**ORI Issues Informational Documents on New Reg**

Two documents are available on the ORI home page to assist institutions to make a smooth transition to the new PHS Policies on Research Misconduct (42 CFR Part 93) that became effective on June 16, 2005.

The documents are **Requirements for Institutional Policies and Procedures on Research Misconduct Under the New PHS Policies on Research Misconduct, 42 CFR Part 93** and an extensive set of Questions and Answers (Q&A) designed to help institutional officials to understand the obligations their institutions have under the new regulation.

“The requirements document provides a brief discussion of the new policies and procedures that must be adopted by institutions to conform with the requirements of the final rule,” Chris Pascal, Director, ORI, said. “It also provides a set of sample provisions that institutions can adopt to bring their policies and procedures into conformity with the new regulation.”

He continued, “These suggested sample provisions for institutional policies and procedures are not required. However, some institutions may find them to be a quick and effective way to bring their policies into conformity with the new regulation. At the end of the document is a set of Endnotes that provide more detail on the new requirements and some explanation on changes from the prior regulation.”

See Informational, page 4

**RRI Program Awards 7 Grants; Adds 2 Agencies**

Seven awards were made this summer by the Research on Research Integrity (RRI) Program which is now co-sponsored by ORI and six other participating federal organizations.

Other participating organizations are the National Cancer Institute (NCI), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute of Nursing Research (NINR), National Institute of Neurological Disorders and Stroke (NINDS), National Institute on Drug Abuse (NIDA), and the Agency for Healthcare Research and Quality (AHRQ).

In addition to the new awards, the RRI program is supporting five continuation awards. Since it began in 2001, the RRI program funded 34 projects.

“The seven awards made this year represent the second highest number of awards in the history of the program,” Dr. Mary Scheetz, Director, ORI Extramural Research Program, said. “We are especially grateful to the NIH components that continued to provide funding this year, NINR, NINDS, and NIDA and to the National Heart, Blood

See Research, page 3

**ORI Annual Report 2004**

The **ORI Annual Report - 2004** is available on the ORI home page for online reading or downloading. The 59-page document reports on the processing of research misconduct cases, education and research programs and compliance activities. Summaries of closed investigations are provided.
Institutions Report Less Research Misconduct Activity in 2004

Institutions reported slightly lower levels in almost all indicators of research misconduct activity in their 2004 Annual Report on Possible Research Misconduct than they did in their 2003 reports.

One hundred institutions reported new and/or continuing research misconduct activity in 2004 compared to 106 in 2003. New activity was reported by 76 institutions in 2004 and 82 in 2003. One hundred and twenty new allegations were reported in 2004 versus 136 in 2003.

The number of new cases opened in 2004, however, was slightly higher, 107 and 105 respectively.

Research misconduct activity is defined as receipt of an allegation or the conduct of an inquiry and/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.

During 2004, 79 institutions conducted inquiries, and 40 conducted investigations compared to 82 and 46 respectively in 2003. In 2004, institutions conducted 110 inquiries and 52 investigations compared to 119 inquiries and 53 investigations in 2003.

The 76 institutions that opened new cases reported receiving 120 new allegations that resulted in 77 inquiries and 26 investigations. Institutions received 48 allegations of falsification, 36 of fabrication, 22 of plagiarism, and 14 others.

Institutions reporting new cases included higher education, 75; research organizations, 13; independent hospitals, 7; and other health, human resources and environmental organizations, 5.

Ten Agencies Enact Federal Misconduct Policy

Nine federal agencies or departments have published policies or regulations implementing the Federal Research Misconduct Policy, another has published a notice of proposed rulemaking, and five others are still drafting theirs, according to the Office of Science and Technology Policy in the White House.

Departments or agencies that have policies or regulations are Health and Human Services, Defense, Labor, Transportation, Veteran Affairs, Environmental Protection Agency, National Aeronautics and Space Administration, National Science Foundation, and the Smithsonian Institution. The Department of Energy has published the notice of proposed rulemaking.

Departments still drafting their policies or regulations are Agriculture, Commerce, Education, Interior and Justice.

Links to available policies or regulations are posted on the ORI website at http://ori.hhs.gov/policies/regulations.shtml.

Contributions Invited to ORI Home Page

ORI invites contributions to several sections of its home page—RCR Resources, Research Results, Societies & Assns., Upcoming Events—that are related to the responsible conduct of research, research integrity or research misconduct from individuals, institutions, societies, and associations.

Contributions should describe the item or event and indicate how the item or additional information on the event may be accessed through the Internet or other means. Citations should be provided for published articles, monographs, and books. Contributions may include, but are not limited to:

• RCR Resources – web-based instruction modules, videos, tools, newsletters, textbooks, web sites

• Research Results – published articles and monographs

• Societies & Assns. – guidelines, policies, curricula

• Upcoming Events – conferences, workshops, symposia, award ceremonies

Please send the contributions to LRhoades@osophs.dhhs.gov.
RRI Articles Published; Four More In Press

Researchers supported by the Research on Research Integrity (RRI) Program have recently published a commentary and two articles in three journals—Nature, New England Journal of Medicine, Contemporary Clinical Trials—and have four other articles in press with two journals—Accountability in Research and Ethics and Behavior.


Citations to the two recently published articles follow. A complete list of RRI publications is available on the ORI website at http://ori.hhs.gov/research/rri_publications.shtml.


Citations to the four articles that are in press follow. The first three articles are based on presentations made during the third Research Conference on Research Integrity held in San Diego last November.


Another article based on a presentation made during the third Research Conference on Research Integrity is also in press:


Attorney Joins Research Integrity Team

An attorney who taught the biological sciences in Africa as a Peace Corps member has joined the Research Integrity Team in the Office of the General Counsel, HHS, where he will work on legal matters related to ORI.

Brian Bewley joined the OGC Research Integrity Team on July 11, 2005. Other team members are Jo An Leonce and Chris Mahler, Team Leader.

Bewley previously served in the U. S. Department of Justice where he was the attorney-advisor to the Chief Administrative Law Judge for the Drug Enforcement Administration, an appointment he accepted through the Attorney General’s honor program for law graduates.

He received his law degree from Washington University School of Law in St. Louis in 2004 where he was the Executive Notes Editor for the law review.

Bewley taught the biological sciences in Burkina Faso, West Africa for two years following graduation in December 1998 from Drury University.

Research Awards Abstracts Posted (from page 1)

and Lung Institute and NIAAA which are providing funding for the first time.”

Total funding for the RRI Program in 2005 is $2,586,498, the highest in the five-year program. New grants received $1,480,792, continuations received $1,105,706. ORI contributed $1,820,013; NIH components contributed $766,485.

Seven of the 47 applications were supported for a funding rate of 14 percent. Awards provide up to $175,000 in direct costs, plus indirect costs, for each year of two years.

Award abstracts are posted on the Research page on the ORI website along with a list of publications produced by projects supported by the RRI program. For information on the RRI program contact Dr. Scheetz, at 240-543-8438 or mscheetz@osophs.dhhs.gov.

- Mentoring the Responsible Conduct of Research. Celia B. Fischer, Fordham University.
- Procedural Justice, Identity, and Research Integrity. Brian Martinson, Health Partners Research Foundation.
- Evaluation of the Quality of Clinical Trials. Benjamin Djulbegovic, Moffit Cancer Center.
- Data Analysis Practices in Drug Prevention Evaluation. Dennis M. Gorman, Texas A&M University.
- Research Extenders and Research Integrity: A New Frontier. Leslie B. Alexander, Bryn Mawr College.
Research Misconduct Study to Be Conducted by Gallup

A study of the reporting of suspected research misconduct in biomedical and behavioral research, conducted by The Gallup Organization for ORI, will be in the data collection phase this fall.

The self-administered questionnaire which incorporates extensive comments received from the Association of American Medical Colleges and the Federation of American Societies for Experimental Biology will be sent to 5,200 principal investigators conducting research supported by the PHS.

Subjects will be asked to report suspected research misconduct they observed in their department in the last three academic years, 2002-2005. The study will use the definition of research misconduct contained in the new PHS Policies on Research Misconduct (42 CFR Part 93):

“Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”

ORI commissioned the study on the reporting of suspected research misconduct to assess the conflicting views held in the research community concerning the frequency of research misconduct. The dominant view, probably based on the low number of “known” cases, holds that research misconduct is extremely rare and only committed by “bad apples.” The minority view, probably based on the underreporting of suspected research misconduct, holds that the “known” cases are the “tip of the iceberg.”

“The research community has consistently asked us over the last 15 years for data showing that research misconduct is a problem,” Larry Rhoades, Director, Division of Education and Integrity, said. “This study provides the community with an opportunity to collaborate in an effort to collect data that should be helpful in defining the problem.”

RCR Resources RFP Focuses on Skills

The new request for proposals for the RCR Resource Development Program available on the ORI home page is focused on the development of tools for learning skills and competencies rather than on general RCR education.

“The 49 projects ORI has funded since 2002 are mostly aimed at general education,” Loc Nguyen-Khoa, program director, said. “Now, we want to focus on the development of specific skills and competencies such as managing the integrity of the data (including the recording, interpreting, and reporting of the data), negotiating authorship, establishing collaborations, writing proposals, managing labs, and so on.”

“The tools should require the active participation of the user in the learning process and require the learner to demonstrate the skills being taught,” Nguyen-Khoa said. The new RFA allows for awards up to $50,000. Submission deadline will be February 24, 2006. For application information contact Loc Nguyen-Khoa at LNguyen-Khoa@osophs.dhhs.gov.

ORI Conferences – 2005

- **October 1** – Plagiarism Across the Science Disciplines: An Exploration of the Parameters of Plagiarism in Scholarly and Scientific Publications, New York, NY.
- **October 7** – Promoting RCR in Research in the Social, Behavioral and Educational Sciences, San Antonio, TX
- **October 20-21** – Responsible Conduct of Research: Essentials for Research Success and Integrity, Pocatello, ID


Informational Documents Issued (from page 1)

The extensive Q&A document contains 61 Q&As categorized under five headings: (1) Primary Changes from Old Rule, (2) Finding Research Misconduct, (3) Institutional Responsibilities, (4) Authorities of ORI and HHS, and (5) Hearing Process.

“This document is particularly helpful for institutional officials who are responsible for adopting new policies and procedures under the regulation, implementing the new regulation, or conducting or monitoring inquiries and investigations,” Pascal said. “It also can be used by the general public or others who have a need to understand the new regulation.”
Primary Changes Between New and Old Research Misconduct Regulation

**Applicability.** The new rule includes PHS intramural research programs and contracts that support research, research training or activities that are related to research or research training. The new rule applies to an allegation that PHS-supported research involving journal or grant peer review has been plagiarized. Section 93.102.

**Limitations Period.** Because of the problems that may occur in investigating older allegations and the potential unfairness to the respondent in defending against them, the new rule is limited to research misconduct occurring within six years of the date on which HHS or the institution receives the alleging of misconduct, unless: (1) the respondent continues or renews any incident of alleged research misconduct that occurred outside the six-year limit through the citation, republication or other use for the potential benefit of the respondent of the research record that is the subject of the allegation; (2) ORI, or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public; or (3) if HHS or the institution received the allegation before the effective date of the new rule. Section 93.105.

**Definition of Research Misconduct.** Consistent with the Office of Science and Technology Policy (OSTP) government wide definition and guidelines on research misconduct, the new rule uses the term “research misconduct” rather than “misconduct” or “misconduct in science” and, among other changes, defines this term to include a new element: misconduct occurring in connection with the “reviewing” of research. The “other practices” part of the existing definition has been dropped. Section 93.103. Falsification, fabrication, and plagiarism have also been separately defined.

**Burden of Proof.** Consistent with the OSTP guidance that the exclusion of honest error or difference of opinion from the definition of research misconduct does not require HHS and the institutions to disprove possible honest error or difference of opinion, the new rule provides that these elements are an affirmative defense that the respondent has the burden of proving by a preponderance of the evidence. However, the institutions and HHS retain the burden of proving research misconduct by a preponderance of the evidence, and any admissible, credible evidence the respondent submits to prove honest error or difference of opinion must be weighed in determining whether the institution and HHS have carried this burden. Sections 93.106(b)(1) and (2) and 93.516(b).

**Institutional Responsibilities.** The new rule describes in greater detail the responsibilities of the institutions in responding to allegations of research misconduct. Institutions must take certain steps to ensure a fair and thorough investigation, such as securing the evidence and giving the respondent opportunities to access the evidence and comment on the investigational report. In addition, the new rule provides greater detail on ORI’s oversight of the institution’s investigation or other misconduct proceeding and the actions that ORI may take if an institution fails to comply with the rule. Subpart C, Sections 93.300 - 93.319.

**Hearing Process.** The new rule sets forth a detailed hearing process that is modeled on the HHS Office of Inspector General (OIG) regulation, 42 CFR part 1005, that governs the hearing process for the exclusion of health care providers from Medicare and State health care programs. Among the changes from the current ad hoc hearing process is that the trier of fact will be an Administrative Law Judge, rather than a three-person panel of the Departmental Appeals Board (DAB). Subpart E, Sections 93.500 - 93.523.

**Responsibilities of ORI and the ASH.** The new rule changes the respective responsibilities of ORI and the Assistant Secretary for Health (ASH). The ALJ’s findings of fact and conclusions of law constitute a recommended decision to the Assistant Secretary for Health (ASH). Under the final rule, the ASH may let the ALJ’s recommended decision stand, or take final agency action, exercising authority to affirm, reverse, or modify the ALJ’s recommended decision, if it is found to be arbitrary and capricious, or clearly erroneous. If debarment or suspension from eligibility for Federal financial assistance and/or contracts is proposed, the decision of the ALJ or of the ASH, as the case may be, constitutes proposed findings of fact to the HHS Debarring Official. If the ASH takes final action on the ALJ’s recommended decision and the Debarring Official concurs, the ASH decision constitutes final agency action. Section 93.523. In order to ensure a separation of this ASH responsibility from the responsibility of making a finding of research misconduct, ORI will propose initial findings of research misconduct, subject to the DAB hearing process, and recommend settlements to HHS. This change will maintain the separation between investigation and adjudication, because ORI will not conduct any inquiry or investigation on behalf of HHS. There will rarely be a need for HHS, rather than an institution, to conduct an inquiry or investigation, but if it is necessary, the OIG would carry out that responsibility. Sections 93.400, 93.404, 93.500, and 93.523.

For more information on the changes see the informational documents on the ORI home page.
Third RCR Expo Scheduled for SRA Meeting in Milwaukee in October

At least 9 institutions and organizations will exhibit the RCR instructional materials they have developed at the third RCR Expo that will be held in conjunction with the annual meeting of the Society of Research Administrators International in the Midwest Airlines Center in Milwaukee on October 17-18, 2005.

The exhibiting institutions and organizations and title and description of their resource follow:

**Exhibitor:** Clinical Tools, Inc.  
**Product:** An Interactive, Internet-based Course for the Oversight of Data Management.  
This course includes background information and tools and resources to help researchers oversee the management of data. The course contains information and suggestions about defining research staff roles and responsibilities related to data management and establishing a communication plan. Interactive features – such as a self-quiz, case studies, and planning checklist – provide active learning.

**Exhibitor:** Boston College  
**Product:** RCR Educational Program for Administrative Staff Members  
This program provides training for administrative staff members and enhances the research environment of an institution that uses it. The program will train research administrators to 1) identify when situations present ethical conflicts, 2) reason among possible courses of action, and 3) effectively implement their best solution to the problem.

**Exhibitor:** University of California Los Angeles  
**Product:** An Interactive Web Course on Research with Human Subjects.

This course includes didactic text, illustrative scenarios and a large annotated bibliography. Real life scenarios are used for pedagogical purposes. The course book includes sections on Experimental Design, Consent, Oversight, Conflicts of Interest, International Research, Genetics, and Malfeasance-Misconduct.

**Exhibitor:** Northern Illinois University  
**Product:** Active Learning Online on Responsible Mentoring and Collaboration  
These modules use adult learning principles based on the Kolb Learning Theory and active learning principles, and make use of the relationships between the two topics. The modules contain a variety of activities such as games, quizzes, cases, and decision trees for engaging diverse learners.

**Exhibitor:** San Diego State University  
**Product:** Web-based Training Course for Community Health Workers and Other Novice Research Staff  
This online course is targeted at community health workers who may have no or little experience in research. Basic knowledge of research methods is provided to ensure that protocols are carried out as intended.

**Exhibitor:** Ohio State University  
**Product:** Assessment Tool for Evaluating University RCR Programs  
The assessment tool helps research administrators evaluate RCR programs. The computer-based instrument interacts the administrator through specific components of an RCR program. The user is able to input information about personnel within the institution who performs RCR tasks. A final printout allows the institution to easily view strengths in the RCR program and gaps in the program.

**Exhibitor:** Children’s Hospital of Philadelphia  
**Product:** A Guidebook for Mentoring International Postdocs  
The guidebook with video supplement addresses the special challenges associated with the training and career development of this large subgroup of postdocs. This electronic guidebook is divided into five content areas, with interactive elements and one or more videotaped vignettes illustrating common problems and alternative courses of action. This training guide is expected to be an effective method of identifying issues, raising awareness, and facilitating problem-solving, with the goal of promoting a positive mentoring environment for both mentor and trainee.
Misconduct Investigations Show Even Split in Findings

Respondents in research misconduct cases have about a fifty-fifty chance of a misconduct finding being made against them if an allegations reaches the investigation stage, according to an analysis of investigations closed by ORI from 1994-2003.

ORI closed 259 investigations during the 10 year period; 133 (51 percent) resulted in research misconduct findings. About 15 percent of the 1,777 allegations received by ORI during that period progressed to an investigation. ORI does not pursue most of the allegations received because they do not contain sufficient information to be actionable or they do not fall under PHS jurisdiction. Some allegations are referred to other agencies.

The number of closed investigations substantially declined (35 percent) between the first and second five-year periods while the percent of investigations producing research misconduct findings increased, but the number of research misconduct findings declined. See Table 1.

The PHS imposed 302 administrative actions on the 133 respondents against whom findings of research misconduct were made for an average of 2.3 actions per respondent. The PHS employed 6 administrative actions during the period: (1) prohibition from advisory service to the PHS, (2) debarment or voluntary exclusion from receipt of federal funds; (3) conducting research under supervision, (4) retraction or correction of published literature, (5) certification of data in PHS grant applications, and (6) certification of acknowledgment of sources. Administrative actions were generally imposed for 3 years, but ranged from 2 to 10 years.

The most frequent administrative actions were prohibition from advisory service to the PHS, given to 95 percent of the respondents, and debarment or voluntary exclusion from the receipt of federal funds, applied to 65 percent of the respondents. See Table 2.

There was little or no change in the percent of respondents prohibited from advisory service to the PHS, conducting research under supervision, or the retraction or correction of published literature between the comparison periods. Noticeable change occurred in the use of debarments and voluntary exclusion and the certification of data or sources.

**International Guide to Human Protections**

An easy reference to the laws, regulations, and guidelines governing the protection of human subjects in 55 countries has been compiled by the Office of Human Research Protections (OHRP) for institutional review boards and researchers engaged in international research.

The International Compilation of Human Subject Research Protections is available on the OHRP website at http://www.hhs.gov/ohrp/.
**Conference, Workshop, and Meeting Proposals Due April 1, 2006.**

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, 2006**. Proposal instructions and an application form are available on the ORI web site at http://ori.hhs.gov/html/programs/confworkshops.asp. Please submit your proposal electronically to stitus@osohs.dhhs.gov. Call Dr. Sandra Titus at 240-453-8400.

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