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# University of Arizona Program in Research Integrity Education Monthly Newsletter

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March 1, 2004

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

Historically, the month of April has been recognized as “*animal rights month*.” We are devoting this and the next issue of the P.R.I.E. newsletter to this topic. The article below cites the most common **myths** regarding animals in research, and also states the **facts** behind these myths. It is used with permission from David Talbot, Director of Communications at the *Foundation for Biomedical Research (FBR)*. You may access the *FBR* web site at <http://www.fbresearch.org/>. We thank the *FBR* for granting permission to use the following piece in the P.R.I.E. newsletter.

### **Introduction**

Animal research has played a vital role in virtually every major medical advance of the last century – for both human and animal health. From antibiotics to blood transfusions, from dialysis to organ transplantation, from vaccinations to chemotherapy, bypass surgery and joint replacement, practically every present day protocol for the prevention, treatment, cure and control of disease, pain and suffering is based on knowledge attained through animal research.

Physicians and researchers overwhelmingly agree that animal systems provide invaluable and irreplaceable insights into human systems. The essential need for animal research is recognized and supported by medical societies and health agencies around the world.

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

Animals play an amazing role in our lives.

Whether they're assisting in search and rescue operations, working with police and fire investigators to solve a crime, living in a setting that teaches us respect and appreciation for all species, animals make our world healthier, happier and safer.

Animals also play a heroic and vitally important role in medical research. Medical progress, for both human health and animal health, requires animal research because there is no complete replacement for a living system on which to conduct basic research. In recent years, a number of non-animal procedures have been developed and that number continues to grow. Indeed, whether they are working on human health or animal health studies, scientists place a high priority on "The Three Rs" – *reduction, replacement and refinement*. Here in the United States, our scientific and medical research communities are committed to supporting the development of techniques that promote humane animal research by:

- ✚ Reducing the number of animals used
- ✚ Replacing animals with other models whenever possible
- ✚ Refining procedures to ensure the most humane treatment possible

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

**Myth:** Computer models and cell cultures can replace animal testing.

**Fact:** Physicians and scientists overwhelmingly agree that animal systems provide invaluable and irreplaceable insights into human systems because there are striking similarities between the genetic and physiological systems of animals and humans.

While medical and scientific advances achieved through animal research are frequently supplemented by knowledge obtained through non-animal methods – such as computer models, in vitro research, clinical observation, epidemiology, and post-marketing drug surveillance – these alternative methods serve only as adjuncts to basic animal research.

As yet, there is no complete alternative to animal research. There is still an essential need to test drugs, medical devices and other promising treatments on some animals before they are tested on humans since even the most sophisticated technology models cannot mimic the complex cellular interactions that occur in a living system.

These models significantly reduce reliance on research animals. Indeed, prospects are favorable for reducing the use of animals in the area of product development and testing. Conceivably, the day may come when animal research is no longer necessary.

**Myth:** Dogs, cats and monkeys are used more than any other animal in medical research.

**Fact:** Practically all research animals are rodents – mice and rats – bred for this purpose. Dogs, cats and non-human primates together account for less than one per cent of the total and their number has been declining for over 20 years. Since 1979, the number of dogs needed in animal research has declined by 66 percent and the number of cats needed has declined by 69 percent. Primate use, representing 0.3 percent, has remained relatively constant – in the 50,000 per year range – for the past decade.

There is an essential need for canines in the study of lung and heart disease as their cardiovascular and respiratory systems closely match those of humans. Nobel Prize winning research on the immunological basis for organ rejection was done with dogs. Similarly, Nobel Prize winning research with felines has contributed enormously to our understanding of eye disorders such as strabismus (or “cross-eye”) and amblyopia, a serious visual impairment that can cause blindness in one or both eyes. There is an essential need for non-human primates, mainly rhesus monkeys, in the study of

arteriosclerosis, reproductive disorders, Alzheimer's, Parkinson's disease and infectious diseases such as viral hepatitis and AIDS.

**Myth:** Lost and stolen pets are sold to labs.

**Fact:** Despite frequent, unsubstantiated accusations to the contrary, there is absolutely no evidence to support the claim that millions of dogs and cats are taken from homes and shelters and sold to laboratories. In fact, scientists neither need nor want to do research on pets. According to United States Department of Agriculture (USDA), one of several government agencies overseeing the use of animals in medical research, 69,516 dogs and 25,560 cats were involved in biomedical research in 2000. The vast majority of these animals were bred specifically for research. The remainder was acquired directly from the “death row” of animal pounds or purchased from one of about 20 USDA-licensed and regulated dealers. In quarterly “trace back” audits of these dealers, the USDA found no evidence of theft.

The *FBR* recommends that all companion animals wear collars and identification tags at all times. Tags, implanted microchips and even tattoos can help to re-unite a lost cat or dog with its family.

**Myth:** There are no laws or government regulations to protect research animals.

**Fact:** The USDA has set forth federal regulations governing the care and use of animals in biomedical research that are more extensive than those covering human research subjects! The Animal Welfare Act sets high standards of care for research animals with regard to their housing, feeding, cleanliness, ventilation and medical needs. It also requires the use of anesthesia or analgesic drugs for potentially painful procedures and during post-operative care. Most importantly, research institutions are required – by law – to establish an Institutional Animal Care and Use Committee (IACUC) to oversee their work with animals. And IACUCs require researchers to justify their need for animals; select the most appropriate species and use the fewest number of animals possible to answer a specific question.

The U.S. Public Health Service (PHS) Act requires that all institutions receiving research funds from the National Institutes of Health, the Food and Drug Administration or the Centers for Disease Control adhere to the standards set out in the Guide for the Care and Use of Laboratory Animals. Under the PHS policy, institutions must follow detailed animal care recommendations and establish an IACUC to ensure that all animals are treated responsibly and humanely.

**Part II of *Fact vs. Myth – About the Essential Need for Animals in Medical Research* will appear in the April 2004 P.R.I.E. newsletter.**

## **UA Human Subjects Program**

### **⇒ Highlights ⇐**

#### **Human Subjects Protection Program Reduces Turn-Around Time**

The Human Subjects Protection Program received feedback from research personnel that turn around time for Social/Behavioral Science projects was too long. A goal was set to address the problem as part of Quality Improvement and Assurance. Initial data collection ensued to determine average turn around times for full committee, expedited and exempt projects. The table below illustrates the outcome of this data collection period.

<b>Project Classification</b>	<b>Average Time to Project Approval</b>
Exempt	23
Expedited*	31
Full Committee*	46

**Table 1.** Time from Submission of Project to Project Approval (data obtained between 3/02 and 3/03).

Several solutions resulted in hiring a new staff member to assist with Social/Behavioral Science expedited projects. Additionally, review goals were determined for initial review of projects. After six months another round of data collection ensued. The table below illustrates **current** turn around times for projects submitted to the Human Subjects Protection Program. Strategies for decreasing the turn around time for projects have resulted in an average reduction time of 13 days for

exempt projects, 20 days for expedited projects and 32 days for full committee projects.

<b>Project Classification</b>	<b>Average Time to Project Approval</b>
Exempt	10
Expedited*	11
Full Committee*	14

**Table 2.** Time from Submission of Project to Project Approval (data obtained between 1/1/04 and 1/31/04)

Turn around time will continue to be monitored in order to solidify progress made in this area.

\*Includes Social/Behavioral Science projects only.

### **⇒ More Highlights ⇐**

#### **Event: Monthly Classes on Project Approval Forms and Informed Consents**

*Sponsored by:* Human Subjects Protection Program and General Clinical Research Ctr.

*Date:* March 3, 2004

*Location:* AZCC Room 3978, 12:00pm

*Presenter:* Rebecca Dahl, Director Human Subjects Protection Program

*All Inquiries:* Jo McClain, 694-2319 or

[mcclainj@u.arizona.edu](mailto:mcclainj@u.arizona.edu)

#### **National Human Subjects Protection Conference**

*From the Past to the Future:*

*Evolving Research Issues*

April 19-20, 2004

Chase Park Plaza

Washington University Medical Center

Saint Louis, MO

<http://www.medicine.wustl.edu/~hsc/education/conferenceindex.html>



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

#### **NATIONAL PROVIDER IDENTIFIER**

The final rule for the establishment of a standard unique health care provider identifier was published by Health and Human Services in the January 23, 2004 *Federal Register*.

The rule becomes effective on May 23, 2005. According to the Centers for Medicare and Medicaid Services (CMS), the rule calls for the adoption of the National Provider Identifier (NPI) as the standard unique

identifier for all health care providers to use in filing and processing health care claims and other health or treatment related transactions.

The proposed rule was published five years ago and is mandated by HIPAA. Each health care provider will be assigned only one NPI, for all health care transactions whether federal (i.e. Medicare), state-administered, (i.e. Medicaid) or private. The NPI will replace existing “legacy” identifiers now being used. Providers currently use several identifiers, depending on the destination of the data.

As of May 23, 2005, providers may begin to apply for their NPIs. CMS will be providing information on how to apply for the new identifier.

Questions? Contact Jeniece Poole, University of Arizona Privacy Officer (520) 621-1465 or [jpoole@email.arizona.edu](mailto:jpoole@email.arizona.edu).

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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**

*Times:* Tue/Thu 9-10

*Rooms:* Tue AHSC 4120/Thu AHSC 5120

*Course Coordinators:*

W. Daniel Stamer, Ph.D.

Room 121B Faculty Office Building

[dstamer@eyes.arizona.edu](mailto:dstamer@eyes.arizona.edu)

626-7767

and

Thomas P. Davis, Ph.D.

Director, Program in Research

Integrity Education

Room 542, Life Sciences North

[davistp@u.arizona.edu](mailto:davistp@u.arizona.edu)

626-7643

*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.

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.

## UPCOMING CONFERENCES/WORKSHOPS

March 19-20, 2004

**Promoting the Responsible Conduct of Research: What it Means to the Research Enterprise**  
Winston, NC

**Co-sponsors:** Winston-Salem State University, Wake Forest University School of Medicine  
[http://ori.dhhs.gov/html/programs/conf\\_workshops\\_2004.asp](http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp)

March 22, 2004

**Does Funding Source Influence Research Integrity?**

Baltimore, MD  
**Co-Sponsor:** Society of Toxicology  
[http://ori.dhhs.gov/html/programs/conf\\_workshops\\_2004.asp](http://ori.dhhs.gov/html/programs/conf_workshops_2004.asp)

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 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)

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**

**Research Integrity Education staff:**

**Thomas P. Davis**, Ph.D. (Program Director)

Alice C. Langen, (Associate Director)

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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:*

*"The years teach much which the days never knew."*

— *Ralph Waldo Emerson*