
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

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Beginning in the mid 1980s the U.S. Department of Education, the National Science Foundation (NSF), and the National Institutes of Health (NIH) began providing resources to encourage study and curricular development in research ethics. The 1989 misconduct regulations from the Public Health Service (PHS) – which includes some federal funding agencies – stated, “Institutions should foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested.”

Principal Investigators are ultimately responsible for the proper scientific and/or scholarly conduct of the project for which they have received an award. They are also responsible for ensuring compliance with the financial and administrative facets of the grant. Principal Investigators are also accountable to ensure that individuals working under their direction are doing good science.

This month the Program in Research Integrity Education (P.R.I.E.) newsletter focuses on the Responsible Conduct of Research (RCR). Each month hereafter, until completed, will highlight one of the nine RCR core instructional areas, which are:

- ✚ Data Acquisition, Management, Sharing and Ownership
- ✚ Human Subjects
- ✚ Animal Subjects
- ✚ Conflict of Interest and Commitment
- ✚ Publication Practices and Responsible Authorship
- ✚ Peer Review
- ✚ Collaborative Science
- ✚ Mentoring
- ✚ Research Misconduct

The source for the information presented in the P.R.I.E. newsletter in these upcoming months, with regard to covering the nine RCR core instructional areas is, “*RCR Education Resources: Online Resource for RCR Instructors.*” The authors of this material are P.D. Magnus and Michael Kalichman. The *RCR Education Resources* web site may be accessed at: <http://rcrec.org/r/index.php>.

Responsible Conduct of Research (RCR)

P.D. Magnus and Michael Kalichman,
September 2002

Why RCR?

RCR includes many elements: the proper treatment of human or animal subjects, managing conflicts of commitment or interest, responsible peer review, the education of new scientists through mentoring, the management of data so as to preserve privacy and integrity, and so on. These are obviously important things. Science could not function without mentoring, peer review, integrity, and all the rest – and so it is hard to argue with the claim that research should be conducted responsibly. Yet, it may not be obvious why separate instruction in RCR is required.

The need is specified, in part, by federal regulations. The first such regulation required that all National Institutes of Health (NIH) Research Training Grants provide an opportunity for trainees to receive instruction in RCR (NIH, 1989 and 1992). It was hoped that institutions would extend this requirement to include all trainees, not just those funded by NIH training grants, but this has not generally been the case.

In 2000, two new requirements were proposed, in part because of well-publicized instances of problems with several clinical trials (NIH, 2000; PHS, 2000). The stronger of these policies was later suspended (ORI, 2001), but is likely to be revised and reintroduced after additional public comment. Many scientists, institutions, and federal agencies continue to recognize the value of promoting RCR instruction.

Many scientists are skeptical about the value of explicit education in RCR. Some concerns about the definition of RCR and the need for instruction are credible, but most arguments against instruction are based on misconceptions.

Isn't responsible conduct just a matter of following regulations? Although there are explicit regulations that govern, for instance, the treatment of

human subjects, these regulations are insufficient to determine every choice a scientist will need to make. Many scientific practices are not directly covered by regulations. Moreover, scientists must always interpret regulations in their scientific practice. Treating human subjects responsibly involves more than just knowing regulations, and so too with other issues of RCR. This point is sometimes expressed by saying that RCR is more about conscience than it is about mere compliance.

Scientists already learn how to do research – doesn't that mean that they're learning how to do it responsibly? Where trainees learn by example, they must discern which features are important and which are not. For instance, they might learn that the reagents used are more critical than the style of music played in the lab. Even if they are trained to do research responsibly, then, they may or may not distinguish the elements that are matters of responsibility from those that are matters of style or manners. Explicit instruction in RCR can reinforce learning by example, by making trainees reflective about where and when issues of responsibility impinge on their research.

Also, scientists who face ethical dilemmas unprepared may not have the presence of mind to do the right thing or the time to figure out even what the right thing is. RCR education encourages scientists to think through ethical problems before they arise, before matters are clouded by demands for immediate resolution.

RCR instruction won't make anyone do the right thing – so what's the point? It is rarely the case that people are intent on doing wrong. Failures of research integrity that result from ignorance or carelessness might be averted by even a modicum of attention to RCR issues. Furthermore, even though a course in research ethics may not set straight a scientist who is intent on falsifying data or mistreating research subjects, such a scientist will interact with peers and coauthors who will be in a position to recognize misconduct. A course in research ethics may be enough to make them more reflective and mindful of ethical issues.

Won't ethical considerations of 'good' and 'bad' get in the way of scientific considerations of true and false? It's wrong to think that RCR is distinct from the demand to do good science. Promoting the integrity of science is one of the demands of responsible conduct. Even so, there may be times when it would be possible to learn something new only by acting irresponsibly. Remember, however, that science is not a disembodied pursuit of truth; it is also a human project. Sometimes the truth would come at too high a price.

Can't science take care of itself? Since science is self-policing, it may be tempting to think that the scientific community can handle any matters of responsibility by its own methods. This is already rebutted by the existence of regulations that govern scientific research. Moreover, RCR education can raise issues for scientists in a way that makes them more reflective and conscious of their role as members of the scientific community. Thus RCR education can help science take care of itself.

Resources

Works cited:

- NIH (1989): Training grant requirement. NIH Guide for Grants and Contracts 18(45).
- NIH (1992): Reminder and update: Requirement for instruction in the responsible conduct of research in National Research Service Award institutional training grants. NIH Guide for Grants and Contracts 21(43)
Requirement (as of Jan 1993) that all predoctoral and postdoctoral trainees are required to have RCR instruction
<http://grants.nih.gov/grants/guide/notice-files/not92-236.html>
- NIH (2000): Required education in the protection of human research participants. Notice OD-00-039, June 5, 2000.
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>
- PHS (2000): PHS policy on instruction in the responsible conduct of research. December 1, 2000.
<http://ori.dhhs.gov/html/programs/finalpolicy.asp>
- ORI (2001): Notice of suspension of 'PHS Policy on Instruction in the Responsible Conduct of Research.' Federal Register: February 21, 2001 66(35):11032-11033.
<http://ori.dhhs.gov/html/programs/congressionalconcerns.asp>

Web sites with resources for RCR instruction:

- Bioethics Resources on the Web, National Institutes of Health
<http://www.nih.gov/sigs/bioethics>
'...a broad collage of annotated web links...'
<http://www.nih.gov/sigs/bioethics>
- Online Ethics Center for Engineering and Science
The online ethics center for engineering and science at Case Western Reserve University
<http://onlineethics.org>
- RCR Instructional Resources, Office of Research Integrity
'...an emerging list of RCR instructional resources to assist institutions in developing RCR programs...'
<http://ori.dhhs.gov/html/programs/instructresource.asp>

- The American Journal of Bioethics
A site with weekly news updates and some introductory material
<http://bioethics.net>

Reports on Responsible Conduct of Research:

- Commission on Research Integrity (1995): Integrity and misconduct in research. Report to the Secretary of Health and Human Services, the House Committee on Commerce, and the Senate Committee on Labor and Human Resources.
<http://gopher.faseb.org/opar/cri.html>
- Institute of Medicine (1989): The Responsible Conduct of Research in the Health Sciences. Committee on the Responsible Conduct of Research, National Research Council. National Academy Press, Washington, D.C.
<http://www.nap.edu/books/0309062373/html>
- National Academy of Sciences (1992): Responsible Science, Volume I: Ensuring the Integrity of the Research Process. Panel on Scientific Responsibility and the Conduct of Research, National Academy of Sciences, National Academy of Engineering, Institute of Medicine. National Academy Press, Washington, D.C.
<http://www.nap.edu/books/0309047315/html>

Next month the featured RCR topic will be:

*"Data Acquisition, Management,
Sharing and Ownership"*

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

**HUMAN SUBJECTS
PROTECTION PROGRAM**

≧**Highlights**≦

**Announcement of New Human Subjects
Research Training Opportunity:**

**Collaborative Institutional Training
Initiative (CITI) Course in the
Protection of Human Research Subjects**

As a research institution committed to upholding the highest standards of scholarship and creative activity, we sought and received full accreditation by The Association for the Accreditation of Human Research Protection Programs, Inc., (AAHRPP) last Fall.

This distinction means that we have committed to protecting the rights and welfare of research participants by promoting scientifically meritorious and ethically sound research and to fostering and advancing the ethical and professional conduct of

persons that engage in research with human participants.

The University of Arizona has an assurance of compliance with the Department of Health and Human Services (DHHS). The assurance of compliance is a written document submitted by an institution (not the Institutional Review Board) that is [engaged](#) in non-exempt human subjects research conducted or supported by DHHS. Through the assurance, the institution commits to DHHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46.

The University of Arizona currently has on file a Federalwide Assurance. The Federalwide Assurance is the only type of assurance currently accepted and approved by the Office for Human Research Protections (OHRP) of DHHS.

When the Signatory Official (the UofA Vice President for Research, Graduate Studies, and Economic Development) signs the document he/she attests to the following statement: *"I recognize that providing all research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied."*

Additionally, in section 12 of the Federalwide Assurance OHRP states the following: *"OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, the following: relevant ethical principles, relevant Federal Regulations, written IRB procedures; OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human subjects. Furthermore, OHRP recommends that a) IRB members and staff complete relevant educational training before reviewing human subject research; and b) research investigators complete appropriate institutional educational training before conducting human subjects research."*

In order to meet federal requirements, the UofA must offer a continuing education program to all research personnel conducting human subjects research. The previous training model (Rochester Manual) used by the University did not afford the institution a method for revising and updating the information studied in preparation for passing the human subjects training test. It also required local resources for administering and maintaining the test module and certificates.

Therefore, the adoption of a new module, the Collaborative Institutional Training Initiative (CITI) Program, offers several advantages for the UofA including its immediate availability, its maintenance and administration by a third party, and most importantly, its widespread use nationally by many respected research institutions. By adopting CITI the University of Arizona is now able to fulfill its obligation to provide investigators with initial and continuing education in the area of human subjects protection and concentrate other limited resources to the areas of protocol review and IRB support and administration.

CITI is a modular-based, on-line system that is customized to meet the needs of both Behavioral and Biomedical researchers. To access the program log onto the system at www.citiprogram.org, and register with the user name and the password you choose. You can then log on as often as needed to review all of the required modules and take the quizzes. You can complete the training a little at a time, or all at once. This program also allows for collaborators, not affiliated with the University of Arizona, to take the training on-line so they can be part of your research team.

**UPDATED PHASE-IN DATES FOR
TRAINING AND CONTINUING
TRAINING OF ALL RESEARCH
PERSONNEL
(SUPERSEDES ALL PREVIOUS
COMMUNICATIONS RELATED TO CITI)**

- ✚ All new researchers (those taking the test for the first time) will be required to use CITI for completion of their human subjects training, effective May 15, 2006.
- ✚ All other researchers and study staff whose training date is older than 2 years as of January 1, 2007, are required to update their training by completing the CITI Program modules prior to January 1, 2007.
- ✚ Research personnel will be required to update their training every two years in order to meet continuing education requirements.
- ✚ ***Effective January 1, 2007, Verification of Human Subjects Training Forms submitted for new projects, continuing review of existing projects, or personnel changes, may not contain training dates more than two years old.***

Should you have any questions related to the adoption of the CITI program or the timeline for its implementation, please contact Rebecca Dahl,

Director, Human Subjects Protection Program, at 626-5925 or rdahl@email.arizona.edu.



Good Laboratory Practices

Information for FDA researchers

Two new documents were recently released by FDA. The initiatives described in these documents are part of FDA's Center for Devices and Radiological Health's enhanced program to facilitate development of new medical devices.

The first document on medical device innovation promotes early interaction between the FDA and industry to optimize review times and foster innovation. This initiative will expand current efforts to promote scientific innovation in product development, focus device research on cutting edge science, modernize the review of innovative devices, and facilitate a least burdensome approach to clinical trials.

As part of this broad initiative, FDA also announced today a critical step forward in modernizing the medical device development process by issuing new guidelines to outline the use of adaptive clinical trial designs. The draft guidance titled, "Bayesian Statistics in Medical Device Clinical Trials," provides FDA's recommendations on the use of Bayesian statistical methods in the design and analysis of medical device clinical trials.

<http://www.fda.gov/cdrh/ocd/mdii.html>

<http://www.fda.gov/cdrh/osb/guidance/1601.html>

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Institutional Biosafety Committee



Bulletin



**University of Arizona
Biosafety Handbook**

The purpose of the *University of Arizona Biosafety Handbook* is to provide information and procedures which will serve as a reference for the specific practices, procedures, facility construction and operational standards required for safe handling, containment and use of biohazardous materials for research, clinical and teaching activities at the University of Arizona (UofA).

The instructions and information contained in this handbook are set forth and adopted by the UofA Institutional Biosafety Committee and are based on federal, state, county and university regulations and guidelines. Wherever possible, the pertinent reference or regulatory document has been included in the Appendix.

Biosafety is a team effort involving the Principal Investigator, laboratory research and support staff, Biosafety Committee members, Risk Management, Animal Care, Human Subjects and Radiation Safety, and is inextricably linked to the other aspects of laboratory safety. This handbook has been structured to reflect this approach.

A successful biosafety program depends on investigators who are committed to a safe working environment and who are knowledgeable of the intricacies of laboratory safety. It is the Principal Investigator's responsibility to become thoroughly familiar with the contents of this handbook, to make sure that his or her workers become equally familiar with it, and to ensure that all work with biohazardous materials is in accordance with the instructions and information contained herein.

The University of Arizona Biosafety Handbook may be accessed through the following web address: <http://www.abc.arizona.edu/WebBiosafetyman/toc-title.html>. You may also call the UofA Biosafety Office with your suggestions, comments, concerns and questions, at 621-3441; or, by via email: Mark Grushka - mgrushka@u.arizona.edu or Margaret Stalker - stalkerm@u.arizona.edu.

University of Arizona – Animal Care Quality Care for Research Animals



Entrances to Animal Facilities

Entrances to animal facilities are secured at all times. The main entrance to the AHSC facility is room 1182. There are two additional entrances into that animal facility – one through the College of Pharmacy and one through Life Sciences North. Individuals using the AHSC facilities will need keys to the first door of the double entrance doors, a security card access to the second door of the double entrance doors, and keys to individual animal rooms. The main entrance to the Central Animal Facility (CAF) building is located on the southeast corner of the building. Individuals with animals housed in the CAF will need security card access to the first door of the double entrance doors at CAF, a key to the second door of the double entrance doors, a key to the elevator, and keys to individual animal rooms. The Veterinary Science/Microbiology (VSM) building research staff will need security card access to the entrance to VSM, a key to the elevator, and keys to individual animal rooms. Access to the Primate Research Facility must be cleared through the Assistant Director of UAC (626-2055).

Access to the animal facilities is restricted to those individuals who are listed as participants in IACUC approved protocols.

KEY ISSUE PROCEDURE: Keys and access cards to animal facilities can only be obtained through UAC. If keys and/or security access cards for the entrance and individual animal room keys are needed, a *request for access form* which is found at (<http://www.ahsc.arizona.edu/uac>) must be used. The form must be copied onto the departmental letterhead of the requesting individual. UAC must have the copy with the original signatures.

To receive keys and have security access granted, the investigator or technician must drop off the forms requesting keys and security card access in room 1128 AHSC or 114 CAF. It may take 48 hours for UAC to complete their part of the paperwork. When the paperwork is ready for pick-up, UAC will notify the Investigator or technician. UAC issues a key card to the person, signs the key desk authorization slip(s), and attaches a memo from UAC to the Facilities Maintenance key desk requesting key(s)/card for the individual. **Keys and card access to University Animal Care Facilities cannot be obtained in any other manner.** University Animal Care also handles all security card authorization activation to animal facilities.

When a technician, a student and/or investigator is no longer employed by the department, please notify University Animal Care. Return all keys to the key desk where they were originally picked up. For the security of the facilities and animals, it is imperative to return keys and cards of individuals who leave or terminate employment.

As a reminder: Your CatCard is the property of the issuer and is non-transferable. If lost or stolen, call (520) 621-7043. If found, cards can be returned to: University of Arizona CatCard Office, 1303 E. University Blvd. Each CatCard allows one person to enter the Animal Facility. **Do not allow anyone to “piggy back” in on your CatCard.** If an individual does not have CatCard access authorization, they are not allowed access at any time. Each staff member **must** use their own CatCard for access. The visitor policy is stated below.

Keys are issued to individuals. They must not be loaned to non-authorized individuals. Lost keys may result in re-keying doors to UAC. Investigators will be re-charged any costs associated with lost keys.

If keys or cards are lost, missing, or stolen, please immediately notify UAC so that measures can be taken to protect the facilities and animals.

Visitors: In an effort to protect research animals and minimize any possibility of disease transmission, visitors who are immunocompromised and, especially children under the age of twelve, are

discouraged from entering the animal facilities. All visitors must have prior approval of UAC. For admission of visitors into the AHSC facility, please contact the office at 626-6702. For admission to main campus facilities, contact the Central Animal Facility Office at 621-1330. Visitors will be asked to sign a guest book and required to wear a visitor's badge before entering a facility. Authorized personnel must accompany visitors/guests at all times while they are in the animal facilities.

Please contact Assistant Director of Facilities (626-2055) for key access and any questions.



News from HIPAA.....

Frequently Asked Questions and Answers

Question: *What is the relationship between the Privacy Rule and the HHS and FDA Protection of Human Subjects Regulations?*

Answer: There are two main differences. First, the HHS and FDA Protection of Human Subjects Regulations are concerned with the risks associated with participation in research. These may include, but are not limited to, the risks associated with investigational products and the risks of experimental procedures or procedures performed for research purposes, and the confidentiality risks associated with the research. The Privacy Rule is concerned with the risk to the subject's privacy associated with the use and disclosure of the subject's Private Health Information (PHI).

Second, the scope of the HHS and FDA Protection of Human Subjects Regulations differs from that of the Privacy Rule. The FDA regulations apply only to research over which the FDA has jurisdiction, primarily research involving investigational products. The HHS Protection of Human Subjects Regulations apply only to research that is conducted or supported by HHS, or conducted under an applicable Office for Human Research Protections (OHRP) - approved assurance where a research institution, through their Multiple Project Assurance (MPA) or Federalwide Assurance (FWA), has agreed voluntarily to follow the HHS Protection of Human Subjects Regulations for all human subjects research conducted by that institution regardless of the source of support. By contrast, the Privacy Rule applies to a covered entity's use or disclosure of PHI, including for any research purposes, regardless of funding or whether the research is regulated by the FDA.

Upcoming Conferences/Workshops

July 24-25, 2006

[Mentoring and Supervision for the Responsible Conduct of Research](#)

St. Louis, MO

Co-sponsor: Washington University School of Medicine

September 14-15, 2006

Statistics, Images, and Perceptions of Truth: Detecting Research Bias and Misconduct

Birmingham, AL

Co-sponsor: University of Alabama School of Medicine

September 28-29, 2006

New Capabilities, Emerging Issues and Responsible Conduct in Data Management

Baltimore, MD

Co-sponsor: University of Maryland-Baltimore

October 16-17, 2006

Fourth Annual RCR Expo

Quebec City, Canada

Contact: LNguyen-Khoa@osophs.dhhs.gov

December 1-3, 2006

[Research Conference on Research Integrity](#)

Tampa, FL

Co-sponsors: Association of American Medical Colleges, American Association for the Advancement of Science

Abstracts due: April 28, 2006 (see ORI web site for details on submitting abstracts and to obtain a conference schedule: <http://ORI.hhs.gov>).

Questions should be addressed to Nick Steneck at nsteneck@umich.edu.

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Words of Wisdom:

“In everyone's life, at some time, our inner fire goes out. It is then burst into flame by an encounter with another human being. We should all be thankful for those people who rekindle the inner spirit.”

—Albert Schweitzer, 1875-1965