
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

June 1, 2005

Volume 5, No. 6

A Message from the Director

Thomas P. Davis, Ph.D.

This month marks the retirement of our Vice President for Research and Graduate Studies, Richard C. Powell, Ph.D. Dr. Powell has honorably and ably led the office of the Vice President for Research (VPR) since 1999. We will miss his outstanding leadership and guidance. Many, many thanks to Dr. Powell for guiding the development of P.R.I.E. and supporting this newsletter as a means to communicate compliance education.

We are highlighting the University of Arizona *Code of Research Ethics* this month as our feature article. We feel it is good to remind our research community of exactly what the UofA has adopted as policy regarding research ethics, and why it is important to receive and read the Program in Research Integrity Education (PRIE) newsletter. By receiving the PRIE newsletter you are kept abreast of compliance education information that will be required of you.

Also included in this month's newsletter is an article entitled, "*Misconduct of Others: Prevention Techniques for Researchers.*"

Again, our very best regards to Dr. Richard Powell and to a job well done! And, welcome to our new Vice President for Research, Dr. Leslie Tolbert!

The University of Arizona Code of Research Ethics

Subscribed to and Adopted by the
University of Arizona Faculty Senate
On December 7, 1998
for University of Arizona Faculty
and Research Personnel

We the members of the University of Arizona (UofA) faculty and UofA researchers (hereafter: research community) are engaged in the quest for knowledge, in scholarly and artistic pursuits (hereafter: research) with the ultimate goal of benefiting humankind. Our quest is founded on the fundamental principles of honesty and trust.

The UofA research community pledges, by the adoption of this code, to engage in the responsible practice of research, required for keeping such trust, by adhering to and being accountable for the following principles and practices.

I. In fulfilling our obligation to the public as a whole, we expect that all individuals within the UofA research community shall:

promote and follow research and professional practices that enhance the public interest and well-being;

use public and private funds responsibly in the pursuit of research endeavors;

adhere to government and institutional regulations for research such as those ensuring the welfare of human subjects, the welfare of fellow researchers, the comfort and humane treatment of animal subjects and the protection of the public and the environment; and

report research findings resulting from public and private funding in a full, open, and timely fashion to the relevant research community;

II. In fulfilling our obligations to our colleagues, we expect that all individuals within the UofA research community shall

have actually carried out experiments, projects and other scholarly activity in the manner reported;

represent their best understanding of the work in their descriptions and analyses of it;

accurately describe experimental methods utilized in sufficient detail to help insure their repeatability by others;

share unique propagative materials developed through publicly-funded research with others in the field in a reasonable fashion;

not report the work of others as if it were their own; strive to insure that due recognition is given where credit is due to collaborators including students and trainees;

adequately summarize previous relevant work and ideas with proper attribution to those who pioneered the work;

when acting as reviewers or editors, treat submitted manuscripts and grant applications confidentially and refrain from inappropriate use;

and,

disclose financial and other interests that might present a conflict-of-interest, and make every effort to avoid such conflicts perceived or real.

III. In fulfilling obligations to students and trainees, we expect that all individuals within the UofA research community shall

provide training and experience to advance the students' and trainees' scholarly skills and their understanding of the importance of ethical practice and behavior;

provide appropriate support in advancing the careers of students and trainees;

recognize publicly and appropriately the scholarly contributions of the trainees;

encourage and support the publication of results of trainees' research in a timely fashion without undisclosed limitations; and,

work together to create and maintain a working environment that is safe and that encourages individual integrity, plurality, open communications, and fairness without regard to gender, race or belief.

(<http://w3fp.arizona.edu/senate/ethicode.htm>)

The University of Arizona Faculty Center
1400 E. Mabel Street PO Box 210473
Tucson, AZ 85721-0473

VOICE 520-621-1342 FAX 520-621-8844

facsen@u.arizona.edu

last updated 6/11/03

**Misconduct of Others:
Prevention Techniques for
Researchers**

By Jane A. Steinberg

Published in *APS Observer* by the
American Psychological Society,
January 2002, Volume 15, Number 1

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.¹ 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.

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

OPPORTUNITIES FOR ON-LINE ETHICS TRAINING

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.

Human Subjects Research Online Training, "Protecting Human Subjects" From the Department of Health and Human Services

This educational training series is designed to provide you with:

- Historical background for behavioral and biomedical research;
- Ethical principles for human subject research;
- Case studies;
- Information on the role of an Institutional Review Board (IRB).

Background

As an Agency of the U.S. Department of Health and Human Services (HHS), the Health Resources and Services Administration (HRSA) has certain responsibility for the protection of participants in human research studies.

These responsibilities are mandated under HRSA's [Federalwide Assurance \(FWA\)](#) with the [HHS Office for Human Research Protections \(OHRP\)](#) as well as the Agency's own policy: [Program Protection of Human Subjects Participating in Research Programs Conducted or Supported by HRSA](#). The protections apply to studies conducted internally by HHS staff, as well as to external studies conducted by grantees and contractors.

If you are a HRSA staff member, researcher, grants and contracting official, grantee or someone outside the agency (including institutional officials, reviewers, students, investigators, or IRB members), you will find information provided in this training valuable.

Getting Started

The HRSA Center for Quality and OHRP are pleased to provide you with this special training series.

The entire training should take you about 90 minutes to complete; however, you can complete each module independently of the others. Module 1 is 22 minutes. Module 2 is 28 minutes and Module 3 is 36 minutes.

Module 1: "[EVOLVING CONCERN: Protection for Human Subjects](#)"

Module 2: "[THE BELMONT REPORT: Basic Ethical Principles and Their Application](#)"

Module 3: "[BALANCING SOCIETY'S MANDATES: Criteria for Protocol Review](#)"

If you are interested in additional resources, you may find the [OHRP Institutional Review Board Guidebook](#) helpful.

The 1993 Guidebook is designed to assist IRB members research, and institutional administrators in fulfilling their responsibilities for protecting the rights and welfare of human subjects as defined in the HHS regulations (45 CFR 46) entitled, "Protection of Human Subjects," revised June 18, 1991.

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.

The educational modules will help satisfy Accreditation Council for Graduate Medical Education (ACGME) requirements for education on pro-fessionalism and industry professional relationships as well as similar requirements by the American Board of Medical Specialties.

Physicians can earn AMA PRA category 1 credit for the online self-study version. Local sites can issue CME credit for the classroom version of the downloadable educational modules.

For more information visit the following site: <http://www.ama-assn.org/ama/pub/category/8405.html>

UNIVERSITY OF ARIZONA RESEARCH AND SERVICE GROUP (RSSG)

UA HUMAN SUBJECT PROTECTION PROGRAM

≡Highlights≡

Human Subjects "Forms Online:"

To access the appropriate forms that apply to your

study, please use the links below. Note: As of September 19, 2001 there is now a secondary Institutional Review Board that specializes in behaviorally related reviews.

[Behavioral Science Forms](#)

[Biomedical Forms](#)

[Continuing Review Forms](#)

[Genetic Science Forms](#)

[HIPAA Authorization Form](#)

[Verification of Human Subjects Training Form \(VOTF\)](#) - for submittal to IRB (for continuing review and changes in personnel)

Amendments and Adverse Events must be reported to the Human Subjects Protection Office. For more information, see the [Investigator Checklist](#) or [contact the office](#).

Project termination or completion - Use [continuing review forms](#) for reporting project termination or completion

Reminder

New Videos Available on Human Protection

Three new training videos on the protection of human subjects have been made publicly available by the Health Resources and Service Administration in cooperation with the Office for Human Research Protections.

The videos may be access through the ORI home page by clicking on Human Subjects in the RCR resources section. The three videos run a total of 90 minutes.



Good Laboratory Practices (GLP)

U.S. Environmental Protection Agency

Good Laboratory Practice Standards

<http://www.nabr.org/AnimalLaw/EPA/>

The U.S. Environmental Protection Agency (EPA) enforces "Good Laboratory Practice" (GLP) regulations that apply to all studies related to approvals of new pesticides or industrial chemicals "to ensure the quality and integrity of test data submitted to the Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA)." The GLPs address all areas of laboratory operations, including provisions specifying standard operating procedures for the housing, feeding, handling and care of animals. The EPA compliance monitoring program inspects facilities, audits data and prepares detailed inspection reports. Noncompliance with GLPs can result in the federal agency's refusal to consider a study in support of an application; disqualification of the testing facility; or, in extreme cases, recommendation for criminal prosecution.

[EPA Good Laboratory Practice Standards](#)
[Subpart A - General Provisions](#)
[Sec. 160.1 Scope](#)
[Sec. 160.15 Inspection of a testing facility.](#)
[Subpart C - Facilities](#)
[Sec. 160.43 Test system care facilities.](#)
[Sec. 160.45 Test system supply facilities.](#)
[Subpart E - Testing Facilities Operation](#)
[Sec. 160.90 Animal and other test system care.](#)



News from HIPAA.....

Frequently asked questions:

Question: Does the HIPAA Privacy Rule require that covered entities document all oral communications?

Answer: No. The Privacy Rule does not require covered entities to document any information, including oral information that is used or disclosed for treatment, payment or health care operations.

The Rule includes, however, documentation requirements for some information disclosures for other purposes. For example, some disclosures must be documented in order to meet the standard for providing a disclosure history to an individual upon request. Where a documentation requirement exists in the Rule, it applies to all relevant communications, whether in oral or some other form. For example, if a covered physician discloses information about a case of tuberculosis to a public health authority as permitted by the Rule at 45 CFR 164.512, then he or she must maintain a record of that disclosure regardless of whether the disclosure was made orally, by phone, or in writing.

University of Arizona – Animal Care Quality Care for Research Animals



Frequently asked questions....

Question: What happens to animals once an experiment is completed?

Answer: The majority of animals under study must be euthanized in order to obtain tissue for pathological evaluation and for use in *in vitro* tests. Euthanasia is the act of inducing a humane death. The American Veterinary Medical Association publishes euthanasia methods considered acceptable. Those animals involved in experiments

that do not require tissue for pathological evaluation may take part in additional experiments. However, except in rare circumstances, federal regulations do not allow an animal to be used in more than one major surgical procedure.



Radiation Control

Personnel Dosimetry

Individuals working with radiation may need to be monitored for radiation exposure. Each department is evaluated for dosimetry needs. This evaluation is performed when an individual returns the [Radiation Worker Data Sheet & Training Record \(RC-088\)](#). This form needs to be completed with your supervisor and forwarded to the Radiation Control Office prior to working with radiation.

The Radiation Control Office provides radiation dosimeters free of charge. However a \$25.00 fee will be assessed to departments when individuals fail to return a dosimeter according to the [Unreturned Dosimeter Policy](#). The department has the option to recover this fee from the individual who was delinquent. To view the Radiation Dosimetry Policy [click here](#).

The Radiation Control Office performs bioassays for research personnel working with 50 mCi or more of ^3H in a single procedure. Research personnel working with materials totaling more than 1 mCi of ^{125}I or ^{131}I in a calendar quarter must have a thyroid bioassay within 6 to 72 hours following each use. Likewise, clinical personnel administering more than 30 mCi of ^{131}I in a single dose are required to have a thyroid bioassay after each administration above this threshold within the same timeframe. Other bioassay requirements may be imposed when use conditions or incidents warrant it.

Institutional Biosafety Committee



Frequently Asked Questions:

Question: What types of research must be submitted to the Institutional Biosafety Committee for review?

Answer: The Committee provides expert review of research projects to ensure compliance with all relevant Biosafety guidelines. Researchers working with recombinant DNA, microbial pathogens, or implementing human gene therapy projects must submit a Memorandum of Understanding and Agreement (MUA) form to the IBC. In this form

researchers describe the nature of the research and specific Biosafety practices and containment that will be used during the course of the research. The Committee reviews all proposed research projects regardless of funding status.

In May, 1995 the IBC initiated Biosafety reviews of the UofA courses involving recombinant DNA, microbial pathogens (including human blood, fluids, tissues, or bone), and field trips. These reviews are annual, and updated teaching forms are required only when changes to be course are made that necessitate additional Biosafety practices.

UPCOMING CONFERENCES/WORKSHOPS

June 3-4, 2005

Responsible Conduct of Basic and Clinical Research
Warsaw, Poland

» [The Responsible Conduct of Basic and Clinical Research – June 3-4, 2005, Warsaw, Poland](#)

June 9-10, 2005

Ethics and Social Responsibility in Engineering and Technology Linking Workplace Ethics Education
Los Angeles, CA

<http://www.gonzaga.edu/Academics/Continuing+Education/Current+Programs/Engineering+Ethics/default.htm>

June 12-17, 2005

Teaching Survival Skills and Ethics
11th Annual Trainer-of-Trainer Conference
Snowmass, CO

http://www.survival.pitt.edu/forms/trainer_application.asp

June 13-14, 2005

Promoting a Productive and Responsible Environment
Sacramento, CA

» [Promoting a Productive and Responsible Research Environment – June 13-14, 2005, Sacramento, CA](#)

June 16-17, 2005

The Research Coordinator: Strategies for Promoting Integrity in Clinical Research
Bryn Mawr, PA

» [The Research Coordinator: Strategies for Promoting Integrity in Clinical Research – June 16-17, 2005, Bryn Mawr, PA](#)

August 4-5, 2005

Mentoring and Human Subjects' Protection
Little Rock, AR

Co-sponsor: University of Arkansas for Medical Sciences

October 1, 2005

Plagiarism in the Science Disciplines: The Good, the Bad and the Really Ugly

New York, NY

Co-sponsors: New York University Medical School, St John's University, Columbia University College of Physicians and Surgeons, City University of New York

October 7, 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

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 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)

rhk@u.arizona.edu

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

The P.R.I.E. newsletter is compiled by Ruth Daniels.

Words of Wisdom:

"Relativity applies to physics, not ethics."

~ Albert Einstein (1879-1955)