
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

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A Message from the Director
Thomas P. Davis, Ph.D.

This month we highlight *Updates on Research Misconduct from the Office of Research Integrity (ORI)*. You may access the ORI website at: <http://ori.dhhs.gov/>.

We wish you all a happy holiday season.

UPDATES ON RESEARCH MISCONDUCT FROM THE OFFICE OF RESEARCH INTEGRITY

ORI Issues Informational Documents on New Regulation

(Information extracted from the September, 2005 issue of the *Office of Research Integrity Newsletter*, Volume 13, No. 4)

Two new documents are available on the Office of Research Integrity (ORI) home page (<http://ori.dhhs.gov/>) 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 15, 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.

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.”

In addition to these documents, ORI intends to draft a new version of the ORI Model Policies and Procedures that have been utilized by numerous institutions to comply with the prior regulation.

“ORI encourages the research community to make comments on these and future documents and let us know if they are helpful, whether they contain errors or mistakes, or how they can be improved,” Pascal said. “ORI is committed to working collaboratively with the research community in implementing the new regulation.”

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 Office of Research Integrity website at <http://ori.hhs.gov/policies/regulations.shtml>.

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.

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.

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.

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."

UNIVERSITY OF ARIZONA RESEARCH AND SERVICE GROUP (RSSG)

HUMAN SUBJECT PROTECTION PROGRAM

≧Highlights≦

Federal Regulations and Arizona State Law

The Code of Federal Regulations requires that Institutional Review Boards review proposed research with regard to applicable law 45 CFR 46.107(a). Abiding by Federal laws, regulations, and guidelines however is not enough. State laws

must also be adhered to and each state has its own statutes, regulations, and case law that may impose stricter or additional requirements on research than those imposed by federal regulations. The issues affected by state law can include the following:

- Age of consent;
- Capacity to consent/legally authorized representatives and who can serve in that capacity;
- Child assent;
- Genetic research;
- Confidentiality of medical records;
- HIV/STD reporting requirements; and
- Laws governing referral fees, recruitment methods, clinical research, investigational drugs, vulnerable patients, medical practice and delegation of authority to perform procedures

One way in which federal laws and state laws interact is that federal laws defer to state law in determining the age of consent for participation in research. For example, in the state of Arizona, the age in which an individual may consent to participate in research is 18 years of age or older.

State laws can also govern who can make health care decisions. In the state of Arizona, a hierarchy not only includes family members but siblings, and close friends.

Another Arizona state law that can affect research is the use of tissue that comes as a result of a spontaneous abortion. These tissues can be used for research purposes whereas tissue from a terminated pregnancy cannot be used for research purposes.

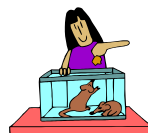
State laws which require certain activities and conditions are also important. In the state of Arizona child and elder abuse are reportable activities. However, in a research study it is not required that the researcher report such activities if they are not among those individuals required to report abuse such as physicians, nurses, counselors, social workers, etc. Additionally, under Arizona state law, the status of a person infected with a Sexually Transmitted Disease must be reported by a health care provider to the local health department (within 5 business days of the diagnosis/treatment).

Federal regulations require that researchers conduct research in compliance with applicable state law. State law can affect researchers in a number of ways and in a variety of situations. Although the above-mentioned areas can affect research conducted in the state of Arizona, there are numerous other instances in which state laws can

impose additional restrictions. Understanding how and when to apply state law is an ongoing challenge to the research community.

*Kaltman, S., & Isidor, J. (2002). State Law. In R. J. Amdur and E. A. Bankert (Eds.), Institutional Review Board Management and Function (pp. 339-341). Sudbury, MA: Jones and Bartlett.

University of Arizona – Animal Care Quality Care for Research Animals



Always keep the following tips in mind:

- It is best to keep research and office areas secured at all times.
- If you work in or around a research area, wear identification and be prepared to present it. If you see people in your research area not displaying an ID card, ask them if they need assistance.
- Non-staff people in a research area should be escorted by a staff member at all times.
- You know your work areas the best. Do not handle suspicious or unknown packages.
- Watch your area for strangers and unusual activity. If you see someone unknown to you in a research area, ask him or her if you can help.
- Be particularly aware of vehicles that have been left unattended near university buildings.
- Watch for doors or windows that have been propped open or marked with graffiti.
- Back-up valuable computer data and store it off site.
- Change the password on sensitive databases, using a combination of symbols and upper and lower case letters.
- Be cautious of unusual e-mail messages and do not open unfamiliar attachments.
- Monitor your Web site for potential defacement.



News from HIPAA.....

HIPAA Update on National Provider Identifiers

The Center for Medicare and Medicaid Services (CMS) will replace the use of Unique Physician

Identification Numbers (UPINs) with National Provider Identifiers (NPI) on May 23, 2007. The initial replacement will be in the CMS claims processing system

HIPAA requires that health care providers have a national standard identifier to use in the health care system, and CMS has stated that the NPI will be that identifier.

Jeniece I. Poole, Privacy Officer
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Good Laboratory Practices (GLP)

Information for EPA researchers

NAFTA Guidance for Conducting Terrestrial Field Dissipation Studies

Under the North American Free Trade Agreement (NAFTA), EPA and the Canadian Pest Management Regulatory Agency (PMRA) have agreed to harmonize their testing guidelines so that one set of tests can be used for the registration of pesticides in Canada and the United States. The NAFTA harmonized guidance for terrestrial field dissipation (TFD) studies are conducted to demonstrate the transformation, transport, and fate of pesticides under representative actual use conditions. These field studies are needed to substantiate the physicochemical, mobility, and biotransformation data from laboratory studies. Environmental fate studies have shown that pesticide dissipation may proceed at different rates under field conditions and may result in degradates forming at levels different from those observed in laboratory studies. The objective of this revised guidance document is to help ensure that TFD studies are conducted in a manner that will provide risk assessors and risk managers with more confidence in the data generated and with a better understanding of the assumptions and limitations of the data and estimated half-lives of the pesticide.

The revised guidance can be found at: http://www.epa.gov/oppefed1/ecorisk_ders/efed_final_draft_tfd_guidance.pdf.

Marilyn M. Marshall, QAO, (520) 621-1469



Radiation Control

The Radiation Control Office is offering to permanently transfer the following items to a University department in need of a network printer.

1. Hewlett Packard Laser Jet 4Si network printer.

2. Two 4Si laser printer cartridges.
3. Extra paper trays.

Please note the equipment is under no warranty via manufacturer or the Radiation Control Office. Interested department must transport equipment and sign transfer of equipment memo for Property Management.

Please call Lisa or Diane at 626-6850 for additional information.

Upcoming Conferences/Workshops

Teaching Research Ethics – A Workshop at Indiana University

Thirteenth Annual Workshop, May 10-13, 2006

The need for explicit training for scientists in research ethics is widely recognized; mentoring and modeling ethical behavior are no longer considered sufficient. The National Institutes of Health, The National Science Foundation, the American Association for the Advancement of Science, and the Council of Biology Editors, among many other professional organizations, have expressed concern over scientists' ability to recognize and deal with the ethical questions that arise in the course of research and publication. These organizations and others have voiced similar concerns over the need to ensure that the next generation of scientists can recognize and resolve difficult and often subtle issues in the responsible conduct of research.

The Poynter Center has extensive experience in designing curricular materials for teaching the responsible conduct of research and in conducting faculty development workshops in teaching ethics.

Much more information regarding this workshop may be found at the following web address: <http://poynter.indiana.edu/tre/>. You may also contact Glenda Murray, Program Associate, at (812) 855-0262, or via email at glmurray@indiana.edu.

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*The P.R.I.E. newsletter is researched
and compiled by Ruth Kurash Daniels.*

Words of Wisdom:

*“If there is no joyous way to give a
festive gift, give love away.”*

~ Unknown