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# University of Arizona Program in Research Integrity Education Monthly Newsletter

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April 1, 2004

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

This issue of the P.R.I.E. newsletter contains Part II of *Fact vs. Myth – About the Essential Need for Animals in Medical Research*. The March 2004 issue contained Part I of this article which cites the most common **myths** regarding animals in research, and also states the **facts** behind these myths. We would again like to thank David Talbot, Director of Communications at the *Foundation for Biomedical Research (FBR)* for granting permission to use this material in the P.R.I.E. newsletter. You may access the *FBR* web site at <http://www.fbresearch.org/>.

### **Fact vs. Myth** **About the Essential Need for** **Animals in Medical Research** **(Part II)**

**Myth:** Researchers are indifferent to the well being of animals.

**Fact:** For humane, compassionate and scientific reasons, researchers are deeply concerned about the condition of the animals they study. This is not a controversial position – there is no constituency for inhumane or irresponsible treatment. Poor care results in unreliable research data. For results to be valid, animal subjects must be in good condition and appropriately healthy.

Also, pain and distress are thought to have a negative impact on the immune system so researchers are careful to protect their animals from undue stress.

In the words of the esteemed Dr. Michael E. DeBakey, Chancellor Emeritus of the Baylor College of Medicine and Director of the DeBakey Heart Center: “These scientists, veterinarians, physicians, surgeons and others who do research in animal laboratories are as

much concerned about the care of the animals as anyone can be. Their respect for the dignity of life and compassion for the sick and disabled, in fact, is what motivated them to search for ways of relieving the pain and suffering caused by diseases.”

It is well recognized that animals have been indispensable to the cause of medical and scientific research. We have a moral duty to provide them the best care and treatment possible.

**Myth:** Research animals are kept in pain.

**Fact:** The vast majority of biomedical research does not result in significant pain or distress to research animals.

The 2000 USDA Annual Report reveals that 63 percent of all research procedures with animals involved no more than slight or momentary pain or distress (i.e.: an injection). Twenty-nine percent of the research procedures employed anesthesia and postoperative painkillers.

In seven percent of the procedures, neither anesthesia nor pain medication could be used, as they would have interfered with research results. However, when this is the case, pain is minimized as much as possible. One example of this kind of test is the study of pain itself, a major health problem for humans and animals and an area in which considerable progress has already been made.

**Myth:** There is no need to test consumer products on animals – some companies don't.

**Fact:** Manufacturers of food, drugs, household good, cosmetic products, pesticides and other chemicals have **an ethical and legal obligation to protect consumers** from hazardous consumer products. They are able to meet that obligation through animal testing, for which there is no completely valid alternative.

Some companies promote their products by claiming they do not test on animals. This can mislead consumers into believing that animal testing is not necessary when in fact, **such products – or their ingredients – were previously tested on animals**, probably by another company and found to be safe. Once an ingredient or formula has been tested and proven safe, it rarely has to be tested a second time.

Household product testing not only determines a product's safety; it also evaluates the consequences of its misuse. These important data are invaluable to the poison control centers that dispense advice in emergency situations such as when a small child or family pet swallows a pharmaceutical or cleaning product.

**Myth:** If you really love animals, you support the animal rights movement and its efforts to end animal research.

**Fact:** The vast majority of Americans support improving human and animal health through the responsible and humane use of animals in medical and scientific research. And most Americans love animals! The two concepts are not mutually exclusive – when you know the facts.

Though it isn't easy to reconcile our love and appreciation for animals and the essential need for animal research, knowing that the animals are treated respectfully, responsibly, and humanely, strengthens our understanding and respect for animal research.

Those who seek to end animal research – either because they choose to reject its well established validity and usefulness or because they believe the life of a rat is equal in importance to the life of a child – have gone to shocking lengths to subvert medical and scientific progress. University laboratories have been broken into, animals stolen and years of precious research data destroyed. Though many animals' rights organizations refuse to condemn such criminal behaviors, law-abiding Americans have not, do not now, and will not in the future tolerate violent and radical activist campaigns against the biomedical research community.

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

## Frequently asked questions on Privacy.....

### Question:

Generally, what does the HIPAA Privacy Rule require the average provider or health plan to do?

### Answer:

For the average health care provider or health plan, the Privacy Rule requires actions, such as:

- ✚ Notifying patients about their privacy rights and how their information can be used.
- ✚ Adopting and implementing privacy procedures for its practice, hospital, or plan.
- ✚ Training employees so that they understand the privacy procedures.
- ✚ Designating an individual to be responsible for seeing that the privacy procedures are adopted and followed.
- ✚ Securing patient records containing individually identifiable health information so that they are not readily available to those individuals who do not need them.

Responsible health care providers and businesses already take many of the kinds of steps required by the Rule to protect patients' privacy. Covered entities of all types and sizes are required to comply with the Privacy Rule. To ease the burden of complying with the new requirements, the Privacy Rule gives needed flexibility for providers and plans to create their own privacy procedures, tailored to fit their size and needs. The scalability of the Rule provides a more efficient and appropriate means of safeguarding protected health information than would any single standard. For example:

- ✚ The privacy official at a small physician practice may be the office manager, who will have other non-privacy related duties; the privacy official at a large health plan may be a full-time position, and may have the regular support and advice of a privacy staff or board.
- ✚ The training requirement may be satisfied by a small physician practice's providing each new member of the workforce with a copy of its privacy policies and documenting that new members have reviewed the policies; whereas a large health plan may provide training through live instruction, video presentations, or interactive software programs.

✚ The policies and procedures of small providers may be more limited under the Rule than those of a large hospital or health plan, based on the volume of health information maintained and the number of interactions with those within and outside of the health care system.

☑ *Good Laboratory Practices*  
*Reminder*

All University of Arizona research conducted as a GLP (Good Laboratory Practices) should fully comply with 21 CFR 58 [FDA] and 40 CFR 120 [EPA] regulations. For more details contact Marilyn M. Marshall, Quality Assurance Officer at 621-1469 or visit at 1203 N. Mountain.

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## **UA Human Subjects Program**

### »Highlights«

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#### **Human Subjects Protection Program Consent Form Modification**

The Human Subjects Protection Program has received numerous inquiries from investigators concerning the use of second person (you, your) instead of first person (I, my) in research consent forms. The University of Arizona initiated the use of first person many years ago when little regulatory guidance was available. The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) recommend the use of “you” rather than “I” in consent instruments. In addition, investigators who are collaborating with other institutions have encountered difficulties in obtaining approval for use of the U of A consent forms because of this difference. This results in frustration and delays for University of Arizona investigators, the UA Institutional Review Board (IRB), study personnel, and IRBs at collaborating institutions.

For existing projects, consenting instruments using first person will be accepted for the life of the project. For new projects, use of second person is recommended, but not required. Further information concerning implementation of this modification will be forthcoming.

If you have questions, please call 626-6721.

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## **UNIVERSITY OF ARIZONA RESEARCH AND SERVICE GROUP (RSSG) Educational Opportunities**

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### **OPPORTUNITIES FOR ON-LINE ETHICS TRAINING**

#### **Online Fellowship in Physician Ethics and Professionalism**

The Institute for Ethics at the American Medical Association (AMA), together with the [Medical College of Wisconsin's](#) (MCW) Graduate Program in Bioethics, now sponsors an Online Fellowship in Physician Ethics and Professionalism. [You may get more detailed information on the fellowship.](#)

#### **NIH Human Protections Course Available**

A free web-based course that will enable physicians, researchers, nurses, and data managers to satisfy the NIH requirements for training about the rights and welfare of human participants in research studies is available. More information is at the following web site: <http://cme.nci.nih.gov>.

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



#### **More Educational Opportunities PHCL 595b (PS 595b, BME 595b, CBIO 595b) Scientific Writing Strategies and Ethics**

*Course Coordinators:*

W. Daniel Stamer, Ph.D. – 626-7767 –  
[dstamer@eyes.arizona.edu](mailto:dstamer@eyes.arizona.edu), and  
Thomas P. Davis, Ph.D. – 626-7643 –  
[davistp@u.arizona.edu](mailto:davistp@u.arizona.edu)

### *Purpose, Scope and Philosophy of the Course*

The purpose of this course is to provide students with knowledge and skills to write/communicate effectively for a variety of scientific audiences; including scientific employers as well as administration in journals, funding institutions, potential academia and industry. The course will also cover the nine core instructional areas of the responsible conduct in research (RCR) and thus will satisfy the ethics requirement for many Federal grant programs. Content of the course will draw from the experience of 20 interdisciplinary faculty members with success in communicating ideas, hypotheses and data. The course will assist students in identifying and appropriately targeting scientific audiences and familiarize students with submission and peer-review processes.

*This course satisfies the requirement for research ethics training by the N.I.H./N.S.F.*

Contact Dr. Stamer at 626-7767, or at [dstamer@eyes.arizona.edu](mailto:dstamer@eyes.arizona.edu) for more details.

### **HIPAA VIDEOCONFERENCE TAPE AVAILABLE**

The Society for Research Administrators (SRA) International Satellite Videoconference from January 23, 2003 is available on tape. It is three hours long, and contents are:

**Part I:** General Confidentiality Issues in Sponsored Agreements, and

**Part II:** Privacy/HIPAA Issues.

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).

Also, after viewing the video, please notify the P.R.I.E. office (Ruth Daniels at 626-6282) to receive a *Certificate of Completion* for your files and grant submissions.

### **CONFERENCES/WORKSHOPS**

April 13-14, 2004

**Responsible Conduct of Research in Psychological Science**

Washington, DC

**Co-Sponsor:** American Psychological Association  
[http://ori.dhhs.gov/html/programs/conf\\_workshops\\_2004.asp](http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp)

April 19-20, 2004

**National Human Subjects Protection Conference**

*From the Past to the Future: Evolving Research Issues*

Saint Louis, MO

[http://www.medicine.wustl.edu/~hsc/education/conference\\_index.html](http://www.medicine.wustl.edu/~hsc/education/conference_index.html)

April 22-25, 2004

**American College of Physicians Annual Session 2004:  
Ethics and Human Rights Offerings**

New Orleans, LA

<http://www.acponline.org/ethics/as2003-04.htm>

May 19-22, 2004

**Eleventh Annual Teaching Research Ethics Workshop**

Indiana University Bloomington/Poynter Center

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

June 21-22, 2004

**The RCR Summit: A National Dialogue on Future Directions of RCR**

East Lansing, MI

**Co-Sponsor:** Michigan State University

[http://ori.dhhs.gov/html/programs/conf\\_workshops\\_2004.asp](http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp)

June 28-29, 2004

**The RCR Summit: A National Dialogue on Future Directions of RCR**

East Lansing, MI

**Co-Sponsor:** Michigan State University

October 14-15, 2004

**Research Integrity and Financial Conflicts of Interest in Clinical Research: Legal Issues and Regulatory Requirements**

Charlottesville, VA

**Co-Sponsor:** University of Virginia School of Medicine, Center for Biomedical Ethics

[http://ori.dhhs.gov/html/programs/conf\\_workshops\\_2004.asp](http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp)

October 23-27, 2004

**RCR Expo**

Salt Lake City, UT

**Co-Sponsor:** SRA International

[http://ori.dhhs.gov/html/programs/conf\\_workshops\\_2004.asp](http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp)

November 12-14, 2004

**ORI Research Conference on Research Integrity – 2004**

San Diego, CA

**Co-Sponsor:** University of California – San Diego

[http://ori.dhhs.gov/html/programs/conf\\_workshops\\_2004.asp](http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp)

December 1-3, 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**

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

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*Words of Wisdom:*

*Don't ever take a fence down until you know why it was put up.*

– G.K. Chesterton