ORI Newsletter

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FINAL RCR POLICY PROVIDES FLEXIBILITY AND MORE TIME TO INSTITUTIONS

The final PHS Policy on Instruction in the Responsible Conduct of Research (RCR) gives institutions considerable flexibility in designing an educational program for their research staff and extends the implementation period to October 1, 2003.

The final policy, a summary of the comments received on the draft policy, a set of Q&As, and a list of educational resources, may be accessed by clicking on News on the ORI home page.

By October 1, 2001, institutions should have a written description of their RCR education program that must be submitted to ORI upon request. Following revision of PHS Form 398, institutions will submit their RCR assurances to ORI by signing the face page of the PHS grant application and by submitting their Annual Report on Possible Research Misconduct for CY 2001 and thereafter.

Institutions may reasonably determine which employees are subject to the policy that defines "research staff" as staff at the institution who have direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training supported by PHS funds or who otherwise work on the PHS-supported research project even if the individual does not receive PHS support. Collaborators at other institutions who work on PHS-supported projects are also covered.

Institutions also have the flexibility to determine the exact content, length, level, and method of instruction, decide whether a demonstration of competency will be required, and establish the method of documenting that instruction has occurred.

In addition, institutions may exercise reasonable discretion in selecting which of the following core areas are applicable to the research staff receiving instruction: (1) data acquisition, management, sharing, and ownership; (2) mentor/trainee responsibilities; (3) publication practices and responsible authorship; (4) peer review; (5) collaborative science; (6) human subjects; (7) research involving animals; (8) research misconduct; and (9) conflict of interest and commitment.

Implementation of an institution's program of instruction for current staff should be completed by October 1, 2003. Research staff employed after October 1, 2003, "shall receive instruction in RCR prior to working on a research project, or as soon thereafter as practicable, but no later than one year after beginning work on the research project." Any research staff member may be given credit for instruction already received in a core area.

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DREYER HEARING TERMINATED AFTER SETTLEMENT FOR MISCONDUCT

On November 15, 2000, Evan B. Dreyer, M.D., Ph.D., entered into a Voluntary Exclusion Agreement with the Public Health Service (PHS) bringing an end to his appeal of the PHS findings of scientific misconduct and proposed debarment issued on April 14, 2000. Based on evidence from a joint inquiry panel of representatives from the Harvard Medical School and the Massachusetts Eye and Ear Infirmary (MEEI), as well as additional information developed during ORI's oversight review, the PHS found that Dr. Dreyer engaged in six acts of scientific misconduct by fabricating experimental results and reporting those results in six places, including two NIH grant applications and an abstract and unsubmitted manuscript for the Triologic Society. The fabricated results purported to prove the central hypothesis of the research, namely, that elevated levels of glutamate, an excitatory amino acid, would play a role in causing Meniere's disease. On May 10, 2000, Dr. Dreyer appealed the PHS findings to the HHS Departmental Appeals Board (DAB) which, on October 30, 2000, commenced a *de novo* hearing to consider the charges of scientific misconduct. Although the hearing was originally scheduled to run 3 weeks, the parties entered into a settlement about half-way through the proceedings, after which the DAB dismissed the case.

When the PHS originally issued its scientific misconduct findings, the debarring official proposed that Dr. Dreyer be debarred for 5 years from receiving Federal funds and be precluded from serving in an advisory capacity to the PHS. However, after his misconduct hearing commenced, Dr. Dreyer agreed to a settlement under which he voluntarily excluded himself from receiving Federal funds and advising the PHS for 10 years. This limitation would not apply to Dr. Dreyer's practice of clinical medicine or to Federal funds used for clinical teaching and training.

Under the terms of the Voluntary Exclusion Agreement, Dr. Dreyer admitted to 1 of the 6 counts of scientific misconduct, *i.e.*, that he fabricated 21 chromatograms contained on a magneto-optical disk that he provided to institutional officials who were investigating the allegations of scientific misconduct against him. As for the other five counts of scientific misconduct, Dr. Dreyer did not admit that he falsified or fabricated any of the amino acid results at issue, but recognized that, if the hearing were to proceed to conclusion before the DAB, there was sufficient evidence upon which the DAB could make a finding of scientific misconduct against him.

The Voluntary Exclusion Agreement contains several other provisions. First, Dr. Dreyer certified that, to the best of his knowledge, information and belief, he is currently in compliance and will use all reasonable efforts to maintain compliance with all government and hospital rules and regulations regarding patient care, medical licensing and/or human subject research. Second, Dr. Dreyer agreed to request the Federal District Court to dismiss with prejudice the *qui tam* action

under the False Claims Act he had filed against MEEI and two named defendants, who were also witnesses in this case. After the United States declined to intervene, Dr. Dreyer had previously requested dismissal of the *qui tam* without prejudice-meaning that he could refile it at any time. Finally, Dr. Dreyer agreed to waive all civil claims against the United States, MEEI, Harvard, and all of their employees, agents and assigns, together with any witnesses or other participants in the proceedings before the institutions or the Federal government.

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ORI EXHIBITS AT ANNUAL MEETINGS

ORI exhibited at four annual meetings of scientific societies and professional associations in 2000 to increase contact and generate a dialogue with members of the research and academic communities.

Exhibits were held during meetings of the National Council of University Research Administrators in November, the Association of American Medical Colleges Group on Graduate Research Education and Training in October, the American Sociological Association in August, and the American Association for the Advancement of Science in February.

The exhibits allowed ORI staff to talk to researchers, research administrators, postdocs, graduate students, professional association officials, and high school science teachers about research integrity, the RCR policy, the research conference and program, collaborative workshops and conferences, and institutional policies for responding to allegations of research misconduct. Interested societies and associations should contact Anita Ousley at 301-443-5300 or **aousley@osophs.dhhs.gov**.

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ELECTRONIC SUBMISSION OF ANNUAL REPORT BEGINS

Most institutional officials will be able to submit their Annual Report on Possible Research Misconduct for CY 2000 by hitting a few keys on their computer as ORI switches to electronic transmission of the report. Detailed instruction for accessing and updating the web-based system can be found by clicking on News on the ORI web site. The submission period is from January 1 to March 1, 2001.

The system is in three sections: Institutional Information, Annual Report, and Password Management.

Institutions will be able to update the Institutional Information section at any time. This section contains the name of the institution, address, phone and fax numbers, name of responsible official, and an e-mail address. All changes made to this section will be confirmed by e-mail so institutions should furnish an e-mail address and keep it current.

The Annual Report section replicates the hard copy form previously used. This section asks about the availability of a policy for responding to allegations of research misconduct, the misconduct activity that occurred, if any, and the receipt of any bad faith allegations. Institutions may access this section only during January and February of each year. Institutions will receive e-mail confirmations of their Annual Report submission. Institutions may print a copy of the submitted Annual Report for their files.

The Password Management System allows institutions to restrict access to the institutional official of record.

For comments, questions and problems, contact John Butler at 301-443-5300; **jbutler@osophs.dhhs.gov**.

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MEETING

May 9-12, 2001 - Teaching Research Ethics: Eighth Annual Workshop. Indiana University, Bloomington. Contact Kenneth Pimple, **pimple@indiana.edu**, Phone: 812-855-3315; Fax: 812-855-3315.

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FUNDING FOR RCR RESOURCES OFFERED BY SBIR/STTR PROGRAMS

The development of resources for education in the responsible conduct of research (RCR) will be included in the omnibus solicitation for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs that will be issued in January 2001.

Information on the responsible conduct of research solicitation will appear in the Grants - Program Descriptions and Research Topics section before the NIH listing. The web site address is **http://grants.nih.gov/grants/funding/sbirsttr1/index.htm.**

The SBIR program is only open to small businesses. The STTR allows collaboration between a small business and an academic institution. Resources produced through these grants must be sold. Applications are due April 1, 2001, for funding after December 1, 2001.

Areas in which resource development is needed include: (1) data acquisition, management, sharing and ownership; (2)mentor/trainee relationships; (3) publication practices and responsible authorship; (4) peer review; (5) collaborative science; (6) protection of human research subjects; (7) use of animals in research; (8)research misconduct; and (9) conflict of interest and commitment.

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PUBLICATION OF FEDERAL DEFINITION AND PROCEDURES

A notice stating the new Federal definition of research misconduct and the procedures for responding to allegations of research misconduct was published in the *Federal Register* on December 6, 2000. The definition and procedures may be accessed by clicking on News on the ORI home page, **ori.hhs.gov**.

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INSTITUTIONS SHOULD RESOLVE AUTHORSHIP OR CREDIT DISPUTES

ORI frequently receives allegations of plagiarism involving authorship or credit disputes either among current or former collaborators or members of labs who make independent use of jointly-developed work. Researchers making these allegations may be disappointed to discover that ORI policy does not consider most of these disputes as falling within the Public Health Service (PHS) definition of scientific misconduct. (See **http://ori.hhs.gov/html/about/plagiarism.asp**) Rather, as the "ownership" of the intellectual property in many of these cases is seldom clear, ORI believes these disputes are better handled at the researchers' institutions.

Although ORI is not able to handle these types of disputes, authorship and credit issues are very important and scientists and their institutions do have an obligation to resolve them. ORI's lack of jurisdiction should not be used by institutions as a reason for refusing to resolve them internally. Institutions may use other procedures such as faculty or student grievance procedures or alternative dispute resolution processes. Officials should deal appropriately with authorship and credit disputes between former collaborators as a matter of fairness and because failure to deal directly with these arguments within an institution has resulted, in some very public cases, in prolonged and expensive litigation.

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NOTABLE QUOTE

"Our editors invited a distinguished scientist in the field to write a Perspective on the paper. The author now discovers, to her embarrassment, that what she wrote was a thoughtful evaluation of a non-experiment. Scientists unknown to us relied on meaningless results, perhaps altering their own research plans as a consequence, and busy peer reviewers wasted valuable time. There is an even heavier cost: Each such case represents another depreciation of trust, not only within our community but also on the part of our public patrons." Donald Kennedy, editor, *Science*, "Reflections on a Retraction" Vol. 289(5482): p.1137, 2000.

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DRAFT WHISTLEBLOWER PROTECTION REGULATION PUBLISHED

On November 28, 2000, the Department published a notice of proposed rulemaking (NPRM) to 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 of institutions' implementation of the standards. The NPRM, "Public Health Service Standards for the Protection of Research Misconduct Whistleblowers," is at 65 Fed. Reg. 70830 (2000) and may be accessed by clicking on News on the ORI home page, **ori.hhs.gov**.

Comments on the NPRM are due by Jan. 29, 2001.

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RCR RESOURCE PAGE CREATED; MODULE LINKS SOLICITED

ORI is developing a resource page on its web site that lists web-based modules on the nine core instructional areas listed in the PHS Policy on Instruction in the Responsible Conduct of Research (RCR).

"ORI hopes this mechanism will help institutions assist each other in developing their RCR education program," Chris Pascal, Director, ORI, said, "and negate the necessity of each institution developing its own program from scratch."

The core instructional areas are: data acquisition, management, sharing, and ownership; mentor/trainee responsibilities; publication practices and responsible authorship; peer review; collaborative science; human subjects; research involving animals; research misconduct; and conflict of interest and commitment.

Institutions may offer their modules for listing on the resource page by sending the web address of the module to **aousley@osophs.dhhs.gov**. Please indicate if there is a charge for access. The number of modules listed under a core instructional area may be limited.

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RESEARCH CONFERENCE ON RESEARCH INTEGRITY DRAWS LARGE TURNOUT

An enthusiastic group of researchers shared their ideas, data and findings in plenary, concurrent, and poster sessions for a day and a half during the first ORI Research Conference on Research Integrity, and then recommended that ORI organize another conference in 2 years.

The program covered topics including interviews with scientists against whom misconduct findings have been made, an ethnographic study of the relationships between scientific practices, accountability, and the use of records and recordkeeping in a research lab, a content analysis of instruction to authors in journals, trend analysis of conflicts of interest, a survey of attitudes toward data editing, an experiment involving informed consent, field investigations into organizational influences on scientific integrity, a developmental study of professional identities

in doctoral candidates, and the evaluation of education programs in the responsible conduct of research.

Over 200 researchers, doctoral candidates, graduate students, and administrators attended the conference that was held at the Bethesda Hyatt Hotel on Nov. 19-20, 2000. Registration was stopped several weeks before the conference because it was oversubscribed. About 60 conference participants sharpened their skills by attending the grant writing workshop that immediately followed the research conference.

The conference materials, including abstracts, a review of the literature, and bibliography are available on the ORI web site by clicking on News on the home page. Conference proceedings will be posted on the ORI web site when completed. Selected papers will be submitted to journals for publication.

Chris Pascal, Director, ORI, characterized the conference as the beginning of a long-term process "to develop a science-based understanding of the research process that will lead to improved strategies for maintaining research integrity." Connie Atwell, Associate Director for Extramural Research, National Institute of Neurological Disorders and Stroke (NINDS), indicated her agency was interested in research integrity not only because it promoted compliance with the rules, but because "integrity makes research better." NINDS co-sponsors the Research Program on Research Integrity with ORI.

Nick Steneck, University of Michigan, who co-organized the conference and research program with Mary Scheetz, ORI, suggested that researchers employ neutral concepts to investigate the research process and not rely solely on the moral-laden terms of misconduct and integrity. The keynote speaker, Debra Stewart, President, Council of Graduate Schools, asserted that graduate schools should make "ethics education a higher and more visible priority in the education of our research scientists."

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INDIA REVISES GUIDELINES TO PROTECT HUMAN SUBJECTS

Revised guidelines for the conduct of biomedical research involving humans adopted by the Indian Council of Medical Research (ICMR) in September 2000, assert that all such proposals "should be reviewed by an appropriately constituted Institutional Ethics Committee (IEC)."

Besides conducting the initial review, the guidelines assign IECs "a continuing responsibility of regular monitoring for the compliance of the ethics of the approved programmes till the same are completed. Such an ongoing review is in accordance with the Declaration of Helsinki and all the international guidelines for biomedical research."

The guidelines stipulate that the scientific evaluation of the proposal must be completed before

the ethical review begins and recommends that ethical reviews be done in formal meetings rather than through the circulation of proposals. The guidelines further recommend that IEC records be retained for at least 15 years.

Independence and competence are cited as the criteria for IEC membership. A person from outside the institution is preferred as the IEC chair. Membership should be a mix of medical, non-medical, scientific and non-scientific persons.

The guidelines outline the obligations of investigators regarding informed consent and the essential information that must be provided to prospective research subjects. Compensation to participants and the treatment of special populations such as pregnant or nursing women, children, mentally challenged individuals, prisoners, and economically or socially disadvantaged persons are addressed. Other topics covered include clinical trials; epidemiological, human genetics and transplantation research; and reproductive technologies.

The ICMR document "Ethical Guidelines for Biomedical Research on Human Subjects" is available at **http://icmr.nic.in/vsicmr/wel.htm**.

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CASE SUMMARIES

Evan B. Dreyer, M.D., Ph.D., Harvard Medical School and Massachusetts Eye and Ear Infirmary. See article on page 1 of this issue.

Randall P. French, Ph.D., Fox Chase Cancer Center (FCCC): Based on the report of an investigation conducted by FCCC and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. French, postdoctoral associate, FCCC, engaged in scientific misconduct by fabricating published research supported by National Cancer Institute, National Institutes of Health (NIH), grants T32 CA09035 and P30 CA06927. Specifically, Dr. French fabricated research results published in *Developmental Biology* 217:62-76, 2000, by falsely claiming in the text and Table 1 that he had assayed mouse embryos transgenic for a modified DNA construct (cG5/lacZ-F) for a study on the expression of cGATA-5 transcription factor during heart development in mice. An erratum replacing the fabricated data was published by the authors in *Developmental Biology* 223:463, 2000.

Dr. French accepted the PHS finding and entered into a Voluntary Exclusion Agreement with PHS in which he voluntarily agreed for a 3-year period beginning September 28, 2000, to exclude himself from serving in any advisory capacity to PHS, and his participation in any PHS-funded research is subject to supervision requirements.

Caroline E. Garey, Boston College (BC): Based on the Report and Addendum of the BC Research Misconduct Investigation Committee and additional analysis conducted by ORI in its

oversight review, PHS found that Ms. Caroline E. Garey, former doctoral student, BC, engaged in scientific misconduct by falsifying research supported by National Institute of Neurological Disorders and Strokes (NINDS), NIH, grant R01 NS23355. Specifically, Ms. Garey falsified restriction fragment length polymorphism (RFLP) data for ABP and DBA backcross mice DNA samples by misrepresenting results from multiple assays of identical backcross ABP DNA samples as being from different animals, and misrepresenting the autoradiograms of backcross ABP DNA samples as the results from experiments on backcross DBA mice. Ms. Garey reported this falsified data in her doctoral dissertation, "Defect in the ceruloplasmin gene associated with epilepsy in the EL mouse," and in an article in *Nature Genetics* 6:426-431, 1994. She caused her falsified data to be reported by her laboratory director in NINDS, NIH, grant application 2 R01 NS23355-08A1 and at an international workshop on epilepsy on September 24, 1994. Ms. Garey also fabricated a translation table that she used to assign falsified RFLP data to individual backcross DBA mice. As a result of falsifying these assays over a minimum of 2½ years, none of Ms. Garey's research can be considered reliable. These actions adversely and materially affected the laboratory's ongoing research on the genetic causes of epilepsy. Ms. Garey also engaged in a pattern of dishonest conduct that indicates that she is not presently responsible to be a steward of Federal funds. This pattern of behavior includes a history of falsely claiming that she has performed scientific experiments when she has not, and repeated instances in which she misrepresented her credentials to prospective employers, colleagues, customers, and the general public as including a Ph.D. degree even though BC refused to grant her a doctoral degree because of her scientific misconduct. The publication affected is: Garey, C.E., Schwarzman, A.L., Rise, M.L., & Seyfried, T.N. "Ceruloplasmin gene defect associated with epilepsy in EL mice." *Nature Genetics* 6:426-431, 1994 (retracted in *Nature Genetics* 11:104, 1995).

While Ms. Garey does not admit the findings of scientific misconduct, she entered into a Voluntary Exclusion Agreement with PHS in which she voluntarily agreed for a 5-year period beginning September 25, 2000, to exclude herself from any contracting, subcontracting, or nonprocurement transactions with the United States Government, and to exclude herself from serving in any advisory capacity to PHS.

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ORI CO-SPONSORING 4 NATIONAL CONFERENCES IN 2001; REGIONAL RCR MEETINGS

May 4, 2001 "*Promoting Research Integrity in Communication Sciences and Disorders and Related Disciplines*"

ORI is co-sponsoring a national meeting with the American Speech-Language-Hearing Association (ASHA) on the responsible conduct of research in Rockville, MD, on May 4, 2001. This workshop will focus on educating advanced doctoral students, post-doctoral fellows, junior faculty and others in the early stages of their research careers. Contact Dr. Sharon Moss, ASHA,

Phone: 301-897-5700; Fax: 301-897-7354.

May 6-7, 2001 "*Research Compliance: Challenges and Opportunities*"

ORI is co-sponsoring a national meeting in Baltimore, MD, with the Johns Hopkins University (JHU) School of Medicine on creating effective research compliance programs within academic institutions. The conference is expected to cover issues such as education in the responsible conduct of research, use of human subjects in research, managing possible conflicts of interest, managing a research integrity program, and the use of animals in research. For further information, contact Julie Gottlieb, JHU School of Medicine, Phone 410-955-9545; Fax 410-955-3890.

May 17-19, 2001 "*Educating for the Responsible Conduct of Research in the New Millennium*"

ORI is co-sponsoring a national conference in the Washington, DC, area with Public Responsibility in Medicine and Research (PRIM&R) on the tools, methods, and strategic approaches to developing programs on educating for the responsible conduct of research. A series of four regional meetings are expected to follow this event. For further information, contact Tammy Plante, PRIM&R, Phone: 617-423-4112; Fax: 617-423-1185.

May 30-31, 2001 "*Legal Issues and Strategies in Responding to Research Misconduct Allegations*"

ORI is co-sponsoring a national conference with the American Association for the Advancement of Science (AAAS), The Johns Hopkins University, and Howard University on changes in regulatory policy and litigation regarding research misconduct. The conference will be held in Washington, DC, and will focus on how legal issues are shaping the way institutions and government respond to research misconduct. For more information, contact Rachel Gray, Program Associate, Program on Scientific Freedom, Responsibility and Law, AAAS, Phone: 202-326-6600; Fax: 202-289-4950.

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RESEARCH PROGRAM APPLICATION

The submission deadline for the first request for applications (RFA) for the Research on Research Integrity Program was December 15, 2000. By November 17, 2000, 17 letters of intent were received. Another RFA is expected to be issued for the second round of submissions in 2001. The RFA will be posted on the ORI web site when available.

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NEW WEB SITE AVAILABLE FOR RCR EDUCATION

A new web site is available to assist institutions in creating or revising educational programs in the responsible conduct of research (RCR). The web site address is **http://rcr.ucsd.edu**.

All users are encouraged to provide suggestions to improve the site's content and format. Please complete the on-line evaluation form or contact Dr. Michael Kalichman, Research Ethics Program Director, University of California, San Diego at **kalichman@ucsd.edu**; Phone: 858-822-2027; or Fax: 858-534-4722.

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