
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

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A Message from the Director

Thomas P. Davis, Ph.D.

In the July 4, 2005 issue of *The Scientist*, the editor discusses three very important items: 1) A highly-cited paper in *Science* had to be retracted due to data fabrication/falsification; 2) the addition of "reviewing" application to ORI's ethics rules, and; 3) the results of a survey of several thousand researchers on incidences of misconduct in research.

Please read these very important items as they focus on the real need for research integrity education (RIE).

All Misdeeds Great and Small

By [Richard Gallagher, Editor](#)

Below is an editorial from *The Scientist*,
Volume 19 | [Issue 13](#) | Page 6 | Jul. 4, 2005

A clutch of research misconduct stories has hit the news in recent weeks. Is it a crisis?

Item 1: *The retraction of a highly-cited paper by Science after one of the paper's authors was found guilty of fabricating and falsifying data by an investigatory committee at the University of North Carolina at Chapel Hill.*¹ The work concerns the mechanism underlying Cockayne Syndrome, a rare disorder in which patients exposed to UV radiation lose the capacity to perform a certain type of DNA repair.

Crisis? No, but there's room for concern here given that eight years had gone by between the paper's publication and its retraction. That's particularly galling given that research by the fabricating author, Steven Leadon, had been under the ethical microscope before. He had retracted one of his own papers, and resigned his position as director of radiobiology amidst an investigation into other work.²

While high-profile retractions leave a sour taste, they're mercifully rare. As Tony Waldrop, UNC's vice chancellor for research and economic development, points out: "The case referenced in the *Science* retraction affirms that the scientific process works. Data are checked and rechecked so that the correct result will emerge. **Public trust in the integrity and ethical behavior of scholars**

must be maintained if research is to continue to play its proper role in our university and society."

Item 2: *The US Office of Research Integrity recently made changes to its ethics rules, including "reviewing" as part of its definition of misconduct – meaning a reviewer who plagiarizes an application for federal funding can be charged with misconduct.* The change is apparently inspired by allegations of plagiarism in peer reviewers of applications for NIH funds.

Crisis? Again, no; again, vigilance is required and the occasional miscreants should be "named and shamed."

Item 3: A commentary with the tantalizing title 'Scientists behaving badly.'³ This turns out not to be lewd tabloid revelations but a survey of the professional conduct of several thousand researchers. "US scientists engage in a range of behaviors extending far beyond falsification, fabrication and plagiarism (FFP)" the authors conclude. Actually the series of misdemeanors are less serious, than, not far beyond, FFP. But the collective admission of guilt is shockingly high. One-third of scientists admitted to at least one transgression from a list of 16 that range from questionable to intolerable. ***These included 15% who changed the design, methods, or results of their research under pressure from a sponsor, 12.5% who overlooked other scientists' use of flawed data or questionable interpretations, 7% who ignored "minor rules" involving research subjects, and, 6% who withheld data that contradicted their previous conclusions.***

Crisis? It possibly is. The full extent of these questionable practices is unknown, their growth over time is unexplored, their impact is undiscovered and the proper response to them is unclear. Clearly more study is needed.

"The level of competition in science has absolutely skyrocketed," lead author Brian Martinson was quoted saying in one paper. "There is often a level of desperation that may lead people to behave badly."⁴ But with no historical data, we can't blindly accept this as a recent and growing problem.

Re-education in ethics – especially for more senior scientists, who are more likely to offend – must be another priority. *We may need a precise code of practice, along with enforceable penalties.*

Finally, a word on press coverage. The retraction by *Science* received only modest coverage, mainly local to the affected labs. The minor misconduct study was reported widely and fairly. The exception being a couple of freakish attention-grabbing headlines from the *Washington Post* ("Mad scientists' emerge in study") and London's *The Times* ("Medically speaking, they're liars").

That, at least, is a positive.

References

1. G Flores "Scientist retracts highly cited paper," <http://www.the-scientist.com/news/20050617/01> *The Scientist Daily News* June 17, 2005
2. P Brickley "Repairing BRCA1 science," <http://www.the-scientist.com/news/20030618/04> *The Scientist Daily News* June 18, 2003
3. BC Martinson, MS Anderson, R de Vries "Scientists behaving badly," *Nature* 435: 737. [[Publisher Full Text](#)] June 9, 2005
4. E Ferreri "Coauthor shocked by data falsification," <http://www.herald-sun.com/orange/10-618364.html> *Herald Sun* June 17, 2005

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 professionalism 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)

HUMAN SUBJECT PROTECTION PROGRAM

≡Highlights≡

Conflict of Interest/ Financial Conflict of Interest*

What is conflict of interest?

Conflict of interest is a set of conditions in which an investigator's judgment concerning a primary interest (e.g., subject's welfare, integrity of research, reporting of results, etc.), may be biased by a secondary interest (e.g., personal gain). In other words one outcome is preferred to another due to a financial association that would cause preferential decision-making. Conflict of interest may be found at the institutional as well as the individual level.

What are some of the key issues with regard to individual versus institutional conflict of interest?

Individual Level

- Investigator closely tied to area of research under review;
- Investigator holds significant financial interest in the sponsor of the research;
- Investigator may receive monetary or non-monetary bonuses for meeting recruitment/enrollment goals (e.g., token gifts, authorship, future participation, post study incentives).

Institutional Level

- Desire for institution to protect its reputation or prestige;
- Desire to promote research versus protecting subjects;
- Protection of the institution from liability;
- Pressure for speedy turn-around-time from compliance units and contractual units;
- Objectivity and integrity of the research, itself;

- Appropriate use of sponsor or University funds;
- Integrity of academic and administrative decision making;
- Open publication and sharing of research results.

What is financial conflict of interest?

Financial conflict of interest is a financial association or relationship that would cause an individual to prefer one outcome over another based on these financial associations.

What is the reporting threshold for an individual at the University of Arizona?

\$10,000 in annual income or 5% equity ownership in a company as defined in the UA Conflict of Interest and Commitment Policy. More information regarding the guidelines at the University of Arizona can be found at <http://vpr2.admin.arizona.edu/rie/COIwebs/COICPolicy.1198.pdf>.

If I find that I exceed the threshold for disclosure, what do I do next?

Access the Vice President for Research website at <http://www.vpr.arizona.edu/>. Then, click on the link which indicates "Conflict of Interest" at: <http://www.vpr.arizona.edu/conflict-of-interest/index.html>. There you will find the forms and the instructions for filing a disclosure.

What do the regulations say about financial conflict of interest?

The Food and Drug Administration (FDA) issued a final rule in 1998 that requires sponsors to certify the absence of financial interests of investigators who conducted their studies or to disclose those interests. Such interests include patents, equity or *significant payments of other sorts* of \$25,000 or more to support investigator activities outside of conducting the clinical study (e.g., equipment, honoraria, or consulting fees). This disclosure is tied to the submission of a marketing application to the FDA, and the intent is to protect the integrity of supporting data.

According to "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection" (2004), institutions and individuals involved in human subjects research may establish financial relationships related to a particular research project. Those financial relationships may create financial interests of monetary value, such as payments for services, equity interests, or intellectual property rights and may create a financial conflict of interest that may affect the rights and welfare of human subjects.

Where can I get information related to NIH's financial conflict of interest policy?

The NIH has had a longstanding interest in objectivity in research and financial conflict of interest. The web site which has been initiated to provide information on this important topic is: <http://grants1.nih.gov/grants/policy/coi/index.htm>.

In essence, the problem with *conflict of interest* is one of bias in judgment...where the potential for bias is such that decisions may be called into question. The educational and research activities of a University should be, and should appear to be, motivated primarily by a concern for the advancement of knowledge and the pursuit of truth, not by the pursuit of reward whether financial or otherwise. Although the attention nationally is towards financial conflict of interest, any association that would cause an Investigator or research personnel to prefer one outcome to another is problematic.

*Nelson, D. (2002). Conflict of interest: Researchers.. In R. J. Amdur and E. A. Bankert (Eds.), Institutional Review Board Management and Function (pp. 197-203). Sudbury, MA: Jones and Bartlett.



Good Laboratory Practices (GLP)

The **Quality Assurance Officer, Marilyn M. Marshall** is available to the research community to assist laboratories conducting research under GLP (Good Laboratory Practices) to ensure that their studies fully comply with 21 CFR 58 (FDA) and 40 CFR 160 (EPA). These regulations state that the Quality Assurance Unit shall monitor "each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the GLP regulations." Specifically the QA Unit shall:

- Review and sign GLP animal protocols before sending to IACUC, (University of Arizona/ University Animal Care requirement);
- Maintain a master schedule of all non-clinical studies conducted at the testing facility;
- Maintain copies of all protocols;
- Inspect each study at intervals adequate to assure the integrity of the study, and maintain written and properly signed records of each inspection;
- Periodically submit to management, and the study director, written status reports on each study noting any problems and identifying or recommending appropriate corrective action;

- Determine that no deviations from approved protocols or SOPs were made without proper authorization and documentation;
- Review the final study report to assure that it accurately describes the methods and SOPs and that the reported results accurately reflect the raw data of the study.

Please contact Marilyn M. Marshall, QAO, by emailing her at marshalm@u.arizona.edu, or by calling her at 621-1469, or faxing to 621-1429.



News from HIPAA.....

Frequently asked questions:

Question: Must a covered health care provider obtain an individual's authorization to use or disclose protected health information to an interpreter?

Answer: No, when a covered health care provider uses an interpreter to communicate with an individual, the individual's authorization is not required when the provider meets the conditions below. Covered entities may use and disclose protected health information for treatment, payment and health care operations without an individual's authorization, 45 CFR 164.506(c). A covered health care provider might use interpreter services to communicate with patients who speak a language other than English or who are deaf or hard of hearing, and provision of interpreter services usually will be a health care operations function of the covered entity as defined at 45 CFR 164.501.

When using interpreter services, a covered entity may use and disclose protected health information regarding an individual without an individual's authorization as a health care operation, in accordance with the Privacy Rule, in the following ways:

- When the interpreter is a member of the covered entity's workforce (i.e., a bilingual employee, a contract interpreter on staff, or a volunteer) as defined at 45 CFR 160.103;
- When a covered entity engages the services of a person or entity, who is not a workforce member, to perform interpreter services on its behalf, as a business associate, as defined at 45 CFR 160.103. A covered entity may disclose protected health information as necessary for the business associate to provide interpreter services on the covered entity's behalf, subject to certain written satisfactory assurances set forth in 45 CFR 164.504(e). For instance, many providers

(including those that are recipients of federal financial assistance and are required under Title VI of the Civil Rights Act of 1964 to take reasonable steps to provide meaningful access to persons with limited English proficiency) will have contractual arrangements with private commercial companies, community-based organizations, or telephone interpreter service lines to provide such language services. If a covered entity has an ongoing contractual relationship with an interpreter service, that service arrangement should comply with the Privacy Rule business associate agreement requirements.

In addition, a covered health care provider may, without the individual's authorization, use or disclose protected health information to the patient's family member, close friend, or any other person identified by the individual as his or her interpreter for a particular healthcare encounter. In these situations, that interpreter is not a business associate of the health care provider. As with other disclosures to family members, friends or other persons identified by an individual as involved in his or her care, when the individual is present, the covered entity may obtain the individual's agreement or reasonably infer, based on the exercise of professional judgment, that the individual does not object to the disclosure of protected health information to the interpreter, 45 CFR 164.510 (b)(2). For example, if a covered health care provider encounters a patient who speaks a language for which the provider has no employee, volunteer member of the workforce or contractor who can competently interpret, but then is able to identify a telephone interpreter service to communicate with the patient, the provider may contact the telephone interpreter service and identify the language used by the patient, so that the interpreter may explain to the patient that the interpreter is available to assist the patient in communicating with the provider. If the provider reasonably concludes that the patient has chosen to be assisted by the interpreter, and, by the patient's willingness to continue the health care encounter using the interpreter, reasonably infers that the individual does not object to the disclosure, protected health information may be disclosed in accordance with 45 CFR 164.510(b) without a business associate contract.

Organizations that are subject to both HIPAA and Title VI must comply with the requirements of both laws, though not all HIPAA covered entities are recipients of federal financial assistance and thus, required to comply with Title VI; and not all recipients of federal financial assistance are also

HIPAA covered entities, subject to the Privacy Rule. For information about the obligation of recipients of federal financial assistance to take reasonable steps to provide meaningful access to persons who are limited English proficient, see *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* available at <http://www.hhs.gov/ocr/lep/>. Included in this *Guidance* is information for recipients of federal financial assistance about important considerations for determining the competency of interpreters, such as their understanding of applicable confidentiality requirements that should be taken into account when using interpreters arranged by the provider or when individuals elect to use friends, family or others as interpreters.

HIPAA covered entities may also be required to comply with the Americans with Disabilities Act and/or Section 504 of the Rehabilitation Act of 1973, both of which have requirements for the provision of sign language and oral interpreters for people who are deaf or hard of hearing. The use of communications assistants as part of a Telecommunications Relay Service (TRS) was the subject of a previous FAQ available at <http://www.hhs.gov/ocr/hipaa> (click on Your Frequently Asked Questions About Privacy, and then search on "TRS").

University of Arizona – Animal Care Quality Care for Research Animals



"Side-by-Side" Reviews of Animal Research: Change in IACUC Animal Protocol Review Submission Process

In April 2005, the UA Institutional Animal Care and Use Committee (IACUC), as directed by the Vice President for Research, began requiring that the animal procedure sections of all grants and contracts must be submitted to the IACUC along with the Animal Protocol Review Form (APRF). The background for this decision was as follows:

Under the provisions of the Animal Welfare Act and the Public Health Service Policy, the IACUC is charged with reviewing activities that involve the use of animals.

The AWA states the charge as follows: "Review and approve.....components of proposed activities related to the care and use of animals."

The PHS Policy, which refers to all studies funded by any PHS branch, lists the charge this way: “.....the IACUC shall conduct a review of those components (of PHS-funded projects) related to the care and use of animals and determine that the proposed research projects are in accordance with this Policy.”

In the early days of the IACUC, the charge for review of “activities” involved actual review of the grant. With the inception of the UA IACUC’s Animal Protocol Review Form, the IACUC no longer required the grant to be submitted to the IACUC for review.

Since 2000, The Office of Laboratory Animal Welfare (OLAW) has required that institutions ensure that procedures in IACUC approved studies match the animal procedures in funded grants. After consultation with OLAW, in 2000, the UA’s IACUC added a Principal Investigator/Department Head assurance statement in the APRF. By their signatures, the Principal Investigator and Department Head certified that the procedures in the APRF and grant match.

Recently there have been several cases where our IACUC has determined that APRF’s did not match the procedures listed in funded grants. Such discrepancies can lead to loss of funding for the specific grants and additional sanctions by the PHS on the University of Arizona. To ensure the protection of individual researchers, the research community, and the University as a whole, animal procedure sections of all grants and contracts must be submitted to the IACUC along with the APRF.

Since April, some Protocols have been submitted with the correct attachments; many have not. **Effective September 1, 2005, any protocol, which represents a study to be conducted for a funding agency, that does not include the appropriate sections of the proposal, will NOT be reviewed by the IACUC and will be returned to the Principal Investigator for the addition of the proposal information. Additionally, all APRF’s must have the same title of the proposal they are representing.**

Questions can be addressed to Linda Musgrave at musgravl@email.arizona.edu, (621-9305), or to Susan Wilson-Sanders at Wilson-s@u.arizona.edu, (626-1066).

Institutional Biosafety Committee



IBC Forms

Below are links to IBC forms which may also be accessed at: <http://www.ibc.arizona.edu/>

- [IBC Memorandum of Understanding and Agreement Form \(MUA\)](#)
- [Teaching Lab and Field Course Biosafety Review Form](#)

UPCOMING CONFERENCES/WORKSHOPS

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 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:

“Reality is merely an illusion, albeit a very persistent one.”

~ Albert Einstein