
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

September 1, 2005

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A Message from the Director Thomas P. Davis, Ph.D.

This month we focus on education in Responsible Conduct of Research (RCR). Shown below is the required list of the nine core instructional areas, along with opportunities for promoting RCR education. Also featured is an article from *The Scientist* which updates previously issued NIH ethics rules.

In a 3D Memo released today, it is announced that, effective with the Fall 2005 semester, the University of Arizona has launched, and President Likins has approved, a ***New Code of Academic Integrity***. The changes in process resulted from concerns raised by faculty and students. Although the faculty and student roles remain essentially unchanged, the new ***Code of Academic Integrity*** provides shorter timelines in most cases, and an expanded list of prohibited conduct items which include violations of ***professional ethics***. Faculty members also have a broader range of sanctions at their disposal.

The University of Arizona, ***Code of Academic Integrity*** is available on the Dean of Students website (<http://web.arizona.edu/~dos/index.html>).

Responsible Conduct of Research (RCR)

The Office of Research Integrity (ORI) supports RCR education programs by focusing on the following ***nine core instructional areas***:

- 1) Data Acquisition, Management, Sharing and Ownership
- 2) Conflict of Interest and Commitment
- 3) Human Subjects
- 4) Animal Welfare
- 5) Research Misconduct
- 6) Publication Practices and Responsible Authorship
- 7) Mentor / Trainee Responsibilities
- 8) Peer Review
- 9) Collaborative Science

Responsible Conduct of Research (RCR) Opportunities Abound for Promoting RCR Education

Numerous opportunities exist within colleges, universities, medical schools, and research institutes

to promote responsible conduct of research education through activities that already routinely happen in those organizations, according to Julie Simpson, Manager, Research Conduct and Compliance Services, University of New Hampshire, enumerated those opportunities as follows:

- ✚ Research methods courses
- ✚ Departmental faculty meetings
- ✚ Training sessions offered by Institutional Review Boards, Institutional Animal Care and Use Committees, and Institutional Biosafety Committees
- ✚ Experiential research programs for graduate and undergraduate students
- ✚ Orientation sessions for new faculty, postdoctoral fellows, graduate students, and graduate assistants
- ✚ Training sessions for new department chairs
- ✚ Meetings or luncheons for new faculty hosted by university officials
- ✚ Departmental activities such as dissertation groups, seminar series, journal clubs
- ✚ Institution-wide lecture or discussion series
- ✚ Professional development programming offered by the graduate school
- ✚ Activities sponsored by graduate student and postdoc organizations
- ✚ Feature articles on RCR issues in the campus newspaper and organizational web sites
- ✚ Collaboration with graduate program coordinators to promote RCR training
- ✚ Communications between the chief research officer and the campus community

RCR EXPO – 2005 Free Space Available

The RCR Expo 2005 will be held October 17th and 18th in conjunction with the Society of Research Administrators International Annual Meeting held in Milwaukee, Wisconsin.

The meeting will be held in the new Midwest Express Center. With over 1,500 top research administrators attending the SRA meeting, this event will be an excellent opportunity for institutes and businesses to showcase their RCR educational materials, videos, training tools, web sites, and/or programs.

Exhibits may focus on one or more of the RCR core areas or on other areas deemed related to responsible conduct. Products related to the administration of RCR programs are included, such as train the trainer programs and databases for tracking completion of instruction.

The RCR core areas are (1) data acquisition, management, sharing, and ownership; (2) mentor/trainee responsibilities; (3) publication practices and responsible authorship; (4) peer review; (5) collaborative science; (6) human subjects; (7) research involving animals; (8) research misconduct, and (9) conflicts of interest and commitment.

Free floor space will be provided, a covered 6-foot table, two chairs, name tags, and electricity. TV monitors, DVD players, Internet connection, and other options are available upon request. ORI will not provide computers, projectors, or security for the displays. Exhibitors are expected to monitor their booths at all times.

Space is limited to the 25 exhibitors. Those interested in becoming an exhibitor at the RCR Expo 2005 should email [Loc Nguyen-Khoa](mailto:Loc.Nguyen-Khoa), and include your name, institution, and description of your product or program. The registration deadline is Friday, September 16, 2005.

Visit the [SRA International web site](http://www.sra-international.com) for more information about the annual meeting.

NIH Eases Ethics Rules **Stock ownership allowed but ban on consulting for biotech and drug companies remains**

By [Ted Agres](#)

From *The Scientist*, Monday, August 29, 2005
<http://www.the-scientist.com/news/20050826/01>

The National Institutes of Health (NIH) will ease previously issued ethics rules, the agency announced yesterday (August 25). The leader of a group of senior intramural NIH scientists that had criticized the rules expressed relief at the announcement.

The [final regulations](#) allow most NIH scientists and employees to own stock in biotech and drug companies, and to participate in activities with nonprofit professional and scientific organizations. But a total ban on outside consulting with pharmaceutical, biotech, and medical device companies remains in place for all employees.

The final regulations soften a set of "sweeping" [ethics reforms](#) announced February 1 that had been [severely criticized](#) by scientists and others as being overly broad. Critics said they would have

impaired NIH's ability to recruit and retain talented scientists.

"We are extremely satisfied with what we understand the regulations will be," said Ezekiel Emanuel, chief of clinical bioethics at NIH's Warren G. Magnuson Clinical Center and a member of the executive committee of the [Assembly of Scientists](#), an organization representing NIH intramural researchers. "It comes pretty close to what we had [suggested five months ago](#)," he told *The Scientist*.

The new rules limit stock ownership in biotech, drug, and other "substantially affected organizations" to \$15,000 per company for about 200 senior NIH employees and their families, including institute and center directors and their deputies, as well as scientific and clinical directors. The earlier rule would have applied the holdings cap to about 12,000 NIH employees and would have required about 6,000 intramural scientists, all senior officials, and those having contracting and grant-making authority to divest of all stock in drug and biotech companies.

After receiving some 1,300 comments to the earlier rules, "we decided to adjust in terms of degree some of the decisions we had made before," NIH director Elias A. Zerhouni told reporters yesterday. "The issues that we were facing were not related to stock holdings in great part." The final regulations also ease earlier restrictions on involvement with nonprofit academic, scientific, and professional societies, and participating in civic activities.

"Our research should be based on scientific evidence that is not influenced by any other factors," Zerhouni said. "The trust of the public and the ability for us to provide scientific advice that is untainted is the number one goal of all of our efforts."

While resolving the conflict of interest issue is a "positive step," Emanuel said, larger morale issues still remain for NIH scientists. These include unnecessary restrictions on travel, increasingly burdensome paperwork required to approve outside activities and, most importantly, the need to increase salaries for junior-level scientists.

"NIH has to pay competitive salaries to attract good junior people. That's how we get our senior people," Emanuel said. "If we can't replenish the younger ranks, NIH will become a dying institution."

Links for this article

"Summary of NIH-Specific Amendments to Conflict

of Interest Ethics Regulations."

http://www.nih.gov/about/ethics/summary_amendments_08252005.htm

T. Agres, "NIH bans all consulting," *The Scientist*, February 2, 2005.

<http://www.biomedcentral.com/news/20050202/02/>

T. Agres, "NIH sees fight on ethics rules," *The Scientist*, February 25, 2005.

<http://www.biomedcentral.com/news/20050225/01/>

OPPORTUNITIES FOR ON-LINE ETHICS TRAINING

Ethical Guidelines for Gifts to Physicians from Industry

Free educational modules now available

The AMA's national initiative on *The Communication of Ethical Guidelines for Gifts to Physicians from Industry* is now offering four free online modules for CME credit. Each educational module is available in two formats:

- Online self-study for CME credit; and
- Downloadable resources educators can use to build one-hour learning experiences.

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

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

On-Line Module or Short Course in "The Ethics of Research with Human Subjects"

The Least of My Brothers

Funded by the [National Institutes of Health](#)
(Grant Number 1 T15 AI07601)

The Least of My Brothers is an on-line module (or short course) in the ethics of research with human subjects. You may view more course information at the following web address: <http://poynter.indiana.edu/sas/lb/>, or you may also contact Kara Lochridge at: (812) 856-4968, or klochrid@indiana.edu.

UNIVERSITY OF ARIZONA RESEARCH AND SERVICE GROUP (RSSG)

HUMAN SUBJECT PROTECTION PROGRAM

»Highlights«

Advertisements for Research*

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral

Research [authors of the *Belmont Report*] identify the equitable selection of subjects as one of the major ethical principals. Federal regulations (45 CFR 46.111) also state that the selection of subjects must be equitable. Recruitment of study participants is considered the beginning of the research process. For this reason, the Institutional Review Board (IRB) must consider all recruitment **materials and methods** used for recruitment purposes before they are implemented.

Some commonly used materials for recruitment include flyers, posters, brochures, press releases, or advertisements. Distribution of materials may occur via bulletin boards, newspaper, TV, radio, or websites. Recruitment letters and announcements or presentations made at various meetings are still another form of advertising.

The Food and Drug Administration (FDA) Information Sheet: Recruiting Study Subjects presents the following guidelines for study advertisements:

- Name and address of the Principal Investigator;
- Purpose of the research;
- Inclusion/exclusion criteria;
- A brief list of study procedures;
- Time or other commitment required (e.g., number of study visits);
- Compensation or reimbursement;
- Location of the research;
- Contact person for further information.

In other words, the information must be adequate, accurate and balanced so that potential participants can make an informed decision about possible participation.

The method must also be taken into account and receive IRB approval prior to implementation. For example, recruitment materials such as flyers or posters are often placed in strategic locations or distributed in order to target a specific population. Where recruitment materials are placed and how materials are distributed is just as important as the material itself.

Another issue related to method of recruitment is the 'who' of recruitment. In certain situations, the Investigator may not be the best individual to recruit, as s/he may unduly influence an individual to participate (e.g., teachers recruiting students, employers recruiting employees) particularly if the Investigator has direct supervisory oversight over these individuals.

The next issue to consider is the 'when' of recruitment. The time at which an individual is approached should be convenient and not increase an individual's anxiety level. Presenting research

studies in advance and allowing potential participants time to review the consent and recruitment material is paramount to good recruitment practices.

The Principal Investigator is key to the development of recruitment materials that are appropriate and adequately describe the study. Institutional Review Board approval must be obtained for both recruitment materials and procedures prior to implementation. Questions to ask oneself include: 'what' materials will be used, 'how' will recruitment procedures be performed, 'who' will perform the recruiting procedure, 'when' will recruitment occur, and 'where' will the activity take place.

*Homer, R. Krebs, R. & Medwar, L. (2002). Advertisements for Research. In R. J. Amdur and E. A. Bankert (Eds.), Institutional Review Board Management and Function (pp. 179-184). Sudbury, MA: Jones and Bartlett.

Good Laboratory Practices (GLP)

When are Good Laboratory Practices required?

Any non-clinical study that **supports** or is intended to **support** applications for research or marketing permits for products regulated by **FDA** including:

- Animal food additives
- Human and animal drugs
- Medical devices for human use
- Biological products
- Electronic products

When your research requires GLP Compliance, please contact:

Marilyn M. Marshall, SpM
Quality Assurance Officer
1203 N. Mountain
621-1469 phone
621-1429 fax
marshalm@u.arizona.edu



News from HIPAA.....

Frequently asked questions:

Question: Does the Privacy Rule provide research participants the right to access research records/results?

Answer: With few exceptions, the Privacy Rule gives patients the right to inspect and obtain a copy of health information about themselves that is maintained by a covered entity or its business associate in a "designated record set." A designated record set is basically a group of records which a covered entity uses to make decisions about individuals, and includes a health care provider's medical records and billing records, and a health plan's enrollment, payment, claims adjudication, and case or medical management record systems. While it may be unlikely that a researcher would be maintaining a designated record set, any research records or results that are actually maintained by the covered entity as part of a designated record set would be accessible to research participants unless one of the Privacy Rule's permitted exceptions applies.

One of the permitted exceptions applies to protected health information created or obtained by a covered health care provider/researcher for a clinical trial. The Privacy Rule permits the individual's access rights in these cases to be suspended while the clinical trial is in progress, provided the research participant agreed to this denial of access when consenting to participate in the clinical trial. In addition, the health care provider/researcher must inform the research participant that the right to access protected health information will be reinstated at the conclusion of the clinical trial.

University of Arizona – Animal Care Quality Care for Research Animals



Notice from the IACUC Office Regarding Sub-contracted Animal Research

PHS Policy Notice NOT-OD-01-017 requires that when animal research is sub-contracted from the primary institution, the primary institution either must review the animal work or have an arrangement with the sub-contractor, which allows the sub-contractor's IACUC to review and approve the research. During 2004, the IACUC discovered that there were a number of PHS-funded awards to The University of Arizona, which have sub-contracted animal studies being performed at other sites. For many of these, no arrangements had been made with our IACUC.

After review by the IACUC, and with approval of the Vice President for Research, it was determined that all sub-contracted projects funded

by PHS will be reviewed by the sub-contracting institution, as long as the sub-contractor has an Animal Welfare Assurance on file with the Office for Laboratory Animal Welfare (OLAW-NIH). The University spent a number of months determining how to best facilitate obtaining the information our IACUC would need, and, as a result, has developed two separate contracts, one with the UA Principal Investigator (PI) and one with the Sub-Contracting Institution. The PI will be responsible for providing the following:

1. Prior to the initiation of the animal study, the UA IACUC must receive a copy of the approved sub-contracting institution's IACUC protocol with any revisions made by the sub-contractor's IACUC.
2. As occurring, the following must be received by the UA IACUC:
 - Copies of any amendments approved by the sub-contractor's IACUC;
 - Copies of annual protocol review and/or triennial protocol revisions approved by the sub-contractor's IACUC;
 - Timely information on adverse events related to the animal studies conducted for the UA at the sub-contracting institution;
 - Copies of reports written to USDA, PHS, FDA or any other organization or government body related to the conduct of the animal research for the sub-contract.

The Sub-contracting Institution's IACUC will be responsible for providing the following information to the UA IACUC:

1. PRIOR to the initiation of any animal research for the sub-contracted research:
 - The title of the sub-contractor's approved protocol, whether revisions were made to the original protocol, the date of approval and ending date of approval;
 - Verification of approval signed by the Institutional Official.
2. Once work is initiated, following IACUC approval, The University of Arizona's IACUC must receive the following information at the following frequency of reporting:
 - Semi-annually: verification that the IACUC inspection and programmatic review applicable to the animals utilized in the sub-contract has occurred and if any major deficiencies were found related to the sub-contracted study.
 - Annually: verification of continued approval and if any amendments have occurred during the year.

- Triennially: that the revised protocol has been reviewed and approved; if any revisions were required by the IACUC.

The IACUC is in the process of establishing contracts for currently funded research; for all new animal research proposals that will include sub-contracted animal research, please contact the IACUC office and alert the IACUC Coordinator (621-9305), so that we can initiate contact with the sub-contractor's IACUC.

For any study performed at an institution that DOES NOT have a PHS-Assurance, our IACUC must review and approve the research.

For additional information, copies of the PI or Sub-contracting Institutions Contract with the UA IACUC, or other questions, please contact: Susan Wilson-Sanders at 626-1066 or wilson-s@u.arizona.edu.

Institutional Biosafety Committee



Responsibilities of the Principal Investigator

The Principal Investigator (PI) is defined as the faculty member in whose assigned space a research activity is conducted.

The PI is responsible for full compliance with the policies, practices and procedures set forth in this University of Arizona *Biosafety Handbook*. This responsibility extends to all aspects of Biosafety involving all individuals who enter or work in the PI's laboratory or collaborate in carrying out the PI's research. Although the PI may choose to delegate aspects of the Biosafety program in his/her laboratory to other laboratory personnel or faculty, this does not absolve the PI of the ultimate responsibility. The PI remains accountable for all activities occurring in his/her lab. Documentation of training and compliance with appropriate Biosafety practices and procedure is essential. The PI is responsible for assuring the appropriate safety training of employees and for correcting errors and unsafe working conditions.



Radiation Control

Training Requirements

The Radiation Worker Training Policy requires radiation safety training for users of radioactive materials and radiation producing devices (ionizing and nonionizing). The Approval Holder is

responsible for ensuring that initial and recurring training are completed as required. The worker must operate under direct and close supervision of trained staff until the Approval Holder is assured of the worker's proficiency.

Job-Specific Training: The Approval Holder or another experienced member of the laboratory staff authorized by the Approval Holder provides this training. It is documented by completing an RCO Form [RC-088](#). (See the form and its instructions for guidance). This training must be provided to each individual worker prior to the initiation of work with ionizing (UA and UMC) or nonionizing (UA) radiation.

Certificate Courses: The RCO provides certificate course training for various categories of radiation workers, usually non-clinical personnel. RCO training must be successfully completed prior to commencement of work with radioactive material or radiation producing devices. A completed [RC-088](#) must be submitted at time of registration. Registration date and time will be confirmed via email.

- Basic Radiation Protection Course ([BRPC](#)) – Required for laboratory personnel working with ‘free’ or ‘unsealed’ radioactive materials, also described as ‘wet-chemistry’ work.
- Radiation Sources Protection Course ([RSPC](#)) – Required for personnel working with non-exempt sealed or fixed isotopic radiation sources or devices, such as soil moisture gauges and gamma irradiators.
- Radiation Machine Protection Course ([RMPC](#)) – Required for personnel working in research laboratories with machines producing ionizing radiation, which may include x-ray diffraction and fluorescence equipment, cabinet x-ray systems, and Van de Graaff or particle accelerators.
- Laser Radiation Protection Course ([LRPC](#)) – Required for personnel working with regulated devices producing nonionizing radiation, which primarily includes Class 3b and 4 lasers.

Regulated uses of magnetic fields, microwave, radiofrequency, ultraviolet, and high-intensity visible radiation may require training. Contact the RCO to determine what training is required for non-laser nonionizing radiation producing devices.

Periodic In-Services: Periodic in-services are required for several categories of UMC and UA employees. A completed [RC-088](#) is required prior to attending the clinical in-services. Contact your supervisor for more information.

Clinical staff and institutional support personnel working with ionizing radiation have an annual in-service requirement. These in-services are

orientations that provide radiation safety training to radiation workers that are principally targeted to their type of work. This training shall be completed within 45 days of start of work with ionizing radiation.

Physicians must attend an in-service training every three years.

UPCOMING CONFERENCES/WORKSHOPS

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 23-26, 2005

48th Annual Biological Safety Conference

Westin Bayshore, Vancouver, British Columbia

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

October 25, 2005

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

San Antonio, TX

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

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

Words of Wisdom:

“A new idea is delicate. It can be killed by a sneer or a yawn; it can be stabbed to death by a joke or worried to death by a frown on the right person's brow.”

_____ Charles Brower