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# University of Arizona Program in Research Integrity Education Monthly Newsletter

*A Federally Mandated Compliance Education Program*

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The Program in Research Integrity Education (P.R.I.E.) newsletter's featured article this month is entitled, "*Misconduct of Others – Prevention Techniques for Researchers.*" The article is reprinted from the *American Psychological Society (APS)* web site. Please see below for more information.

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## MISCONDUCT OF OTHERS *Prevention Techniques for Researchers*

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**BY JANE A. STEINBERG**  
Special to the *Observer*

Reprinted from the *APS Observer*

Published by the *American Psychological Society*

January 2002, Volume 15, Number 1

[www.psychologicalscience.org/observer/0102/misconduct.html](http://www.psychologicalscience.org/observer/0102/misconduct.html)

Few people can distinguish between the smell of day-old fish and the odor of the paper in which it was wrapped. That's just how it is with scientific misconduct. The misconduct of those working with you may become yours. In the worst case, your lab is shut for the investigation, your publications are retracted, and your name becomes suspect. Even if *you* reported the suspected misconduct, and the investigation is fair, the accuser and the accused may become intertwined as the investigation proceeds. All too often, the reporter and the reported blame each other, making the investigation protracted and contentious until the allegation is sustained or not.

The good news is that you can protect yourself against the misconduct of others by prevention techniques that mesh well with good supervision.

Exactly what are you trying to prevent? Federal regulations define scientific misconduct as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.<sup>1</sup> It does not include honest error or honest differences in interpretations or judgments of data. Other types of misconduct

can occur in the research setting, but these are addressed through other laws and regulations and are not considered *scientific* misconduct (e.g., theft, harassment, discrimination).

### PREVENTION STRATEGIES

Some believe that if staff or colleagues want to dupe you, they will. I do not think this is true; prevention can work. Begin by making it completely clear that fabricators will be caught. There is no need to say you are monitoring for misconduct, simply let your staff and partners know that you personally check and verify data collection, entry, and any corrections to the data. Then do it, and let them see you doing this! Ask questions about stray marks or erasures. If electronic data are written over or corrected, find out why.

If appropriate and reasonable for the study, ask participants if you may re-contact them for quality control reasons. If they consent to being contacted again, call some from each recruiter or data collector for verification. Ask them if the data collector actually met with them, if they meet the eligibility criteria, if they knew the recruiter/collector before the study, if the study ran the appropriate duration, or if all aspects of consent were covered. Take parallel precautions with animals by tracking animal usage and lab notes carefully.

Set a tone of respect for the research protocol and for study participants. Avoid hyperbole and jokes about getting the data *no matter what*. Someone could confuse your humor with pressure to generate findings through falsification, skimping on the prescribed human or animal protections, improper analyses, or misleading interpretations of results.

Inoculate staff against the temptation to find a "better" way to run the study midstream. Let them know you want to hear their ideas for the next study, but that fidelity to the current design is essential. Remind them that the current design is the only one approved by the institution's human or animal protection board. Explain what an unrecognized between-subjects

variable, such as a shift in procedures for some subjects, does to the study's analysis and interpretation. Then watch for individuals who are working too quickly or too well. Most protocols have an average run time - is anyone collecting data at a suspiciously fast rate? If so, find out why. Are the recruitment rates of one staff member significantly better than all others? Some people just have the knack, but you may want confirmation.

### **PROMOTE RESEARCH INTEGRITY**

Finally, and most positively, promote research integrity. Do so by teaching it in your classes and labs. Explicitly teach the standards of conduct in research psychology. Review cases of scientific fraud and the ramifications for the researchers, the field, and the public trust. Be sure that you explain what to do if misconduct is suspected at your institution.

Hold lab meetings to explain that some rules are not firm across labs or disciplines (e.g., authorship, ownership of data, and conflicts of interest) and present the rules that your lab follows. These shifting areas all require discussion at the beginning of a new collaboration so your new staff members know what to expect for their degree of contribution. My guess is that few entering graduate students have had such discussions, resulting in feelings of entitlement to authorship or a data file if they collect or analyzed data for you. I know I did. By making the meeting a discussion rather than a lecture about your lab's standards, you can learn about conventions from other labs and can incorporate desirable changes immediately. Such shared expectations avoid misperceptions over breeches in authorship and data access, which although less serious than allegations of falsification, are much more prevalent and generate plenty of hard feelings.

To close with some context, documented scientific misconduct is rare, but a little goes a long way. With each finding of misconduct, researchers across science ask if this could happen in their lab. They look for easy tip-offs to wrongdoing, but by the time there is reason to be suspicious, the damage may be done. By the time someone has made an unauthorized copy of your data set, you are in the thick of it.

The smart move is to incorporate preventive strategies into your every day business practices so staff and colleagues know what is expected of them and of you.

<sup>1</sup> [Code of Federal Regulations 42 C.F.R. Part 50, Subpart A, Section 102](#)

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

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### **Institutional Biosafety Committee**



Bulletin



**Question:** How long does it take to get approval from the IBC on my Memorandum of Understanding and Agreement Form (MUA)?

**Answer:** The IBC Staff is committed to creating and maintaining a review process that is both efficient and effective. Completed MUA's that are submitted at least one week before the meeting date are placed on the agenda of the IBC, provided there are no unresolved questions relating to the MUA. IBC Staff notifies the Principal Investigator within 48-72 hours about the outcome of the meeting. The earlier a Principal Investigator can submit an MUA the better the system works. If questions arise during the required pre Committee review, then they can be answered before the IBC Meeting.



### **News from HIPAA.....**

## **TAKE A LOOK**

As we get busy with our day to day routines, we may forget that our work areas may house various forms of PHI that need to be kept confidential.

Here is a quick checklist so that you may perform your own onsite review of your area.

Observe your area and answer each question *Yes* or *No*.

1. Computer monitor is positioned so that the public does not have access to it?

2. Reports and computer print outs are not left in areas where non-authorized personnel or the public can view them?
3. Fax location minimizes or eliminates risk of PHI exposure?
4. There is a shred bin or other designated location for the destruction of materials containing PHI?
5. Conversations regarding PHI are kept low and to a minimum?
6. All computer screens have a screensaver that is password protected?

If you answered No to any of the questions, implement the necessary changes to be HIPAA compliant. Should you have any questions, please contact Jeniece Poole, Privacy Officer at 621-1465 or [Jpoole@email.arizona.edu](mailto:Jpoole@email.arizona.edu).

Jeniece Poole, Privacy Officer  
Office of the Vice President for Research  
[jpoole@email.arizona.edu](mailto:jpoole@email.arizona.edu)



## Good Laboratory Practices (GLP)

### Compliance Help Information is Now at Your Finger Tips!

#### New Look for Sponsored Projects Proposal Routing Sheet

This new format was revised to assist Principal Investigators with user friendly compliance information. The idea is the result of a recently formed “Integrated Compliance Committee.” This first project was designed to have compliance information available on the computer with a key stroke.

Information is available for each compliance area. Place your cursor on the compliance checkbox area at the bottom of the SPR sheet and click. This takes you to the web site for each area and facilitates faster access to University research compliance web pages than searching for the individual University web sites by area.

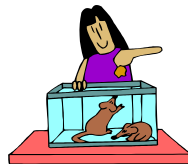
The committee thanks Lori Schultz, Assistant Director of Sponsored Projects for her technical support in setting up the interactive URL information.

The *Integrated Compliance Group* is composed of Frank Demer, Risk Management and Safety, and Mark Grushka, Jeniece Poole, Marilyn

Marshall of the Office of the Vice President of Research.

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

#### The University of Arizona Institutional Animal Care and Use Committee Welcomes the Following New Members:

*Wayne Peate, MD, MPH:* Dr. Peate received an MD from Dartmouth Medical School, an MPH in Occupational Medicine from Harvard, and completed a residency in Occupational Medicine from the University of Arizona. He is board certified in occupational and environmental medicine and medical management. He is a faculty member at the UA College of Medicine and is the Principal Investigator for the CDC-funded Arizona Department of Health Services Tribal Emergency and Public Health Preparedness grant providing preparedness training for 12 tribes in Arizona and California. His expertise in Occupational Health and Safety will be particularly useful to the IACUC in its role in oversight of the Animal Hazards Program of The University of Arizona.

*Stephanie J. Munger:* Stephanie graduated with a B.S. in Biology, minors in Mathematics and Animal Science in March 1984 from the University of Wisconsin, River Falls, Wisconsin. She taught Science and Mathematics for eight years in Arizona before joining the transgenic core at the Mayo Clinic in Scottsdale. While at the Mayo Clinic, she coordinated all Core work including DNA and ES cell injections, cryopreservation, and rederivations. In addition to the Transgenic Core, she was acting manager for the animal facilities.

Stephanie then moved to the Washington D.C. area, first working at George Washington University, and later at the Children’s National Medical Center. She established a transgenic

core at each site in addition to managing a lab for the director of the neuroscience department. This year, she has joined the BIO5 GEMM Core team. The IACUC welcomes her expertise in genetically modified mice, as we see this area of our animal care and use program rapidly expand.

NEW IACUC CHAIR: *Dr. Charles Sterling*, Professor and previous Head of the Veterinary Science and Microbiology Department has assumed leadership of the IACUC. Dr. Sterling is internationally recognized for his work with animal models of numerous parasitic diseases. He has been a regular member of the IACUC for several terms and brings his knowledge of animal models, animal welfare, and administration to his role as IACUC Chair.

Dr. Richard Vaillancourt, long-time Chair of the IACUC stepped down and returned to regular service on the IACUC July 1, 2007. We thank Dr. Vaillancourt for his excellent service as Chair of the IACUC.

Susan E. Wilson-Sanders, D.V.M., M.S.  
 Director, University Animal Care  
 (520) 626-1066 Fax: (520) 626-4079  
[wilson-s@u.arizona.edu](mailto:wilson-s@u.arizona.edu)



## **Radiation Control**



### **Laser Radiation Protection Course**

Registration is required. To register, send completed Form RC-088 to the Radiation Control Office, P.O. Box 245101, Campus. Hand-delivered forms may be dropped off at the Radiation Control Office, 1717 E. Speedway, Suite 1201, the Babcock Building. *Registration date and time will be confirmed via email.*

Please direct questions regarding registration to the Radiation Control Office (RCO) at 626-6850, or [rcohelp@u.arizona.edu](mailto:rcohelp@u.arizona.edu).

*These times are just for the course. They do not include the exam that generally takes half an hour.*

### **Requesting Accommodations for a Disability:**

Persons with a disability may request a reasonable accommodation, such as a sign language interpreter, by contacting the Disability Resource Center (DRC) at 621-3268, or by con-

tacting Diane Mayer by the use of email at: [dmayer@u.arizona.edu](mailto:dmayer@u.arizona.edu). Requests should be made as early as possible to allow time to arrange the accommodation.

Radiation Control Office Training Room	9/14/2007	9:00 AM - 11:00 AM
Radiation Control Office Training Room	9/27/2007	1:00 PM - 3:00 PM
Radiation Control Office Training Room	10/9/2007	9:00 AM - 11:00 AM
Radiation Control Office Training Room	10/29/2007	1:00 PM - 3:00 PM
Radiation Control Office Training Room	11/9/2007	9:00 AM - 11:00 AM
Radiation Control Office Training Room	11/28/2007	1:00 PM - 3:00 PM
Radiation Control Office Training Room	12/13/2007	9:00 AM - 11:00 AM

## **HUMAN SUBJECTS PROTECTION PROGRAM**

### **≡Highlights≡**

#### **The Orphan Drug Act\***

There are many diseases and conditions, such as Huntington's disease, cystic fibrosis, and muscular dystrophy that affect small numbers of individuals residing in the United States. The Orphan Drug Act (1983) was designed specifically to meet the needs of these individuals with rare diseases or conditions for which no adequate drug has been developed. Drugs that have been developed for these rare diseases are commonly referred to as "orphan drugs." For the purposes of this article, the term "rare disease or condition" means any disease or condition which (a) affects less than 200,000 persons in the United States, or (b) affects more than 200,000 in the United States for which there is no reasonable expectation that the cost of developing and making available in the United

States a drug for such disease or condition will be recovered from sales in the U.S.

The Department of Health and Human Services has established the **Orphan Products Board** which functions to promote the development of drugs for rare disease and conditions and the coordination among Federal, other public, and private agencies in carrying out their respective function relating to the development of the drug. The Orphan Products Board also provides the following:

- Evaluates the activities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration for the development of orphan drugs
- Assures appropriate coordination among the Food and Drug Administration and other Federal institutions to assure that the activities of each agency are complementary
- Assures appropriate coordination among all interested Federal agencies, manufacturers, and organizations representing patients, in their activities relating to such drugs
- With the consent of the sponsor, informs physicians and the public with regard to the availability of the drug
- Seeks business entities and others to undertake the sponsorship of the drug in order to facilitate the development of the drug

If a drug is designated as a drug for a rare disease or condition, it is recommended that the drug sponsor design a protocol for a clinical investigation of the drug for those individuals with the disease. Orphan drug trials generally follow the same regulatory development path as any other pharmaceutical treatment. These investigations can be carried out under section 505(i) of the Federal Food, Drug, and Cosmetic Act with testing focusing on the characterization of the molecule(s), stability, safety, and efficacy.

Under the act many drugs have been developed, including drugs to treat glioma, multiple myeloma, cystic fibrosis, and snake venom. From January 1983 to June 2004, a total of 1,129 different orphan drug designations have been granted by the Office of Orphan Products Development and 249 orphan drugs have received marketing authorization.

\*U.S. Food and Drug Administration. The Orphan Drug Act (as amended). January 1983. Access date 29 June 2007.

<http://www.fda.gov/orphan/oda.htm>.

\*Wikipedia. Orphan Drug. Updated 26 July 2007. Access date 20 August 2007.

[http://en.wikipedia.org/wiki/Orphan\\_drug](http://en.wikipedia.org/wiki/Orphan_drug).

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## Academic Societies Produce Additional RCR Products

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Several new products are available from awards made by the ORI Association of American Medical Colleges (AAMC) Responsible Conduct of Research (RCR) Program for Academic Societies.

During the life of the program 39 awards were made to 33 different academic and scientific societies. The program has supported the development of guidelines, standards, policies, and publications (including RCR articles in journals, newsletters, and on society Web sites), committees, annual conferences, core competencies, curricula, and other resources related to the core RCR components.

Some program products recently made available include:

- The American College of Neuropsychopharmacology: a “Code of Conduct for Sustaining Corporations;”
- The American Society for Bioethics and Humanities: an article, “Educational Approaches to the Responsible Conduct of Clinical Research: An Exploratory Study” in *Academic Medicine*, January 2007, (Vol. 82, No. 1, p. 32-39);
- The Council on Social Work Education: a “National Statement on Research Integrity in Social Work” and an “Action Plan for Promoting Research Integrity in Social Work;”
- The Gerontological Society of America: a “Guidebook for Multidisciplinary Clinical Geriatric Research;” and
- The American College of Physicians: a patient education brochure, “Volunteering for a Research Study?” They have also posted materials from their recent workshop on “Doing Research in the Office: Professionalism and Pitfalls.”

Links to all program products are available on a recently revised web page located at the following site: <http://www.aamc.org/ori/>.

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## OPPORTUNITIES FOR ON-LINE ETHICS TRAINING

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### Online Study Guide University of New Hampshire Responsible Conduct of Research

[http://ori.hhs.gov/education/products/unh\\_round1/  
www.unh.edu/rcr/index-2.html](http://ori.hhs.gov/education/products/unh_round1/www.unh.edu/rcr/index-2.html)

### 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).

Please visit the following web address which contains more information regarding this valuable online course:

[http://ori.hhs.gov/education/products/montana\\_round1/research\\_ethics.html](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 the Accreditation Council for Graduate Medical Education (ACGME) requirements for education on professionalism and on industry professional relationships, as well as satisfy 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. If you require 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](mailto:klochrid@indiana.edu).

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## Upcoming Conferences/Workshops

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### September 9-12, 2007

National Radon Conference

<http://www.crcpd.org/radon/RnMtg2007/Agenda.pdf>  
Jacksonville, Florida

### 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](http://www.esf.org/conferences/researchintegrity)

### October 6-11, 2007

<http://www.ahima.org/convention/2007/>

American Health Information Management Association (AHIMA)'S 79<sup>th</sup> Convention and Exhibit  
Philadelphia Convention Center  
1101 Arch St, Philadelphia, PA

### October 18-21, 2007

[programcommittee@asbh.org](mailto:programcommittee@asbh.org)

American Society for Bioethics + Humanities (ASBH)  
Renaissance Washington DC Hotel  
Washington, DC

### May 13-16, 2008

Fourteenth Annual *Teaching Research Ethics Workshop*

Indiana Memorial Union, Bloomington, Indiana

See [Teaching Research Ethics Overview](#) for the agenda.

For registration and fee information, see:

<http://poynter.indiana.edu/tre/workshop.shtm>

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

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## *Words of Wisdom:*

*"Labor was the first price, the original purchase-money that was paid for all things. It was not by gold or by silver, but by labor, that all wealth of the world was originally purchased."*

— Adam Smith