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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, "Protection of Human Participants in Research: Problems and Recommendations," is an excerpt from the September 2004 N.I.H., Office of Research Integrity (ORI) newsletter, and may be found at the following web address: <http://ori.dhhs.gov/>. This quarterly newsletter is published by the Office of Research Integrity, Office of the Secretary of Health and Human Services, and is distributed to applicant or awardee institutions and Public Health Services (PHS) agencies to facilitate pursuit of a common interest in handling allegations of misconduct, and promoting integrity in PHS-supported research. The ORI web site is the definitive location to find all pertinent information regarding research ethics and integrity. I highly recommend review of this web site to all individuals who participate in research at the University of Arizona.

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### **Protection of Human Participants in Research: Problems and Recommendations**

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The protection of human participants in research will not be improved by reforms solely aimed at conflicts of interest, the lack of institutional review board (IRB) resources, or the volume and complexity of clinical research because they fail to adequately address 15 structural, procedural and performance assessment problems, according to a recently published article.

The article, *Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals*, by Ezekiel J. Emanuel, Chair, Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, NIH, and others is published in the August 17, 2004 issue of the *Annals of Internal Medicine*.

The structural problems are: (1) federal regulations do not apply to all research involving humans; (2) current regulations and guidelines for protection of human research participants are inconsistent; (3) no effective mechanisms exists for addressing fundamental and recurring ethical issues in clinical research; (4) institutional conflicts of interest are inherent in the current system of review; (5) multiple guidelines for managing conflicts of interest involving IRB members or investigators are incompatible; (6) the review process for single multi-site studies is repetitive; (7) IRBs need more resources, and (8) education in research ethics is haphazard.

Procedural problems are: (1) the review process is time-consuming, protocols frequently require prior review by scientific and other communities; (2) IRBs may lack the scientific expertise to conduct the review; (3) IRBs lack substantive guidance on their operations, such as criteria for appointment or dismissal of members; (4) IRBs spend too much time scrutinizing informed consent documents and producing excessively long detailed forms; and (5) the process of reporting adverse events is confusing and repetitive.

Performance assessment problems include (1) no validated measures exist for evaluating the performance or outcomes of the system, and (2) no data are collected to systematically monitor the overall safety of clinical research.

Recommended solutions include: (1) establish a single federal office with regulatory authority over all human participants research conducted in the United States or by investigators based in the United States; (2) create a permanent advisory committee to systematically examine ethical issues related to human participants research and recommend authoritative policies; (3) mandate single IRB review of all multisite research proposals with liability protection for local institutions; (4) increase funding for oversight of human participants by both the federal government

and commercial sponsors of research, and (5) develop standards to assess the performance of the oversight system, and systematically collect and disseminate data on adverse events and the functioning of the human participants research oversight system.

## **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).

### **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.

### **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 four free modules include:

1. **Overview of Ethical, Professional, and Legal Issues for Physicians' Relationships with Industry**  
[Online self-study](#) [Downloadable resources for educators](#)
2. **Physicians' Expectations of Industry and Sales Personnel**  
[Online self-study](#) [Downloadable resources for educators](#)
3. **Professionalism and Gifts to Physicians from Industry**  
[Online self-study](#) [Downloadable resources for educators](#)
4. **American Medical Association Ethical Guidelines on Gifts to Physicians from Industry**  
[Online self-study](#) [Downloadable resources for educators](#)

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.

*These modules are for educational purposes only, and do not constitute legal advice. Laws that are referred to in these modules are subject to change and federal and state agencies are constantly updating their interpretive guidance concerning the pharmaceutical industry and its relationship with physicians. For further information, please consult with qualified legal counsel to ensure compliance with appropriate legal requirements.*

If you would like more information please visit the following web address: <http://www.ama-assn.org/ama/pub/category/8405.html>.

### **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.](#)

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

### **UA HUMAN SUBJECT PROTECTION PROGRAM**

#### **»Highlights«**

#### **Accreditation**

In 1998, the Office of the Inspector General recommended that Institutional Review Boards under the jurisdiction of the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) undergo regular performance-based evaluation. In addition, the recommendation was that these performance-based evaluations be carried out in accordance with the federal regulations. The result of this and other recommendations was the creation of an organization established to develop a voluntary accreditation system for the protection of human subjects in research.

The Association for the Accreditation for Human Subjects Protection Program (AAHRPP) was established as an independent, nonprofit organization created to “offer voluntary accreditation to organizations that conduct or review research with human participants, using a process based on self assessment, peer review, and education” in order to promote preservation of the rights and welfare of research subjects and compliance with relevant ethical principles and regulations.\*

The AAHRPP accreditation process involves two parts – a *self-assessment* and a *site visit*. The self-assessment consists of written responses to five domains that affect the protection of human subjects in research, namely; the Organization (University of Arizona), Institutional Review Boards, Investigators, Sponsored Research and Participant Outreach. The focus is not solely on the Human Subjects Protection Program, but includes an evaluation of the *organizational system* in which the Human Subjects Protection Program is embedded.

The site visit is conducted by a team of experts in the field of human subject protection and members of the research community. The site visits are collegial and encourage the sharing of solutions for human subject protection. The length of the visit is determined by the size of the institution’s program of human research, type of research conducted, and complexity of issues to be reviewed. During the site visit, the Human Subjects Protection Program will be provided guidance on how to improve the program’s function as well as feedback on preliminary findings from the site visitors.

The University of Arizona is committed to the protection of human subjects in research and has begun the process necessary for accreditation. If accredited, the Human Subjects Protection Program will be identified as going beyond the federal regulations in protecting the rights and welfare of research subjects. The process of review that includes a self-assessment and site visit indicates that the *institution* as a whole values the protection of human subjects – including Program staff, institutional officials, and the University of Arizona research community.

*(Information from this newsletter item adopted from the citation listed below).*

Fish, S. S. (2002). Accreditation of an IRB. In R. J. Amdur and E. A. Bankert (Eds.), *Institutional Review Board Management and Function* (pp. 353-355). Sudbury, MA: Jones and Bartlett.

\*Association for the Accreditation on Human Research Protection Programs, Retrieved from the World Wide Web on March 3, 2005:

<http://www.aahrpp.org/www.aspx>.



## News from HIPAA.....

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

**Question:** Where can I find other consumer Health and Human Services (HHS) information?

**Answer:** HHS provides a wealth of consumer health information that you can use every day to help improve your health or prevent illness through diet, exercise and preventive activities.

A wide range of consumer health and human services information is available on the following sites:

- ✚ MedlinePlus at: <http://www.medlineplus.gov> (provides health topics, drug information, links to directories, interactive tutorials, information on clinical trials, and health information specifically for Seniors);
- ✚ Healthfinder at <http://www.healthfinder.gov> (provides a health library and information about health professionals);
- ✚ The Health and Human Services *Subject Directory* may be located at the following web address:

<http://www.hhs.gov/about/referlst.html>. This directory provides an extensive health and human service topical list with links to agency web sites and phone numbers).



## Radiation Control

### Institutional Biosafety Committee



## Bulletin

### "IBC Basics" Workshop



The National Institute of Health (NIH), Office of Biotechnology Activities (OBA) is partnering with Public Responsibility in Medicine and Research (PRIM&R), the Applied Research Ethics National Association (ARENA), and the NIH Office of Laboratory Animal Welfare in sponsoring a one-day educational workshop on the roles and responsibilities of Institutional Biosafety Committees (IBCs). The workshop, which is titled "IBC Basics: An Introduction to the NIH Guidelines and the Oversight of Recombinant DNA Research," will take place on **March 13, 2005** prior to the PRIM&R and ARENA Annual Institutional Animal Care and Use Committee

(IACUC) Conference. The venue for the meeting will be the Town and Country Resort Hotel in San Diego, California.

"IBC Basics" is intended for IBC members and staff who have an interest in the oversight of recombinant DNA research, as well as research administrators, biological safety officers, regulatory affairs officers, and the members and staff of other institutional oversight committees such as IACUCs.

To view registration information and to view more workshop information, please visit: [http://www.primr.org/education/2005\\_IACUC/program\\_IA05.html](http://www.primr.org/education/2005_IACUC/program_IA05.html). If you have questions about the program, you may also contact Kathryn Harris, Ph.D., Senior Outreach and Education Specialist (Contractor), NIH OBA, at 301-435-2195.

## University Animal Care Quality Care for Research Animals



### University of Arizona Animal Care

### Frequently asked questions....

**Question:** What assurances exist that stolen or lost pets are not used in research?

**Answer:** While some research requires that dogs and cats are used, the vast majority of laboratory animals are rodents specifically bred for research. Nearly half of the dogs and cats needed for research are also bred for that purpose. Since state laws and local policies prevent many animal pounds and shelters from providing dogs and cats to research facilities, animal dealers are the primary source for the other half of the animals scientists require. These dealers must be licensed by the United States Department of Agriculture (USDA) and must adhere to Animal Welfare Act standards of care. Both dealers and research facilities can obtain dogs and cats only from specified sources and must comply with detailed record-keeping and waiting-period requirements. In addition, USDA conducts unannounced inspections of dealers and research facilities for compliance to help ensure research animals are not missing pets.



## Good Laboratory Practices



### Compliance Policy Guide

#### Sec. 130.300

\*FDA Access to Results of Quality Assurance Program Audits and Inspections\*  
(CPG 7151.02)

**BACKGROUND:**

\*Within all FDA regulated industries, some firms establish quality assurance units (QAU) to perform functions independently from the manufacturing or quality control organization. The QAU may periodically audit and critically review processes and procedures (for example, data collection, manufacturing practices, and quality control processes) to determine whether established protocols and procedures have been followed.

In the preambles to the final regulations on Good Manufacturing Practice for Medical Devices (43 FR 31508; July 21, 1978) (21 CFR 820) and on Good Laboratory Practice for Nonclinical Laboratory Studies (43 FR 59986; December 22, 1978) (21 CFR 58), FDA announced its policy not to review or copy a firm's records and reports that result from audits of a quality assurance program when such audits are conducted according to a firm's written quality assurance program at any regulated entity. The intent of the policy is to encourage firms to conduct quality assurance program audits and inspections that are candid and meaningful.\*

**POLICY:**

\*During routine inspections and investigations conducted at any regulated entity that has a written quality assurance program, FDA will not review or copy reports and records that result from audits and inspections of the written quality assurance program, including audits conducted under 21 CFR 820.20(b) and written status reports required by 21 CFR 58.35(b)(4).\*

FDA may seek written certification that such audits and inspections have been implemented, performed, and documented and that any required corrective action has been taken. District personnel should consult with the appropriate headquarters office prior to seeking written certification.

\*FDA will continue to review and copy records and reports of such audits and inspections:  
1. In "directed" or "for-cause" inspection and investigations of a sponsor or monitor of a clinical investigation;  
2. In litigation (for example, and not limited to: grand jury subpoenas, discovery, or other agency or Department of Justice law enforcement activity [including administrative regulatory actions]);

- 3. During inspections made by inspection warrant where access to records is authorized by statute; and,
- 4. When executing any judicial search warrant.

FDA will continue to have access to, review, and copy records and reports required by regulation, relating to quality control investigations of product failures and manufacturing errors.\*

\*Material between asterisks is new or revised.\*

Issued: 03/01/83

Revised: 03/16/89

Revised: 06/03/89

Revised: 01/03/96

(You may find the above information at the U.S. Food and Drug Administration (USDA) web site:

[http://www.fda.gov/ora/compliance\\_ref/cpg/cpggen/cpg130-300.html](http://www.fda.gov/ora/compliance_ref/cpg/cpggen/cpg130-300.html)).

**UPCOMING  
CONFERENCES/WORKSHOPS**

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/Current+Programs/Engineering+Ethics/default.htm>

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

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

Alice C. Langen, Director, Research Compliance

Ruth K. Daniels (Program Coordinator)

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

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:*

*"Success is not final, failure is not fatal: it is the courage to continue that counts."*

— *Winston Churchill*