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# University of Arizona Program in Research Integrity Education Monthly Newsletter

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

This month we are presenting Part III, the final section of three parts entitled, "Research Issues, Justice, and Conflict of Interest." Offered here is a section of an ethics module found at the Michigan State University website. As mentioned in the last edition of the P.R.I.E. newsletter, the section below is used with the permission of Dr. Howard Brody, Module Director, Center for Ethics & Humanities/Family Practice, (517) 355-7550.

Once again, we thank Dr. Brody for granting permission to use this piece in the P.R.I.E. newsletter. The module may be viewed at [http://www.msu.edu/course/hm/546/w8\\_intro.htm](http://www.msu.edu/course/hm/546/w8_intro.htm), and Dr. Brody may be reached at the follow email address: [brody@msu.edu](mailto:brody@msu.edu).

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### **Research Issues, Justice, and Conflict of Interest Part III**

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#### ***The Integrity of Research***

The second large area of research ethics has less to do with the protection of the subject and more to do with the fundamental integrity of the research process itself.

Research as we conceive of it demands commitment to certain basic principles, including truthfulness in gathering and reporting data, and openness in sharing results so that they can be duplicated and criticized by the larger community of scientists.

For many years, it seemed as if the major threat to these principles came from a few individual scientists, motivated by fear of being thwarted in their career advancement, who deliberately falsified research data. More recently we have become more aware of a systematic threat to research integrity from the increasing commercialization of medical research.

When pharmaceutical and biotechnology firms invest millions of dollars in the development of a new treatment – and when rumors of a treatment's failure in research trials might cause the company's stock to lose a quarter or a third of its value in the market – then financial incentives within the industry may run directly counter to the integrity of the scientific process as traditionally conceived. Firms have a strong incentive to squelch the publication of experimental data which are unfriendly to its product, and to keep positive experimental findings secret so that competitors cannot gain an advantage. We even see a rush to patent genes, cell lines, and other products of human biology.

In recent years numerous "scandals" related to the commercialization of research have appeared in the public and medical press. Physician-investigators have lost their jobs or been threatened with lawsuits by drug companies for trying to publish data which the company did not want released. Drug companies, frustrated with the slowness of the university research process, have turned to for-profit, non-academic research firms to conduct the drug trials required for approval of new drugs. This has in turn spawned a cottage industry of private physicians, with little research training, contracting with the for-profit firms to conduct clinical trials. At least a few such physicians have been found submitting fraudulent data so as to maximize their own profits. For-profit research firms have turned to for-profit IRBs to provide "ethical" review of the research studies and the use of human subjects.

#### ***The Individual Physician and Research Integrity***

The ethical issues in assuring the integrity of the scientific research process may at first seem quite distant from the life of the individual medical practitioner – assuming that the practitioner has not elected to run a for-profit clinical trial business out of his office. But included in this set of ethical

issues is the general question of the correct relationship between the medical profession and the various industries that supply essential products needed to treat patients. Hardly anyone wants to stop the development of new drugs or shut down companies which devote themselves to producing high-quality, high-purity products. So how can the medical profession as a whole, and the individual physician as part of the profession, reap the appropriate benefits of the relationship with industry, while avoiding practices which threaten the ethical integrity of medicine?

This issue arises in a microcosm in an everyday ethical problem – how physicians should relate to drug detail people and others who market drugs and other medical products. The marketing of drugs to physicians has become a huge business, with more being spent annually in the U.S. on marketing to physicians than is spent on all medical schools and all residency programs combined. Defenders of these practices – which may include something as innocent as a free ballpoint pen with the name of a popular drug printed on it, all the way up to all-expense-paid vacations at plush resorts (spouse included) for physician "opinion leaders" who agree to listen to a 3-hour "medical education" program organized by the company – argue that this is the most effective way in a capitalist society to disseminate new information to practitioners, and that individual practitioners can properly assess the value of the information provided without undue bias. Opponents point to studies that the information provided by detail people is often slanted or wrong and that physicians are indeed heavily biased by this information though they often do not recognize this.

The line between medical research ethics and individual practitioner integrity is often crossed in marketing efforts because at least some ethically questionable marketing practices are packaged as research. For instance, physicians may be paid a fee to fill out a short form each time they prescribe a new drug. Ostensibly the physician is being paid to provide research data to the company as part of post-drug-release surveillance. But critics charge that what is often happening is that the scientific value of such forms is nil, and physicians are instead being paid a fee for prescribing the new drug as much as they can.

What counts as a balanced approach to this area of practice, which accepts the positive value of a capitalist, free-market culture and system of

supply, while still preserving the integrity of the profession by demanding that the drug prescribed for the patients should represent the physicians' best scientific judgment, and not which company bought them dinner at an expensive restaurant last week?

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## **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)

#### ***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.

**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. Please contact the following web site: <http://poynter.indiana.edu/sas/lb/>. You may also contact Kara Lochridge at: (812) 856-4968, or [klochrid@indiana.edu](mailto:klochrid@indiana.edu).

**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 pro-fessionalism 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>.

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

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**UA HUMAN SUBJECT  
PROTECTION PROGRAM**

**≧Highlights≦**

**Evaluating Research Intent**

*Federal regulations define research as; "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102 (d), 1991). The first element – **systematic investigation** may be characteristic of both research and no-research activities. Quality assurance projects, program and course evaluations are examples in which data may be collected and analyzed in a manner identical to that of research projects, but may not be research. "All well-designed medical research involves a systematic approach to investigate a scientific hypothesis, but a systematic investigation is not synonymous with research intent" (Amdur & Speers, 2002, p. 120). The second element - **generalizable** means the degree of assurance that the findings obtained from the research sample can be extrapolated to the population.*

As noted above, systematic investigation and generalizability of results do not necessarily identify research intent. In order to classify a project as either a research or a nonresearch activity, the individual must ask about the intent of the activity. The defining factor frequently used is whether the individual intends to publish the proceedings of the activity or present information obtained from the activity in an academic forum. Although this is not a bad way to proceed, the focus should not be whether the individual wants to publish or present results in the future, but rather would the project be done as planned if **academic recognition** was definitely not a possibility? (Amdur & Speers, 2002) The question to be asked then is as follows: "Would the project be conducted as proposed if the project investigator knew that he or she would never receive any form of academic recognition for the project, including publication of results in a journal or presentation of the activity at an academic meeting?" The individual's response to this question can assist in determining research intent.

On occasion, the activity may begin as quality assurance, program evaluation or another type of nonresearch activity. As the project progresses the individual finds that the collected information might be worthy of publication. It is at this point that review by an Institutional Review Board (IRB) must be sought. Many times, projects involving use of data that already exist can be given an administrative review and classified as an exempt project. Classification of the activity as exempt may also depend on the sensitivity and anonymity of the previously collected information. If information is being collected in an ongoing manner and the individual determines that his/her intent has changed to include a research component, other requirements (such as informed consent) may be requested by the Institutional Review Board (IRB).

The system for protecting the rights and welfare of potential research participants depends on the integrity of the individual conducting the activity. To identify research intent, the individual must thoughtfully consider the role of *academic recognition* in the conduct or performance of the activity.

Amdur, R. J., & Speers, M. A. (2002). Identifying Research Intent. In R. J. Amdur and E. A. Bankert (Eds.), Institutional Review Board Management and Function (pp. 118-124). Sudbury, MA: Jones and Bartlett.

*Code of Federal Regulations. Title 45A-Department of Health and Human Services; Part 46-Protection of Human Subjects. Updated August 19, 1991. Retrieved December 12, 2004 from the World Wide Web: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.*



All University of Arizona research conducted as a GLP [Good Laboratory Practices] should fully comply with 21 CFR 58 [FDA] and 40 CFR 160 [EPA] regulations. For more details contact Marilyn M. Marshall, Quality Assurance Officer at 621-1469 or visit at 1203 N. Mountain.

- 21 CFR 58 [FDA] Good laboratory practices for conducting non-clinical laboratory studies that support applications for research or marketing permits for products regulated by the FDA, including food, and color additives, animal food additives,

human and animal drugs, medical devices for human use, biological products, and electronic products.

- 40 CFR 160 [EPA] Good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing.



## News from HIPAA.....

***The first person convicted under HIPAA was sentenced to 16 months in prison on Nov. 5, 2004.*** According to the U.S. Attorney's Office for the Western District of Washington, Richard Gibson of SeaTac, Washington, also received three years of supervised release and will pay more than \$9,000 in restitution for wrongful disclosure of individually identifiable health information for economic gain. Gibson admitted that he obtained a cancer patient's name, date of birth and social security number while he was employed at the Seattle Cancer Care Alliance, and that he disclosed this information to get four credit cards in the patient's name. Gibson used the cards to "rack up more than \$9,000 in debt in the patient's name," federal prosecutors allege.

## HIPAA VIDEOCONFERENCE TAPE AVAILABLE

The Society for Research Administrators (SRA) International Satellite Videoconference from January 23, 2003 is available on tape.

To request use of the tape, please contact **Alice Langen**, Director, Research Standards & Compliance, Office of the VP for Research (621-5196) or [langena@u.arizona.edu](mailto:langena@u.arizona.edu). After viewing, you will receive a *Certificate of Completion* for your files and grant submissions.



## Radiation Control

### ❖ **RELOCATION** –

The Radiation Control Office's (RCO) moving date has been delayed to January 10th - 12th. We are moving to the Babcock Bldg. #151, 1717 E. Speedway, Suite 1201. Beginning, Monday, January 10, 2005, the office will be closed for walk-in business through January 13, 2005.

*Our website will be down January 8 through January 11, 2005.*

All phone numbers will remain the same. In case of emergencies, please call the emergency pager, 516-8758. \*Note: we will have our main number, 626-6850, forwarded to a cell phone on the 1/11/05, if you need to reach the RCO.

Our campus mailing address will remain the same, and is:

*Radiation Control Office,  
PO Box 245101  
Tucson, AZ 85724*

❖ The position of **Director, Radiation Control Office** is open and will remain open until filled. To apply, please complete the online application at <http://www.hr.arizona.edu>.

## Institutional Biosafety Committee



### Frequently asked questions...

**Question:** What is the Institutional Biosafety Committee?

**Answer:** The Institutional Biosafety Committee (IBC) was formed October, 1976, per a national directive from the National Institutes of Health (NIH). The initial purpose of the IBC was to review all research with recombinant DNA on the University of Arizona campus, subject to rule provided by the Office of Recombinant DNA Research at NIH. Later, a similar set of rules governing recombinant DNA research in agriculture was provided by the U.S. Department of Agriculture (USDA). At that time, the Committee began to work closely with the Animal and Plant Health Inspection Service (APHIS) Office of the USDA and with the Arizona Department of Agriculture and Horticulture. In the fall of 1988, in response to local needs and federal regulations, the Committee expanded its role to include the review of research involving microbial organisms pathogenic to plants, animals and humans. In February 1991, the Committee agreed to review research protocols involving biohazards submitted by the Tucson Veterans Affairs Medical Center.

## University Animal Care Quality Care for Research Animals



### University of Arizona Animal Care

#### Frequently asked questions...

**Question:** Why can't alternatives such as computer models and cell cultures replace animal research?

**Answer:** Computer models and cell cultures, as well as other adjunct research methods, are excellent avenues for reducing the number of animals used. These methods are used to screen and determine the toxic potential of a substance in the early stages of

investigation, thereby reducing the total number of research animals needed. The final test, however, has to be done in a whole, living system. Even the most sophisticated technology cannot mimic the complicated interactions among cells, tissues and organs that occur in humans and animals. Scientists must understand these interactions before introducing a new treatment or substance into humans.

In addition, there are very strong economic incentives to replace animals with computers or other adjunct methods. Research animals are very expensive to acquire and care for and are only used because no alternatives currently exist.

For the near future, however, these adjunct technologies will be used in conjunction with, not instead of, laboratory animals.

### UPCOMING CONFERENCES/WORKSHOPS

February 20-24, 2005

**1<sup>st</sup> Global Quality Assurance Conference and, 21<sup>st</sup> Society of Quality Assurance (SQA) Annual Meeting –**

**“Committed to Quality in Research”**

Orlando, FL

<http://www.sqa.org/gqac/index.asp>

February 24-27, 2005

**Fourteenth Annual Meeting**

**Association for Practical and Professional Ethics**

San Antonio, TX

<http://www.indiana.edu/~appe/program.html>

May 12-14, 2005

**Twelfth Annual Teaching Research Ethics Workshop**

Indiana Memorial Union

Bloomington, IN

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

June 9-10, 2005

Ethics and Social Responsibility in Engineering and Technology

**Linking Workplace Ethics Education**

Los Angeles, CA

<http://www.gonzaga.edu/Academics/Continuing+Education/Curent+Programs/Engineering+Ethics/default.htm>

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P.R.I.E. – Program phone number: (520) 626-6282

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

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### Words of Wisdom:

*"Twenty years from now you will be more disappointed by the things that you didn't do than by the ones you did do. So throw off the bowlines. Sail away from the safe harbor. Catch the trade winds in your sails. Explore. Dream. Discover."*

– Mark Twain