

## **RCR POLICY SUSPENDED; REVIEW BEGINS THIS MONTH**

Implementation of the PHS Policy on Instruction in the Responsible Conduct of Research was suspended in February 2001 to permit review of the substance of the policy and the process followed in its adoption in response to a congressional inquiry that questioned whether the requirement should have been processed as a proposed regulation rather than as a policy.

A letter from Representative W.J. Tauzin, Chairman, Committee on Energy and Commerce, and Representative James C. Greenwood, Chairman-designate, Subcommittee on Oversight and Investigations, to Chris Pascal, Director, ORI, states that the policy "appears to be a final substantive rule" and its adoption should have followed "the various statutes designed to ensure sound regulatory decisionmaking."

In his response, Mr. Pascal cited five reasons for issuing the RCR program as a policy:

- "The RCR policy is the outgrowth of a longstanding sentiment in the scientific community that efforts to enforce rules against research misconduct should be coupled with programs to prevent such episodes from occurring in the first place." Two reports from the National Academy of Sciences and the report of the congressionally mandated Commission on Research Integrity are cited.
- The RCR initiative fits into a pre-existing regulation that requires institutions to "foster a research environment that discourages misconduct in all research . . ." 42 C.F.R. § 50.105. A key component of any institutional effort to promote such an environment would be an RCR program.
- The Secretary of Health and Human Services has the authority to impose additional conditions on awards. 42 C.F.R. § 52.9.
- The RCR policy lacks the normative standards typically associated with a substantive rule because the policy gives institutions broad discretion to determine how virtually every aspect of the educational program will be implemented.
- Extensive efforts were made to ensure that the extramural research community had ample notice and opportunity to comment on the draft RCR policy. Public comments were substantially incorporated into the revised policy.

Mr. Pascal concluded, "Even though we continue to believe that the RCR policy as described above was appropriately issued, in recognition of the recent White House directive calling for a period of review, we believe that its implementation should be delayed."

A *Federal Register* notice published February 21, 2001, states that "[p]ending completion of that review, institutions that might otherwise be subject to the RCR policy are under no obligation to implement the policy unless further public notice is issued in the *Federal Register*. Any future PHS action taken to implement the RCR policy would provide extended implementation time frames that take into consideration this suspension."

The letter from Representatives Tauzin and Greenwood, the response by Mr. Pascal, and the *Federal Register* notice are posted on the ORI web site.

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### **NIH INTRAMURAL PROGRAM PROCEEDS WITH RCR INSTRUCTION**

Suspension of the PHS policy on instruction in the responsible conduct of research (RCR) will not affect implementation of an RCR instruction program in the intramural research program at the National Institutes of Health (NIH).

Michael Gottesman, M.D., Deputy Director for Intramural Research, NIH, said, "Our current plans are to implement the RCR instruction as we described them (in The NIH Catalyst). These plans are an important part of training in the intramural program and we see no reason to delay their implementation."

The article, authored by Dr. Gottesman and Joan P. Schwartz, Ph.D., Assistant Director, Office of Intramural Research, NIH, in the January-February 2001 issue defines "research staff" as senior investigators, tenure-track investigators, staff scientists and clinicians, research and clinical fellows, pre- and post-doctoral trainees, technicians, research nurses, and special volunteers or guest researchers who have "direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training."

The RCR instruction will be delivered through a web-based computer module that will be developed over the next several months. The module will cover the following core areas: data acquisition, management, sharing, and ownership; mentor and trainee responsibilities; publication practices and responsible authorship; peer review; collaborative science; research misconduct, and conflict of interest and commitment. Human and animal subjects are covered in other required courses at NIH, but will be included in the module to the extent necessary. Most core areas are addressed in Guidelines to the Conduct of Research in the Intramural Program at the NIH.

Dr. Schwartz said the module will contain "a system of recording when someone has taken each required section, so we will be able to document fulfillment of the requirement." All current staff will be expected to complete the instruction by October 2003. The module will be incorporated into a web-based orientation package for all new staff.

"We feel that all-NIHers involved in research need to learn about RCR now," Dr. Schwartz said, "and basically, we want the intramural program to set standards."

The NIH Committee on Scientific Conduct and Ethics (CSCE) has recommended that annual refreshers be provided through research ethics case discussions involving groups of 20-30 persons and a facilitator. This mechanism also will permit intramural researchers to be informed about new or changed policies. CSCE is developing a web site for research ethics case studies to illustrate each core area. Facilitators are being trained.

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### **WORKSHOP BEGINS IMPLEMENTATION OF FEDERAL RESEARCH MISCONDUCT POLICY**

Federal agencies have until December 6, 2001, to implement the Federal Research Misconduct Policy that was published by the Office of Science and Technology Policy (OSTP) in the *Federal Register*. The policy, developed by the National Science and Technology Council, requires each Federal agency that sponsors research to establish a policy and procedures for responding to allegations of research misconduct in their intramural and extramural research programs. The policy is on the ORI web site at [policies/regs/statutes](#) under Handling Misconduct.

Clifford J. Gabriel, Deputy to the Associate Director for Science, OSTP, told some 80 representatives from 25 agencies who attended the Research Misconduct Policy Implementation Workshop on February 1, 2001, that the interagency Research Misconduct Policy Implementation Group would regularly meet this year to facilitate implementation. At the workshop, agency officials discussed the new Federal requirements and addressed issues they may confront in implementing the policy in their agency and awardee institutions.

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### **ARCHAEOLOGIST PHOTOGRAPHED SALTING EXCAVATION SITE**

Archaeologists in Japan were shaken recently when photographs of a noted amateur archaeologist planting artifacts in an excavation site were published on the front page of a leading national daily, according to Science.

Reporters from the newspaper had been tracking Shinichi Fujimura for 6 months because of rumors about the veracity of his earlier discoveries. At a subsequent news conference, Fujimura confessed to planting artifacts at one other site, but colleagues are questioning all of his work, which includes 33 excavations directly and extends to 160 other efforts.

The misconduct raised questions about the practice of archaeology in Japan where competition supposedly has allowed press conferences to take precedence over publications in announcing

discoveries which are subjected to little critical review or scholarly debate before or after their announcement.

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## **IOM PREPARING REPORT ON ASSESSING INTEGRITY IN RESEARCH ENVIRONMENTS**

ORI has commissioned the Institute of Medicine (IOM) to prepare a report on the conceptual issues related to assessing integrity in research environments as a precursor to the development of a longitudinal database for tracking institutional and PHS efforts to foster integrity in research environments.

The project study committee held its first meeting on February 5-6, 2001, at the National Academy of Sciences in Washington. Additional open meetings are tentatively scheduled in Washington for April 25-26 and June 28-29, 2001. For latest information see <http://www.iom.edu/ori>.

The PHS regulation on responding to allegations of scientific misconduct states that “institutions shall foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested.”

“We are trying to create a database that can be useful in guiding the development of education, prevention, and research programs related to research integrity and in evaluating the effectiveness of such programs,” Chris Pascal, Director, ORI, said. “We are not trying to assess the integrity of the research conducted at individual institutions.”

Conceptual issues expected to be addressed in the IOM report include (1) defining the concepts “research environment” and “research integrity,” (2) identifying elements of the research environment, (3) indicating how the elements may be measured, (4) distinguishing between those environmental elements that promote research integrity and those that do not, (5) suggesting appropriate methodology for collecting the data, (6) stipulating unit(s) of analysis, and (7) proposing appropriate outcome measures.

To prepare the report, IOM will review the literature, appoint a study committee, and commission scholarly papers. The study committee will solicit comments from the research community, and the study is expected to be completed in early 2002.

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## **ANALYSIS OF INSTITUTIONAL POLICIES PROVIDES OPTIONS AND BEST PRACTICES**

A content analysis of 156 institutional research misconduct policies has generated a list of options and best practices that have been developed by institutions to address 18 issues involved in responding to allegations of research misconduct.

The report, *Analysis of Institutional Policies for Responding to Allegations of Scientific Misconduct*, is expected to be available on the ORI web site in April under Breaking News or by selecting Publications and clicking on Studies/Reports. The study was conducted by the Center for Health Policy Studies, Columbia, MD, under contract with ORI.

"The analysis should assist institutions to develop a research misconduct policy or revise an existing policy to make it more useful and effective," Lawrence J. Rhoades, Director, Division of Education and Integrity, ORI, said, "because the analysis identifies options that have been developed by institutions to handle the pertinent issues and indicates how many institutions are employing those options."

The study population contained policies that were selected for analysis by ORI because the policies provided detailed guidance on one or more of the following issues: (1) defining research misconduct; (2) reporting allegations; (3) pursuing an allegation; (4) maintaining confidentiality; (5) handling conflicts of interest; (6) providing appropriate expertise; (7) establishing the rights of respondents; (8) appointing the inquiry committee; (9) conducting an inquiry; (10) preparing the inquiry report; (11) appointing the investigation committee; (12) conducting an investigation; (13) preparing the investigation report; (14) imposing sanctions; (15) creating an appeals process (16) restoring the reputation of respondents; (17) protecting whistleblowers; and (18) taking interim administrative actions. The report contains data on 89 questions related to these issues. Results of the analysis will be used to create a web-based module on creating an institutional research misconduct policy, workshops, and other educational activities.

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## **SURVEY FOCUSES ON RESEARCH INTEGRITY MEASURES IN BIOMEDICAL RESEARCH LABS**

A survey to determine the types of and the extent to which research integrity measures are utilized in biomedical research laboratories will be conducted by the American Institutes for Research for ORI in 2001.

The study population will be 5,000 randomly-chosen principal investigators (PIs) who have PHS support for the conduct of biomedical or behavioral research. The survey focuses on PIs because it assumes that most PIs are laboratory directors. There is no current data on biomedical laboratory directors. In addition, the survey will collect data on the characteristics of the host institution, the laboratory, and the PI. The study is expected to create a database for secondary analysis by other researchers. Several biomedical laboratory

directors were consulted on the survey.

Results will be reported to all institutions with an assurance on file with ORI and researchers through the ORI Newsletter, the ORI web site, and journal articles. The results also will be used by ORI in its education program.

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### **PROPOSED WHISTLEBLOWER PROTECTION GENERATES COMMENTS**

Forty-three comments were received by ORI during the 60-day comment period on the notice of proposed rulemaking (NPRM) on PHS Standards for the Protection of Research Misconduct Whistleblowers that closed January 29, 2001.

The proposed rulemaking, published in the *Federal Register* on November 28, 2000, would establish standards for preventing and responding to retaliation against persons who make a good faith allegation that an institution or one of its members engaged in or failed to respond adequately to an allegation of research misconduct. The NPRM would also protect persons who cooperate in good faith with an investigation of research misconduct and would provide for monitoring institutional implementation of the standards.

Comments were received from whistleblower organizations, universities, professional associations, media, a government agency, and individuals. The regulation is mandated by the NIH Revitalization Act of 1993. In the next several months, ORI will analyze the comments and make recommendations for any needed changes to the NPRM to PHS and the Department.

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### **GLOBAL FORUM DISCUSSES CLINICAL RESEARCH IN DEVELOPING COUNTRIES**

The third meeting of the Global Forum for Bioethics in Research will be held in The Gambia in November 2001 to continue the discussion of the ethical dilemmas involved in the conduct of clinical research and clinical trials in developing countries.

A fourth meeting is scheduled to be held in 2002 in Latin America or the Caribbean. Summaries of the meetings held in Bethesda in November 1999 and Bangkok in October 2000 are available at <http://www.nih.gov/fic/programs/bioethics/globalfrm.html>.

Initiated by the Fogarty International Center, NIH, the Global Forum promotes discussion among medical researchers in low- and middle income nations and organizations, including the pharmaceutical industry, that support clinical research. The Global Forum is sponsored by the World Health Organization, the Pan American Health Organization, and the NIH.

A tangible result of the first meeting was the creation of the International Bioethics Education and Career Development Award Program by the Fogarty Center. The program, open to U.S. and

international educational and research institutions, aims to 1) improve the quality of international ethics training by supporting the development of courses to provide skills for teaching and research related to bioethics and the conduct of medical research in developing countries, 2) support the advance training of developing country professionals who can assume the roles and responsibilities of bioethicists involved in ethical review of clinical trial design in research and clinical investigation in their countries, and 3) develop and provide intensive short courses specifically designed for individuals directly involved in human subjects research ethical review.

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### **NOTABLE QUOTE**

"The claim that scientific integrity is based on trust is often an effort to avoid public scrutiny. From those outside the endeavor it rings bells; as when in a business transaction an accountant or treasurer tells you, "Trust us, you don't need to see the books." Jonathan King, Professor of Molecular Biology, M.I.T. *Science and Engineering Ethics* 5:216, 1999.

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### **SECOND RFA SLATED FOR RESEARCH ON RESEARCH INTEGRITY**

A second request for applications (RFA) for the Research Program on Research Integrity is expected to be issued by June 2001 with a submission deadline of November 19, 2001. The RFA will be published in the NIH Guide for Grants and Contracts and posted on the ORI web site.

The 25 applications that were received in the first round last December will be reviewed in April 2001 with awards made in July 2001. The RFA for the first round is posted on the ORI web site under Quick Links.

The grant program is designed to foster research on the institutions, processes, and values that positively and/or negatively influence integrity in research. Sponsors, ORI and the National Institute of Neurological Disorders and Stroke, are particularly interested in studies that inform policymakers and research administrators on effective ways to foster integrity in publicly funded research programs.

ORI will commit another \$500,000 in Fiscal Year 2002 to fund three to five new grants. Applicants may request up to a 2-year project period and direct costs up to \$100,000 per year. Awards will be contingent on availability of funding and merit of applications.

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### **RESEARCH CONFERENCE PROCEEDINGS AVAILABLE THIS SUMMER**

About 45 papers presented during the Research Conference on Research Integrity in November 2000 will be published by this summer as conference proceedings that will be

available on the ORI web site in the research section under Programs.

Entitled "Investigating Research Integrity: Proceedings of the First ORI Research Conference on Research Integrity," the papers will be grouped under the following headings: Norms and Environmental Issues, Medical Practice and Clinical Research, Teaching, and Research Theory and Methods.

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### **CASE SUMMARY**

Michael K. Hartzler, Ph.D., Oakland University (OU): Based on the report of an investigation conducted by OU and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Dr. Hartzler, former Associate Professor of Biomedical Sciences, Eye Institute, OU, engaged in scientific misconduct by falsifying the status of support materials in eight National Eye Institute (NEI), National Institutes of Health (NIH), grant applications. Specifically, Dr. Hartzler falsified the status of 11 manuscripts in 8 grant applications by listing them as "accepted" or "in press" when the papers had either not been subsequently published or had been rejected. The repetition of these actions over several years indicates a pattern of knowingly misrepresenting the research record. Dr. Hartzler accepted the PHS finding and entered into a Voluntary Exclusion Agreement with PHS in which he voluntarily agreed for the 3-year period beginning November 20, 2000: (1) that with each PHS research application or continuing application or report, he must submit a statement of certification, endorsed by an institutional official, that all manuscripts or publications are properly and accurately cited in the application; the institution must also submit a copy of the certification to ORI; and (2) to exclude himself from serving in any advisory capacity to PHS.

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### **CONFERENCE PROPOSALS DUE JUNE 1**

ORI is seeking proposals from institutions, professional associations, and scientific societies that wish to collaborate with ORI in developing a conference or workshop on promoting research integrity or handling scientific misconduct allegations. The funding available generally ranges from \$5,000 to \$20,000. ORI intends to hold four to six regional conferences or workshops each year in strategic locations around the country.

June 1, 2001, is the target date for receiving applications. Instructions and an application form are available at <http://ori.hhs.gov>, or call 301-443-5300, or e-mail to [askori@osophs.dhhs.gov](mailto:askori@osophs.dhhs.gov)

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### **ORI CO-SPONSORING 4 NATIONAL CONFERENCES IN 2001**

May 3-4, 2001 "Promoting Research Integrity in Communication Sciences and Disorders and Related Disciplines" For more information, contact Dr. Sharon Moss, American Speech-Language-Hearing Association, Phone: 301-897-5700; Fax: 301-897-7354; or see [http://professional.asha.org/announcements/2001\\_Res\\_Int\\_wkshp.htm](http://professional.asha.org/announcements/2001_Res_Int_wkshp.htm)

May 6-7, 2001 "Research Compliance: Challenges and Opportunities" Contact Laura Friend, Office of Continuing Medical Education, Johns Hopkins University School of Medicine, Phone: 410-955-2959; Fax: 410-955-0807; or see <http://www.med.jhu.edu/cme/events/research.html>

May 17-19, 2001 A workshop on "RCR 101: Tools and Methods for Teaching Responsible Conduct of Research" followed by a conference on "Promoting Responsible Conduct of Research: New Policies, Opportunities and Challenges" For further information, contact Tammy Plante, Public Responsibility in Medicine and Research, Phone: 617-423-4112; Fax: 617-423-1185; or see <http://www.primr.org>

May 30-31, 2001 "Legal Issues and Strategies in Responding to Research Misconduct Allegations" For more information, contact Rachel Gray, Program Associate, Program on Scientific Freedom, Responsibility and Law, AAAS, Phone: 202-326-6600; Fax: 202-289-4950; or see <http://www.aaas.org/spp/legal>

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## NOTABLE QUOTE

"All honest scientists are victims of scientists who commit misconduct. Jobs in science, research funds and journal space are all scarce. Every job occupied, every grant received and every paper published by someone who engages in misconduct deprives at least one honest scientist of an opportunity to which he or she was entitled." Herbert N. Arst, Jr., Imperial College School of Medicine, London. *Nature* 403:478, 2000.

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## PUBLICATIONS

*A Guide to Training and Mentoring in the Intramural Research Program at NIH.* This booklet suggests the broad principles on which training programs should be based, sets forth criteria for good mentoring, and complements Guidelines for the Conduct of Research in the Intramural Research Program at NIH. The guide is available at <http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/mentor-guide.htm>. The guidelines are available at <http://www.nih.gov/news/irnews/guidelines.htm>.

*Making the Right Moves in Handling Research Misconduct Allegations.* Program highlights

of a satellite video conference held on March 24, 2000, co-sponsored by the National Council of University Research Administrators and ORI. Available at <http://ori.hhs.gov/html/programs/makingtherightmoves.asp>.

*The Role and Activities of Scientific Societies in Promoting Research Integrity.* Report of a conference held in Washington, DC on April 10, 2000, co-sponsored by the American Association for the Advancement of Science and ORI, and written by Elizabeth DuMez. The report is available at <http://www.aaas.org/spp/dspp/sfrrl/projects/integrity.htm>.

*Educating for the Responsible Conduct of Research in the Next Millennium: New Dilemmas, Continuing Questions, and Effective Strategies.* Proceedings from a conference held in Bethesda, MD, on May 13-14, 1999, co-sponsored by PRIM&R, ARENA, AAMC, Tufts University School of Medicine, NIH, and ORI, and edited by Ruth L. Fischbach. Includes presentations on course, program and curriculum development, mentorship, data management, and authorship. Call PRIM&R at 617-423-4112 for cost information. E-mail: [info@primr.org](mailto:info@primr.org).

*Management of Biomedical Research Laboratories: A National Conference Proceedings.* Conference held October 1-3, 1998, co-sponsored by the University of Arizona and ORI. Edited by Thomas P. Davis, University of Arizona. Includes presentations on the role of the laboratory director: authority, responsibilities, skills; mentoring: responsibilities, effectiveness, conflicts; managing the research agenda: strategy, change, competing interests; quality control: experiments, analysis, reporting; data management; recording retention, access, ownership; collaborative research: expectations, conflicts, resolution; and assigning credit for productivity: how, by whom, for what, when. Available in hard copy from ORI upon request.

*Developing a Code of Ethics in Research: A Guide for Scientific Societies.* This booklet provides a blueprint for developing a code of ethics in research and therefore it contains information that may be fruitfully considered in RCR training. Includes chapters on creating a positive research environment, applying for research support, conducting research, reporting research, and enforcement. Contact AAMC at 202-828-0416 for cost information.

*Enhancing the Postdoctoral Experience for Scientists and Engineers.* This practical guidebook assesses the postdoctoral experience and provides principles, action points, and recommendations for enriching it. The guidebook may be read free online at <http://www.nap.edu> or may be purchased from National Academy Press, 2101 Constitution Ave., N.W., Washington, DC 20418.

*Tomorrow's Cures Today? How to Reform the Health Research System.* A collection of mostly-published articles by Donald R. Forsdyke, a biochemist for more than 30 years, that critically examines the current health research system, particularly the review and funding of

applications. Contact Harwood Academic Publishers at <http://www.gbhap.com> for cost information.

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## NOTABLE QUOTE

"Plainly, journals, as the places for which research results are headed, have some responsibility (for research integrity). Although they cannot create deception-proof peer review; they can treat retractions honestly and forthrightly. They can express the community's interest in the trustworthiness of results and close their pages to transgressors. They should also praise responsible actions, especially when those carry personal costs." Donald Kennedy. *Science* 289:1137, 2000.

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## GUIDANCE FOR EDITORS; CHINESE EDITION

ORI granted permission in January 2001 to a journal publisher in China to translate *Managing Allegations of Scientific Misconduct: A Guidance Document for Editors* into Chinese as instructional material in two workshops for editors of scholarly journals in China. The translation will also be posted on a web site on editorial practice.

Published in January 2000, the original edition was mailed to 1,200 members of the Council of Science Editors, and is on the ORI web site.

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