
University of Arizona Program in Research Integrity Education Monthly Newsletter

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A Message from the Director

Thomas P. Davis, Ph.D.

This month we focus on bringing to our campus a few community updates and more information on the Health Insurance Portability and Accountability Act (HIPAA). The University of Arizona Privacy Officer has provided information on *Job Entitlement*. Also provided is valuable information regarding *HIPAA and Research* which may also be found at the United States Department of Health and Human Services (DHHS) website. The site address is <http://www.hhs.gov/ocr/hipaa/>.

The following was written for the P.R.I.E. newsletter by Jeniece I. Poole, University of Arizona Privacy Officer. She may be reached at the following: 621-1465 or by email at: jpoole@email.arizona.edu.

HIPAA and Job Entitlement

The April 14, 2003 implementation of the HIPAA Privacy Regulations has changed the way you may access Personal Health Information (PHI) including your own PHI.

The formation of an Organized Health Care Arrangement (OHCA) between the University of Arizona, University Medical Center and The University Physicians allows us to share information between the three entities for the purpose of health related treatment, payment and health care operations. Various software programs are used to provide essential information on patient care and to maintain patient medical records.

You probably don't work for the covered component of the OHCA that maintains and supports the computer program. For example, UMC grants access to and maintains CITRIX, Sunrise Clinical Manager and Keystone.

Based on your job responsibilities, you have been given access to the system(s) to view or input information. In most departments, you have signed a confidentiality agreement stating that you will not share passwords or disclose health information outside of your work related responsibilities.

System access does not entitle you to:

- Look up information that is not directly related to your job function.
- Access the medical records of your family members unless their records directly relate to your job responsibility.
- Access your own medical records.
- Access your own laboratory results because the physician's office has not yet called you with the results.
- Look up coworker's records because you have access to the system and they don't.

Medical Power of Attorney does not give you permission to go into the computer systems to access Personal Health Information. The medical record belongs to the treating physician, therapist, or facility and the patient. Being able to look up information does not entitle you to access the system for personal or non-job related situations. By doing so, you may be jeopardizing your job and your computer privileges may be suspended.

The HIPAA regulations require that Covered Entities track the users of the systems that contain PHI, audit the information that has been accessed, and have a sanction policy for dealing with privacy breaches. An audit can reveal that you have viewed information that is not within the scope of your job responsibilities. This can lead to disciplinary action.

The HIPAA Privacy Rule and Research

The Department of Health and Human Services (HHS) issued the Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to provide the first comprehensive Federal protection for the privacy of personal health information. While certain provisions of the Rule specifically concern research and may affect research activities, the Privacy Rule recognizes that the research community has legitimate needs to use, access, and disclose Protected Health

Information (PHI) to carry out a wide range of health research protocols and projects. The Privacy Rule protects the privacy of such information while providing ways in which researchers can access and use PHI when necessary to conduct research.

This web site has been developed to provide the research community with information about the HIPAA Privacy Rule and how it might affect research. [Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule](#), a booklet discussing how provisions of the Privacy Rule may affect research, is now available. HHS has developed [sample language](#) that covered entities may wish to consider when developing an authorization for use and disclosure of protected health information for research. Additional companion pieces to the booklet that will address the possible affects of the Privacy Rule on specific types of research activities are under development and will be available soon through this web site.

HHS Office for Civil Rights (OCR) has also developed tools to help entities determine whether they are covered entities and subject to the Rule. You may access these tools at: <http://www.cms.hhs.gov/hipaa/hipaa2/support/tools/decisionsupport/default.asp>.

To view the HIPAA Resources Web Site for OCR go to: <http://www.hhs.gov/ocr/hipaa/>. To view the complete final Privacy Rule go to: <http://www.hhs.gov/ocr/hipaa/finalreg.html>.

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 at the following: <http://www.friendsresearch.org/award.html>.

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

UNIVERSITY OF ARIZONA OFFICE OF THE VICE PRESIDENT FOR RESEARCH PRESENTS

A ONE DAY SEMINAR

DATA INTEGRITY IN ANY LABORATORY Emphasizing GLP / GCP Compliant Research

January 27, 2004

University Marriott Hotel

PLAN TO ATTEND IF YOU ARE:

- *Considering future FDA or EPA studies*
 - *Seeking to learn good practices for good science*
- Required to attend if you are doing FDA/ EPA studies for regulatory submission**

Dr. Belinda Lawler, Quality Assurance Officer for the Veterinary Diagnostic Laboratory, College of Veterinary Medicine, Iowa State University will conduct the seminar. Dr. Lawler has been a consultant to industry, contract testing laboratories, veterinary diagnostic labs and academic institutions. Her areas of expertise include GLP quality assurance, protocol review, contract laboratory inspection and set-up for regulated research trials and study monitoring.

The registration fee (including notebook, continental breakfast, break snacks and lunch) is:

- \$175 Per Individual
- \$125 Per Person (Three or more – same lab)
- \$200 Non University of Arizona personnel.

You may register on line at the VP Research website: <http://portal1.vpr.arizona.edu/register>.

All inquiries concerning the seminar may be directed to Marilyn M. Marshall, Quality Assurance Officer, 621-1469 or via email at marshalm@u.arizona.edu.

Security Awareness

Security Awareness Day (Month) is designed to promote information **security** and privacy among all members of the University of Arizona: students, staff and faculty. Information Security awareness means understanding the various threats that exist in one's environment and taking reasonable steps to guard against them. It requires prudence but not paranoia, diligence but not obsession. The **security**-aware individual invests a little time up front learning about risks and countermeasures so that he or she will be less likely to have to spend a lot of time – or face more dire consequences – as a result of unnecessary vulnerability. While even the most diligent person is not immune to harm, a small expenditure of effort can greatly enhance information security and privacy.

The theme of the **Security Awareness** Day (Month) is “**Protection and Privacy in the New Millennium,**” emphasizing the fact that every person can benefit both on and off campus by taking the initiative to safeguard self and property and put would-be attackers on the defensive.

The keynote speaker for the event is Christopher T. Pierson, Ph.D., J.D. Dr. Pierson is an attorney with Lewis and Roca LLP in the firm's Commercial Litigation and Intellectual Property Practice Groups. He helped to establish the firm's Cybersecurity & Cyberliability practice area. Dr. Pierson has substantial information technology experience and expertise and speaks across the country on these issues.

The agenda for the event can be viewed at <http://security.arizona.edu/awareness.html>. Please check this site often for more information. Following, you will find more information on the Security Awareness Day.

Information Security Awareness Day Protection and Privacy in the New Millennium

Tuesday December 2nd, 2003

Two locations:

Main Campus, Student Union South Ballroom
Noon – 8:00 p.m., and

Arizona Health Sciences Center

8:00 am – 3:00 pm

Presentations by:

Chris Pierson, Lewis & Roca Law Firm
Melissa Guenther LLC, Security Awareness
Consultant,
Calence, Inc., Cisco Systems, Inc., Kerio
Technologies, Inc.

The above is sponsored by the [University Information Security Office](#). More Information is available at security.arizona.edu/awarenessday.html.

Program contacts are Kelley Bogart and Fiona McKenzie. Kelley may be reached at 626-8232 or at bogartk@u.arizona.edu, and Fiona may be reached at 621-0787 or at fionam@u.arizona.edu.

ONLINE FELLOWSHIP IN PHYSICIAN ETHICS AND PROFESSIONALISM

Pursue an Ethics Fellowship...
from anywhere in the world.

Study at your own pace. Study in your
own home. Learn online.

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. This program is a unique opportunity for physicians on Institutional Review Boards, Privacy Boards, and ethics committees or for those who want to learn more about applied ethics.

Our online program is current, comprehensive, and convenient, with courses taught by expert faculty from the AMA, MCW, and around the world. Courses can be chosen to fit your specific interests.

Benefits to you:

1. You will complete four online courses on topics such as:

- ✚ The history of medical professionalism
- ✚ Common Clinical Ethics dilemmas
- ✚ The ethics of scientific and medical research
- ✚ The relationship between ethics, philosophy and law

2. You will participate in a five-day seminar series:

- ✚ Meet leaders in bioethics and policy making during the annual meeting of the AMA's House of Delegates in Chicago

- ✚ Learn how the AMA establishes ethics policy and the code of ethics that sets the standard for physician professionalism.

3. You will earn credits toward a Master's Degree in Bioethics.

Be a pioneer of online medical learning. Call today. [Get more detailed information on the fellowship.](#)

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.

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 studies 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](#)
(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, you may contact <http://poynter.indiana.edu/sas/lb/>. You may also contact Kara Lochridge at: (812) 856-4968, or klochrid@indiana.edu.

UPCOMING CONFERENCES/WORKSHOPS

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

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

Words of Wisdom:

"Be faithful in small things because it is in them that your strength lies."

————— *Mother Teresa*