
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

July 1, 2007

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This month the Program in Research Integrity Education (P.R.I.E.) newsletter is highlighting the topic of *Responsible Research*. We trust you will find the information contained in the newsletter helpful and informative.

We wish you a safe and happy **Independence Day!**

Correction to Announcements

Regarding the new *UA Ethics and Compliance Hotline* announced in the June 2007 P.R.I.E. newsletter – the telephone number given (886) 364-1098, was incorrect. The correct telephone number for the hotline is (866) 364-1908.

Safe Driving and Responsible Research

Office of Research Integrity (ORI) Introduction to the Responsible Conduct of Research, Part V

Reprinted from the Office of Research Integrity web site:
<http://ori.dhhs.gov/education/products/RCRintro/Parts/p5.html>

It is not easy to go through life doing everything we must or should do all of the time. It should therefore come as no surprise that in many small and some significant ways, researchers do not always follow the rules of the road for responsible conduct in research. They roll through stop signs when they clean up their data more than they should, accept honorary authorship, purchase something with grant funds that is not strictly allowed, or give colleagues more favorable reviews than they deserve. From time to time, they drive faster than the posted speeds to arrive at their destination – a grant, a publication, new knowledge – a little more quickly.

We ignore musts and shoulds in life for different reasons. For one, society sends mixed messages about obeying rules. Should you turn in someone for cheating or “mind your own business?” Rules also can conflict with one another. Should you report misconduct if doing so puts your career at risk? And finally, we are

amazingly adept at “bending” or “stretching” the rules by thinking up good reasons why a questionable course of action is acceptable under a particular set of circumstances, that is, at justifying our actions, whatever they are.

The ease with which rules can be bent or ignored is particularly evident early in the career track the majority of researchers traditionally follow. Studies consistently suggest that well over half and probably closer to three-quarters of college students cheat during their undergraduate years. In two separate studies, 1 in 10 research trainees reported a willingness to break the rules to get grants funded or papers published. Roughly the same number of students applying for research fellowships and residencies in medicine significantly misrepresents their research publications on résumés, as confirmed in studies conducted in six medical specialties. Presumably most individuals who cheat or inflate résumés know that it is wrong to do so, but they nonetheless find reason for engaging in these practices.

The same patterns of behavior can easily spill over into other aspects of research. The pressures that prompt students to bend or ignore the rules do not disappear after graduation. Getting into good schools is replaced by getting a good job and promotions. Competition for grades is replaced by competition to get funded and published. Too little time to study for tests is replaced by too little time to teach, mentor, provide service, and do research. The stakes may even increase later in careers, as family responsibilities are added into the mix and personal ambitions grow, making it even easier to put more pressure on the accelerator to get to your destination a little faster.

There are many quick-and-easy reasons that can be called up to justify bending or ignoring some of the rules of the road for responsible research:

- I already have enough information to know what the results will be, so there is no need to run the controls again, even though they

did not give me the expected results the first time.

- No one funds truly exploratory research, so the only way to test new ideas is to use funds from an existing grant, even though these funds are for other work.
- If my bosses read my research papers rather than counting them, I wouldn't have to publish the same research twice or chop it up into small, insignificant pieces.
- Given the competition in this field, you cut your own throat if you share your methods and information with colleagues too freely.
- They will cut off my funds if I report these results, so for the good of my laboratory and staff I should sit on them for a while longer.
- I know my research is not going to harm anyone, so why waste my time and the time of the IRB getting permission.

Rules are not always reasonable or rationally applied. Life and colleagues are not always fair. Good guys do sometimes seem to come in last.

However, the problem with quick-and-easy justifications and catchy phrases is they fail to take into consideration the larger consequences of our actions. What would happen if everyone decided, for one "good" reason or another, to run stop signs, drive on the wrong side of the road, or ignore the speed limit? Obviously, chaos would quickly ensue and driving would no longer be safe (or become even more hazardous than it is already). The same would be true of research if researchers routinely ignored responsible research practices and did what they thought was necessary simply to achieve some end, whether the discovery of truth, the development of something useful, or personal success.

There is no one best way to undertake research, no universal method that applies to all scientific investigations. Accepted practices for the responsible conduct of research can and do vary from discipline to discipline and even laboratory to laboratory. There are, however, some important shared values for the responsible conduct of research that bind all researchers together, including honesty, accuracy, efficiency, and objectivity. There are no excuses for compromising these values. Their central role in research is the responsibility of each and every

researcher. Drive safely and be a responsible researcher.

UNIVERSITY OF ARIZONA
RESEARCH SUPPORT SERVICES GROUP
(RSSG)

 **Good Laboratory Practices:**
(GLP)

Regulatory Cooperation Expanded

The US Food and Drug Administration (FDA), the European Commission (EC), and the European Medicines Agency (EMA) have agreed to expand their current cooperative activities in several important areas. At a meeting June 14-15, 2007, the FDA and the EU reviewed the past year's activities under the existing Implementation Plan for the confidentiality arrangement. The ultimate goal of the initiative is to promote and protect public health, reducing regulatory burden and costs, and bringing innovative products to patients in a timely manner. Furthermore, important safety information about medicinal products is shared among the parties.

Building on the achievements in cooperation on vaccines, oncology, and pharmacogenomics, it was agreed to expand further the interactions in the areas of pediatrics and medicinal products for rare diseases ("orphan drugs"). Furthermore, scientific dialogue has been widened to include extensions of therapeutic indications and risk management plans. Based upon the newly adopted pediatric legislation in the EU, a "[Principles of Interactions](#)" document that will facilitate the timely exchange of information on scientific and ethical issues for pediatric therapeutics has been finalized.

The [Implementation Plan](#) on transatlantic medicines regulatory cooperation was revised to describe under what circumstances information will be shared among the parties.

Following the Framework for Advancing Transatlantic Economic Integration between the EU and the FDA, new areas of transatlantic regulatory cooperation were discussed, notably regulatory cooperation on medical devices and on cosmetics. Discussions on these topics will continue.

In an effort to avoid future disharmony, upstream regulatory cooperation on new medicines legislation was discussed. In addition, planning progressed on a Transatlantic Workshop on Administrative Simplification in Medicines Regulation. This workshop will be held on 28 November 2007 in Brussels, Belgium.

Transatlantic regulatory cooperation under the EC, EMEA and US FDA collaboration has allowed each side to share common experiences and gain an understanding of each other's regulatory system. Additionally, each side strives to reduce unnecessary differences in regulations and reduce associated costs to the consumer and industry. All parties concur that this activity continues to be a success in fostering transatlantic cooperation and promoting public health protection.

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)



News from HIPAA.....

HOW TO PREVENT INAPPROPRIATE PRIVACY-RELATED BEHAVIOR AMONG STAFF

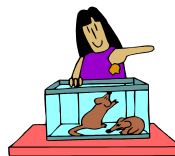
Impulsive or lighthearted reactions – even about HIPAA – are commonplace human responses to stressors in the work environment. But off-handedness or humor should not replace sensitivity to privacy, nor be allowed to hide the seriousness of many healthcare workers' frustration and confusion concerning their privacy responsibilities. Most of the scenarios above might have been prevented if staff knew how to appropriately respond to work situations involving privacy matters.

Helping the members of your staff integrate HIPAA privacy practices into their daily routines should be a key objective for your organization. Although HIPAA is complex in language and interpretation, it need not be experienced as a major distraction or impediment to the delivery of care. Too often, policies/

procedures are written and conceptual training on them provided, but the last step in the learning process – guidelines and scenarios for applying privacy concepts to everyday (and unique) situations – are ignored. As a result, staff members resort to responses that feel safest or easiest, like the extreme (but real) examples reported above. Discussing such examples with your team members can effectively help them cope with perceived on-the-job HIPAA dilemmas. Providing authoritative guidelines, explanations, scenarios and scripts will show workers how they can meet their HIPAA privacy obligations, as well as minimize frustration for themselves, patients and their families. Practical, forward-thinking education and attentive supervision will help to convert old habits and inappropriate behaviors into appropriate, HIPAA-compliant actions – and transform your organization into a genuinely privacy-sensitive healthcare delivery operation.

Jeniece Poole, Privacy Officer
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University of Arizona – Animal Care



Quality Care for Research Animals

Biometric Cat Card System

University Animal Care (UAC) has implemented the new Biometric Cat Card system for entering all animal facilities; each individual who needs access must have their own Biometric Card. The following provides information on how to obtain your new card for any of the facilities:

Requirements for obtaining animal facility access:

- 1) You must be listed on an active protocol.
- 2) Must have completed all the required IACUC modules/hands on training required for the species you are working with. If you have questions regarding IACUC certifications, please contact the IACUC Instructional Specialist at 621-3931.

If you currently have a Cat Card and you have had access to the animal facility in the past:

- 1) Make sure your name is on the list to be able to get a Biometric Cat Card. You do this by calling Cheryl Johnson at 626-6702.
- 2) If you're not on the list, you will need to complete a new Key Request/Access Form. Remember to put the form on your departmental letterhead and turn the form into the UAC Business Office, Room 1126 for departmental review and approval.

If you do not have access to the Animal Facility you will need to do the following:

- 1) Complete the Key Request/Access Form. Remember to put the form on your departmental letterhead. Bring the form to the UAC Business office, Room 1126, or fax the form to 626-4079. If faxing, send the original form to the UAC Business Office, PO Box 245092. Note the following when filling out the form: If you do not have a Cat Card, leave that space blank.
- 2) If all of the requirements for obtaining access have been met, you will then be added to the list to be able to get a Biometric Cat Card and will be notified by E-mail.
- 3) Once you have received notification, you may then go to the Cat Card Office to obtain your card. Once you get your card, please send a copy of the card to the Business Office, Room 1126, or stop by the business office and they will make a copy for you.
- 4) Once your new Cat Card number has been received, it will take 24 to 48 hours for your access to be activated.

The Key Request/Access form for UAC is found on the University Animal Care website: www.uac.arizona.edu.

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“Virtually every medical achievement of the last century has depended directly or indirectly on research with animals”
—U.S. Public Health Service

Institutional Biosafety Committee



Bulletin



Shipping of Dangerous Goods

If you or your department ship materials by air that are considered *Dangerous Goods*, both the University of Arizona and various federal and international regulatory agencies require training. Training is available in the following formats:

- ✚ Institutional Biosafety Committee Website
General Awareness Level Only
<http://www.abc.arizona.edu/>
See Link under PDFs posted on March 30, 2007 for Shipping Training.
- ✚ Risk Management and Safety Department
Course Held on Demand
Function Specific Level
Shipping Hazardous Materials by Air Course. For information contact Jeff Christensen at 621-5861 or jgchrist@email.arizona.edu.
- ✚ Available on Loan Basis from Risk Management and Safety Department and IBC Office (Competency-Based and Required to Actually Package, Label and Ship Dangerous Goods) Saf T Pak Shipping Class 6.2 Dangerous Goods. Compliance Training Reference Manual and Computer Aided Instruction CD.

For more information, please contact Jeff Christensen at 621-5861, or Mark Grushka at 621-5279.



Radiation Control



SECURITY OF RADIOACTIVE MATERIALS

Arizona Radiation Regulatory Agency (ARRA) regulations have two provisions relating to the security of radioactive materials.

R12-1-426 **Security of Stored Sources of Radiation** – A licensee or registrant shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored.

R12-1-427 **Control of Sources of Radiation Not in Storage** – A licensee shall control and maintain constant surveillance of licensed radioactive material that is in an unrestricted area and is not in storage or in a patient.

In addition, licensees are reminded that they are required to report any stolen, lost or missing radioactive material. If the quantity is greater than 1,000 times Appendix C of Article 4 of the regulations, the report is due immediately upon discovery. If the quantity is less than 1,000 times Appendix C but greater than 10 times Appendix C, the report is not due for thirty days although we would like to get them as soon as possible.

Licensees should review their use and security of radioactive materials; both at fixed locations and at temporary job sites, and determine whether they need to improve security. The following actions should be considered in this review:

1. Control personnel access, including verification of the identities of all personnel entering areas containing large amounts of radioactive materials that could be used for terrorist attacks, especially readily dispersible, high specific activity radioactive materials.
2. Become aware of the presence of any suspicious packages transported by personnel or observed in the vicinity of the facility.
3. Provide heightened control of vehicle access to areas near the materials if your facility could release large quantities of radioactive materials.
4. Limit the potential for theft or sabotage of radioactive materials. Assure material is locked and secure when not in use.
5. Lock unoccupied vehicle that contain radioactive materials.

If any radioactive materials should become lost or stolen, call the Arizona Radiation Regulatory Agency at (602) 255-4845, during business hours, or (602) 223-2212 after business hours.

Information taken from the Arizona Radiation Regulatory Agency (ARRA) web site:
<http://www.arra.state.az.us/newsdocs/SECURITY%20of%20RAM.pdf>

HUMAN SUBJECTS PROTECTION PROGRAM

≧Highlights≦

Deception of Research Participants*

Research in which the participant is intentionally deceived is not uncommon in social psychological research. Deception is used mainly when it is not possible to obtain accurate information about an individual if the individual is knowledgeable about the topic of study. Deception also occurs when the researcher desires to observe or evaluate individuals without their awareness.

The justification of such research is grounded in the belief that it is impossible to study certain human behaviors without the use of deception. The issue then becomes a question of risk/benefit and does the risk of possible harm caused by the deception outweigh the benefit of the knowledge to be gained. Also important is the possibility of minimizing the potential harm to the individuals participating in such studies.

The American Psychological Association (APA) has developed a specific code of conduct that address the above cited issues.

- *Psychologists do not conduct studies involving deception unless they have determined that the use of deceptive techniques is justified by the study's prospective scientific, educational, or applied value and that equally effective alternative procedures that do not use deception are not feasible. (6.15)*
- *Psychologists never deceive research participants about significant aspects that would affect their willingness to participate such as physical risks, discomfort, or unpleasant emotional experiences. (6.15)*
- *Any other deception that is an integral feature of the design and conduct of an experiment must be explained to participants as early as is feasible. Preferable, at the conclusion of their participation, but no later than at the conclusion of the research. (6.15)*
- *Psychologists provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and psychologists attempt to correct any misconceptions that participants may have. (6.18).*

- *If scientific or humane values justify delaying or withholding this information, psychologists take reasonable measures to reduce the risk of harm. (6.18)*

In essence, the APA is instructing researchers to determine the risk/benefit and consider the potential for harm created by the use of deception, consider alternative methodologies, and fully explain the nature of the deception at the study conclusion. If the researcher desires that the deception not be explained to participants, the rationale behind such nondisclosure needs to be fully explained.

Researchers must keep the safety of the participants as their first concern, ensuring proper and appropriate research procedures are in place during the pursuit of scientific knowledge.

*Sloan, L. and Hull, J. (2002). Deception of Research Subjects. In R. J. Amdur and E. A. Bankert (Eds.), Institutional Review Board Management and Function (pp. 244-249). Sudbury, MA: Jones and Bartlett.

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

September 9-12, 2007

National Radon Conference

[draft agenda](#)

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

October 18-21, 2007

programcommittee@asbh.org

American Society for Bioethics + Humanities (ASBH)

Renaissance Washington DC Hotel

Washington, DC

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and compiled by Ruth Kurash Daniels.

Words of Wisdom:

“Liberty is the great parent of science and of virtue; and a nation will be great in both always in proportion as it is free.”

~ Thomas Jefferson