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# University of Arizona Program in Research Integrity Education Monthly Newsletter

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December 1, 2004

Volume 4, No. 12

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

This month we are presenting Part II 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. 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 II**

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### *The Animal Subject*

Some philosophers of the 17<sup>th</sup> and 18<sup>th</sup> century argued that animals were mere objects which humans could ethically use for their benefit and convenience however they pleased. Surgical experiments on awake animals (vivisection) were commonly performed during this era. Both philosophical debate and public outcries against vivisection led to a gradual alteration of views, and it is now widely held that some ethical duties are owed to animal subjects as well as to human subjects. Regulations now exist to protect animals from unnecessary pain and suffering in the experimental setting.

In this teaching unit we will deal very little with animal rights, and with arguments that even with these new regulations, exploitation of animals for most experiments to benefit humans is unethical. We will simply note that this area of ethics is a serious debate with thoughtful views on many sides. Unfortunately, many physician-investigators have generalized from the "kooks" at one fringe of the animal-rights movement, and have concluded that any restrictions on the use of animals in experiments to benefit humans are ridiculous on their face. We

find it unfortunate that otherwise intelligent scientists have been so quick to dismiss a valid and complex area of ethical discussion.

### ***Recent Developments***

The general content of the research-ethics debate has changed since the 1980's when the informed consent and IRB movement was just becoming established. The current IRB structure is increasingly under attack, not from investigators yearning for the old days of no oversight, but from thoughtful investigators who argue that IRBs have become too bureaucratic and now protect the research subject from non-existent risks while ignoring more serious risks coming from another direction.

Research subjects have also chimed in with their own objections to the subject-protection bureaucracy. The predominant anecdote of the 1970's was the Tuskegee experiment and the Nazi exploitation, so naturally the focus of the rules promulgated in that era was protecting subjects from harm. In the late 1980's the predominant anecdote was how AIDS patients were being kept out of trials of new, promising, antiretroviral drugs because the investigators had decided that they did not quite meet the ideal study criteria. Subjects were now less worried about being saved from harm, and more concerned that a paternalistic bureaucracy would deprive them of the benefit from new treatments. Due to political pressure from AIDS activists, the inclusion criteria for some of these studies was considerably relaxed.

Also more recently, philosophers like Franklin Miller have begun to dispute the traditional distinction between the physician-patient and investigator-subject relationships. Miller has argued that it is psychologically unrealistic to expect that a well-trained physician who then undertakes a career in research will suddenly lose all her instincts to care about the well-being of patients, and search only for the advancement of knowledge. Nor should the blurring of roles be seen as an ethical defect, since it actually constitutes an additional protection for the individual subject. Miller is not proposing that we throw out IRBs and research regulations, but he does

propose that we accept that this distinction is muddier than the bioethicists had at first proclaimed.

One way of making Miller's point is to return to an often-quoted phrase from Henry Beecher's 1966 expose: "the [most] reliable safeguard [is] provided by the presence of an intelligent, informed, compassionate, responsible investigator." In the 1970's most bioethicists viewed this statement as a cop-out and demanded more regulations and bureaucracy. In the 21<sup>st</sup> century we now see that regulations and bureaucracy have created their own problems and have not necessarily provided the wholesale protection for subjects that we fondly imagined. We are now back to exploring how to hone the ethical sensitivities of the investigator, realizing that the ethical investigator is indeed an indispensable element in the ethical conduct of research.

### ***Cross-Cultural and International Dilemmas***

The increasingly international conduct of medical research has also caused a strain on the two ethical principles invoked in the 1970's— respect for autonomy and justice. In the cross-cultural and international setting, it is not always clear what these mean.

The dilemma was well exemplified in 1998 by the debate over trials of antiretroviral drugs in West Africa and Thailand, in which a lower-dose regimen was compared to placebo in preventing transmission of HIV from mother to fetus. The trials were attacked because the lower-dose regimen was compared to placebo and not to the standard dose regimen currently in use in the US. Some commentators even compared these trials to the Tuskegee syphilis study as an exploitation of third-world populations without adequate consent. Opponents of the trials argued that the lower-dose drug regimen was still too expensive for the host nations, and so if it was shown effective, the benefit would accrue to the US by allowing us to save money on anti-HIV drugs in pregnancy. Supporters of the trials pointed out that the present standard of care in the host countries was no care at all, so that the placebo control group was defensible.

What does the principle of respect for autonomy require in this setting? Does it mean that people all over the world need to individually read and sign a Western-style consent form – even if they are illiterate and there is no satisfactory way to translate some complex medical concepts into the local language? Or does it mean that the consent process should mirror the extant cultural practices of the local community, such as consent by the village elder rather than by each individual person – even if some of those cultural decision processes reduce women and others in the community to second-class status?

What does the principle of justice require in this setting? Does it mean that subjects in the experiment must receive a level of care equivalent to patients in the West – even if such care is well beyond the ability of the host nation to pay for, and even if providing that level of care is tantamount to demanding that the agency funding the research single-handedly reform the health care system of the host nation? Or does it mean that the level of care provided and tested should deal with the real-world problems and economic limitations of the host nation – even if that level of care is well below that of the US, and even if US populations may reap substantial benefits from the results of the research?

When two well-meaning and thoughtful observers can survey an experimental study in a third-world country, and one sees shameless exploitation of the local populace where the other sees a realistic attempt to help the host country with its health problems, this particular debate within research ethics is bound to continue.

*See Part III in the January 2005 issue.*

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## **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. 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≡**

***Certification of IRB Professionals\****

*Certification is a defining characteristic of a profession that denotes a level of knowledge and proficiency in a specialized field. Institutional Review Boards have reached the level of complexity in that it is now appropriate to have a certification process. Certification is granted by a professional group and is a form of recognition rather than registration or licensure and is increasingly recognized as an important part of an effective human subjects protection program. The Applied Research Ethics National Association (ARENA) assisted in the development of the Certified IRB Professional (CIP) program – a rigorous program which requires a substantial time commitment on the part of the applicant.*

*National certification of professionals involved in the oversight and monitoring of research offers the public, legislators, and sponsors a standard for professional practice and helps assure adherence to regulatory requirements, good clinical practice, and ethical principles.*

This process of credentialing (in which certification is one part of the process) establishes a core body of knowledge that promotes improved protection of human research participants and facilitates productive interaction between the human subjects programs and the research community. The individual who passes the certification examination is identified as possessing a high level of technical expertise and is certified as having met the requirements and demonstrated an understanding of a specific body of knowledge at a level sufficient to meet established standards.

This month the Human Subjects Protection Program staff wishes to recognize one of its' staff members, Judy Skroback for having passed the Certified IRB Professional (CIP) certification examination. Congratulations to Judy for achieving this goal and reaching this high standard.

\*Delano, S.J., Sallyann, H., & Chadwick, G.L. (2002). Certification of IRB Professionals. In R. Amdur and E. Bankert (Eds.), Institutional Review Board Management and Function (pp. 357-359). Sudbury, MA: Jones and Bartlett.

 **Good Laboratory Practices**  
**F.Y.I.**

The Environmental Protection Agency's (EPA's) Good Laboratory Practice Standards (GLPs) compliance monitoring program, through laboratory inspections and data audits, assures the quality and integrity of test data submitted to the Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). This data is used by the Agency to regulate pesticides and industrial chemicals.

**GLP Regulations Advisories**

The GLP [Advisories](#) interpret the GLP regulations (40 CFR part 160 for FIFRA and 40 CFR part 792 for TSCA). EPA's Agriculture Division of the Office of Compliance, which administers the GLP program, issues the interpretations.

**Standard Operating Procedures (SOPs)**

Search the [SOPs](#) used by EPA when conducting GLP inspections and data audits.



**News from HIPAA.....**

**Frequently asked questions on Privacy.....**

**Question:** What does the HIPAA Privacy Rule do?

**Answer:** Most health plans and health care providers that are covered by the new Rule must comply with the new requirements by April 14, 2003. The HIPAA Privacy Rule for the first time creates national standards to protect individuals' medical records and other personal health information.

- It gives patients more control over their health information.
- It sets boundaries on the use and release of health records.
- It establishes appropriate safeguards that health care providers and others must achieve to protect the privacy of health information.
- It holds violators accountable, with civil and criminal penalties that can be imposed if they violate patients' privacy rights.
- And it strikes a balance when public responsibility supports disclosure of some forms of data – for example, to protect public health.
- For patients – it means being able to make informed choices when seeking care and

- reimbursement for care based on how personal health information may be used.
- It enables patients to find out how their information may be used, and about certain disclosures of their information that have been made.
- It generally limits release of information to the minimum reasonably needed for the purpose of the disclosure.
- It generally gives patients the right to examine and obtain a copy of their own health records and request corrections.
- It empowers individuals to control certain uses and disclosures of their health information.

### 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

### Regarding a Radiation Spill...

#### *Notes and Precautions:*

Spreading of radiation beyond the spill area can easily occur by the movement of personnel involved in the spill or cleanup effort. Prevent spread by confining movement of personnel until they have been monitored and found free of contamination. A minor radiation spill is one that the laboratory staff is capable of handling safely without the assistance of safety and emergency personnel. All other radiation spills are considered major. Call the Radiation Control Office (626-6850) to ensure proper procedures are being taken to clean up the spill.

#### *Always remember to "S.W.I.M."*

- ✓ **Stop the spill;**
- ✓ **Warn other personnel;**
- ✓ **Isolate the area;**
- ✓ **Minimize the exposure to radiation and contamination.**

#### *Minor Radiation Spill:*

- Confine the spill immediately.
- Alert people in the immediate area of the spill and keep non-essential personnel out of the area.

- Notify Laboratory Manager or Radiation Safety Office (626-6850).
- Wear Protective equipment, including safety goggles, disposable gloves, shoe covers, and long-sleeve lab coat.
- Place absorbent paper towels over liquid spill. Place towels dampened with water over spills of solid materials.
- Using forceps, place towels in plastic bag. Dispose in radiation waste container.
- Monitor area, hands, and shoes for contamination with an appropriate survey meter or method. Repeat cleanup until contaminating is no longer detected.

#### *Major Radiation Spill:*

- ❖ Attend to injured or contaminated persons and remove them from exposure.
- ❖ Alert people in the laboratory to leave the immediate area.
- ❖ Have potentially contaminated personnel stay in one area until they have been monitored and shown to be free of contamination.
- ❖ Notify Laboratory Manager or Radiation Safety Office (626-6850).
- ❖ Close doors and prevent entrance into affected area.
- ❖ Have person knowledgeable of incident and laboratory assist emergency personnel.

### Institutional Biosafety Committee



#### IBC Background

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.

## IBC Contacts

**Please note:** Access to the Biosafety Committee members is restricted to University faculty and staff. Please contact the UofA Biosafety Office at (520) 621-5279 to access the committee member list

***Institutional Biosafety Committee has moved to...***

**1230 N. Park, Suite 205**

**P.O. Box 210420**

**Tucson, AZ 85721-0420**

**Margaret Stalker, Program Coordinator Senior,  
520-621-3441**

**Mark Grushka, Biosafety Officer,  
(520) 621-5279; Office Fax (520) 621-6159**

## **University Animal Care Quality Care for Research Animals**



### *University of Arizona Animal Care Mission Statement*

University Animal Care is an animal care research center with facilities located at the University of Arizona Health Science Center (**AHSC**) and the main campus Central Animal Facility (CAF). Our department is in charge of the campus wide animal care and use program and its personnel are located primarily in the AHSC, CAF and **Veterinary Science Microbiology buildings.**

Our primary **mission** is to assure that healthy animals are available for use by faculty members and students who have received approval to perform research, testing, or educational studies on animal subjects. UAC ensures humane and appropriate animal care and use by providing for the animal's daily care needs, providing necessary veterinary care, monitoring use of animals by principal investigators and their technical personnel, and by ensuring that the highest standards are met relating to animal care and health so that each animal's well-being is attended to.

## **Announcing the 1st Global Quality Assurance Conference and 21st Society of Quality Assurance (SQA) Annual Meeting**

This precedent-setting conference and pre-conference training will be held Sunday through Thursday, 20 - 24 February 2005, in Orlando, Florida, USA, with the theme, "Committed to Quality in Research." The International Organizing Committee, through SQA, is accepting abstracts for the Conference. [Submit your abstract now](#) for a 30-minute topic, a complete 90-minute session (traditionally three 30-minute topics) or a poster. The submission deadline was September 13, 2004. The Program Committee will consider all regulatory QA topics: manufacturing (GMPs), preclinical (GLPs) and clinical (GCPs). Other areas of interest may include animal health, bioanalysis, biotechnology, computer validation, medical devices, scientific archiving, university issues and much more.

### **UPCOMING CONFERENCES/WORKSHOPS**

December 2-3, 2004

**Developing Policy on Institutional Conflict of Interest**  
Las Vegas, NV

**Co-Sponsor:** University of Nevada – Las Vegas  
[http://ori.dhhs.gov/html/programs/conf\\_workshops\\_2004.asp](http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp)

December 8, 2004

**Ethics and Responsible Conduct of Research Workshop**  
Washington, DC

**Co-Sponsor:** Council of Graduate Schools  
[http://ori.dhhs.gov/html/programs/conf\\_workshops\\_2004.asp](http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp)

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

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Alice C. Langen, Director, Research Compliance

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

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### *Words of Wisdom:*

*"Problems worthy of attack prove their  
worth by fighting back."*

*- Paul Erdos (1913-1996)*