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# 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.*

The article below, “*Studies Report Behaviors that Adversely Impact Research*,” is an excerpt from the December 2005 *Office of Research Integrity* (ORI) newsletter, which may be read in its entirety at the following web address:

<http://ori.hhs.gov/publications/documents/Dec05ORINewsletter2.pdf>

We in the Program in Research Integrity Education at the University of Arizona wish you all a healthy, happy and prosperous 2006!

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## **Studies Report Behaviors That Adversely Impact Research**

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It is generally agreed that three major forms of dishonest behavior—fabrication, falsification, and plagiarism (FFP), violate the fundamental values of research and should be regulated by government. Other questionable practices are thought to be of lesser consequence and therefore left to the oversight of the research community. Two studies published earlier this year raise questions about the relative importance of improper behaviors that adversely impact research.

Brian Martinson of the HealthPartners Research Foundation in Minneapolis, MN, and colleagues are studying factors that can adversely impact research behavior. To assure their work looks at improper behaviors researchers themselves consider important, they interviewed 51 researchers during six focus-group sessions at several top-tier research universities and received additional input from six research compliance officers. The final “top ten” list of improper behaviors is made up primarily of so-called questionable practices, suggesting that researchers regard these practices as important and potentially harmful to research as FFP. *See Table 1.* Martinson’s study also found that researchers self-report engaging in these practices at alarmingly high rates.

Saana Al-Marzouki of the Department of Epidemiology and Population Health, London School of Hygiene & Tropical Medicine, England,

and colleagues are interested not so much in the causes of improper behaviors as their impact. Using a Delphi survey rather than focus groups, they asked 32 clinical researchers to suggest ways “scientific misconduct . . . can arise in the design, conduct, analysis and reporting of a clinical trial.” They then asked the same group to rate the potential impact and likely occurrence of the identified behaviors. Their final listing therefore contains improper behaviors that researchers believe will adversely impact the research process and are likely to occur. *See Table 2.* Interestingly, when the likelihood of occurring is factored in, improper behaviors equivalent to FFP drop off the list, leaving primarily behaviors that fall into the category of questionable practices. Studies such as these are helpful in two ways. First, they suggest areas for future investigation. The perception that questionable practices may impact research more than FFP needs to be confirmed with empirical evidence. Methods also are needed to quantify the impact of different improper behaviors. Second, these and other similar studies suggest targets for responsible conduct of research (RCR) education. When no clear intent to deceive is evident, potential problems could be due to lack of proper training. Martinson’s and Al-Marzouki’s lists might therefore provide useful outlines for designing RCR education programs.

**Table 1. Partial List of  
Martinson’s Ten Top Misbehaviors**

- Ignoring major aspects of human-subject requirements
- Using another’s ideas without obtaining permission or giving due credit
- Unauthorized use of confidential information in connection with one’s own research
- Failing to present data that contradict one’s own previous research
- Overlooking others’ use of flawed data or questionable interpretation of data
- Falsifying or ‘cooking’ research data

**Table 2. Partial List of Behaviors That Have an Adverse Impact and are Likely to Occur According to Al-Marzouki's Study**

- Over-interpretation of “significant” findings in small trials
- Selective reporting of outcomes in the abstract
- Negative or detrimental studies not published
- Inappropriate subgroup analyses
- Selective reporting of positive results or omission of adverse events data
- Failure to report results or long delay in reporting
- Post-hoc analysis not admitted

**Notes**

Martinson, B. C., Anderson, M. S., et al. (2005). Scientists behaving badly. *Nature* 435(7043): 737-738.

Al-Marzouki, S., Roberts, I., et al. (2005). The effect of scientific misconduct on the results of clinical trials: a Delphi survey. *Contemp Clin Trials* 26(3): 331-7.

**OPPORTUNITIES FOR ON-LINE ETHICS TRAINING**

**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).

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.

**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>

**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](mailto:klochrid@indiana.edu).

**UNIVERSITY OF ARIZONA RESEARCH AND SERVICE GROUP (RSSG)**

**HUMAN SUBJECT PROTECTION PROGRAM**

**≧Highlights≦**

**Policies and Procedures\***

Policies and procedures explain why and how certain matters are handled. The policies are the general statements and principles, and the procedures are the specific, step-by-step directions. The policies provide overall guidance, but the procedures are what are followed on a day-to-day basis.

Written procedures are required by federal regulations and the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Food and Drug Administration (FDA) audit letters sanctioning Institutional Review Boards (IRB), almost always include one with a finding of “failure to have and follow written procedures for IRB functions and operations in accordance with 21 CFR 56.108 and 812.66”. AAHRPP’s standard 1.7 requires written procedures governing all research involving human subjects.

The University of Arizona Human Subjects Protection Program (HSPP) has newly developed policies and procedures. They can be found on the HSPP website at [www.arizona.edu](http://www.arizona.edu). The following sections **provide the title and general description** for existing HSPP policies and procedures:

**Section I: Authority and Institutional Commitment** – Institutional authority under which the IRB is established and empowered, cooperative agreements, and research conducted with the Southern Arizona VA Healthcare System

**Section II: IRB Compliance Activities** – Investigating, managing, and reporting issues related to non-compliance.

**Section III: IRB Review Procedures** – Committee responsibilities, determinations, and motions, IRB composition, and materials to be reviewed by the IRB.

**Section IV: IRB Informed Consent Process** – Obtaining legally effective and prospective informed consent.

**Section V: Records, Documentation, and Fees** – Documentation of minutes, processing applications, and organization of the research file.

**Section VI: Investigator Responsibilities** – General responsibilities, conflict of interest, certificates of confidentiality, and data and safety monitoring plans.

**Section VII: IRB Membership** – Member conflict of interest, compensation, and relationships to other University of Arizona committees.

**Section VIII: HSPP Education and Training** – Training requirements for HSPP administrative staff, IRB members, and the research community.

**Section IX: Vulnerable Populations** – Research with special categories of individuals (i.e., children, prisoners, pregnant women, and those individuals with cognitive impairment).

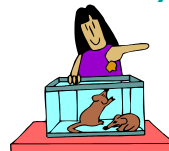
**Section X: Conduct of Research** – HIPAA, compensation for injury, payment, recruitment /advertising, and student/employee participation in research.

**Section XI: Investigational Drugs, Biologics, And Devices** – Storage, handling, dispensing, and disposal of investigational drugs, devices and biologics.

Written procedures are the references used by HSPP administrative staff, IRB members, and the institution’s research community. It is required that institutions have written procedures for regulatory and accreditation purposes. This requirement provides consistency, reduction in errors, training for the research community and equitable treatment of complaints and grievances.

\*Walker, C. S. & Barnard, D. (2005). Documentation, Policies, and Procedures. In E. A. Bankert and R. J. Amdur (Eds.), Institutional Review Board Management and Function (pp. 33-39). Sudbury, MA: Jones and Bartlett.

### University of Arizona – Animal Care Quality Care for Research Animals



### Time to Renew Your SwAEBR Membership

The mission of the **Southwest Association for Education in Biomedical Research** is to develop and implement a strong proactive campaign to educate school children, as well as the general public, in the vital role biomedical research plays in their everyday lives.

The Association disseminates information necessary to improve the public's understanding of how responsible and humane bio-medical research has led to significantly improved health for humankind and its animal companions.

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## News from HIPAA.....

### HIPAA's TOP TEN ARE:

- 10) Know your compliance requirements;
- 9) Understand implementation deadlines;
- 8) Ask the right questions;
- 7) Assign responsible parties;
- 6) Prioritize your compliance activities;
- 5) Evaluate current procedures;
- 4) Revise policies and procedures to incorporate HIPAA requirements;
- 3) Remember to document;
- 2) Provide education/separate Fact from Fiction,  
**AND.....**

- 1) Contact the HIPAA Privacy Officer for assistance including answers to question, training and HIPAA Resources!!

Jeniece Poole, [jpoole@email.arizona.edu](mailto:jpoole@email.arizona.edu)  
**Privacy Officer**  
 621-1465 / 621-1429 (fax)

## Institutional Biosafety Committee



### Responsibilities of Department Heads

Department heads have the following responsibilities:

- A. Insure that prior to initiation of research, each investigator or laboratory director using recombinant DNA, microbial pathogens or human blood and tissues that may harbor a microbial pathogen, complete and file and IBC Memorandum of Understanding and Agreement (MUA) form.
- B. Insure that students have had instruction in safety procedures in teaching laboratories or field situations where the potential for exposure to a biohazardous agent or material exists.
- C. Determine that appropriate facilities and safety equipment are available for proposed research or instruction involving biohazardous agents.
- D. Provide leadership in laboratory safety at the management level in the department.



## Radiation Control

UMC/Clinical – Physician Training  
**Radiation Safety for Medical X-Ray**  
 (No registration required)

AHSC, Room 1556	1/10/2006	2:00 PM - 3:00 PM
AHSC, Room 1556	2/14/2006	2:00 PM - 3:00 PM
AHSC, Room 1556	3/14/2006	2:00 PM - 3:00 PM
AHSC, Room 1556	4/11/2006	2:00 PM - 3:00 PM
AHSC, Room 1556	5/9/2006	2:00 PM - 3:00 PM
AHSC, Room 1556	6/13/2006	2:00 PM - 3:00 PM
AHSC, Room 1556	7/11/2006	2:00 PM - 3:00 PM
AHSC, Room 1556	8/8/2006	2:00 PM - 3:00 PM
AHSC, Room 1556	9/12/2006	2:00 PM - 3:00 PM
AHSC, Room 1556	10/10/2006	2:00 PM - 3:00 PM
AHSC, Room 1556	11/14/2006	2:00 PM - 3:00 PM
AHSC, Room 1556	12/12/2006	2:00 PM - 3:00 PM

## Upcoming Conferences/Workshops

February 17, 2006

[Responsible Conduct in Research in the Social and Behavioral Sciences](#)

Chicago, IL

Co-sponsors: University of Illinois-Chicago, American Association of State Colleges and Universities

May 10-13, 2006

Teaching Research Ethics – A Workshop at Indiana University

<http://poynter.indiana.edu/tre/>

### University of Arizona Program in Research Integrity Education staff:

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 P.R.I.E. – Program phone number: (520) 626-6282  
*The P.R.I.E. newsletter is researched and compiled by Ruth Kurash Daniels.*

### Words of Wisdom:

*“There are no great limits to growth because there are no limits of human intelligence, imagination, and wonder.”*

*~ Ronald Reagan*