
University of Arizona Program in Research Integrity Education Monthly Newsletter

October 1, 2003

Volume 3, No. 10

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

This month we focus on *Quality Assurance*. The article below was written by Marilyn M. Marshall, SpM., Quality Assurance Officer, Office of the Vice President for Research, University of Arizona, Tucson, Arizona. You may reach Marilyn at the following:
621-1469 (phone), 621-1429 (fax), email marshalm@u.arizona.edu.

Quality Assurance Happenings.....

The Quality Assurance Officer position with the Office of the Vice President for Research has been in place since June 2, 2003, and reports to the Director of Research Compliance, Alice Langen. One of the Quality Assurance Officer's major responsibilities is to assure that all University of Arizona research conducted as a GLP [Good Laboratory Practices] study fully comply with 21 CFR 58 [FDA] and 40 CFR 120 [EPA] regulations. These regulations state that the Quality Assurance Unit shall:

- Review all GLP protocols
- Maintain a master schedule of all studies conducted at the testing facility
- Maintain copies of all protocols
- Inspect each study at intervals adequate to assure the integrity of the study, and maintain written and properly signed records of each inspection.
- Periodically submit to management, and the study director, written status reports on each study noting any problems and identifying appropriate corrective action.

- Determine that no deviations from approved protocols or SOPs were made without proper authorization and documentation.
- Review the final report to assure that it accurately describes the methods and SOPs and that the reported results reflect the raw data of the study.

Good Practices = Good Science

Currently, only a few campus laboratories are funded to conduct research requiring GLP protocol. However the basic **principles** of GLP can be applied to a research laboratory in a **good practices = good science** concept. This means that good practices can be achieved without formally complying with federal GLP regulations. Any investigator can implement **good practices** strategies in a mode that best suits each individual research laboratory. Good practices can be applied by investigators, lab managers and personnel **deciding to undertake** documentation and safety procedures outlined below. But it is important to remember, any research funded as a formal GLP study, must comply with FDA and EPA regulations.

- Maintain updated training records for all laboratory personnel [including graduate and undergraduate students] for the following:

Chemical Laboratory Safety Training

<http://w3fp.arizona.edu/riskmgmt/laborato.htm>

Animal Care Training

<http://www.iacuc.arizona.edu/animalhazardsprogram>

Radiation Training

<http://www.radcon.arizona.edu/main.asp>

Biosafety Procedures

<http://www.abc.arizona.edu/>

- Develop and update job descriptions for laboratory personnel
- Assure all procedures are written and readable
- Use data sheets, log book entries and check lists to ensure Good documentation. Always remember, *if it is not written down.....it did not happen!*
- Maintain equipment maintenance records
- Maintain chemical inventory
<http://w3fp.arizona.edu/riskmgmt/laborato.htm>
- Maintain a schedule for hazardous waste RM&S:
<http://w3fp.arizona.edu/riskmgmt/laborato.htm>
- Implement general laboratory safety procedures

The Office of the Vice President for Research and the Director of Research Compliance strongly support the concept **Good Practices = Good Science**. The use of good practices helps make research laboratories safe and competitive. Good practices are not required by federal regulation, but the implementation of good practices can:

- help prevent accidents
- facilitate safety
- promote personnel training
- provide documentation procedures
- validate generated raw data
- provide an advantage when applying to funding agencies requiring a Quality Assurance plan.

The *spirit* of good practices does help prevent accidents and save resources and equipment loss by minimizing down time. Effective documentation validates raw data thus making report writing easier.

The Quality Assurance Officer and the Office of the Vice President for Research encourage laboratories to engage in good practices. The Quality Assurance Officer is available to assist research laboratories obtain information and can provide checklists and other laboratory formats appropriate for

documentation. Hopefully, all laboratories will embrace the *spirit* of good practices as the University of Arizona continues to pursue excellence in research.

Good Practices = Good Science



A Quality Assurance Moment

Courtesy of:

Marilyn M. Marshall, SpM
University of Arizona
Quality Assurance Officer
marshalm@u.arizona.edu

Everyone bears responsibility

for Compliance:

- Management
- Study Director
- Study Facilitates
- Quality Assurance

SCIENTIFIC SOCIETIES PROMOTE RESEARCH INTEGRITY

A special issue of *Science and Engineering Ethics* acknowledges what scientific societies have done to promote research integrity and suggests what else they can do as custodians of the norms and traditions of scientific disciplines and as an important source of professional identity for scientists.

Published in April 2003, the issue, *The Role of Scientific Societies in Promoting Research Integrity*, Volume 9, Number 2, was edited by Stephanie J. Bird, Massachusetts Institute of Technology, and Mark S. Frankel, American Association for the Advancement of Science (AAAS).

Several articles in the issue were originally presented at a conference, The Role and Activities of Scientific Societies in Promoting Research Integrity, co-sponsored by AAAS and ORI in April 2000. Complete information on the issue is available on the publisher's web site at www.opragen.co.uk.

RESEARCH ETHICS AWARD NOMINATIONS INVITED

Nominations are invited for the annual Research Ethics Award presented by the

Friends Research Institute, Inc., (FRI), for significant original contributions to knowledge in research ethics. The award, made at the FRI's annual ethics conference, includes \$10,000 and a plaque. The 2003 awardee was Jay Katz, M.D., Yale University.

All nominations should be submitted by email to mhipsley@friendsresearch.org by December 1 of each year. Details on the award process are available at <http://www.friendsresearch.org/award.html>.

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

Educational Opportunities

**HIPAA VIDEOCONFERENCE TAPE
AVAILABLE AT THE
UNIVERSITY OF ARIZONA**

The Society for Research Administrators (SRA) International Satellite Video-conference 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.

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.

**NCI PROVIDES TUTORIAL
ON CLINICAL TRIALS**

A web-based tutorial designed for professionals and clinical research staff that are new to conducting clinical trials has been developed by the National Cancer Institute (NCI). The course focuses on the conduct of cancer clinical trials, but information provided also applies to other clinical trials.

The course, *Incorporating Clinical Trials into Your Practice*, includes a brief overview of cancer clinical trials, explains ways to become involved in clinical trials, and continues with practical information and guidance for professionals interested in

referring patients to, or conducting, clinical trials.

Participants will hear from experienced clinicians about issues they faced by including trials in their practices and how these issues were addressed. The course contains case studies, sample forms, and practical tools. See <http://cme.cancer.gov>.

**NIH HUMAN PROTECTIONS
COURSE AVAILABLE**

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

The NIH Course on Human Research Protections utilizes interactive modules, case studies, and exercises to cover the following topics: roles and responsibilities of researchers and their key personnel, guiding ethical principles for research, federal regulations, informed consent, institutional review boards, ongoing protections throughout the course of study, data and safety monitoring, reporting of adverse events, privacy and confidentiality, and historical events that have impacted policy and legislation.

**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](http://www.nih.gov)
(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. Content for the module was developed by the Poynter Center for the Study of Ethics and American Institutions at Indiana University-Bloomington (Kenneth D. Pimple, Project Director; Julia A. Pedroni, Co-Director; Victoria Berdon, Graduate Assistant) in collaboration with WisdomTools, Inc., which also provided the technical realization of the course. The module is now ready for use by interested teachers and researchers.

For complete information and to review the module at no charge, please contact <http://poynter.indiana.edu/sas/lb/>, or contact Kara Lochridge at: (812) 856-4968, or klochrid@indiana.edu.

**UPCOMING
CONFERENCES/WORKSHOPS**

***Integrity & Accountability
In Clinical Research***

**Presented by:
National Patient Safety Foundation
November 2-4, 2003
Washington, DC**

For all stakeholders determined to meet the standards of integrity and accountability expected of research with human subjects, The National Patient Safety Foundation invites leaders of the healthcare community to engage in a second conference on human subject research. This conference will address the issues of balancing benefit and risk in human subjects research, the two recently-released IOM reports and recommendation on research integrity and on human subjects research, the increasing focus on patient privacy and preservation of dignity, and concerns that we may be making regulatory compliance in human subjects research a virtual impossibility for academic medical centers and the migration of human subjects research to foreign shores.

This conference will build on the successful 2002 conference *Balancing Risk & Benefit* held in Indianapolis. [Register now](#) to take advantage of the Early Registration discount rate.

More Conferences/Workshops.....

October 9, 2003

[Introductory Workshop for Institutional Research Integrity Officers](#)

Farmington, CT

Co-sponsors: University of Connecticut Health Center and University of Connecticut-Storrs

October 18-22, 2003

[Responsible Conduct of Research \(RCR\) Expo](#)

Pittsburgh, PA

Co-sponsors: Society of Research Administrators (SRA) International

October 10, 2003

[Advanced Workshop for Institutional Research Integrity Officers: A Dialogue on Research Misconduct and the Promotion of Research Integrity](#)

Farmington, CT

Co-sponsors: University of Connecticut Health Center and University of Connecticut-Storrs

November 7, 2003

[RCR 101 Educational Workshop](#)

New Orleans, LA

Co-sponsors: Public Responsibility in Medicine and Research and Tulane University

November 7-9, 2003

[The Journal's Role in Research Misconduct Cases](#)

Leesburg, VA

Co-sponsor: Council of Science Editors

November 15, 2003

[Enhancing Integrity in Clinical Research](#)

Los Angeles, CA

Co-sponsor: University of California-Los Angeles

December 3, 2003

Ethics and Responsible Conduct of Research Workshop
San Francisco, CA

Co-sponsor: Council of Graduate Schools

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

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

Alice C. Langen, (Associate Director)

Ruth K. Daniels (Program Coord.) 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.

Words of Wisdom:

“Example is not the main thing in influencing others; it’s the only thing.”

——— *Albert Schweitzer*