
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

June 1, 2007

Volume 7, No. 6

This month the Program in Research Integrity Education (P.R.I.E.) newsletter article highlights the United States Department of Health and Human Services *Fact Sheet*, which focuses on "Promoting Integrity in Research." You will find this, and more information, at the Health and Human Services (HHS) web address, which is: <http://www.hhs.gov/news/factsheet/integrity.html>.

Announcements:

The following is an excerpt from an announcement made on May 10, 2007, in a 3D Memo from Dr. Leslie P. Tolbert, Vice President for Research, Graduate Studies and Economic Development.

"It gives me great pleasure to announce the appointment of Lucinda Rankin, Ph.D., as Research Integrity Office (RIO) The RIO is an important post at the University as it strives to preserve high scholarly standards through the institutional oversight procedures outlined in UHAP 2.13.09. Dr. Rankin is a lecturer in the Department of Physiology, College of Medicine, and last month was selected as one of the 2006-2007 recipients of the Graduate and Professional Education Teaching and Mentoring Awards."

Our best wishes go out to Dr. Rankin!

On May 29, 2007, President Robert Shelton distributed via email a memorandum of which the subject was: *UA Ethics and Compliance Hotline*. Below is an excerpt from the memo.

I am pleased to announce the establishment of a 24-hour a day University of Arizona Ethics and Compliance Hotline program beginning July 1, 2007. The "Hotline" telephone number is (886) 364-1098.

Establishing the UA Ethics and Compliance Hotline program provides a new reporting mechanism and enhances existing programs on campus. The new program assures that employees, guests, students, or members of the general public having concerns about perceived ethics and compliance violations can express their concerns to a non-University party anonymously and have those concerns addressed by the appropriate University officer or unit.

The "Hotline" telephone number may be used to report many perceived illicit or undesirable activities such as: Fraud, Waste, Abuse, Hate crimes/bias-related incidents, Non-compliance with regulatory requirements.

However, the hotline should not be used to report emergencies, crimes or situations placing the caller or someone else in imminent danger. These activities should be reported immediately to the University of Arizona Police Department (UAPD) tel. 9-1-1.

For more information you may access the following web site:

http://www.president.arizona.edu/prescomm_mor_e.cfm?t_ID=3

Promoting Integrity in Research

Overview:

The Department of Health and Human Services (HHS) operates a collaborative system to promote integrity in biomedical and behavioral research supported or conducted by agencies of the U.S. Public Health Service (PHS). The system for preventing, detecting, and investigating research misconduct and promoting research integrity involves cooperative efforts among individual scientists, research institutions, and PHS agencies, especially the National Institutes of Health. The HHS Office of Research Integrity (ORI) oversees this system. Some 4,000 institutions receive research funds from PHS agencies. Institutions that receive PHS support for research or research training are required to establish policies to respond to allegations of research misconduct, including protections for both the accused (also referred to as the respondent) and the complainant. When misconduct is found, HHS may propose that certain administrative and corrective actions be imposed. If a finding of research misconduct is made, the respondent may request a hearing before the HHS Departmental Appeals Board (DAB).

In 2005, HHS adopted new regulations on research misconduct on May 17, 2005 to implement the Federalwide definition of research

misconduct and make other updates to the original HHS regulation published in 1989. The new regulation was published at Federal Register, Vol. 70, p. 28370, May 17, 2005. It will be codified as 42 CFR Part 93. The new definition of research misconduct means “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” This regulation became effective on July 16, 2005 and will apply to any new allegations made after that date. All allegations made before July 16, 2005, will be subject to the old definition of scientific misconduct included in 42 CFR Part 50, Subpart A. A new Subpart E of 42 CFR Part 93 will govern any appeals to the HHS Departmental Appeals Board, where the respondent requests an opportunity to contest the charges of research misconduct after July 16, 2005. Both the new regulation and the old regulation are posted on the ORI website at the following: <http://ori.dhhs.gov> More information about HHS efforts to promote research integrity is available on the Web at ori.dhhs.gov.

BACKGROUND

Public concerns about integrity in research gained national attention in the U.S. following the public disclosure of misconduct cases at four major research centers in 1980. Congressional and public attention to the issue continued throughout the 1980s. In 1985, Congress enacted the Health Research Extension Act, which required institutions seeking PHS research funds to establish “an administrative process to review reports of scientific fraud” and “report to the Secretary any investigation of alleged scientific fraud which appears substantial.” To carry out the law, the PHS in March 1989 created the Office of Scientific Integrity (OSI) in the Office of the Director at NIH, and an Office of Scientific Integrity Review (OSIR) in the HHS Office of the Assistant Secretary for Health. In June 1992, these offices were merged to create the Office of Research Integrity (ORI), and HHS established a mechanism to provide scientists formally charged with misconduct with an opportunity for a hearing.

In 2000, HHS modified ORI's role to focus more on education and outreach. In addition to its oversight responsibilities, ORI now emphasizes education and training in the responsible conduct of research in order to promote research integrity and prevent misconduct, and

research and evaluation programs. Consistent with this mission, ORI has developed resources with the research community to provide education programs in the responsible conduct of research and, in collaboration with NIH, developed a new research program to study integrity issues.

RESEARCH INTEGRITY - A SHARED RESPONSIBILITY

Promoting research integrity requires a collaborative effort involving scientists, institutions and the PHS. The PHS is responsible for ensuring the integrity of the research it supports, protecting public health, and monitoring compliance with the misconduct regulations. Under the ORI regulation, primary responsibility for responding to allegations of research misconduct rests with institutions, which generally have the administrative and scientific expertise to assess allegations.

On occasion, an institution may not be in a position to properly conduct its own investigation. In such instances, institutions can enlist the services of other organizations or individuals that specialize in conducting such investigations. In 2000, ORI established a Rapid Response for Technical Assistance program to provide direct help to institutions conducting inquiries and investigations. ORI generally is responsible for overseeing the collaborative system for promoting research integrity in PHS-supported research programs. ORI also provides technical assistance and policy guidance to enable institutions to conduct their own investigations effectively. ORI staff includes scientists, attorneys, educators and other personnel with expertise and experience in oversight and investigations, education, technical assistance, research and evaluation, and compliance issues. ORI staff responds to more than 200 allegations of research misconduct each year. Since 1992, ORI has addressed about 3,000 allegations of misconduct, about 20 percent of which require a formal inquiry.

RESPONDING TO MISCONDUCT ALLEGATIONS

HHS regulations require each PHS applicant or awardee institution to have an administrative policy for responding to allegations of research misconduct. Generally, when an allegation of research misconduct is received by an institution, a preliminary assessment is conducted to determine whether the allegation falls within the PHS definition of misconduct, whether PHS

funding or an application for funding is involved, and whether the allegation is specific enough to allow for investigation. If these criteria are met, the institution initiates an inquiry to determine whether there is sufficient substance to the allegation to warrant a full investigation. If an institution decides that an investigation is needed, the institution seeks to determine whether misconduct occurred, who committed it, and the extent and seriousness of the misconduct. If misconduct is found, many institutions permit the respondent to appeal the finding within the institution.

In some cases, it may be necessary for HHS to conduct the investigation, such as when an allegation raises special public health or safety issues or an unavoidable conflict of interest exists for the research institution. When an HHS investigation is required, ORI will refer the allegation to the HHS Office of Inspector General (OIG). The OIG may supplement its investigation team with scientific experts as necessary. If the OIG determines that a criminal statute was violated, the matter is referred to the U.S. Department of Justice. The U.S. Department of Justice may also initiate its own civil or criminal investigation. The institution must submit a report of the investigation and its resulting findings to the ORI. The ORI reviews the report to determine whether the investigation was thorough, competent, objective, and fair. As part of its oversight responsibilities, ORI will perform a careful review of the record of the institution's investigation, including documents and witness testimony, to determine whether the available evidence supports the institution's findings.

If an investigation results in a finding of misconduct, ORI will review the finding and the supporting evidence as well as any actions recommended by the institution. If ORI concludes that a finding of misconduct is warranted, it will issue PHS findings of research misconduct and seek to resolve the case through appropriate administrative actions. Potential administrative actions may include: correction of the scientific literature; special plan of supervision to ensure integrity of future scientific research; required certification of the accuracy of scientific data; required certification of the accuracy of sources and contributions for scientific ideas and writings; and prohibition against service on PHS advisory committees or as a consultant. Under the ORI regulation, the HHS

Debaring Official may also issue a notice of proposed debarment, which would prohibit the accused scientist from receiving Federal funds. These actions are for specified periods depending on the nature and gravity of the misconduct.

If the ORI and Assistant Secretary for Health make a finding of misconduct, the accused scientist may request, within 30 days of receipt of the notification of findings, a hearing before the HHS Departmental Appeals Board (DAB) under the new Subpart E of the revised 2005 research misconduct regulations. Throughout this process, counsel may represent the accused scientist, and the ORI (with legal support from the HHS Office of the General Counsel) will represent the Department.

PROTECTING ALL PARTICIPANTS

The HHS research misconduct regulation provides protection for respondents and complainants in research misconduct cases. Institutions are required to protect the confidentiality of the individuals involved, including the respondent. Respondents are informed about the allegation. During an inquiry, a respondent is usually interviewed, confronts and presents evidence, and suggests witnesses. The draft inquiry report is presented to the respondent for comment. If an investigation follows, the respondent is interviewed, sometimes more than once, confronts and presents additional evidence, and suggests additional witnesses. The investigation report is also presented to the respondent for comment. In addition to protecting the confidentiality of the complainants, institutions are required to undertake diligent efforts to protect the position and reputation of those individuals who make allegations of research misconduct in good faith. The institution is also required to take reasonable steps, as appropriate, to restore the reputations of respondents when allegations are not confirmed.

Opportunities Abound for Promoting RCR Education

Reprinted from The Office of Research Integrity (ORI) web site at: <http://ori.dhhs.gov/education/RCRopportunities.shtml>

Numerous opportunities exist within colleges, universities, medical schools, and research institutes to promote responsible conduct of research (RCR) education through activities that already routinely happen in those organizations, according to 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

**UNIVERSITY OF ARIZONA
RESEARCH SUPPORT SERVICES GROUP
(RSSG)**

**HUMAN SUBJECTS
PROTECTION PROGRAM**

≧Highlights≦

**Waiver of Parental Permission
in Research With Children***

The Code of Federal Regulations Part A of 45 CFR 46 defines children as a vulnerable population that requires additional protections. One specific protection afforded a child participating in research is the permission of the parent(s). As required, all information that is normally provided to a research participant must be given to the parent in order for the parent to make an informed decision. However, under certain circumstances it is possible to waive the permission by the parent.

Part A of 45 CFR 46 provides four criteria for waivers of any or all of the elements of informed consent (these same criteria apply to waivers of parental permission). However, in order to waive any or all of the elements of informed consent, the Institutional Review Board (IRB) must determine that all criteria listed below have been met.

- *The research involves no more than minimal risk.* Minimal risk means “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”
- *The waiver or alteration will not adversely affect the rights and welfare of the subjects.* Since neither “rights and welfare” nor “adverse affect” are defined in the regulations, the IRB must make this determination based on interpretation of the proposed research study. It is important to remember that other laws protect the rights of the child and the parent. For example, The Protection of Pupil Rights Amendment (PPRA) may require written parental permission for research on sensitive topics. In other words even though a waiver could be made under 45 CFR 46, the PPRA would not allow such a waiver if the topic presented to the child were of a sensitive nature.
- *The research could not practicably be carried out without the waiver or alteration.* Inconvenience and expense are not factors that are considered acceptable when considering a waiver. Scientific validity can be considered a viable factor.
- *Whenever appropriate, the participants will be provided with additional pertinent information after participation.* However, this requirement may also be waived due to the specific wording of “whenever appropriate” and may not be practical for the researcher or the participant.

Although a waiver of any or all of the elements of informed consent exists, it is important to remember that researchers must respect the rights of parents with regard to their child’s research experience and be committed to protect those children who are central to that research project.

*Hicks, L (2006). Research in Public Schools. In E. A. Bankert and R. J. Amdur (Eds.), Institutional Review Board Management and Function (pp. 341-345). Sudbury, MA: Jones and Bartlett.



News from HIPAA.....

Centers for Medicare and Medicaid Services (CMS) expects to propose a regulation in July that will tighten the HIPAA security rule in the

wake of several recent security incidents related to the use of laptops and other portable and mobile devices storing protected health information, says a notice in the April 30 *Federal Register*. The notice is HHS's semi-annual regulatory agenda, which identifies regulatory actions of interest that the agency intends to take. The agenda's deadlines are not always met, but they do provide a preview of what HHS will be focusing on. Some of the regulatory actions that may be of interest to the health care IT industry include:

- ✦ This month, the slated publication of the data dissemination processes for the National Provider Identifier;
- ✦ A proposed rule, expected to be released in August, to set e-prescribing standards under the Medicare Part D drug benefit program;
- ✦ A proposed rule slated for August to exempt some investigatory materials in databases from certain provisions in HIPAA in order to restrict the disclosure of confidential data that can impede ongoing investigations, invade personal privacy and reveal confidential sources;
- ✦ The formation in September 2008 of a standard plan for electronic claims attachments; and
- ✦ Final HHS action, expected in June 2009, to identify version 8.1 of the National Council for Prescription Drug Programs' SCRIPT standard as a "backward compatible" update.

To view HHS's semiannual regulatory agenda, visit AIS's [Government Resources](#); click on "2007 *Federal Register*."

Jeniece Poole, Privacy Officer
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Good Laboratory Practices: (GLP)

Newly released May 2007 Computerized Systems Used In Clinical Investigations

US Department of Health and
Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Commissioner (OC)

This guidance supersedes the guidance of April 1999 and supplements the guidance for industry on Part 11, Electronic Records; Electronic signatures—Scope and Application.

The principles outlined in this guidance should be used for computerized systems that contain any data that are relied on by an applicant in support of a marketing application, including computer-

ized laboratory information management systems that capture analytical results of tests conducted during a clinical trial.

This document can be down loaded from
<http://www.fda.gov/cder/guidance/7359fnl.pdf>

Contact for information and guidance for good practices....

Marilyn M. Marshall, SpM, Quality Assurance Officer
Office of the Vice President for Research
621-1469 (p), 621-1429 (f)

University of Arizona – Animal Care



Quality Care for Research Animals

Changes to Requirements in Documentation Section on IACUC Animal Protocol Review Form

Recently, the UA was visited by the United States Department of Agriculture Animal Care Veterinarian. The visit included inspection of the animal facilities and records. The inspector indicated that our current IACUC protocol form is not specific enough to ensure that the search for alternative techniques (3R's: Replace, Reduce, Refine) is adequately addressed. She also did not find evidence in most protocols that databases specifically geared to address alternatives were commonly used by researchers at the UA.

To address the concerns, which could result in citations for violation of the Animal Welfare Act, the IACUC is requiring that all literature searches performed after AUGUST 1, 2006, must include at least one search engine that can address alternative techniques. Examples of acceptable data bases include:

- **ALTWEB:** <http://altweb.jhsph.edu/>
Alternatives to Animal Testing on the Web serves as a gateway to alternatives news, information and resources on the Internet and elsewhere.
- **ALTBIB:** <http://toxnet.nlm.nih.gov/altbib.html>
This site is under the National Library for Medicine.
- **AnimAlt-ZEBET Database:**
<http://www.dimdi.de/static/en/db/index.htm>
This German site provides a full-text database of alternative methods (3Rs) to animal experiments in biomedicine and related fields (Click on Databases, then Databases A-Z, and then on AnimAlt-ZEBET)
- **ECVAM SIS (Scientific Information Service) Database:**

<http://www.nc3rs.org.uk/category.asp?catID=3>

Provides factual and evaluated information on advanced non-animal methods for toxicology assessments; offers full method descriptions, including development and validation status:

- INVITRODERM:
<http://www.invitroderm.com/> Provides alternatives to skin irritation/corrosion testing in animals.
- ALTWEB Pain Management (Anaesthesia/Analgesia) Database:
http://apps1.jhsph.edu/altweb/aadb/aadb_search.cfm Information about anesthesia and analgesia for most commonly used laboratory animals.
- ALTWEB Humane Endpoints Database:
<http://apps1.jhsph.edu/altweb/humane/> Designed to help researchers find the earliest "endpoint" that is compatible with the scientific objectives of their research, i.e., the earliest point at which an experimental animals pain and/or distress is terminated, minimized, or reduced.
- European Resource Centre for Alternatives in Higher Education (EURCA):
<http://www.nc3rs.org.uk/category.asp?catID=3> Information about alternatives to using animals in higher education.

The following sites can help you develop strategies for searching for alternatives and can link you to data bases that will perform the searches:

- Animal Welfare Information Center: Alternatives:
http://riley.nal.usda.gov/nal_display/index.php?info_center=3&tax_level=1&tax_subject=183. This site provides many avenues to consider for searches and gives information on how to design your search for alternatives.
- Databases section of the University of California Center for Animal Alternatives (UCCAA) website:
http://www.vetmed.ucdavis.edu/Animal_Alternatives/database.htm
- FRAME Guide to Searching for Alternatives:
<http://www.frame.org.uk/Searching%20for%20Information/Search%20Guide%20Index.htm>

If you have questions regarding this new requirement, please contact one of the following individuals:

Richard Vaillancourt, Chair IACUC: 626-4374
vaillancourt@pharmacy.arizona.edu

Susan Wilson-Sanders, IACUC member: 626-1066
wilson-s@u.arizona.edu

Paula Johnson, IACUC member: 621-3483
pauladj@email.arizona.edu



Radiation Control



HHS Launches New Online Toolkit for Medical Responses to Radiation Emergencies

The United States Health and Human Services (HHS) has developed a new downloadable online diagnostic and treatment toolkit designed for health care providers, primarily physicians, who may have to provide medical care during a radiation incident.

The new information package includes easy-to-follow procedures for diagnosis and management of radiation contamination and exposure, guidance for the use of radiation medical countermeasures, and a variety of other features to facilitate medical responses. This new information package is now available on the Radiation Event Medical Management (REMM) Web site: (<http://REMM.NLM.GOV>).

“The REMM toolkit is part of our effort to improve public health emergency preparedness and response,” Secretary Leavitt said. “It reflects the department's commitment to help instill a spirit of preparedness throughout our nation.”

Guidance on diagnosis and treatment will help health care providers by describing:

- types of radiation emergencies they may face
- initial medical actions at the incident site and or medical facility
- key steps in patient care

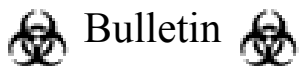
Critical information is presented in a format that will quickly and efficiently orient and guide health care providers during a mass casualty radiation event. In addition to online access, federal, state and local medical response teams will be able to download REMM information on laptop computers for quick access when they are deployed to a radiation incident or for training sessions. Users can also register for automatic e-mail updates whenever information is changed or added to the REMM Web site.

Future plans include formatting the REMM material for use on Personal Digital Assistant (PDA) devices, additional multimedia graphics, and more topic areas, such as follow-up patient care of radiation's chronic effects.

A team of subject matter experts from the HHS' Office of the Assistant Secretary for Preparedness and Response, the National Institutes of Health's National Cancer Institute and National Library of Medicine and the Centers for

Disease Control and Prevention collaborated on the development and design of the REMM tool.

Institutional Biosafety Committee



Frequently Asked Questions....

Question: Do I have to fill out a new MUA if the grant application is for the purpose of continuing an already approved project?

Answer: You do not have to submit a new MUA for a project that has been previously approved by the IBC when no changes have occurred relating to key criteria such as title change, sponsor, project description, procedures relating to biosafety practices and/or biosafety containment level, location of work and personnel.

OPPORTUNITIES FOR ON-LINE ETHICS TRAINING

Online Research Ethics Course

This course was developed through the Practical Ethics Center at the University of Montana with Office of Research Integrity support during the 2002-03 academic year. Six course sections include: *Session One* (Ethical Issues in Research); *Session Two* (Interpersonal Responsibility); *Session Three* (Institutional Responsibility); *Session Four* (Professional Responsibility); *Session Five* (Animals in Research); *Session Six* (Human Participation in Research).

The following web address contains more information regarding this valuable online course: http://ori.hhs.gov/education/products/montana_round1/research_ethics.html

Ethical Guidelines for Gifts to Physicians from Industry

Free educational modules now available

The American Medical Association's (AMA) national initiative on *The Communication of Ethical Guidelines for Gifts to Physicians from Industry* is now offering four free online modules for CME credit. Each educational module is available in two formats:

- Online self-study for CME credit; and
- Downloadable resources educators can use to build one-hour learning experiences.

These educational modules will help satisfy Accreditation Council for Graduate Medical Education (ACGME) requirements for education on

professionalism and industry professional relationships, as well as similar requirements by the American Board of Medical Specialties (ABMS).

For more information, you may visit the following internet web address: <http://www.ama-assn.org/ama/pub/category/8405.html>.

On-Line Module or Short Course in "The Ethics of Research with Human Subjects" *The Least of My Brothers*

Funded by the **National Institutes of Health**
(Grant Number 1 T15 AI07601)

The Least of My Brothers is an on-line module (or short course) in the ethics of research with human subjects. For more details and course information, please access the following internet web address: <http://poynter.indiana.edu/sas/lb/>, or you may also contact Kara Lochridge at: (812) 856-4968, or klochrid@indiana.edu.

Upcoming Conferences/Workshops

June 10-15, 2007

Teaching Survival Skills and Research Ethics Workshop
Snowmass, CO
Co-sponsors: University of Pittsburgh and NIH

June 11-15, 2007

<http://www.hsph.harvard.edu/bioethics/>
Ethical Issues in International Health Research Workshop
Boston, MA

September 17-19, 2007

First World Conference on Research Integrity
Lisbon, Portugal
Co-sponsor: European Science Foundation
To pre-register: www.esf.org/conferences/researchintegrity

October 18-21, 2007

programcommittee@asbh.org
American Society for Bioethics + Humanities (ASBH)
Renaissance Washington DC Hotel
Washington, DC

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Words of Wisdom:

*"Better than a thousand days of
diligent study is one day with a great
teacher."*

Japanese proverb