

Office of Research Integrity

N E W S L E T T E R

The *ORI Newsletter* is published quarterly by the Office of Research Integrity, Office of the Secretary of Health and Human Services, and distributed to applicant or awardee institutions and PHS agencies to facilitate pursuit of a common interest in handling allegations of misconduct and promoting integrity in PHS-supported research.



Five Awards Made by Research Program

Five awards were made this month by the Research on Research Integrity (RRI) Program increasing the number of studies supported in the first four years to 27.

Award abstracts and the new request for applications (RFA) are posted on the ORI web site on the Research webpage. Submission deadline is November 22, 2004.

To date, the research program has produced 13 publications in 7 journals

including the *Journal of the American Medical Association*, the *British Medical Journal*, *Academic Medicine*, *Accountability in Research: Policies and Quality Assurance*; *Proceedings of the American Society for Clinical Oncology*, *Health Affairs*, and *Minnesota Medicine*. See the Research webpage on the ORI website for citations.

Many RRI researchers will make presentations during the third biennial **See Changes, page 3**

ORI Creates Web Page for RCR Resources

The first 11 resources developed under the RCR Resource Development Program are available on the ORI web site for use in RCR education programs at institutions and research organizations around the world.

The resources are posted on the RCR Resources webpage that may be accessed directly on the ORI home page or by clicking on Education in the Program section. The resources were

developed by 9 universities and a commercial firm.

“We are very pleased to make these resources created by the research community available to researchers and their institutions around the world,” Chris Pascal, Director, ORI, said. “We would like the RCR Resources webpage to serve as a depository for RCR resources so ORI invites institutions to **See RCR Resources, page 7**

ORI Newsletter Invites Contributions

ORI is opening the columns of this newsletter to the research community to broaden and expand communications regarding the responsible conduct of research, research integrity and research misconduct.

“We know there is a lot more happening in this country and the world regarding those topics that currently is not reported,” Larry Rhoades, Director, Division of Education and Integrity, ORI, said. “We also know there are more people thinking about and researching these topics who do

not have outlets for their efforts. So we are ready to expand the newsletter to accommodate such contributions.”

The contributions may take many forms—news articles, commentaries, opinion pieces, research findings, calls for papers, conference announcements, or case summaries not involving PHS funded research.

News articles should focus on the new, pioneering, or innovative actions that **See Contributions, page 11**

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HHS Proposes Institutional Review Board Registration System

The creation of a single Department of Health and Human Services (HHS) registration system for institutional review boards (IRB) was proposed in notices of proposed rulemaking published by the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) last summer.

The notices appeared in the *Federal Register*, V. 69, #128, July 6, 2004, pp. 40584-40590 and pp. 40556-40562. Deadline for comments is October 4, 2004.

“OHRP and FDA plan to operate a single registration system for HHS in which all IRBs that review research conducted or supported by HHS or clinical investigations regulated by FDA can be registered,” the notice states. “The HHS IRB registration system will be operated at a single Internet site on the OHRP web site.”

The registration system will (1) create a census of IRBs; (2) identify those IRBs reviewing research conducted or supported by HHS under an assurance of compliance approved for federalwide use by OHRP; and (3) increase the efficiency of OHRP and FDA educational and outreach efforts.

The requested information will include contact information for the institution or organization operating the IRB, the senior or head official responsible for overseeing the IRB, the person providing the registration information, and the IRB chairperson. In addition, an IRB roster will be required that includes the names, earned degrees, gender, areas of specialty and affiliation of each voting and alternate IRB members.

The approximate number of active protocols undergoing initial and

continuing review, the approximate number of full time positions devoted to the IRB’s administrative activities also will be mandatory. In addition, the registration process will include information required by FDA including the number of active protocols involving FDA-regulated products reviewed and a description of the regulated products.

Information must be furnished on whether the IRB is accredited, and if so, the date of its last accreditation and the name of that accrediting organization. OHRP, however, specifically asked for comments on the perceived value of collecting information on IRB accreditation. OHRP also solicited comments on whether review boards in other countries should be required or invited to register.

Protection of Human Participants in Research: Problems and Recommendations

The protection of human participants in research will not be improved by reforms solely aimed at conflicts of interest, the lack of institutional review board (IRB) resources, or the volume and complexity of clinical research because they fail to adequately address 15 structural, procedural and performance assessment problems, according to a recently published article.

The article, Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals, by Ezekiel J. Emanuel, Chair, Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, NIH, and others is published in the August 17, 2004 issue of the *Annals of Internal Medicine*.

The structural problems are: (1) federal regulations do not apply to all research involving humans; (2) current regulations and guidelines for protection of human research participants are inconsistent; (3) no effective mechanisms exist for addressing fundamental and recurring

ethical issues in clinical research; (4) institutional conflicts of interest are inherent in the current system of review; (5) multiple guidelines for managing conflicts of interest involving IRB members or investigators are incompatible; (6) the review process for single multisite studies is repetitive; (7) IRBs need more resources, and (8) education in research ethics is haphazard.

Procedural problems are : (1) the review process is time-consuming, protocols frequently require prior review by scientific and other committees; (2) IRBs may lack the scientific expertise to conduct the review; (3) IRBs lack substantive guidance on their operations, such as criteria for appointment or dismissal of members; (4) IRBs spend too much time scrutinizing informed consent documents and producing excessively long detailed forms; and (5) the process of reporting adverse events is confusing and repetitive.

Performance assessment problems include (1) no validated measures exist for

evaluating the performance or outcomes of the system, and (2) no data are collected to systematically monitor the overall safety of clinical research.

Recommended solutions include (1) establish a single federal office with regulatory authority over all human participants research conducted in the United States or by investigators based in the United States; (2) create a permanent advisory committee to systematically examine ethical issues related to human participants research and recommend authoritative policies; (3) mandate single IRB review of all multisite research proposals with liability protection for local institutions; (4) increase funding for oversight of human participants by both the federal government and commercial sponsors of research, and (5) develop standards to assess the performance of the oversight system, and systematically collect and disseminate data on adverse events and the functioning of the human participants research oversight system.

Keynote Speaker Named for Research Conference

A noted neuroscientist who actively promotes research integrity will be the keynote speaker at the third biennial Research Conference on Research Integrity that will be held at the Paradise Point Resort in San Diego, November 12-14, 2004.

The conference program and registration information are available on the conference website on the ORI home page at <http://ori.hhs.gov>.

Michael J. Zigmond, Ph.D., University of Pittsburgh, was a member of the Committee on Assessing Integrity in Research Environments that produced the Institute of Medicine report, *Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct*.

Dr. Zigmond has co-directed the Survival Skills and Ethics Program at the University of Pittsburgh since 1985 which he developed as the director of a NIH-funded training program in

neuroscience. Since then, the program has expanded to include workshops for trainees and trainers at the local, national, and international levels. Currently, he directs two NIH-training grants in neuroscience.



Dr. Zigmond also chaired the committee in the Society for Neuroscience that developed a code of conduct in writing, reviewing, and publishing. In addition, he serves on the editorial advisory board for *Science and Engineering Ethics*.

An active neuroscientist, Dr. Zigmond is the Associate Director for Research and for Training of the Pittsburgh Institute for Neurodegenerative Disorders and co-director of a National Parkinson's Foundation Center of Excellence. His laboratory explores issues of neuronal death and neuroprotection as they apply to neurodegenerative diseases, particularly Parkinson's disease. He currently is investigating the influence of stress and exercise on the vulnerability of dopamine-containing neurons to neurotoxins.

Dr. Zigmond served as secretary of the Society for Neuroscience and chaired its Social Issues Committee.

Changes Made to RRI Program (from page 1)

Research Conference on Research Integrity that will be held at the Paradise Point Resort, San Diego, November 12-14, 2004. See ORI home page for program and registration information.

The program received the highest number of applications (52) in 2003 almost doubling the previous high of 31. Maximum direct costs were increased from \$100,000 to \$250,000 per year, and the project period was extended from 2 to 3 years.

Previously, funding for the applications came from the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Nursing Research (NINR), the National Institute on Drug Abuse (NIDA) and ORI.

This year ORI is funding four grants and partially funding the fifth grant with NINR. Funding for continuation awards is provided by NINDS, NINR, NIDA and ORI. Funding for the fourth round

(new and continuations) totaled \$1.97 million. ORI provided \$1.37 million for the fourth round; NINR, NIDA and NINDS provided \$0.6 million. NINDS also covers the cost of the review process and grants management.

"ORI plans to commit \$1.5 million annually to the research program," Chris Pascal, Director, ORI, said. "And we will continue our efforts to secure additional support from the PHS agencies."

"To ensure long-term viability of the research program, the maximum direct costs have been decreased to \$175,000 per year and the maximum project period has been reduced to 2 years in the new RFA," Pascal said. "This will enable ORI to maintain a workable balance between new and continuation awards."

For information on the RRI program contact Dr. Mary Scheetz, Director, Extramural Research Program, at 301-443-5300 or scheetz@osops.dhhs.gov.

Grant titles, principal investigators, and institutions for the 2004 awards follow:

Authorship and Conflicts of Interest in Clinical Trials, William Gardner, Children's Research Institute, Ohio State University.

Competition between Science and Care in Clinical Trials, Charles W. Lidz, University of Massachusetts Medical School.

Environmental and Educational Influences on Scientists' Ethical Decisions, Michael D. Mumford, University of Oklahoma.

Monitoring Fidelity to Promote Research Integrity, Sheila J. Santacroce, Yale University School of Nursing.

Defining the Learning Curve in Research Trials, Jeffrey M. Taekman, Duke University.

Research Misconduct Activity Exceeds 10 Year Averages

The amount of research misconduct activity reported by institutions in their 2003 Annual Report on Possible Research Misconduct substantially exceeds the averages for four reporting categories for the previous 10 years (1993-2002) and establishes new highs for three categories.

One hundred and six institutions reported research misconduct activity in their 2003 reports; 82 institution reported opening new cases; institutions reported receiving 136 new allegations; and opening 105 new cases. The 10-year averages for those categories are 81, 55, 105 and 69 respectively.

The new highs were established in the number of institutions reporting research misconduct activity, the number of institutions opening new cases, and the number of new cases opened.

Research misconduct activity is defined as receipt of an allegation or the conduct of an inquiry or investigation in the reporting

year or carried into the reporting year. Reportable activities are limited to alleged research misconduct involving PHS-supported research, research training or other research related activities.

The 106 institutions that reported research misconduct activity resulting from allegations received during or prior to 2003 conducted 122 inquiries and 55 investigations in 2003.

Eighty of the 106 institutions reported opening 105 new cases in 2003 upon receipt of 136 allegations. Institutions received 48 allegations of falsification; 34 of plagiarism; 30 of fabrications; and 24 others. These allegations resulted in 76 inquiries and 19 investigations in 2003.

Institutions reporting new cases included higher education, 61; research organizations, 7; health organizations, 7; independent hospitals, 5; and small businesses, 2.

Survey Researchers Address Curbstoning

Two years ago ORI reported that three institutions had asked ORI: “Does fabrication or falsification of data by lower level staff who conduct surveys or interviews or administer questionnaires with human subjects constitute ‘scientific misconduct’?” ORI responded: “Yes.”

The Public Health Service (PHS) has made findings of scientific misconduct against ten persons (see p. 11 for one) for falsification or fabrication of survey data (“curbstoning”). These cases involved the acquisition of data through questionnaires or interviews, administered face-to-face, over the telephone, or through the use of a computer interface for a variety of research situations, ranging from epidemiological studies of diseases to the assessment of the effectiveness of therapeutic interventions or of health services delivery systems.

Seven of these PHS findings involved surveys administered by individuals who were not members of the faculty or the professional, senior research staff, but rather were interviewers hired by the institution or staffing service. The institutions questioned whether these individuals were actually members of the “scientific community” subject to PHS regulations on scientific misconduct. ORI responded that the PHS regulations apply to any individual, regardless of their position, who is involved in proposing, conducting, or reporting of research supported by PHS funds or proposed in applications for PHS funds.

Over the last two years, Alan Price, Associate Director for Investigative Oversight, ORI, has engaged the survey research community in a dialogue to explain ORI’s potential concerns in dealing with such matters, to assist that community in understanding ORI’s regulation and responsibility to protect taxpayer funds, and to engage in an open and non-confrontational discussion of the **See Curbstoning, page 11**

Research Misconduct Activity: 1993 - 2003

Year	Institutions Reporting Activity	Institutions Reporting New Cases	New Allegations	New Cases
2003	106	82	136	105
2002	99	71	163	83
2001	78	61	127	72
2000	82	60	103	62
1999	72	46	89	63
1998	67	41	69	54
1997	73	48	92	64
1996	88	54	127	70
1995	96	61	104	81
1994	79	50	89	64
1993	73	53	86	77

Responsibility for Value System

“Research mentors, laboratory directors, department heads, and senior faculty are responsible for defining, explaining, exemplifying, and requiring adherence to the value systems of their institutions.” *Responsible Science: Ensuring the Integrity of the Research Process*. Vol. 1:7, NAS, 1992.

Agencies Implementing Federal Misconduct Policy

Four of the 14 federal agencies or departments that fund research have established policies or regulations implementing the Federal Policy on Research Misconduct that was published by the Office of Science and Technology Policy on December 6, 2000: the National Science Foundation (NSF), the Department of Transportation (DOT), the Department of Labor (DOL) and the Environmental Protection Agency (EPA).

Two others - Department of Health and Human Services (HHS) and the National Aeronautics and Space Administration (NASA) - have published notices of proposed rulemaking (NPRM).

Eight other departments report that their policies have been drafted and are undergoing internal review: Agriculture, Commerce, Defense, Education, Energy, Interior, Justice and Veterans Affairs.

The four adopted policies or regulations are posted on the ORI website under Federal Policies in the Policies/Regs/Statutes section along with the two NPRMs.

ORI Employment Opportunity

ORI is seeking a researcher who has had extensive experience with responsible conduct of research (RCR) programs - developing, managing, teaching - to work on education programs within its Division of Education and Integrity.

The vacancy announcement will be posted on the ORI home page when it becomes available in October or November, 2004. The position will be advertised at the Grade 13-14 level with a salary range from \$72,108 to \$110,775.

**FABRICATION IS FICTION,
NOT SCIENCE**

Five Academic Societies Receive RCR Awards

Five awards were made this summer by the RCR Program for Academic Societies to facilitate the institutionalization of infrastructure and activities within academic societies that will promote the responsible conduct of research by their members.

The program, a collaboration between the Association of American Medical Colleges and ORI, has supported 20 projects in 18 academic societies in its first two years. The new request for proposals (RFP) is available on the ORI home page along with the abstracts of the 2004 awards. The next submission deadlines are November 5, 2004 and March 5, 2005.

Any academic society in the United States whose members conduct biomedical or behavioral research supported by the U. S. Public Health Service is eligible to apply. The program offers awards up to \$50,000.

The purpose of the awards is to provide funds to academic societies to specifically address some, or all, of the nine core components of the responsible conduct of research: (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) conflicts of interest and commitment, and to mainstream or institutionalize RCR infrastructure, activities, and educational programs into the culture of the societies and disciplines.

Of special interest are projects focused on developing guidelines, standards, policies, publications (including RCR articles in journals, newsletters, and on society websites), committees, annual conferences, core competencies, curricula, and other resources related to the core RCR components.

For further information contact Anthony Mazzaschi, AAMC, at tmazzaschi@aamc.org or at 202-828-0059.

Academic societies receiving awards and project titles follow:

The Gerontological Society of America. Guidebook for Multidisciplinary Clinical Geriatric Researchers.

Society of Teachers of Family Medicine. Primary Care Research Participant Protection Project.

Society for Academic Emergency Medicine. Research Integrity in Emergency Medicine.

American Occupational Therapy Association. Promoting Research Integrity in the Next Generation of Occupational Therapy Researchers Curriculum.

Research and Assessment Corporation for Counseling/National Board for Certified Counselors, Inc. Training Module on Research Integrity for Researchers in Counseling.

New Software to Guide Annual Report Submissions

Institutional officials will be guided by new software, compatible with MacIntosh computers, in submitting the 2004 Annual Report on Possible Research Misconduct that will simplify the process, provide needed information, and reduce incomplete and erroneous reports.

The new software will lead officials through the process which will be shortened for more than 95 percent of the officials. Requested passwords and IPF numbers will be automatically provided, thereby, eliminating the need for emails and phone calls. The program will not allow incomplete reports to be submitted and the availability of an institutional policy for responding to research misconduct will be automatically checked. Receipt of the annual report by ORI will be automatically acknowledged.

Second RCR Expo Slated for SRA International Meeting in Salt Lake City

At least 11 institutions and organizations will exhibit the RCR instructional materials they have developed at the second RCR Expo that will be held in conjunction with the annual meeting of the Society of Research Administrators International in Salt Lake City on October 25-26, 2004.

ORI will also exhibit its RCR Resource webpage that contains RCR resources that are already posted on the ORI website.

The RCR Expo will be located in the Grand America Hotel in a high-traffic space location on the first floor in the Imperial Ballroom reception area during the SRA annual meeting which attracts over 1,400 research administrators.

The exhibiting institutions and organizations, the resource titles, and exhibitors follow:

Northern Illinois University. Online Decision Instruction on Data Integrity, Murali Krishnamurti.

A web-based learning module that addresses data acquisition, data management, data sharing, and data ownership. The materials were developed using the Kolb Learning Cycle as a model for learning.

Bryn Mawr College. Educating Staff in Community Agencies about Human Subjects. Leslie Alexander and Ken Richman.

A web-based tool for training individuals in community agencies about the use of human subjects in research. The resource is targeted to low-income communities and is available in English and Spanish.

Syracuse University. Video Vignettes to Foster the Mentor/Trainee Relationship. Derina Sara Samuel.

Video vignettes focused on the mentor/trainee relationship. A guide accompanies the vignettes to direct and encourage discussion on the scenarios presented in the videos.

St. Jude Children's Research Hospital. Education Clinical Staff on Clinical Research Data. Cheryl Chanaud.

A web site designed to teach hospital clinical staff about the management of research data. The learning materials for clinical staff emphasize the importance of medical documentation as research data, proper data collection methods as they apply to research, and the critical link between protocol compliance and valid research data.

Northern Illinois University. RCR for the Rest of Us. Jeffrey Hecht.

A CD-ROM created to train researchers in the social sciences about the responsible conduct of research. The CD-ROM contains video presentations and a graphically-appealing HTML interface to address issues in RCR as they pertain to non-biomedical research.

Children's Hospital of Philadelphia. A Guidebook for Teaching Selected RCR Topics to Culturally Diverse Trainee Groups. Madeline Alexander.

A guidebook specifically tailored to provide training in data management, research misconduct, and intellectual property to international postdocs and culturally diverse students.

University of Texas Health Science Center. Web-based Course on Conflicts of Interest in Research. Melissa Proll.

An Internet-based education tool to help researchers increase skills to recognize, disclose, and manage conflicts of interest in research. Case-based pedagogy is used that requires users to play the role of a Conflict of Interest Committee member developing a plan to address research conflicts arising from investigator and institutional financial interests. Information to support the user in developing the plan include six streaming-video vignettes showing different constituencies' perspectives/concerns about the conflicts.

Saint Louis University. Behavioral Health Research: An Ethics Case Compendium and Instructional Method. James Dubois and Angie Dunn.

An Internet training tool for instructing researchers on the use of human subjects in behavioral research. The tool contains a collection of ethics cases in behavioral health research, instructional materials to improve ethical decision making, and a bibliography of ethics information.

Columbia University. The Development of RCR Internet-based E-seminars on Mentor/Trainee Responsibilities and Conflict of Interest. Daniel Vagird and Joyce Plaza.

E-seminar courses on mentoring and conflict of interest that use an innovative "problem-oriented case-based study approach" to maximize learning capabilities. Interactive programming allows users to see various resolutions depending on decisions they made throughout the course.

University of Alabama - Birmingham. A Documentary Film: A Round Table on Mentoring and Authorship. Sara Vollmer and Harold Kincaid

A 77 minute video addressing mentoring and authorship that features discussion between principal investigators and graduate students, acted scenarios about lab dilemmas, and interviews.

RCR Educational Consortium (RCREC). Michael Kalichman.

The RCREC is a non-profit, non-governmental consortium of institutions and organizations that provides leadership to the research community in identifying, developing, and promoting RCR education programs. Two RCREC products are a website (<http://rcrec.org>) and an RCR internet course provided free to institutional and organizational members.

RCR Resources Available On-Line; Feedback Requested *(from page 1)*

send us the URLs for RCR resources they developed and are willing to share with the research community.”

Three new resources address all or several core areas; two others provide case studies or ethical dilemmas that address the core areas. The other resources focus on conflict of interest, mentoring, animal welfare, and plagiarism. Resources are under development that address data management, peer review, authorship and publication practices, collaborative research, protection of human subjects, and research misconduct.

The RCR Resources webpage contains a directory of RCR resources that is divided into two sections: resources

developed under the ORI RCR Resource Development Program and resources developed by institutions, federal agencies and other organizations.

Comments on the RCR resources should be sent to webmaster James Egbert at the address provided below. Comments may suggest how the resource may be improved and evaluate its content, ease of use, and instructional value.

For further information on the RCR Resources webpage contact James Egbert at jegbert@osophs.dhhs.gov or 301-443-5300. For further information on the RCR Resource Development Program contact Loc Nguyen-Khoa at LNgyuen-Khoa@osophs.dhhs.gov.

The titles, project directors, and originating institutions or organizations for the completed RCR Resource Development Program projects follow:

Online RCR Study Guide, Julie Simpson, University of New Hampshire.

Online Research Ethics Course, Deni Elliot, University of Montana.

Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS), Fawwaz Ulaby, University of Michigan.

Biomedical Research Integrity Case Studies, Wylie Burke and Kelly Fry-Edwards, University of Washington.

Ethical Dilemmas in Research Integrity, Shawn Spilman, MetaLinker.

Conflicts of Interest, Ruth Fischbach, Columbia University.

Conflicts of Interest, Mark Tumeo, Cleveland State University.

Mentoring, Ruth Fischbach, Columbia University.

In the Lab: Mentors and Students Behind the Scenes, Harold Kincaid and Sara Vollmer, University of Alabama-Birmingham

Contemporary Science, Values and Animal Subjects in Research, Nell Kriesberg and Joseph Herkert, North Carolina State University.

Avoiding Plagiarism, Self-Plagiarism, and Other Questionable Writing Practices: A Guide to Ethical Writing, Miguel Roig, St. Johns University.

ORI Annual Report – 2003

The ORI Annual Report – 2003 is available on the ORI home page. Copies of the report are available upon request while the supply lasts. Contact Robin Dorsey at rdorsey@osophs.dhhs.gov or 301-443-5300.

RCR Resources Program Issues New RFP

Instructional resources that focus on the prevention, handling, or reporting of research misconduct are given the highest priority in the new request for proposals (RFP) for the fourth round of the RCR Resource Development Program.

The RFP which is available on the ORI home page gives high priority to the development of instructional materials on collaborative science, peer review, and data management. High priority is also assigned to the development of RCR materials for research administrators and assessment tools for evaluating RCR education programs. Submission deadline is February 25, 2005.

“No one currently is working on instructional materials related to research misconduct,” Larry Rhoades, Director, Division of Education and Integrity, ORI, said. “That’s probably because everyone is thinking about research misconduct in relation to the regulation.”

He continued, “Falsification is the most frequent type of research misconduct

being committed. We would like to see a module that explicates the concept of falsification and addresses data selection, data analysis, and reporting of results.”

“A module on measures that can be taken in a lab or research project to prevent research misconduct would be useful,” Rhoades said. “Another could address the social situation that develops in a lab or research project when an allegation is made. And a third could instruct whistleblowers on the development of responsible allegations.”

ORI has allocated \$250,000 in its FY 2005 budget to fund 10 projects at \$25,000 each. Awards only cover direct costs; indirect costs are not paid. RCR awards are made through purchase orders, not grants. Awardees must provide a finished product to ORI at the end of the performance period which usually runs for 12 months beginning September 1.

For further information contact Loc Nguyen-Khoa at LNgyuen-Khoa@osophs.dhhs.gov or 301-443-5300.

Harvard Med Revises Conflict of Interest Policy

Harvard Medical School (HMS) will implement a revised conflict of interest policy this fall when its 9,000-plus faculty members file their mandatory annual financial disclosures, according to an HMS announcement.

Revisions to the policy include (1) broadening the definition of faculty members participating in clinical research to include those involved in study design and authorship, (2) expanding the prohibitions of full-time faculty holding leadership posts that imply fiduciary responsibility in companies to include the Chief Medical Officer or Chief Scientific Officer; (3) raising the de minimis amount of stock a faculty member may hold in a publicly traded company doing R&D directly related to his or her research from \$20,000 to \$30,000 provided that the stock was not obtained in any way connected to the faculty member's ongoing research. (Faculty cannot hold an equity interest in privately held companies related to the research conducted by the faculty.); and (4) raising the de minimis amount of consulting and other fees a faculty member may receive from a company directly linked to his or her clinical research from \$10,000 to \$20,000.

Other revisions are (1) expressly limiting the exempt income from licensing royalties to those that accrue post marketing, not pre-marketing stock options, etc.; (2) clarifying the faculty member's right to own a related stock begins after publication of the results; (3) spelling out that if a faculty member sits on a corporate board, that company cannot sponsor projects in that faculty's clinic or lab (this does not apply to those sitting on scientific advisory boards), and (4) expanding the mandate to disclose financial ties to prospective students, prospective fellows, and prospective faculty.

Final Guidance Issued on Financial Interests

A final guidance for institutional review boards (IRBs), investigators, and institutions on financial relationships and interest in research involving human subjects was published by the Office of Public Health and Science, HHS, in the *Federal Register* on May 12, 2004.

The guidance is available on the Office for Human Research Protections (OHRP) website at <http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf>. It replaces the draft interim guidance dated January 10, 2001.

The document raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects and if so, what actions could be considered to protect those subjects.

Conflict of Interest in Scientific Publications

Intense discussion and debate are expected on conflict of interest in scientific publications during a retreat sponsored by the Council of Science Editors (CSE) at the Hyatt Lodge on the McDonald's campus, Oak Brook, IL, from October 29-31, 2004.

Keynote speaker will be Sheldon Krimsky, Tufts University, author of *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research*.

For program and registration information visit the CSE web site at www.councilscienceeditors.org. Funding for the retreat has been provided by the Greenwall Foundation, the American Heart Association, and the American Society of Clinical Oncology.

Conference Focuses on ICOI Policy Creation

Institutions have been urged by two prominent associations to address institutional financial conflicts of interest (ICOI) to preserve the integrity of institutions and the public's confidence in that integrity.

The Association of American Universities (AAU) issued its *Report on Individual and Institutional Financial Conflict of Interest* in October 2001 and the Association of American Medical Colleges (AAMC) published its report, *Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subject Research*, in October 2002.

On December 2-3, 2004, the University of Nevada-Las Vegas and ORI will present a conference on Developing Policy on Institutional Financial Conflict of Interest at the Alexis Park Hotel in Las Vegas. See the ORI home page for program and registration information or contact Connie Correia at 702-895-4240. Registration deadline is November 10, 2004.

The conference will attack what the AAMC report calls "a problem of remarkable complexity" by analyzing its component parts, defining characteristics and challenges, discussing hurdles and sensitive issues, estimating institutional readiness, and identifying success factors related to ICOI policy development.

Conferees will be provided with background reports and policies from selected institutions across the country. Templates for action will be developed that integrate key strategies and recommendations.

The conference is co-sponsored by AAU, AAMC, the National Association of State Universities and Land Grant Colleges, and the American Association for the Advancement of Science.

NIH Creates RCR Course For Intramural Staff

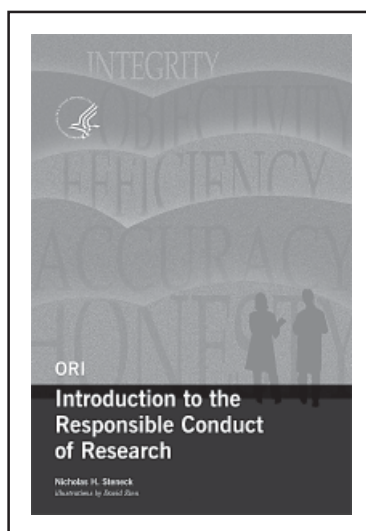
All current NIH intramural research staff must complete a new online RCR training course by October 1, 2004 and all new staff will take the course as part of the web-based orientation package they are required to complete.

The course entitled, *Introduction to the Responsible Conduct of Research*, is available on the NIH website at <http://researchethics.od.nih.gov>. Besides the training course, NIH intramural staff must participate in annual follow-ups that focuses on research ethics case discussions led by trained facilitators. In 2004, the case discussions focus on collaborative science.

The course was developed by the NIH Committee on Scientific Conduct and Ethics, chaired by Joan P. Schwartz, Assistant Director, Office of Intramural Research.

Research staff are all persons who have "direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training," including senior investigators, tenure-track investigators, senior scientists and clinicians, staff scientists and clinicians, research and clinical fellows, pre- and postdoctoral trainees, technicians, research nurses, and special volunteers or guest researchers.

The course covers the 9 core RCR instructional topics and includes quizzes that feature immediate feedback on the correctness of the answers. Conceived as a research ethics resource the course also includes a glossary and a resources section that includes the URLs for numerous other RCR instructional materials. In addition, users can print "key points to remember" and a completion certificate.



ORI RCR Intro Text

The revised ORI Introduction to the Responsible Conduct of Research may be purchased from the Government Printing Office at <http://bookstore.gpo.gov>. Cost is \$14.00 per copy; a 25 percent discount is offered on purchases of every 100 copies sent to the same address. The publications is also available for on-line reading or downloading on the ORI home page at <http://ori.hhs.gov>.

ORI Website Attracting Visitors Worldwide

The ORI website may be the pre-eminent web site in the world on the responsible conduct of research, research integrity, and research misconduct.

In FY 2003, the web site had 74,602 visits by 38,359 unique visitors. Repeat visitors totaled 7,855. The web site averaged 204 visits per day with the average visit lasting a little more than 17 minutes.

Eighty-four percent of the visits were from individuals within the United States; 16 percent were international visits from Canada, the United Kingdom, Australia, China, Germany, Japan, Netherlands, South Korea, Philippines, France, India, Singapore, Israel, Poland, Malaysia, Hong Kong, Italy and Sweden.

Opportunities Abound to Promote RCR Education

Numerous opportunities exist within colleges, universities, medical schools, and research institutes to promote responsible conduct of research education through activities that already routinely happen in those organizations, according to a speaker at the RCR Summit last June.

Julie Simpson, Manager, Research Conduct and Compliance Services, University of New Hampshire, enumerated those opportunities as follows:

- Research methods courses
- Departmental faculty meetings
- Training sessions offered by Institutional Review Boards, Institutional Animal Care and Use Committees, and Institutional Biosafety Committees
- Experiential research programs for graduate and undergraduate students
- Orientation sessions for new faculty, postdoctoral fellows, graduate students, and graduate assistants
- Training sessions for new department chairs
- Meetings or luncheons for new faculty hosted by university officials
- Departmental activities such as dissertation groups, seminar series, journal clubs
- Institution-wide lecture or discussion series
- Professional development programming offered by the graduate school
- Activities sponsored by graduate student and postdoc organizations
- Feature articles on RCR issues in the campus newspaper and organizational web sites
- Collaboration with graduate program coordinators to promote RCR training
- Communications between the chief research officer and the campus community

Case Summaries

Tirunelveli S. Ramalingam, Ph.D., California Institute of Technology:

Based on the report of an investigation conducted by the California Institute of Technology (CIT Report) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Tirunelveli S. Ramalingam, Ph.D., former Postdoctoral Fellow, Division of Biology at CIT, engaged in scientific misconduct in research supported by National Institute for Allergy and Infectious Disease (NIAID), National Institutes of Health (NIH), grant 1 R01 AI41239-01, "Neonatal Fc receptor/IgG interaction." Specifically, PHS found that:

- A. Respondent plagiarized Figures 6a and 7a from: Dustin, M.L. "Adhesive Bond Dynamics in Contacts between T Lymphocytes and Glass-supported Planar Bilayers Reconstituted with the Immunoglobulin-related Adhesion Molecule CD58." *J. Biol. Chem.* 272:15782-15788, 1997 (hereafter referred to as the "JBC 1997 paper").
- B. Respondent also falsified Figures 6a and 7a from the JBC 1997 paper by electronically manipulating the images and representing them as a different experiment in Figure 6 of NIH grant application 2 R01 AI41239-06A1, entitled "Analysis of the Neonatal Fc Receptor/IgG Interaction."
- C. Respondent fabricated timed experimental data obtained from using the fluorescence recovery after photobleaching (FRAP) technique in Figure 7 (upper and lower panels) in a draft manuscript: "IgG can bridge between adjacent membranes containing the neonatal Fc receptor (FcRn): Implications for FcRn-mediated transport of IgG."

The draft manuscript was not submitted for publication; however, due to the laboratory's inability to verify scientific experiments conducted by Dr. Ramalingam, two of his other papers,

published in *Nature Cell Biology* in 2000 and *EMBO Journal* in 2002, were retracted.

Dr. Ramalingam has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of three (3) years, beginning on July 2, 2004: (1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in, nonprocurement programs of the United States Government referred to as "covered transactions" as defined in the debarment regulations at 45 C.F.R. Part 76; and (2) to exclude himself from serving in any advisory capacity to the PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Regina D. Horvat, Ph.D., Northwestern University: Based on the report of an inquiry conducted by Northwestern University (NU Report), the respondent's admission, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Regina D. Horvat, Ph.D., former Postdoctoral Fellow, Department of Cell and Molecular Biology at NU, engaged in scientific misconduct in research supported in part by the following National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH) grants: F32 HD041309, RO1 HD38060-01A1, and T32 HD007068."¹ Specifically, PHS found that:

- Dr. Horvat falsified a western blot of an immunoprecipitation (IP) assay presented as Figure 5B in a manuscript ("Inhibition of Luteinizing Hormone Receptor Desensitization Suppresses the Induction of Ovulatory Response Genes in Granulosa Cells") submitted to *Molecular Endocrinology*. Dr. Horvat falsely labeled an autoradiogram in her laboratory notebook with a piece of tape to misrepresent the data from a

different IP experiment that was actually conducted on October 31, 2001, as the experiment described in Figure 5B. Further, Dr. Horvat falsely used Figure 5B in an oral presentation at a national scientific meeting; and

- Dr. Horvat falsified the intensity of the band in Lane 6 of a luteinizing hormone receptor (LHR) Western blot experiment to quantitate the level of LHR immunoprecipitated with an arrestin2 antibody in cells treated with hCG for 30 minutes in the PowerPoint figure, prepared in response to the initial review of the *Molecular Endocrinology* manuscript. This manuscript was withdrawn.

Dr. Horvat has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed for a period of three (3) years, beginning on June 2, 2004: (1) to exclude herself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) that any institution which submits an application for PHS support for a research project on which the Respondent's participation is proposed or which uses the Respondent in any capacity on PHS supported research, or that submits a report of PHS-funded research in which the Respondent is involved, must concurrently submit a plan for supervision of the Respondent's duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of the Respondent's research contribution. Respondent agrees to ensure that a copy of the supervisory plan is also submitted to ORI by the institution. Respondent agrees that she will not participate in any PHS-supported research until such a supervision plan is submitted to and accepted by ORI.

¹ The T32 award cited in the manuscript was T32 HD21021. A search of the CRISP database showed the correct grant number was T32 HD007068.

Case Summaries

Nancy J. Strout, Ph.D., University of Southern Maine: Based on the report of an inquiry conducted by the University of Southern Maine (USM) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Nancy J. Strout, Ph.D., former interviewer, USM, engaged in scientific misconduct in research supported by Substance Abuse and Mental Health Services Administration (SAMSHA) cooperative agreement UD1 SM52362, "Maine evaluation of consumer-operated services." Specifically, PHS found that the Respondent engaged in scientific misconduct by fabricating interview data for at least 50 interviews of human subjects enrolled in the Maine Evaluation of Consumer-Operated Services Project for mental health services, and possibly up to 150 interviews or more (based on calculations performed by USM), causing the project to nullify all 346 interviews due to her involvement at one or more stages with the subjects. PHS also found that the Respondent is not presently responsible to be a steward of Federal funds because she falsified invoices for interviews and receipts for interview incentive payments in pursuit of a fraudulent scheme to obtain payment for services she did not render.

Dr. Strout has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed for a period of three (3) years, beginning on July 23, 2004: (1) to exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in, nonprocurement programs of the United States Government as defined in the debarment regulations at 45 C.F.R. Part 76; and (2) to exclude herself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

**FALSIFICATION IS FICTION,
NOT SCIENCE**

Curbstoning (from page 4)

issues. That dialogue has produced the following results:

An Interviewer Falsification Summit for Survey Research Organizations in April 2003 hosted by Robert Groves, Director, Survey Research Center, University of Michigan, was attended by 30 senior survey investigators from private and public survey institutions. The group jointly drafted a Best Practices document: "Interviewer Falsification in Survey Research: Current Best Methods for Prevention, Detection, and Repair of Its Effects."

In May 2003, the American Association for Public Opinion Research (AAPOR) held a panel session, *Is Interviewer Falsification Scientific Misconduct?*, attended by 70 survey researchers during its annual meetings. The AAPOR adopted the Best Practices statement and posted it on its website in September 2003.

In September 2003, the American Statistical Association (ASA) published the Best Practices statement on its website after Groves and Roger Tourangeau, Standards Committee Chairman, AAPOR, won the endorsement of the ASA Survey Research Methods Section. A panel on curbstoning was held at the ASA Joint Statistical Meeting in August 2004.

Contributions to Newsletter (from page 1)

promote the responsible conduct of research, research integrity, or the prevention, detection, reporting or investigation of research misconduct. These actions may involve, but are not limited to, the development of organizational infrastructure, the adoption of guidelines or policies, the creation of websites, the institution of training programs, the conduct of self-assessments, and the establishment of awards.

"We want to publicize these actions to promote the cross-fertilization of constructive ideas for improving the

Dissent Mechanisms Could Further Self-Assessment Efforts in Institutions

Social mechanisms used in the U. S. Department of State and by the American Foreign Service Association (AFSA) could be adapted to the ongoing self-assessment of research programs at colleges, universities and elsewhere.

The Department of State has a long-established "dissent channel" that allows employees to directly contact the secretary without the knowledge of their supervisors or the ambassador of the country in which they serve," according to the *Federal Times* (5/24/04).

The AFSA has made Constructive Dissenter Awards annually for more than 30 years to foreign service officers who have demonstrated "the intellectual courage to challenge the system from within, to question the status quo and take a stand, no matter the sensitivity of the issue or the consequences of their actions."

The four awards honor a senior, a midcareer, and a junior officer, and a Foreign Service specialist. The awards and a \$2,500 prize are presented at an annual banquet that has been addressed by Secretary of State Colin Powell and other top State officials.

research enterprise across the research community," Rhoades said. Generally, contributions should be less than 2-pages, single spaced. Contributions must be submitted electronically to ORINewsletter@osophs.dhhs.gov. Deadlines are January 31, April 30, July 31 and October 31 for the March, June, September and December issues. By-lines will be given on accepted contributions that identify the authors and their organizations. Decisions to accept, reject, edit, or submit contributions for peer review are made at the sole discretion of ORI.

Conference, Workshop, and Meeting Proposals Due April 1, 2005.

ORI is seeking proposals from institutions, scientific societies, and professional associations that wish to collaborate with ORI in developing conferences, workshops, symposia, colloquiums, seminars, and annual meeting sessions that address the responsible conduct of research, research integrity, or research misconduct. ORI will provide up to \$20,000, depending on the event proposed.

The next target date for receipt of applications is **April 1, 2005**. Proposal instructions and an application form are available on the ORI web site at <http://ori.hhs.gov/html/programs/conf-workshops.asp>. Please submit your proposal electronically to lrhoades@osophs.dhhs.gov. Call Dr. Larry Rhoades at 301-443-5300.

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