ORI Newsletter

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## 13 RCR Resource Projects Funded; 78 Applications Submitted

ORI is supporting 13 projects designed to generate instructional materials in the next year for use in institutional education programs on the responsible conduct of research (RCR) through the newly established RCR Resource Development Program.

The request for contracts for the second round is available on the ORI web site under Breaking News. Submission deadline is February 28, 2003; awards will be made in May 2003.

"The number of applications we received in the initial round was beyond our most optimistic expectations," Larry Rhoades, Director, Division of Education and Integrity, said. "The competition was very stiff." Seventy-eight applications were submitted; the success rate was 16.7 percent.

"We initially expected to fund eight projects," Rhoades said, "We've done better, but several additional projects deserved support. Hopefully, we will get resubmissions."

The RCR resource program offers up to $25,000 for the development of RCR instructional materials that will be made freely available to other institutions so that each institution is not required to develop its own resources. Indirect costs are not provided. The performance period is generally one year.

The funded projects include comprehensive courses covering the nine core areas: collections of ethical dilemmas and case studies; videos, CD-ROMs, and web-based modules; specialized projects addressing authorship and publication practices; mentoring; conflicts of interest; human subjects; animal subjects; collaborations; and research misconduct.

*See **RCR Development** on page 2.*

## 9 Awards Made For Research on Research Integrity

Nine 2-year awards were made this month by the Research Program on Research Integrity (RPRI). These awards were made in response to 30 grant applications received last November, yielding a success rate of 30 percent for the second round of the grant program.

The RPRI recorded a 20 percent increase in grant applications received, a 28.6 percent increase in the number of awards made, and a 7.1 percent increase in the success rate over the first round. In the first round, 25 applications were received, 7 awards were made, and the success rate was 28 percent.

The RPRI now has 16 active grants; 7 are in their second year, and 9 are in their first year. The RFA soliciting the third round of applications is posted on the ORI web site under Research in the Programs section. The submission deadline is November 15, 2002. Potential research topics posed by the Institute of Medicine report on *Responsible Conduct of Research in the Health Sciences* are available in the same location.

The awards in the first two rounds were supported by the National Institute of Neurological Disorders and Stroke, the National Institute of Nursing Research, and ORI. The National Institute on Drug Abuse joined the

*See **Funding for Research** on page 4.*

## What's Inside

## RCR Development Program Funds Modules, Videos, Case Studies

(from page 1)

The title, principal investigator, and institution receiving awards follows:

- *Completion, Pilot Testing and Refinement of a Learn Anytime, Anywhere Online RCR Course.* Deni Elliott, University of Montana.
- *Ethical Dilemmas in Research Integrity*. Claire Gutkin, metaLinker.com.
- *Responsible Conduct of Research and Scholarly Activity Web-Based Instructional Program.* Julie Simpson, University of New Hampshire.
- *Web-Enhanced Curriculum for Responsible Authorship and Publication Practices.* Nalini Jairath, University of Maryland-Baltimore.
- *Faculty Guide for RCR Cases*. Wylie Burke, University of Washington.
- *A Documentary Film: A Round Table on Mentoring and Authorship*. Sara Vollmer and Harold Kincaid, Univ. of Alabama-Birmingham.
- *Web-based Instruction on Protection of Human Subjects-Informed Consent*. Anne Edwards, Kestrel Corporation.
- *The Development of RCR Internet-based E-seminars on Mentor/Trainee Responsibilities and Conflict of Interest.* Ruth Fischbach, Columbia Univ.
- *Contemporary Science, Values and Animal Subjects in Research*. Joseph Herkert, North Carolina State Univ.
- *How Collaborators Don't Collaborate (A Video).* Thomas Dalglish, Univ. of Louisville.
- *Avoiding Plagiarism, Self Plagiarism, and Other Questionable Writing Practices: A Guide to Ethical Writing.* Miguel Roig, St. John's Univ.
- *Research Integrity Training Program: Conflicts of Interest and Commitment Module*. Mark Tumeo, Cleveland State Univ.
- *Module Development for the University of Michigan Program for the Education and Evaluation of Responsible Research and Scholarship (PEERRS).* Fawwaz Ulaby, Univ. of Michigan.

## Changes Made to Annual Report; Problems Being Addressed

The Annual Report on Possible Research Misconduct for calendar year (CY) 2002 will ask for some new data—outcomes of inquiries and investigations—but no longer ask for data on bad faith allegations.

ORI also is addressing three problems that occurred in submitting the previous report. The system designer has been asked to improve the compatibility with Macintosh computers; modify the system to provide a printable acknowledgment to the user when the annual report has been successfully transmitted, and ensure that the password button is functional.

The submission period for CY 2002 is January 1, 2003, to March 1, 2003. However, institutions may update the institutional section any time. Instructions for submitting the Annual Report will be posted on the ORI home page under Featured Attractions.

A column was added to the Section II tables asking whether a finding of research misconduct was made in an inquiry or investigation underway or initiated in CY 2001, to enable ORI to check the accuracy of its database.

Data on bad faith allegations will no longer be requested. In 5 years, institutions have reported five bad faith allegations. The questions were deleted because bad faith allegations are rare, or the questions measured the willingness to determine whether an allegation was made in bad faith rather than the frequency of bad faith allegations.

## IOM Report Urges Institutions to Develop Research Integrity Programs

The Institute of Medicine issued a report this month that urges research institutions to implement comprehensive programs designed to promote integrity in research, including effective education programs in the responsible conduct of research.

A 1-day workshop, Assessing Integrity in Research Environments, will be held at the National Academy of Sciences in Washington, D.C., on October 10, 2002, to assess the recommendations and discuss their implementation. The report and conference web site may be accessed through the ORI home page.

The report, *Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct*, commissioned by ORI, makes the following six recommendations:

- Funding agencies should establish research grant programs to identify, measure, and assess those factors that influence integrity in research.
- Each research institution should develop and implement a comprehensive program designed to promote integrity in research, using multiple approaches adapted to the specific environments within each institution.
- Institutions should implement effective educational programs that enhance the responsible conduct of research.
- Research institutions should evaluate and enhance the integrity of their research environments using a process of self-assessment and external peer review in an ongoing process that provides input for continuous quality improvement.
- Institutional self-assessment of integrity in research should be part of existing accreditation processes whenever possible.
- The Office of Research Integrity should establish and maintain a public database of institutions that are actively pursuing or employing institutional self-assessment and external peer-review of integrity in research.

## Pharmaceutical Exec to Give Keynote At Second Research Conference

The chairman of research and development for the pharmaceutical giant GlaxoSmithKline will be the keynote speaker at the second Research Conference on Research Integrity that will be held at the William F. Bolger Center for Leadership Development in Potomac, MD, on November 16-18, 2002. The conference web site may be accessed through the ORI home page.

Tadataka Yamada, M.D., previously served as Chairman, Research and Development, Pharmaceuticals, at SmithKline Beecham; as President, SmithKline Beecham Healthcare Services, and as a member of the SmithKline Beecham Board of Directors.

Earlier in his career, Dr. Yamada was Chairman of the Department of Internal Medicine at the University of Michigan Medical School and Physician-in-Chief of the University of Michigan Medical Center.

He is a Councillor of the Association of American Physicians, past President of the American Gastro-enterological Association, Master of the American College of Physicians, and a member of the Institute of Medicine. Dr. Yamada received his bachelors degree in history from Stanford University, and his MD degree from New York University School of Medicine.

Fifty presentations, including seven by principal investigators supported by the Research Program on Research Integrity, are scheduled on: covering current issues, conflict of interest, the role of IRBs in research integrity, student attitudes, investigative techniques, clinical research, instruction in the responsible conduct of research, the role of institutions in research integrity, publications, medical ethics, and assessing integrity in research.

*See **RRI Conference** on page 8.*

## Funding for Research Awards Increases; Abstracts Posted

(from page 1)

third round solicitation. Total funding (new and continuations) for the second year was about $2.14 million, which doubles the $1.03 million allocated in the first year. The grants are limited to $100,000 in direct costs, plus indirect costs for each of 2 years.

Grant titles, principal investigators, and institutions for the awards follow below:

- *Correcting the Literature after Scientific Misconduct.* Anne V. Neale, Wayne State Univ.;
- *Motivating Integrity in Research with Human Subjects.* Wylie Burke, University of Washington.
- *Trainee -Focused Training for Research Integrity.* Richard McGee, Mayo Clinic Rochester;
- *Equipoise and the Research Integrity of Clinical Trials.* Benjamin Djulbegovic, Univ. of South Florida;
- *A Qualitative Study of Editorial Decision-Making.* Lisa A. Bero, University of California-San Francisco;
- *New Graduate Students' Baseline Knowledge of RCR.* Elizabeth Heitman, University of Mississippi Medical Center;
- *Nurses: Research Integrity in Clinical Trials.* Joan Liaschenko, University of Minnesota;
- *Industry-Sponsored Research Contracts: An Empirical Study.* Michelle M. Mello, Harvard School of Public Health; and
- *Effectiveness of RCR Instruction.* Francis L. Macrina, Virginia Commonwealth University;

Award abstracts are posted on the ORI web site at Research/Programs. Contact Mary Scheetz, Ph.D., Director, Extramural Research Program, at 301-443-5300 or mscheetz@osophs.dhhs.gov.

## Research on Research Integrity Topics Suggested by IOM Report

Numerous deficiencies in the knowledge base related to research integrity, the responsible conduct of research, and research misconduct are cited in the IOM report on *The Responsible Conduct of Research in the Health Sciences.*

The knowledge deficiencies are summarized on the ORI web site in Potential Research Topics, under Research in the Program section.

The potential research topics are categorized under three main headings—Research Community, Professional Development, and Research Process—and 14 subheadings.

**Research Community** asks questions about self-regulation, the research environment, research institutions, quality assurance, journals and scientific societies and professional associations.

**Professional Development** addresses professional behavior, mentoring/supervision, and instruction/training.

**Research Process** contains queries concerning data management, publication, authorship, peer review, and research misconduct.

## AAAS Research Integrity Videos Reissued With Updated Materials

AAAS has updated the discussion and resource guide that accompanies five short videos on research integrity. The videos dramatize realistic situations that raise ethical issues in research but leave the participant's dilemmas unresolved, making them ideal for stimulating discussions. The set of tapes and resource materials may be ordered from **http://www.aaas.org/spp/video/video.htm** or by calling 202-326-6216.

## AAMC/ORI Launch Program for Academic Societies

The Association of American Medical Colleges (AAMC) and ORI have entered into a cooperative agreement aimed at encouraging academic societies to take measures to promote research integrity activities within their organizations.

AAMC and ORI are planning to issue a joint program announcement in September or October 2002. The program announcement will be posted on the ORI home page and the AAMC web site at **http://www.aamc.org**.

"AAMC is ideally and uniquely suited to assist ORI in engaging academic societies in the effort to promote the responsible conduct of research because no other organization has such a diverse membership and direct association with DHHS research programs," Chris Pascal, Director, ORI, said.

"ORI feels it is essential to involve academic societies in the promotion of responsible research and the prevention of research misconduct because academic societies play a crucial role in defining and promoting standards for the responsible conduct of research," Pascal said.

Reports by the National Academy of Sciences (NAS) and the Institute of Medicine (IOM) have recommended that academic societies play a greater role in promoting the responsible conduct of research. In *Responsible Science: Ensuring the Integrity of the Research Process*, the NAS recommended that "scientific societies and scientific journals should continue to provide and expand resources and forums to foster responsible research practices and to address misconduct in science and questionable research practices."

In *The Responsible Conduct of Research in the Health Sciences*, the IOM recommended that scientific organizations should "develop educational and training activities and materials to improve the integrity of research . . . assist universities in identifying substandard research and training practices that compromise the integrity or quality of research . . . develop policies to promote responsible authorship practices, including procedures for responding to allegations or indications of misconduct in published research or reports submitted for publication."

The program will support awards in two categories. The first category will fund about 10 grants of $5,000 each in support of single events or limited activities such as special meetings, sessions at annual meetings, national conferences, or a publication.

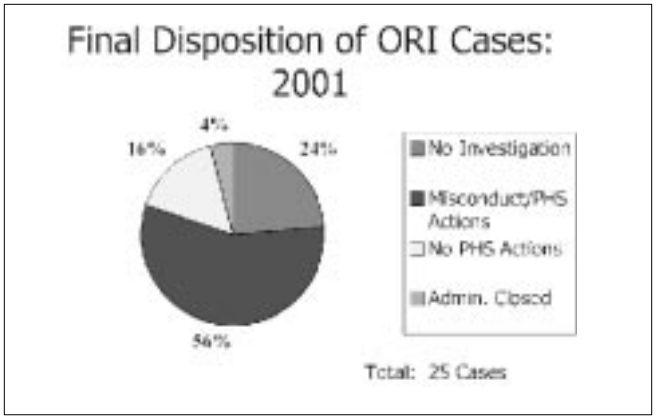
The second category will fund approximately eight grants of $25,000 each for major program initiatives aimed at promoting the responsible conduct of research such as research guidelines, codes of research ethics, curriculum development, instructional materials, instructions to authors, or best practices. Submission deadlines for both categories are October 30, 2002, and March 14, 2003.

## Workshop Summary Available

A summary of the regional workshop *Training in the Responsible Conduct of Research* that ORI co-sponsored with the University of Alabama at Birmingham last November is available on ORI's web site at **http://ori.dhhs.gov/html/programs/pastconferences-workshops.asp**. Seven prominent researchers and Federal officials working and writing on research integrity issues spoke at the meeting. Speakers included Baruch Brody, Director of the Center for Medical Ethics and Health Policy at Baylor College of Medicine and Rice University; Drummond Rennie, University of California at San Francisco; David Resnik, Brody School of Medicine, East Carolina University; Chris Pascal, Director, Office of Research Integrity; Alan Price, Director, Division of Investigative Oversight, Office of Research Integrity; Tony El-Hage, Food and Drug Administration; and Jeremy Sugarman, founding director of the Center for the Study of Medical Ethics and Humanities at the Duke University.

# ORI Closes Record Number of Cases and Expands Research Program

More than half of the research misconduct cases ORI closed in 2001 resulted in misconduct findings, far exceeding the historical average of 34 percent. Of the 25 cases ORI closed in 2001, 14 resulted in misconduct findings and PHS administrative actions, according to the *ORI Annual Report - 2001* (see graphs). Institutions reported increased misconduct activity in their *Annual Report on Possible Research Misconduct* for the third consecutive year.



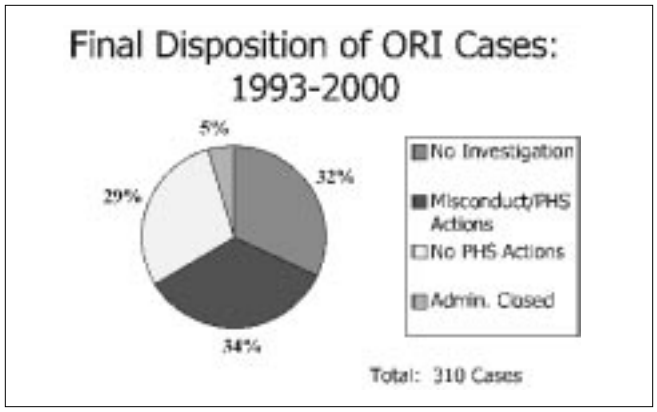

Other highlights of the *Annual Report - 2001* are:

The Department of Health and Human Services published a notice of proposed rulemaking for preventing and responding to retaliation against whistleblowers, and ORI submitted a new draft PHS regulation on handling allegations of research misconduct to the office of the Secretary. The PHS policy on instruction the responsible conduct of research was suspended in February 2001.

Institutions are increasingly taking advantage of ORI's technical assistance program, with 16 institutions receiving help in 2001.

ORI also continued to expand its extramural and intramural research portfolio. The first seven grants in the Research Program on Research Integrity were awarded in September 2001. Two research studies were completed, four were in progress, and one new study began in 2001, including an extramural study of the incidence of research misconduct being conducted by Gallup.

The *Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components* concluded that considerably more medical schools provide some written guidelines for research conduct than in 1990, but the majority are narrowly focused and varied on the topics that they covered. The second study, *ORI Education: A Needs Assessment*, found wide agreement among institutional research integrity officers and responsible conduct of research (RCR) instructors that more training is needed in RCR and managing scientific misconduct allegations.




ORI also held eight conferences or workshops in 2001, with half of those meetings focusing on promoting research integrity or teaching responsible conduct in research and seven being co-sponsored by other institutions or organizations. ORI created three new listservs in 2001 to foster discussion and networking among researchers, RCR instructors, and institutional officials.

ORI added a new section on RCR instructional resources to its web site, held exhibits at seven meetings of scientific societies or professional associations, and developed three sample posters on research integrity.

The ORI Annual Report for 2001 is available on ORI's home page.

## Study Finds Instructions to Authors Could Promote RCR More Effectively

An ORI study of instructions to authors in 41 journals that published articles involved in research misconduct findings suggests that instructions to authors can be more effectively used to promote the responsible conduct of research. The study report is available on the ORI web site under Studies/Reports in the Publication section.

The analysis looked for content addressing authorship, reference practices, publishing practices, financial disclosures, human research, animal research, correcting the literature, research misconduct, peer review, and copyright. The study assumed that these areas are problematic for all journals with the possible exception of human or animal research. The study population contained 17 basic science journals, 13 clinical journals, and 11 journals that published basic and clinical research.

The study found that 58 percent of the journals addressed no more than 4 of the above topics, while 39 percent addressed 7 or more. Nineteen percent addressed no more than 2; 12 percent addressed 9 or more. The majority of journals covered copyright (73 percent), authorship and reference practices (68 percent each), publishing practices (63 percent), and financial disclosures (59 percent). Less than half included peer review (49 percent), human research (44 percent), animal research (36 percent), correcting literature and research misconduct (15 percent each)

## NEJM Retracts Suspicious Paper Without Authors' Consent

*The New England Journal of Medicine* retracted a paper this summer, even though the authors refused to do so, because its editors found a suspicious similarity between a microscope-slide image in the paper, and another image representing different conditions published earlier by the authors in another journal, according to *Nature.* Journal editors J. Drazen and G. Curfman explained the retraction of the paper on heart complications in HIV patients in the July 11, 2002, issue.

## BWF-HHMI Develop Course On Laboratory Management

A course in scientific management of research laboratories developed by the Burroughs-Wellcome Fund and the Howard Hughes Medical Institute was presented to 120 of their fellows this summer for the first time.

The course ran from Saturday evening to Wednesday noon, and covered basic laboratory leadership skills, project management, collaborations, getting funded and published, human research subjects, time management, lab notebooks and data management, mentoring, gender issues, technology transfer, and budgets and budgeting. The two organizations are reviewing their initial experience with the course and analyzing the evaluation data they received from their fellows on each session and the total course before deciding what future the course has.

## Data Collection Underway For Study of Lab Integrity Measures

Data collection began this month by the American Institutes for Research (AIR) under contract with ORI for a survey of measures utilized in biomedical or behavioral research laboratories to protect the integrity of the research conducted there.

Letters were e-mailed to 5,000 randomly-chosen principal investigators with NIH support for biomedical or behavioral research inviting them to participate in this web-based study by completing a 15 minute self-administered questionnaire. Instructions for accessing and completing the survey will contain an identification code and password.

All survey information will be kept confidential. Computer separation of responses from any identifying information will make it impossible for anyone, including AIR, to link the responses to any participant. Only summary and aggregated data and statistics will be provided to ORI or any other government agency.

When completed in 2003, results will be reported in the *ORI Newsletter*, web site, and journal articles.

## 2 IRB Guidance Documents Issued by OHRP

The Office for Human Research Protections (OHRP) has posted the following two guidance documents on its web site: "Guidance on Continuing Review" and "Guidance on Written IRB Procedures" (both are dated July 11, 2002).

The guidance on continuing review may be found at **http://ohrp.osophs.dhhs.gov/humansubjects/guidance/contrev2002.htm**. This document expands on and replaces three of OHRP's prior guidance documents on this topic: (1) "Continuing Review—Institutional and Institutional Review Board Responsibilities" (January 10, 1995); (2) "IRB Approval Periods and Continuing Review of Research" (January 20, 2000); and (3) "Continuing Review of DSMB-Monitored Clinical Trials" (May 22, 2000). This new guidance was developed to assist IRBs, investigators, research institutions and sponsors to implement the requirement for continuing review of human subjects research by an Institutional Review Board (IRB).

The guidance on written IRB procedures can be found at **http://ohrp.osophs.dhhs.gov/humansubjects/guidance/irbgd702.htm.** This document updates OHRP's April 2, 2002, guidance entitled, "OHRP Guidance on Written IRB Procedures." This guidance reflects OHRP's updated advice on continuing review. Minor changes were also made to the April 2, 2002, guidance that addressed IRB review in emergency situations, and the section regarding the inclusion of women and minorities in research was deleted since it was not directly related to the requirements for written IRB procedures at 45 CFR Part 46.

## RRI Conference Slates Posters, Demonstrations (from page 3)

Other highlights are a panel discussion of the Institute of Medicine report on *Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct* and a poster and demonstration session.

## ORI Seeks Co-Sponsors For 2 Conferences

ORI would like to identify an east coast or southern institution or organization that would be interested in co-sponsoring a 1-day *Introductory Workshop for Institutional Research Integrity Officials*.

ORI would also like to identify a Midwest or west coast institution that would be interested in co-sponsoring a research compliance conference, similar to the one ORI co-sponsored with the Johns Hopkins University on May 6-7, 2001.

The institution would be responsible for arranging for meeting space, suggesting possible agenda topics and speakers, taking registrations, creating a web site that includes an on-line registration form, arranging to reserve a block of rooms at a nearby hotel, arranging for continuing medical education credit, assisting in publicizing the meeting, and providing a list of attendees to ORI after the meeting, etc. A registration fee would be charged to participants to cover the cost of food and beverages and materials handed out at the meeting.

ORI would provide $5,000 to $20,000 to the co-sponsoring institution to help defray expenses. If you are interested, please call Dr. Alicia Dustira at 301-443-5300, or send an e-mail to her at adustira@osophs.dhhs.gov.

### The Journal's Role in Preventing, Detecting, Investigating & Correcting the Literature in Research Misconduct Cases

The Council of Science Editors is planning a special conference at the Arlie House Retreat Center in Virginia for fall 2003, that is being co-sponsored by ORI.

Watch the ORI web site for more details.

## Physicists Accused of Data Fabrication

Allegations of data fabrication in two labs have raised concern that research misconduct may be occurring in the hallowed laboratories of the physical sciences, especially physics, previously believed to be protected by precise measurement, replication, and the number of individuals involved in a project, according to *Nature.*

The Lawrence Berkeley National Laboratory (LBNL) recently fired a physicist for allegedly fabricating data to support the purported discovery of two heavy elements—118 and 116. The data in question involved a computer analysis of an experiment in which high-energy krypton ions were fired at a lead target in the LBNL's cyclotron. The dismissed researcher filed a grievance with the University of California, which manages the LBNL for the Department of Energy.

The condensed matter physics community was recently shaken by allegations concerning data in five papers published over 2 years on superconductivity and the use of organic molecules in microelectronics by a Bell Laboratories physicist. The allegations are being investigated by an external panel; the researcher stands by his results and is cooperating with the investigation.

## NSF Issues New Misconduct Regulation

The National Science Foundation (NSF) published its final rule in the *Federal Register* on March 18, 2002, at 67 *Fed Reg*, 11936-11939, to revise its existing misconduct in science and engineering regulations (45 CFR Part 689), to implement the Federal Policy on Research Misconduct issued by the Office of Science and Technology Policy on December 6, 2000.

The final NSF wording requires that a finding of research misconduct rise to the level of a "significant departure from accepted practices," be committed intentionally or knowingly or recklessly, and that the allegation be proven by a preponderance of evidence.

The Department of Health and Human Services expects to issue revised misconduct regulations later this year.

## German Funding Agency Issues Research Misconduct Rule

Five years after a major misconduct scandal, the Deutsche Forschungsgemeinschaft (DFG), Germany's main funding body, issued new binding standards of ethical research last summer. According to *Science*, the rules follow international norms in defining scientific misconduct as "deliberate or grossly negligent falsification or fabrication of data." The new definition also includes plagiarism, manipulation of graphs and figures, selective use of data without making it explicit, use of false information in grant and job applications, destruction of primary data, and sabotage of others' work. Possible sanctions include the loss of research contracts and the revocation of academic titles. See the International section, under Resources on the ORI web site, **ori.hhs.gov**.

To ease the publish-or-perish pressures, the new code also indicates that promotion decisions should be based on quality and originality, rather than on publication volume. The misconduct rules were developed by a special DFG commission in consultation with international fraud experts, and most of Germany's research institutions have adopted the guidelines.

Under the new rules, institutions must appoint an independent ombudsperson to initiate probes of misconduct allegations while protecting whistleblowers. The new rules also state that primary research data must be stored for 10 years wherever possible. Failure to archive research records, or their deliberate destruction, could be judged as gross negligence and be punishable.

## Listservs Available; Subscribe Now

Three listservs to facilitate interaction among members of three important communities that handle research misconduct allegations, promote responsible conduct of research, and conduct research on research integrity are available free by accessing the NIH listserv web site at http://list.nih.gov, then click on Browse, select the name of the listserv, and provide your e-mail address and full name.

## CASE SUMMARIES

**Tatsumi Arichi, Ph.D., National Cancer Institute (NCI), National Institutes of Health (NIH)**: Based the report of an investigation conducted by the NIH, Dr. Arichi's admissions, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Tatsumi Arichi, Ph.D., former Visiting Fellow in the intramural program of the NCI, NIH, engaged in scientific misconduct by falsifying and fabricating published data. Specifically, PHS found that Dr. Arichi falsified data that purported to show potent long-lasting immunization of mice with plasmid DNA leading to protection from challenge with vaccinia virus expressing the hepatitis C core antigen as published in Figures 4, 5, and 6 in *PNAS* 97:297-302, 2000. This paper was retracted in *PNAS* 98:5943, 2001. The research involved use of a potential vaccine against hepatitis C, a virus that infects at least 3 million Americans, many of whom suffer serious health consequences such as cirrhosis and liver cancer.

Dr. Arichi entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for 3 years beginning June 4, 2002, to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude himself from serving in any advisory capacity to PHS.

**James C. Pennington, Brown University (BU)**: Based on the BU report of an inquiry/investigation and additional ORI analysis, PHS found that James C. Pennington, formerly a graduate student in the Department of Cognitive and Linguistic Sciences, engaged in scientific misconduct by fabricating data in his master's thesis. The research was supported by National Institute on Deafness and Other Communication Disorders, NIH, grant R01 DC000314, "Speech and language processing in aphasia." Specifically, PHS found that (1) for Experiment 3, reported as having been conducted with 12 normal subjects, Mr. Pennington fabricated: (a) the mean reaction time data to auditory stimuli presented in Figures 5 and 6, and the results of the associated statistical analyses; and (b) the accuracy data presented in Tables 4 and 5, and the results of the associated statistical analysis; and (2) for Experiment 4, reported as having been conducted with 6 subjects with Broca's aphasia, he fabricated: (a) the mean reaction time data to auditory stimuli presented in Figures 7 and 8, and the results of the associated statistical analyses; and (b) the accuracy data presented in Table 6, and the results of the associated statistical analysis. The fabrication of Experiments 3 and 4, which were intended to incorporate improvements to the procedures used in Experiments 1 and 2, resulted in the premature termination of the planned experimental procedures and indeterminate or possibly misleading findings relative to the influence of negative priming on the processing of auditory stimuli in normal and aphasic subjects.

Mr. Pennington entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for 3 years, beginning on June 21, 2002: (1) to exclude himself from serving in any advisory capacity to PHS, and (2) any institution that submits an application for PHS support for a research project on which his's participation is proposed, or that uses him in any capacity on PHS supported research, or that submits a report of PHS-funded research in with he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Mr. Pennington's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

**Michael Shishov, M.D., Brigham and Women's Hospital, Inc. (BWH)**: Based on the investigation report by BWH, the respondent's admission, and additional ORI analysis, PHS found that the respondent, a former laboratory technician in the Intensive Physiological Monitoring Unit, BWH

*See **Case Summaries** on page 11.*

## CASE SUMMARIES (continued)

General Clinical Research Center, engaged in scientific misconduct in a program of sleep disorder research supported under National Center for Research Resources, NIH, grant M01 RR02635. Specifically, PHS found, and the respondent admitted, that on numerous occasions between May and August 1995, he registered on the Termiflex-computer terminal, as well as writing in hand on blood-draw sheets and laboratory logs, the times that he claimed he drew blood samples from human subjects in investigational sleep research. These times differed from the actual times when the samples were collected. The accurate assessment of the endogenous circadian phase and amplitude of the measured variables, including the timing and amount of blood cortisol, was essential for the studies. However, PHS acknowledges certain mitigating circumstances: (a) that occasionally during this time, the respondent may have been responsible for more protocol procedures than he could reasonably be expected to perform; and (b) that the BWH Report notes that he was respectful and honest during the investigation and that he has participated conscientiously in a program of professional ethics counseling. Therefore, PHS accepts the administrative actions previously imposed by BWH and performed by the respondent: (1) attending an ORI conference on research misconduct; and (2) participating in ethics counseling over a 3-year period.

Dr. Shishov entered into a Voluntary Exclusion Agreement and agreed to exclude himself from serving in any advisory capacity to PHS for 3 years, beginning July 2, 2002.

## Ethics Fellowship

A 1-year training program in research ethics for scientists from sub-Saharan Africa to study bioethics and to do an independent project in their home country is available. Applications for 2003 fellows are due on October 1, 2002. See The Johns Hopkins University Bioethics Institute web site at **http://www.med.jhu.edu/bioethics_institute/** or contact Dr. Suzanne Maman at smaman@jhsph.edu.

## PRIM&R Produces CD-ROM On Human Subjects Research

Public Responsibility in Medicine and Research (PRIM&R) is offering a new compact disk providing education on the responsible conduct of human research and protection of human research subjects. It provides a combination of interactive features such as cross linking, search engines, speakers, slide presentations, transcripts, ethical and research guidelines, and Federal regulatory documents. This CD-ROM may be purchased by institutions with a Federal-wide Assurance (FWA) or a Multiple Project Assurance (MPA). See **http:/ohrp.osophs.dhhs.gov/references/cdrom.pdf** or contact Rebecca Leroux at rebecca.leroux@PRIM&R.org or call 617-423-4112.

## International Guidelines to Good Practices and Quality Issues Available

Use of "good practices" ensures that preclinical and clinical studies of new drugs and vaccines conform to acceptable international quality standards. A variety of guidelines to good practices are available from the Special Program for Research and Training in Tropical Diseases (TDR), an independent global program of scientific collaboration co-sponsored by the United Nations Development Program, the World Bank and the World Health Organization. The guidelines include standard operating procedures for clinical investigators, a good laboratory practice handbook and training manual, and operational guidelines for ethics committees that review biomedical research, and may be found at **http://www.who.int/tdr/about/products/guidelines.htm**.

A draft TDR document that addresses quality issues in basic research investigations and proposes general standards for laboratories to keep records and store data is located at **http://www.who.int/tdr/publications/publications/biomedical.htm**.

## Meeting Proposals Due February 1

ORI is seeking proposals from institutions, professional associations, and scientific societies that wish to collaborate with ORI to co-sponsor sessions at scientific meetings, symposia, etc., on promoting research integrity or handling scientific misconduct allegations. Funding available generally ranges from $2,000 to $20,000.

October 1, 2002, is the next date for the receipt of applications. Instructions and application form are available at **http://ori.dhhs.gov/html/programs/confprop.asp**, or call 301-443-5300, or e-mail askori@osophs.dhhs.gov.

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**ORI NEWSLETTER**

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