

---

# University of Arizona Program in Research Integrity Education Monthly Newsletter

## *A Federally Mandated Compliance Education Program*

---

October 1, 2005

Volume 5, No. 10

---

### *A Message from the Director*

*Thomas P. Davis, Ph.D.*

This month's newsletter is very important to read and understand. It includes new Public Health Service (PHS) intramural research and contract rules. We trust you will read these new rules and realize the Office of Research Integrity (ORI) and the Office of Science and Technology Policy (OSTP) are constantly reviewing the definitions of research misconduct and how it is applied to misconduct in science.

### **Primary Changes Between New and Old Research Misconduct Regulations**

#### *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 allegation 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 (ALJ), rather than a three-person panel of the Departmental Appeals Board (DAB), *Subpart E, Sections 93.500 - 93.523*.

### **Responsibilities of ORI and the Assistant Secretary for Health (ASH)**

The new rule changes the respective responsibilities of ORI and the (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 Debarment Official. If the ASH takes final action on the ALJ's recommended decision and the Debarment 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.

---

### **OPPORTUNITIES FOR ON-LINE ETHICS TRAINING**

---

#### **Ethical Guidelines for Gifts to Physicians from Industry**

*Free educational modules now available*

The AMA's 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.

For more information visit the following site: <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. You may view more course information at the following web address: <http://poynter.indiana.edu/sas/lb/>, or you may also contact Kara Lochridge at: (812) 856-4968, or [klochrid@indiana.edu](mailto:klochrid@indiana.edu).

---

### **UNIVERSITY OF ARIZONA RESEARCH AND SERVICE GROUP (RSSG)**

---

#### **HUMAN SUBJECT PROTECTION PROGRAM**

#### **≧Highlights≦**

#### **Expiration Date of Research Projects**

The expiration date of research projects can be found on the original approval letter, the most recently approved Periodic Review Form, and/or the informed consent document. The date that appears as the EXPIRATION date indicates that your project approval expires at the start of that day. The project approval is active through 11:59 pm on the day prior to the date listed.



#### **Good Laboratory Practices (GLP)**

#### **Report Writing**

The following is taken from the University of Illinois at Chicago web site and may be found at: [http://tiger.uic.edu/~magyar/Lab\\_Help/lghome.html](http://tiger.uic.edu/~magyar/Lab_Help/lghome.html)

A key ingredient for writing a good laboratory report is taking good lab notes and writing down observations.

### Experiment Title

Although self explanatory, the title helps you, as the student, define your understanding of the laboratory experiment.

### Purpose

A brief description (in your own words) of what scientific principle is to be tested or verified.

### Procedure

A brief outline of the experimental procedure, (a detailed report of all the steps taken is not necessary. Your lab instructors have a copy of the laboratory manual if a detailed review is needed). By including a procedure outline in the report your attention is focused on what happened during the experiment. A similar outline is used as preparation of the actual lab experiment.

### Data Collection

This is one of the most critical portions of the lab report. Without good data recording in the laboratory note book, completion of the lab write-up beyond this point is futile or will certainly seem so. Presentation of data in tables allows easy following of the coming data manipulations. Tables should be clearly labeled as to their content and numbered for ease of referral in the discussion section.

Part of the data may involve making observations (color changes, temperature changes, melting point, boiling point, the physical appearance of a chemical substance, etc.). The observations requested in the lab experiment are the bare minimum needed to perform the experiments. Sometimes extra observations you make may provide extra clues.

As an example: You are given a metal sample and told it was either pure gold (Au) or pure silver (Ag). The lab asks you to perform a series of chemical tests, wouldn't the metal's color give you a clue as to its identity? Keep your eyes open.

### Calculations

One clear example of each different type of calculation should be presented as a check of your work. Do not include pages full of each and every calculation - it just wastes your time and paper. Who wants to read 3 pages of the same calculations with different numbers?

### Uncertainty/Error Analysis

We all generally regard our answers as absolute. This is fine for expressions such as  $4 + 5 = 9$ , where the exact solution is known. However, in the real world of experimental chemistry no results (or very few, if any) are absolute.

Therefore, some estimation of the experimental uncertainty is necessary to help explain the results and to verify if the scientific principle tested holds.

### Discussion and Conclusion

This is an area which gives many students trouble. It requires looking at the experimental title, the purpose, the data and calculation sections of the lab report and bringing them all together. Sometimes it involves the comparison of the student's experimentally derived answer to a known literature value. Other times, it requires the student to identify an unknown from a list of unknowns based on the information gathered during the experiment.



## News from HIPAA.....

### HIPAA Requirements Redefined After Katrina Disaster

In order to facilitate rapid response in disaster situations, the office of Health and Human Services (HHS) announced that the HIPAA Privacy Rule allows covered entities (CE's) to "share patient information" in order to assist with disaster relief efforts.

CE's covered by the HIPAA Privacy Rule can now disclose protected health information (PHI) of patients in the following ways:

1. to provide treatment;
2. to notify those responsible for an individual's care of the patient's conditions;
3. to prevent a threat to the health and safety of people;
4. to enable facilities with a patient directory to tell people whether specific individuals are at the facility, and if so, their location and general condition.

HHS has given permission for health related PHI to be shared between covered and non-covered entities. They specifically stated that PHI could be shared with the American Red Cross in dealing with disaster victims.

Centers for Medicare and Medicaid Services (CMS) has stated that billings for services including transport from one facility to another would be covered by Medicare and Medicaid if the person was a Medicare or Medicaid recipient. In addition, providers need not be licensed in the state where services were rendered to bill Medicare or Medicaid.

University of Arizona – Animal Care  
Quality Care for Research Animals



**CERTIFICATION DATES  
FOR OCTOBER 2005**

**TO REGISTER FOR CLASS  
PLEASE GO TO:**

<http://www.iacuc.arizona.edu/training/register.html>  
to register online, or

<http://www.iacuc.arizona.edu/training/Class%20Registration%20Form.pdf>

for the easy print and fax form

If you are not sure if you have completed your classes, please contact Grace Aranda at: [garanda@u.arizona.edu](mailto:garanda@u.arizona.edu)

Public Health Service Policy places responsibility on the Institutional Animal Care and Use Committee (IACUC) for certification of personnel using or caring for animals. Our next set of classes will be held starting October 24, 2005. Certification letters will be awarded upon completion. As part of the protocol review process, **protocols are not approved without proof of certification of all individuals involved in the research study. Anyone working with animals must be certified in Laws and Regulations, Introduction to Animal Hazards Program (both now available online); the species with which they work; and Surgery & Anesthesia if they perform recovery surgery or anesthetize vertebrates.**

Admission to all animal facilities is limited to those persons who have completed the appropriate certification sessions and the Risk Assessment Questionnaire.

Be sure to mark your calendar. Be on time, anyone fifteen minutes late for a class will not be certified for that class.

***Classes may be cancelled if expected attendance is low.***

Protocols are not approved without proof of certification of all individuals involved in the research study. All those working with animals must be certified in Laws & Regulations and Introduction to Animal Hazards; the species with which they work; and Surgery & Anesthesia if they perform recovery surgery or anesthetize vertebrates. Admission to all animal facilities is limited to persons who have completed appro-

appropriate certification sessions and a Risk Assessment Questionnaire.

**Monday, October 24** \* *Room is around the corner from the Medical Bookstore*

Zoonotic Diseases of Amphibians, Reptiles, Fish & Birds: 10:00 - 11:30 a.m. in COM Rm 1108\*

**Wednesday, October 26**

Zoonotic Diseases of Nonhuman Primates: 10:00 - 11:30 a.m. in College of Medicine, Rm 1108\*

**Thursday, October 27**

Surgery & Anesthesia: 9:00 - 10:00 a.m. in Univ Medical Center Rm. 5403

**Friday, October 28**

Zoonotic Diseases of Wild Caught Rodents & Rabbits: 2:00 - 3:30 p.m. in COM Rm 1108\*

**Tuesday, November 1**

Zoonotic Diseases of Dogs & Cats: 10:00 - Noon in College of Medicine Rm 1108\*

**Wednesday, November 2**

Zoonotic Diseases of Big Game Wildlife & Livestock: 2:00 - 4:00 p.m. in COM Rm 1108\*

**Modules available online:**

Laws & Regulations (Mandatory)

Introduction to Animal Hazards Program (Mandatory)

Rodent Handling, Restraint & Techniques

Zoonotic Diseases of Laboratory Rodents & Rabbits

Various other species modules available too!

If you have questions, please contact Grace Aranda at: [iacutrnr@ahsc.arizona.edu](mailto:iacutrnr@ahsc.arizona.edu), or call 621-3931.

**The next set of classes will not be offered until the week of January 23, 2006.**

**Institutional Biosafety Committee**



*Bulletin*



**Responsibilities of  
Laboratory Workers**

Whoever works in the laboratory in a technical (rather than purely administrative) capacity is defined as a laboratory worker, whether the person is a faculty member, a student, an intern, a visiting scholar or a volunteer.

Laboratory staff are the most critical elements in maintaining a safe working environment. Each person must look out for their own safety and that of their co-workers. If individuals do not follow the university and laboratory-specific biosafety practices and procedures in the conduct of their laboratory duties, we cannot have a safe working

environment. It is the laboratory staff's responsibility to:

A. Conscientiously follow lab-specific biosafety practices and procedures.

B. Inform the Principal Investigator of any health condition that may require additional safety precautions so that they can be put in place.

C. Report to the Principal Investigator or the lab supervisor all problems, violations in procedure or spills as soon as they occur.

D. Report to the Biosafety Office any significant violations in biosafety policy, practices or procedures which are not resolved by the Principal Investigator.

E. Refuse to take any adverse action against any person for reporting real or perceived problems or violations of procedures to supervisors, the Principal Investigator, the Biosafety Office or members of the Institutional Biosafety Committee.



## **Radiation Control**

### **Clinical Inservices**

- Nursing In-services – For Nurses, Patient Care Technicians (PCT), Customer Support Associates (CSA), and others assigned to designated UMC patient wards where radiation is used.
- Medical X-ray In-services – For non-ward clinical personnel who work with diagnostic x-rays or sealed sources, including Radiology Technologists, Faculty Physicians, Community Physicians holding privileges at UMC, Fellows, Residents, and Interns, Radiology Attendants, and Biotechnical Support Services personnel in University Animal Care.
- Radiation Safety in Perioperative Services – For operating room personnel.
- Departmental In-services – Provided for many clinical service units, e.g. Nuclear Medicine,

Radiation Oncology, and Emergency Services, upon scheduled arrangement with the Radiation Control Office. New employees and personnel in these departments who fail to attend the annual in-service must attend an appropriate periodic in-service to satisfy the 45-day requirement. Contact RCO for guidance.

---

### **UPCOMING CONFERENCES/WORKSHOPS**

October 16-19, 2005

**Society of Research Administrators (SRA) International Annual Meeting**

Milwaukee, Wisconsin

October 20-21, 2005

**Responsible Conduct of Research: Essentials for Research Success and Integrity**

Pocatello, ID

Co-sponsor: Idaho State University

October 23-26, 2005

**48<sup>th</sup> Annual Biological Safety Conference**

Westin Bayshore, Vancouver, British Columbia

<http://www.absa.org/confsem.html>

October 25, 2005

**Promoting RCR in Research in the Social, Behavioral and Educational Sciences**

San Antonio, TX

Co-sponsors: American Association of State Colleges and Universities and the University of Texas-San Antonio

---

#### **University of Arizona Program in Research Integrity Education staff:**

**Thomas P. Davis, Ph.D. (Program Director)**

Alice C. Langen, Director, Research Compliance

Ruth K. Daniels, Program Coordinator and Editor of the P.R.I.E. Newsletter [rhk@u.arizona.edu](mailto:rhk@u.arizona.edu)

P.R.I.E. – Program phone number: (520) 626-6282

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

---

#### *Words of Wisdom:*

*“If you put off everything till you’re sure of it, you’ll get nothing done.”*

*~ Norman Vincent Peale*