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Office of Research Integrity newsletter

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. Please duplicate and circulate this newsletter freely. An electronic copy is available on the ORI home page.

ORI Supports Lab Management Training

ORI awarded a two-year contract to the Laboratory Management Institute (LMI) at UC Davis in August to develop laboratory management training materials that will make online or face-to-face instruction widely available to graduate students, postdocs, faculty, and other personnel.

Under the contract, LMI will produce a web-based course that may be taken by individuals and would permit faculty to offer face-to-face instruction by organizing workshops or lab management training programs. The course and guidebook will be posted on the ORI web site for use by the worldwide research community for free.

"The course will be based on the day-to-day practice of scientific research," John Galland, Ph. D., Director, LMI, said. "It will be interactive and learner-centered."

See Training, page 2

NSF Funding Requires RCR & Ethics Training

Institutions receiving awards from the National Science Foundation are required to provide training in the responsible conduct of research, survival skills, and research ethics under the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act that was signed by President Bush on August 9, 2007.

The requirements are in two sections of Title VII which authorizes NSF funding: Section 7008 – *Postdoctoral research fellows*, and Section 7009 – *Responsible conduct of research*. Section 8008 of Title VIII – *Accountability and transparency of activities authorized by this Act*, addresses conflicts of interest in subcontracts. See *http://science.house.gov/*

See Act, page 5

NAS Study Focusing on Integrity of Research Data

ORI and other Federal agencies are supporting a study, *Ensuring the Utility and Integrity of Research Data in a Digital Age*, being conducted by the National Academy of Sciences that may recommend data integrity standards to the research community.

The study, conducted by the Committee on Science, Engineering and Public Policy, will review the selection, collection, analysis, handling, oversight, reporting, publishing, ownership, access, and archiving of data. The study report is expected to be completed in early 2008. The project website at *http://www8.nationalacademies.org/cp/projectview.aspx?key=48721* lists the key issues being addressed as:

See Key, page 9

in this issue

Training Focuses on Management and Organizational Skills *(from page 1)*

"This instruction is essential because knowledge of science is a necessary but not a sufficient condition for success in science," Larry Rhoades, Director, Division of Education and Integrity, ORI, said. "Researchers who direct labs face production, personnel, communication, facility and financial problems similar to those faced by chief executive officers of small businesses."

The interactive course will provide instruction in skills useful in managing laboratories including: communication skills; establishing and maintaining a research program; quality control and assurance; managing human resources; leadership, goal setting and strategic planning; financial and business management; health, safety and security; creativity, discovery, problem solving, and innovation; stewardship of resources, and interpersonal relations.

The course will feature LabAct, a pedagogical technique that employs actors to illustrate issues in short videos related to the general topics mentioned above. The short videos will present two or more possible approaches to those issues. In addition, behavioral objectives, background materials, and references will be provided.

The use of specially trained "LabActors" helps bridge the arts and science in a unique way, said Dr. Jade McCutcheon, co-investigator for the project and Associate Professor in the UC Davis Theater and Dance Department.

The downloadable guidebook will contain chapters on the following topics related to laboratory management: leadership, mentoring, best practices, innovation and management. The guidebook will also include PowerPoint presentations, behavioral objectives, background material and assessment instruments.

The LMI was started in 2005 at UC Davis because "researchers devote years of study in their scientific disciplines, but receive little or no laboratory management training that is essential to their success," Galland said.

The LMI graduated 48 postdocs from its 42 contact-hour Laboratory Leadership and Management for Postdoctoral Scholars course. The LMI also trained 22 researchers in its 14 hour Certificate Program in Laboratory Leadership and Management for scientists and research administrators. More than 400 persons have participated in LMI LabAct training. Now that training will be made available to everyone.

2007 Annual Report on Possible Research Misconduct Approaching

ORI will send emails this December to officials responsible for submitting the 2007 Annual Report on Possible Research Misconduct that will contain the password and IPF number for their institution to facilitate submission of that report by the March 1, 2008 deadline and reduce the need to request them from ORI.

Institutions are required by regulation to submit the Annual Report to maintain their research misconduct assurance. If that assurance is not maintained, the institution becomes ineligible to receive PHS support for research, research training, and related research activities.

Filing the Annual Report requires officials to state whether their institution has a policy that conforms with the PHS Policies on Research Misconduct (42 C.F.R. 93), update their institutional contact information, and report the number of research misconduct allegations received involving PHS supported research or research training and the subsequent number of inquiries and investigations conducted. All data fields in the institutional information and misconduct activity sections must be completed before the Annual Report can be submitted. Receipt of the Annual Report by ORI will be automatically acknowledged.

ORI uses the contact information provided by institutions for mailing the *ORI Newsletter,* the *ORI Annual Report* and other publications, for emails announcing conferences, programs, and breaking new developments, and for referring research misconduct allegations to appropriate officials.

Bi-weekly reminders will be sent in January and February to institutions that have not already filed their 2007 Annual Report. Further information and assistance is available from Robin Parker at *Robin.Parker@hhs.gov* or 240-453-8400.

Seven Awards Made by Research on Research Integrity Program

Research on ethical decision-making, government industry research relationships, standards of scientific conduct and record keeping and data sharing practices are among the topics supported by the seven awards made this summer by the Research on Research Integrity (RRI) program.

Since it began in 2001, the RRI program funded 46 projects that have resulted in 39 publications—27 articles, 1 commentary, 1 letter to the editor, 8 abstracts, and 2 literature reviews—in 15 journals.

Total funding for the RRI program in 2007 was $2,815,761, just slightly below the all-time high of $3,070,404 in 2006. New grants received $2,040,243; continuations received $775,518. ORI contributed $1,488,228; NIH institutes contributed $1,327,533.

The new awards were supported by the National Library of Medicine and ORI. Continuation awards were funded by the National Human Genome Research Institute, the National Cancer Institute, and the National Institute of General Medical Sciences. The National Institute of Nursing Research provided grants management support and the Center for Scientific Review provided grant review services.

Seven of the 22 applications were supported for a funding rate of 31 percent. Awards provide up to $175,000 in direct costs, plus indirect costs, for each of two years.

Award abstracts are posted on the ORI web site along with a list of publications produced by projects supported by the RRI program. For information on the RRI program contact Nick Steneck at *nsteneck@umich.edu*.

The new announcement is posted on the ORI home page. Submission deadlines are November 20, 2007 for RO3 awards and November 21, 2007 for R21 awards.

The grant titles, principal investigators, and awardee institutions follow:

Government Industry Relationships in Science
Eric G. Campbell
Massachusetts General Hospital

Quality of Research on Treatment Harms in Cancer
Benjamin Djulbegovic
H. Lee Moffitt Cancer Center & Research Institute

Duplicate Article/Plagiarism Discovery
Harold R. Garner
University of Texas Southwestern Medical Center

Standards of Scientific Conflict
Michael W. Kalichman
University of California - San Diego

Development of Strategies for Improving Ethical Decision-Making in the Sciences
Michael D. Mumford
University of Oklahoma

Barriers and Opportunities for Sharing Research Data
Amy Mehraban Pienta
University of Michigan

Responsible Record Keeping Practices: Standards & Practices of Funded Researchers
Kenneth R. Wilson
East Carolina University

RRI Researchers Published Three More Articles

Three more articles have been published by investigators supported by the Research on Research Integrity (RRI) Program. Thirty-nine publications—articles, abstracts, commentaries, reviews, letters to the editor—have been produced by RRI investigators since the program began in 2000. See *http://ori.hhs.gov/research/extra/rri_publications.shtml*

- Neale AV, Northrup J, Dailey R, Marks E, Abrams J. "Correction and Use of Biomedical Literature Affected by Scientific Misconduct." *Science and Engineering Ethics*, 2007, 13: 5-24.
- Pryor, E., Habermann, B., Broome, M. "Scientific Misconduct from the Perspective of Research Coordinators: A National Survey." *Journal of Medical Ethics*, 2007, *33*, 365-9.
- Tereskerz PM, Moreno J. "Ten Steps to Developing a National Agenda to Address Financial Conflicts of Interest in Industry Sponsored Clinical Research." *Accountability in Research*, 2005 12(2): 139-55.

ORI Retains Its Working Definition of Plagiarism under New Regulation

By John Dahlberg, Director, Division of Investigative Oversight, ORI

In its December 1994 newsletter, ORI published a brief note describing how ORI intended to interpret the definition of plagiarism in the PHS regulation (42 C.F.R. Part 50) as applied to ORI cases. A new regulation on "Public Health Service Policies on Research Misconduct" was published in the Federal Register on May 17, 2005, and became final on June 16, 2005 (42 C.F.R. Part 93) (abbreviated as 'Part 93' below). In this new regulation plagiarism is defined as "the appropriation of another person's ideas, processes, results, or words without giving appropriate credit."

ORI interpreted its definition of plagiarism to apply to the theft or misappropriation of intellectual property and/or the substantial unattributed textual copying of another's work. ORI's interpretation does not include authorship or credit disputes or "self-plagiarism" of one's work from one paper to another or from a paper to a grant application.

ORI has been asked by various institutions and individuals whether this policy is applicable under Part 93. The answer is yes—ORI will continue to exercise a standard that is notably more forgiving than the standard in general use at institutions. There are multiple reasons for this.

The most important is the independent authority of an institution to impose additional and stricter standards of behavior on employees. This is explicitly spelled out in §93.319:

Institutional standards.

(a) Institutions may have internal standards of conduct different from the HHS standards for research misconduct under this part. Therefore, an institution may find conduct to be actionable under its standards even if the action does not meet this part's definition of research misconduct.

(b) An HHS finding or settlement does not affect institutional findings or administrative actions based on an institution's internal standards of conduct. (§93.319)

Collaborative Disputes

ORI generally pursues plagiarism allegations when, for example, wholesale copying of language and data has been used to produce crucial portions of a grant application such as the preliminary results. However, when reuse of data and language involves former or current collaborators, ORI does not consider this to be plagiarism, but an outcome of the joint development of ideas, data, or language where it frequently is impossible to objectively sort out who was responsible for what.

When modest amounts of language are reused (sentences, paragraphs, or even whole pages) without proper attribution that can be considered background information, or the boilerplate language often seen in descriptions of methods, and the copied material is not misleading, ORI generally does not consider this to be sufficient to be considered plagiarism under ORI's working definition. Certainly institutions are permitted to make their own findings on the reuse of language and seek suitable remedies. Most cases of "minor" plagiarism are not significant enough to warrant ORI oversight.

Self-Plagiarism

ORI often receives allegations of plagiarism that involve efforts by scientists to publish the same data in more than one journal article. Assuming that the duplicated figures represent the same experiment and are labeled the same in both cases (if not, possible falsification of data makes the allegation significantly more serious), this so-called "self-plagiarism" does not meet the PHS research misconduct standard. However, once again, ORI notes that this behavior violates the rules of most journals and is considered inappropriate by most institutions. In these cases, ORI will notify the institution(s) from which the duplicate publications/grants originated, being careful to note that ORI had no direct interest in the matter.

The take home lesson is that little has changed in the way ORI deals with allegations of plagiarism in light of the issuance of the new Part 93. ORI will continue to exercise care and discretion on what is judged to be plagiarism which is significant enough for a PHS finding. Staff in the Division of Investigative Oversight (DIO) can be reached at 240-453-8800 if questions arise about specific plagiarism allegations at your institution.

GPO Reduces Price On ORI Intro Text

An updated version of the *ORI Introduction to the Responsible Conduct of Research* is available from the Government Printing Office (GPO) at a substantially reduced price for bulk orders—$495.00 per 50 copies sent to the same address. Single copies remain at $14.00 for U. S. orders.

"We appreciate the effort made by GPO to lower the bulk price on the text," Chris Pascal, Director, ORI said. "The lower price which works out to $9.90 per copy may allow the text to be more widely used in graduate and undergraduate research courses."

Over 7,550 copies of the publication have been sold since it was published in June 2004 making it a GPO "best seller." The text has also been translated into Chinese, Japanese and Korean. The Chinese version was published by Tsinghua University Press; the Japanese version by Maruzen Co., Ltd., Tokyo, and the Korean version by the South Korean Ministry of Education and the Korea Research Foundation. A Spanish translation is in preparation.

The limited updating was done prior to the printing of more copies by GPO. All links were updated and a few references were added. The text was not changed.

Copies may be ordered from the GPO at *http://bookstore.gpo.gov*. The publication is available for on-line reading or downloading on the ORI web site at *http://ori.hhs.gov*. An on-line module is available at *http://ori.hhs.gov/education/products/RCRintro/*

First Biennial RCR Conference Slated for St. Louis in April

ORI will hold the first biennial Conference on Responsible Conduct of Research (RCR) Education, Instruction and Training in St. Louis from April 18-20, 2008. The conference will be hosted and co-sponsored by Washington University.

The conference will provide a forum for sharing resources, promoting the cross-fertilization of ideas, discussing models for across-the-curriculum approaches, suggesting outcome assessments, creating collegial networks, and recognizing accomplishments of individuals and institutions.

"We would like to see widespread participation from instructors in RCR, research ethics, survival skills, lab management, human subjects, animal welfare, instructional design, and the social sciences as well as research training grants and the new NIH Translational Research (CTSA) programs, " said conference co-chair Catherine Striley (strileyc@ epi.wustl. edu).

"We also invite participation from the physical sciences and engineering which are required under the America COMPETES Act (HR 2272) to provide appropriate training in the responsible and ethical research to undergraduates, graduate students, and postdoctoral fellows participating in NSF supported research projects," said conference co-chair Nick Steneck.

Additional information and submission directions are available on the ORI home page. Abstracts for sessions, panels and papers should be sent to Nick Steneck at *nsteneck@umich.edu* by October 31, 2007.

Act Covers Postdocs and Students *(from page 1)*

Section 7008 states "that all grant applications that include funding to support postdoctoral researchers include a description of the mentoring activities that will be provided for such individuals and shall ensure that this part of the application is evaluated under the Foundation's broader impacts merit review criterion. Mentoring activities may include career counseling, training in preparing grant applications, guidance on ways to improving teaching skills, and training in research ethics."

Section 7009 of the Act states "each institution that applies for financial assistance from the Foundation for science and engineering research and education describe in its grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers participating in the proposed research project."

Section 8008 states "Any person awarded a grant or contract funded by amounts authorized by this Act shall submit a statement to . . . the Director . . . certifying that no funds derived from the grant or contract will be made available through a subcontract or in any other manner to another person who has a financial interest or other conflict of interest in the person awarded the grant or contract, unless such conflict is previously disclosed and approved in the process of entering into a contract or awarding a grant.

Subawardees Must Comply with ORI and OHRP Assurances

Institutions conducting Public Health Service (PHS) supported research or research training are required to file a research misconduct assurance with ORI, based on 42 C.F.R. Part 93. Institutions must file a separate human subjects assurance, based on 45 C.F.R. Part 46, with the Office for Human Research Protections (OHRP) if the research involving human subjects is supported by the Department of Health and Human Services (HHS).

"Some institutional officials seem to think that one assurance covers both areas," Nancy Davidian, Deputy Director, Division of Investigative Oversight, ORI, said. "But protecting human research subjects is quite different from protecting Public Health Service research products and funds."

ORI has noted several instances in recent years where allegations of research misconduct arose at a small clinic or hospital conducting PHS-supported research through a subaward (subcontract, letter agreement) from an associated institution. In each case, the subawardee had properly obtained IRB approval for the portion of the study being carried out at that facility. However, neither the university nor the clinic/hospital was aware of the legal requirement to comply with 42 CFR 93 wherever PHS sponsored research takes place.

In some of these cases, ORI required that the research misconduct procedures be conducted by the grantee institution, but in others this was not possible to arrange. Consequently, ORI was unable to resolve the research misconduct allegations.

The Public Health Service Policies on Research Misconduct do not directly address this issue. Section 93.214 defines "institutional member" to include contractors, subcontractors, and subawardees and their employees. Section 93.300(f) requires institutions to take all reasonable and practical steps to ensure the cooperation of institutional members with research misconduct proceedings, but neither that section nor any other section addresses who is responsible for conducting research misconduct proceedings if the misconduct is alleged against an employee of a contractor or subawardee of the grantee institution. The grantee is responsible for compliance with its research misconduct assurance for all awarded funds, including those made available to subawardees and contractors. To address this problem, an institution's contracts or subawards should state how an allegation of research misconduct will be handled and whether the grantee or subgrantee will conduct the proceedings.

More information on this topic can be obtained on ORI's webpage, specifically the cites to 42 CFR. 93 *(http://ori.dhhs.gov/policies/statutes.shtml)* and to Q&As discussing ORI's and NIH's interpretation of institutional requirements regarding their responsibilities to monitor compliance with ORI's assurance *(http://ori.dhhs.gov/policies/QA-Reg-6-05.shtml)*. Please contact ORI with questions in specific cases.

More Boot Camps Scheduled for Research Integrity Officers

Three boot camps will be held for institutional research integrity officers (RIOs) and their legal counsels between now and next spring to provide training in the handling of research misconduct allegations at various types of institutions.

A one-day mini boot camp will be held at the annual meeting of the Society of Research Administrators (SRA) in Nashville on October 14, 2007. Although this workshop will be of most immediate use to RIOs and their counsel, any interested person may attend. SRA membership is not a requirement to attend the workshops, but attendees must register through the SRA.

Online registration and the registration form are found at: *http://www.srainter national.org/sra03/template/tntbAM07. cfm?id=1514*. Those who experience any difficulty with registration may contact Stephanie Barnett @ 703.741.0140, ext. 10 or *sbarnett@srainternational.org*.

An intensive RIO boot camp will be held at Johns Hopkins University (JHU) in Baltimore from November 4-7, 2007. These boot camps are designed initially for RIOs and counsels from the top 100 NIH awardee institutions–the location of most research misconduct cases. Participation is by invitation only and is limited to 25 per camp.

Another boot camp for RIOs and counsels from smaller NIH awardee institutions will be held in April, 2008 at the Poynter Center for Ethics and American Institutions at Indiana University in Bloomington. Preliminary information and invitations will be mailed late this year.

FASEB Creates Toolkit to Implement Conflict of Interest Framework

A Conflict of Interest (COI) Toolkit has been created by the Federation of American Societies for Experimental Biology (FASEB) to promote the adoption within the scientific community of more consistent policies and practices for disclosing and managing financial relationships between academia and industry in biomedical research.

The COI Toolkit is designed to implement a framework for a national guideline that is based on three principles: Investigators must conduct research objectively, operate with transparency, and be accountable to all stakeholders. Stakeholders include investigators, institutions, publishers, scientific societies, and industry. The toolkit is available at *http://opa.faseb.org/pages/advocacy/coi/toolkit.htm*

"In the research environment, Federal regulations or policies alone will not serve to promote integrity in research," said Leo T. Furcht, M.D., immediate Past President of FASEB and chair of the committee that developed the program. "Voluntary approaches aimed at integrating practices into primary investigator activities—research, publication, and training—will enhance the regulatory framework. The tools provided can aid investigators and others involved in the conduct and management of academic-industry relationships in addressing key issues."

"The Toolkit provides a platform for the community to share resources with the goal of moving toward a national guideline," Furcht said. Contributions to the Toolkit should be sent to the FASEB Office of Public Affairs at *fasebopa@faseb.org*.

The COI Toolkit contains specific tools for educating investigators on COI issues including points for consideration in institutional COI policies and in academic-industry relationships, model patient disclosure language, sample wording for disclosure of financial interests in publications, points for discussion of academic-industry relationship issues with trainees and laboratory members, who-to-contact card for institutional contacts on industry relationships and technology transfer, and society statements on financial relationships between academia and industry.

"FASEB is concerned that the lack of clarity and consistency in current conflict-of-interest policies may cause confusion by investigators and ultimately inhibit their ability to protect the integrity of research," Furcht said.

FASEB presented its framework for a national COI guideline on July 17, 2007 during a meeting at the National Academy of Sciences that was attended by 75 representatives from scientific societies and other key stakeholders to discuss the process of implementation.

The development of the COI Toolkit was supported by the Responsible Conduct of Research (RCR) Program for Academic Societies, a collaboration between the Association of American Medical Colleges and ORI.

Academic Societies Make RCR Resources Available

Although they are not available online, six products supported by the RCR Program for Academic Societies are available from the producing societies or in journals.

The RCR Program for Academic Societies, a collaboration between the Association of American Medical Colleges and ORI, supported the institutionalization of infrastructure and activities within academic societies that would promote the responsible conduct of its members.

From 2002 to 2006, ORI made 39 awards to 31 societies to develop guidelines, standards, policies, curricula and other resources designed to promote the responsible conduct of research.

For more information on the program and a complete listing of the program products and participating academic societies see *http://www.aamc.org/programs/ori/* Some products are still under development.

The name of the academic society, the title of its product, and its availability follow:

Alliance of Independent Academic Medical Centers
Proceedings of a symposium on "An Ethical Framework for Managing Clinical Trials in the Independent Academic Center"
Available from *Kimberly@aiamc.org*.

American Society for Bioethics and Humanities
An article on "Educational Approaches to the Responsible Conduct of Clinical Research" in *Academic Medicine* in January 2007 82:1, pp. 32-39.
See RCR, page 9

Two Educators Joined ORI Staff in August

Two experienced educators who have a background in the responsible conduct of research (RCR) joined the Division of Education and Integrity, ORI, last August.

Cynthia Ricard, will serve as Director, Extramural Research Program, and Ed Gabriele will serve as Director of Educational Conferences and Liaison Development. Dr. Ricard may be contacted at *Cynthia.Ricard@hhs.gov*; Dr. Gabriele at *Edward.Gabriele@hhs.gov*.

Dr. Ricard, a former assistant professor in the Ophthalmology Department at Saint Louis University (SLU), has managed her own research laboratory which was supported by grants from the National Eye Institute, the Knights-Templar Eye Foundation, Inc., and the Glaucoma Foundation. She held an NIH Postdoctoral Fellowship in biochemistry at Washington University School of Medicine. She has published in such journals as the *Proceedings of the National Academy of Sciences*, the *Journal of Virology,* the *British Journal of Ophthalmology,* and *Experimental Eye Research.*

Dr. Ricard has mentored graduate students and postdoctoral fellows and taught graduate and undergraduate courses. She also taught an RCR course since 2003 and recently served as the RCR course director at SLU. Dr. Ricard received her Ph.D. in biomedical sciences from Albany Medical College in 1994.

Dr. Gabriele was a research ethicist and administrator at the Henry M. Jackson Foundation for the Advancement of Military Medicine for 15 years during which time he held related executive positions in the Department of Defense. He subsequently served as the human subjects protections scientist in the Office of the Army Surgeon General, assistant vice president for research integrity at the MedStar Research Institute, and director of the human research ethics program in the Department of Health and Senior Services for the State of New Jersey.

Dr. Gabriele has taught undergraduate and graduate courses, has developed computer-based, distance learning programs for adult learners, and has published articles in peer reviewed journals. He currently edits the *Journal of Research Administration* that is published by the Society of Research Administrators (SRA) International. He created an RCR learning track at the SRA annual meeting and has served as an officer and committee member in professional associations and academic societies. He received his doctorate in theology and education from the Catholic University of America in 1985.

Data Management Video Available on Web Site

A video-based resource for data management is now available on the ORI website. This product contains 10 video vignettes that address data sharing, technology transfer, data storage, data falsification, data ownership, sharing of resources, and collaboration.

These vignettes address several gray areas. When is it appropriate to share data? Are you allowed to share the research protocol with other universities? Under what circumstances is it appropriate to remove lab books from the lab?

After viewing each 10 second video, the learners are presented with a question to see what action they would take in response to the situation. Consequences for each action are given to allow users immediate feedback about their decision making process.

The product was created by Syracuse University with funding from the ORI RCR Resource Development Program.

RIO Study Underway; Survey Coming Soon

The first phase of a study of institutional research integrity officers (RIOs) that is nearing completion will provide the foundation for a RIO survey that will be conducted this fall or early next year.

The initial phase involves phone interviews with about 100 RIOs, the institutional officials responsible for implementing the PHS Policies on Research Misconduct (42 C.F.R. 93). Results from the interviews will be used to develop a questionnaire that will be sent electronically to about 1,600 RIOs.

The descriptive study conducted by the Research Triangle Institute will look at the authority, qualifications, training, multiple role sets, resources, and longevity of RIOs. The study is expected to be completed in 2008.

Key Issues in Research Data Integrity Study *(from page 1)*

1. What are the growing varieties of research data? In addition to issues concerned with the direct products of research, what issues are involved in the treatment of raw data, pre-publication data, materials, algorithms, and computer codes?

2. Who owns research data, particularly that which results from Federally-funded research? Is it the public? The research institution? The lab? The researcher?

3. To what extent is a scientist responsible for supplying research data to other scientists (including those who seek to reproduce the research) and to other parties who request them? Is a scientist responsible for supplying data, algorithms and computer codes to other scientists who request them?

4. What challenges does the science and technology community face arising from actions that would compromise the integrity of research data? What steps should be taken by the science and technology community, research institutions, journal publishers, and funders of research in response to these challenges?

5. What are the current standards for accessing and maintaining research data, and, how should these evolve in the future? How might such standards differ for Federally-funded and privately-funded research, and for research conducted in academia, government, non-governmental organizations, and industry?

The study will not address privacy issues and other issues related to human subjects.

RCR Products Available From Academic Societies

(from page 7)

American Thoracic Society
A policy statement on "The Ethical Conduct of Clinical Research Involving Critically Ill Patients in the United States and Canada: Principles and Recommendations" in the *American Journal of Respiratory and Critical Care Medicine* December 2004 170:12 , pp. 1375-84

The Council on Social Work Education
National statement on "Research Integrity in Social Work"
Available from *jholmes@cswe.org*.

The Gerontological Society of America
Guidebook for Multidisciplinary Clinical Geriatric Research Order at *http://www. geron.org/ guidebook2006.htm*

Research and Assessment Corporation for Counseling, Inc.
A DVD and training manual on "Conducting Research Responsibly."
Available from *klwester@uncg.edu*

ORI Developing Presence on International Level

Responding to the international nature of science, ORI is gradually expanding its operation to the international level as more countries experience research misconduct cases or seek to promote the responsible conduct of research.

The European Science Foundation and ORI organized the first World Conference on Research Integrity that was held in Lisbon, Portugal from September 16-19, 2007.

ORI regularly hosts visitors from other countries including South Korea, Japan, China, Nigeria, Singapore and England who are interested in learning about the ORI experience as they consider building procedures in their own countries.

The *ORI Introduction to the Responsible Conduct of Research* has been translated into Japanese, Chinese, and Korean. A Spanish edition is being prepared. Individuals from 147 countries visited the ORI web site during 2006.

Case Summaries

Joy Bryant, University of Oklahoma Health Sciences Center:
Based on the report of an investigation conducted by the University of Oklahoma Health Sciences Center (OUHSC) and additional analysis conducted by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Ms. Joy Bryant, Tribal Efforts Against Lead (TEAL) phlebotomist, OUHSC, engaged in scientific misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES008755. Specifically, Ms. Bryant falsified research in the TEAL study by substituting or conspiring with

Case Summaries *(continued)*

another phlebotomist to substitute her blood or blood of another phlebotomist for blood samples of 10-15 child participants in the TEAL study. The TEAL study was aimed at measuring the blood levels of lead in Indian children living in Tar Creek, where abandoned mines and piles of mining wastes left lead (and other heavy metals) leaching into the area's waterways and yards.

Ms. Bryant has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed, for a period of three (3) years, beginning on May 30, 2007: (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 HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 C.F.R. Part 376 *et seq*.; 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.

Diana Layman, University of Oklahoma Health Sciences Center: Based on the report of an investigation conducted by the University of Oklahoma Health Sciences Center (OUHSC) and additional analysis conducted by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Ms. Diana Layman, Tribal Efforts Against Lead (TEAL) phlebotomist, OUHSC, engaged in scientific misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES008755. Specifically, Ms. Layman falsified research in the TEAL study by substituting or conspiring with another phlebotomist to substitute her blood or blood of another phlebotomist for blood samples of 10-15 child participants in the TEAL study. The TEAL study was aimed at measuring the blood levels of lead in Indian children living in Tar Creek, where abandoned mines and piles of mining wastes left lead (and other heavy metals) leaching into the area's waterways and yards.

Ms. Layman has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed, for a period of three (3) years, beginning on May 30, 2007: (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 HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 C.F.R. Part 376, *et seq*.; 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.

James David Lieber, University of California at Los Angeles: Based on the findings of an inquiry report by the University of California at Los Angeles (UCLA) and additional analysis and information obtained by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that James David Lieber, Staff Research Associate, Semel Institute for Neuroscience and Human Behavior, Integrated Substance Abuse Programs, UCLA, engaged in research misconduct in research funded by National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), grant R01 DA15390.

Mr. Lieber knowingly and intentionally falsified and fabricated multiple follow-up interviews, urine samples, and urine sample records of human subject study participants and entered such false and fabricated data into the study's data base. A total of 914 follow-up interviews of opiate users were planned to be completed as part of a study of gender differences in a follow up of opiate users in California. Mr. Lieber was assigned to interview 53 of the 132 subjects located for the follow-up study. Over a six-month period, Mr. Lieber falsely claimed to have conducted face-to-face interviews for the study while subsequent contacts with the subjects revealed that they had not been interviewed for the study. A review by the institution determined that the respondent fabricated interviews for 20 of the 53 interviews assigned to him. In addition, he falsified the urine specimens for those 20 subjects and caused the entry of false information into the study tracking and locating data base for 11 subjects. Aggravating factors included the theft of $5180 for incentive payments to subjects and travel expenses.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on July 2, 2007: (1) Mr. Lieber is debarred from eligibility for 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

Case Summaries *(continued)*

in HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 C.F.R. Part 376, *et seq*.; and (2) Mr. Lieber is prohibited 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.

Carlos A. Murillo, M.D., University of Texas Medical Branch at Galveston: Based on the report of an inquiry conducted by the University of Texas Medical Branch at Galveston (UTMB) and additional analysis and information obtained by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Carlos A. Murillo, M.D., former Surgical Resident, Department of Surgery, UTMB, engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grants R01 DK48498 and T32 DK07639. Specifically, Dr. Murillo falsified research on the amelioration by antisense RNA (siRNA) of dextran-induced colonic toxicity in mice. He altered the concentrations of dextran solution fed to mice to induce colonic inflammation, by intentionally including little or no dextran in the drinking water of siRNA treated mice, so that the animals that received siRNA would have few or no colonic lesions.

Dr. Murillo has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed, for a period of three (3) years, beginning on May 30, 2007: (1) that any institution that submits an application for PHS support for a research project on which Dr. Murillo's participation is proposed or that uses him in any capacity on PHS support research, or that submits a report of PHS-funded research in which 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 Dr. Murillo's research contribution; Dr. Murillo agrees to ensure that a copy of the supervisory plan is also submitted to ORI by the institution and agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to ORI; (2) to exclude himself 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 (3) to request retraction of the abstract entitled "Inhibition of Phosphoinositol 3-kinase Using Anti-p85 siRNA Attenuates Dextran-Sulfate-Induced Inflammatory Bowel Disease" (*Gastroenterology* 126:A49, 2004), by signing the letter of retraction prepared by ORI attached as Attachment 2 and made part of the Agreement.

Kristin Roovers, Ph.D., University of Pennsylvania: Based on an investigation conducted by the University of Pennsylvania (UP) and additional analysis and information obtained by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Kristin Roovers, Ph.D., former postdoctoral fellow, Departments of Medicine, Cell and Developmental Biology, and Pharmacology, and Howard Hughes Medical Institute, and former graduate student, Department of Pharmacology, UP, engaged in misconduct in science in research funded by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL061567, P50 HL057278, and T32 HL07873, National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grants P30 DK52574 and R01 DK066886, National Cancer Institute (NCI), NIH, grant R01 CA72639, and National Institute of General Medical Sciences (NIGMS), NIH, grants R01 GM48224, R01 GM58224, R01 GM51878, and R01 GM69064. Dr. Roovers' manipulations and falsification of data were extensive, encompassing 19 panels of Western blot data, appearing in 11 figures in 3 publications from her research as a graduate student and her first postdoctoral position and in 9 panels of immunoblot data in 8 figures of an unpublished manuscript. Specifically, the findings involved falsification by duplication and reuse of immunoblot data to misrepresent the results as data from different experiments that had been reported in the following manuscript and three publications:

- Figures 2C, 3C, 4D, 4E, 6C, 7B, and supplement Figures 1, 2B, and 3B in a manuscript submitted to the *Journal of Clinical Investigation* entitled: "Akt1 promotes physiologic, but antagonizes pathologic, cardiac growth."
- Figures 3A, 3C, and 4A in: Welsh, C.F., Roovers, K., Villanueva, J., Liu, Y., Schwartz, M.A., & Assoian, R.K. "Timing of cyclin D1 expression within G1 phase is controlled by Rho." *Nature Cell Biology* 3(11):950-957, 2001.
- Figures 1, 2A, 2B, 3A, 3C, 4A, 4B, 6C, 6D, and 6E in: Roovers, K., & Assoian, R.K. "Effects of rho kinase and actin stress fibers on sustained extracellular signal-regulated kinase activity and activation of G(1) phase cyclin-dependent kinases." *Mol. Cell Biol*.

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23(12):4283-4294, 2003. Retracted in *Mol. Cell Biol*. 26(13):5203, July 2006.

- Figures 1C, 2C, 5B, 5D, 6B and 6D in: Roovers, K., Klein, E.A., Castagnino, P., & Assoian, R.K. "Nuclear translocation of LIM kinase mediates Rho-Rho kinase regulation of cyclin D1 expression." *Developmental Cell* 5 (2):273-284, 2003. Retracted in *Developmental Cell* 10(5):681, May 2006.

Corrections were recommended by UP for the *Nature Cell Biology* paper. Dr. Roovers' falsified Western blot data from the publications in *Nature Cell Biology* and from *Developmental Cell* were included in NIH grant applications CA 72639-07 and GM 69064-01.

ORI has implemented the following administrative actions for a period of five (5) years, beginning on June 7, 2007: (1) Dr. Roovers is debarred from eligibility for 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 HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 C.F.R. Part 376, *et seq*.; and (2) Dr. Roovers is prohibited 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.

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