 13 provisions of the PHS regulation apply to both inquiries and investigations.

The review of the 1996 sample of institutional policies indicates that institutions are more likely to incorporate these common provisions in the procedures for an investigation rather than inquiry or omit them from both procedures. All except two of these procedures (time frame for completion and report content) may be efficiently handled by placing them in a general procedures section that applies to both inquiries and investigations.

Two other significant problems were noted. About 32 percent of the policies did not explicitly cover all individuals supported by PHS funding. Consequently, it was not clear whether the policies covered staff or students. Thirty percent of the policies did not include a definition of scientific misconduct or omitted significant elements of the PHS definition such as the terms fabrication, falsification, plagiarism or proposing, conducting, or reporting research.

ORI requested institutional policies from 82 institutions for the

1996 sample. In response, two institutions withdrew their assurances and became ineligible to receive PHS support, two institutions with fewer than 10 employees submitted small organization policy agreements, and 78 submitted policies, four of which could not be reviewed as submitted. Under a small organization agreement, the institution collaborates with ORI in responding to the allegation

ORI completed the review of the 74 policies by December 20, 1996, accepting 25 policies as submitted and requesting revision of 49 policies. An average of 18 deficiencies were noted in the policies for which revisions were requested. As of February 1, 1997, 23 revised policies have been accepted. Twenty-six policies are under revision.

**Table 1:** Percentage of Institutional Policies in 1996 Sample Containing Provisions of the PHS Regulation Common to Inquiries and Investigations. N=74

<u>Provision</u>	<u>Inquiry</u>	<u>Investigation</u>
Expertise	66	76
Conflicts of Interest	65	69
Maintaining Confidentiality	78	81
Comment by Respondent	80	81
Report Health Hazards, etc.*	55	53
Interim Actions	51	64
Premature Termination	42	49
Time frame for Completion**	85	76
Report Content	59	54
Report Given to Respondent	59	69
Restore Reputation	57	73
Protect Whistleblower	65	74
Retain Documentation	64	59

\*Numerous institutions limit this provision to reporting possible criminal violations.

\*\*Many institutions do not include submission of the investigation report to ORI within the 120-day time frame.

**Table 2:** Number of Deficiencies Found in Review of Institutional Policies for Responding to Allegations of scientific Misconduct, 1996 Sample. N=74

Number of Deficiencies	Number of Policies
30 to 36	6
20 to 29	13

10 to 19  
Zero to 9

22  
33

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#### **MEDICAL DISCIPLINE COMMITTEE TAKES ACTIONS AGAINST POISSON**

In 1993, ORI found Dr. Roger Poisson, a researcher at St. Luc Hospital, Montreal, to have committed scientific misconduct by fabricating and falsifying patient data he submitted to the National Surgical Adjuvant Breast and Bowel Project (NSABP) multicenter clinical studies on breast and bowel cancer. As a result of ORI's investigation, Dr. Poisson was debarred for eight years from the receipt of any Federal funding. In a follow up to this matter on November 7, 1996, Dr. Poisson appeared before the Discipline Committee of the Quebec College of Doctors and pled guilty to 13 counts of committing "acts derogatory to the honor and dignity of the medical profession" by his submission of the falsified information to the NSABP. It was recommended that Dr. Poisson be reprimanded, fined, and be permanently restricted from certain activities, including serving as a principal investigator in medical research.

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#### **ORI HANDBOOK WILL BE DISTRIBUTED IN APRIL**

The *ORI Handbook for Institutional Research Integrity Officers* will be mailed in April to institutions that have an active assurance on file with ORI, except small businesses.

Distribution of the handbook, developed to facilitate the partnership established between ORI and institutions to pursue allegations of scientific misconduct efficiently and effectively, was delayed for a year by budgetary constraints and external review. The handbook was sent to 50 institutions for comment.

ORI expresses its appreciation to the institutions that submitted comments on the draft handbook. Many of the comments received were incorporated into the final version. The handbook will be made available on three-hole paper to facilitate further revision. Comments and suggestions for improving the usefulness of the handbook should be sent to the Division of Policy and Education, ORI.

The text of the handbook and many of the appendices are available on the ORI Home Page.

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#### **MEETINGS**

**June 6, 1997.** Introductory Workshop for Institutional Misconduct Officials, Washington, DC. For complete description, see "ORI Presents Workshop for Institutional Misconduct Officials" above. Contact Circle Solutions, Inc. (703) 902-1205.

**June 4-8, 1997.** Graduate Research Ethics Education Workshop, Bloomington, IN. Deadline for applications is April 1. Contact Brian Schrag, Association for Practical and Professional Ethics, 410 North Park Ave., Bloomington, IN 47405; (812) 855-6450; Fax: (812) 855-3315; email: appe@indiana.edu.

**June 28, 1997.** Seminar on Alternatives to Animal Use in Education, Research, and Testing, Bloomington, IN. Contact Kenneth Pimple, Poynter Center, Indiana University, 410 North Park Ave., Bloomington, IN 47405; (812) 855-0261; Fax: (812) 855-3315; pimple@indiana.edu.

**September 17-21, 1997.** International Congress on Biomedical Peer Review and Global Communications, Prague, Czech Republic. Contact Annette Flanagan, 515 N State St., Chicago, IL 60610 USA; Fax (312) 464-5824.

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#### PUBLICATIONS

"An Introduction to Research Ethics" by Paul J. Friedman. *Science and Engineering Ethics*, Vol. 2 (4): 443-456, 1996.

"Proliferation of Authors on Research Reports in Medicine" by Joost P.H. Drenth. *Science and Engineering Ethics*, Vol. 2 (4): 469-480, 1996.

Tenth Anniversary Report, Assessment of Economic Impact, False Claims Act and *Qui Tam* Quarterly Review, and educational video highlighting the effectiveness of the False Claims Act are all available from the False Claims Act Legal Center, (202) 296-4826 or (202) 296-4838.

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\*Lists of Meetings and Publications are neither exhaustive nor all inclusive. Nor should any of the items listed or described be even remotely construed as being favored or endorsed by the Government.

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