
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 the Program in Research Integrity Education (P.R.I.E.) newsletter focuses on issues pertaining to the Health Insurance Portability and Accountability Act (HIPAA). We are pleased to present a superb feature article, *Doctor/Patient E-mail: The Right Prescription with Privacy Safeguards*, which we are using with the permission of the author Janlori Goldman, whom is the Director of the Health Privacy Project at Georgetown University. We thank her for this contribution to the P.R.I.E. newsletter. She may be reached by e-mail at jgoldman@healthprivacy.org.

Doctor/Patient E-mail: The Right Prescription With Privacy Safeguards

By
Janlori Goldman, Director
Health Privacy Project
Georgetown University
January 26, 2004

Imagine e-mailing a question to your doctor and receiving a response complete with test results, advice on drug side effects and links to more information about your condition. You save yourself the hassle of telephone tag or missing hours of work for an in-person appointment. Your physician can reply when it's convenient and print out a transcript of the conversation for your medical record.

Approximately 90% of American adults with Internet access would like to communicate with their doctors by e-mail, according to a [2002 Harris poll](#). However, many doctors hesitate to offer the service. A recent [Stanford University Medical Center study](#) revealed that only 6% of patients surveyed had actually e-mailed a physician. Although legitimate privacy concerns have contributed to physicians' reluctance to embrace e-mail, physicians can, and should, find ways to

address these concerns without sacrificing the convenience and efficiency that e-mail offers.

The American Medical Association, in its "[Guidelines for Physician-Patient Electronic Communications](#)," noted that e-mail "can aid the health care delivery process by allowing written follow-up instructions, test results and dissemination of educational materials for patients, as well as a means for patients to easily reach their physician on routine health matters." By facilitating direct communication between doctor and patient, e-mail presents an opportunity to cement the doctor-patient relationship. It allows for continuous attention to health care between office visits and provides a simple means of monitoring people with chronic conditions. For those patients who cannot make regular in-person appointments, because of work commitments or limited mobility, e-mail allows them to still receive health care. For those patients who use e-mail simply to supplement regular appointments, perhaps to report on side effects or symptoms, e-mail enhances the quality of care that they receive.

However, doctor-patient e-mail is vastly underutilized, in part because physicians and consumers have legitimate concerns about the privacy and security of the information that they transmit. Although e-mail communications may create an illusion of security, without adequate safeguards, breaches of privacy may occur. A patient who e-mails a doctor has no way of knowing who in the doctor's office will read the e-mail. Similarly, doctors worry that the e-mails they send to their patients could be read by family members, employers (if the patient has e-mail through his or her job), or even Internet service providers. Unwanted disclosure of health information can have negative repercussions such as loss of employment or health insurance. Doctors also may find themselves at risk of lawsuits from patients who blame them for the disclosure. With the stakes so high, it is not surprising that many hesitate to use e-mail.

Other doctors worry that electronic communication will undermine the doctor-patient relationship because e-mail lacks nuances of tone and body language. They also worry that patients will send lengthy and unnecessary e-mails or inappropriately use e-mail in emergencies. Doctors are also concerned that insurance companies will not reimburse them for the time they spend replying to e-mails. However, wide public support for e-mail communications with doctors may pressure insurers into covering e-mail, and nearly 40% of people surveyed in the Harris poll indicated that they were willing to pay out-of-pocket for electronic communications.

Both the privacy and security regulations issued in HIPAA offer some guidance regarding doctor-patient e-mail. The [HIPAA security rule](#) says you have to take "reasonable precautions" when communicating with patients by e-mail, according to HHS spokesperson Bill Pierce (National Public Radio, May 28, 2003). The security rule instructs covered entities to "implement technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network." The rule specifically instructs covered entities to implement security measures "to ensure that electronically protected health information is not improperly modified without detection until disposed of" and to implement "a mechanism to encrypt electronic protected health information whenever deemed appropriate." These implementation specifications are "addressable," which means that if a covered entity deems them inappropriate it may implement alternative measures.

The [HIPAA privacy rule](#) also requires covered entities to "have in place appropriate administrative, technical, and physical safeguards" to protect the privacy of electronic communication. Although HIPAA does not explicitly endorse doctor-patient e-mail, one could argue that HIPAA implicitly encourages e-mail by offering guidelines for its use.

Recently, several companies have developed software to facilitate secure e-mail between doctors and patients, and several insurers, including [Blue Cross Blue Shield of Massachusetts](#), have explored reimbursing physicians for electronic communications. Promising strategies for minimizing privacy risks and maximizing efficiency include a Web-based

system that simply sends a notification e-mail to patients' personal e-mail accounts and a triage system in which a nurse screens and directs e-mail. [Blue Shield](#) and [ConnectiCare Inc.](#) of Farmington, Conn., use a "structured interchange" in which patients are directed to fill out a questionnaire that is then sent to their doctor.

The American Medical Association's guidelines, last updated in June 2002, suggest developing an informed consent agreement that describes appropriate communications (including not using e-mail for sensitive subjects such as HIV and mental health), describe security measures (including who in the doctor's office has access to e-mail), and allow patients to waive encryption requirements. The guidelines instruct physicians not to send group mailings where recipients are visible to each other. Dr. Daniel Sands, a Massachusetts physician, has offered additional useful suggestions on his [Web site](#), the Electronic Patient Centered Communication Resource Center.

Doctors and patients' concerns about using e-mail to communicate sensitive medical information are similar to those raised by answering services and fax machines, which the medical community has dealt with for many years. All of these technological developments have helped streamline medical services at a time when many doctors find themselves overburdened with patients and paperwork. For consumers, easier access to doctors is a boon. Like faxes and telephones, e-mail is not a replacement for an in-person doctor visit, but it is a powerful supplement. The effort that will go into ensuring that e-mail is secure and private will pay off in better quality care and closer bonds between doctors and patients. Like many other technological developments, doctor-patient e-mail raises privacy and security problems only when it is used without meaningful and effective protections.

Elizabeth Ida Tossell, the Health Privacy Project's research assistant, contributed to this piece. Ms. Tossell is a graduate of Yale University, and is sharing with HPP her research and writing skills - as well as her passion for improving the world - until she goes to law school next year.

Janlori Goldman is Director of the Health Privacy Project. The Health Privacy Project is dedicated to raising public awareness of the importance of ensuring health privacy in order to improve health care access and quality, both on an individual and a community level. Ms. Goldman can be reached by e-mail at jgoldman@healthprivacy.org.

Good Laboratory Practices

FEDERAL REGULATIONS PERTAINING TO GOOD LABORATORY PRACTICES

Richard Powell, Vice President for Research and Graduate Studies, wishes to remind investigators that research projects conducted at the UA in conjunction with industry and in support of an application for a license or permit from the FDA or the EPA fall under federal regulations pertaining to Good Laboratory Practices (GLPs), and to call attention to sources of assistance available at the UA for help in becoming GLP-compliant. Marilyn Marshall, Quality Assurance Officer (marshalm@email.arizona.edu or at 621-1469), is the first person to contact when contemplating doing studies subject to GLPs. Other links to GLP resources nationwide are may be viewed at the following web address: <http://vpr2.admin.arizona.edu/rie/GLP/GLP.htm>. This site also has a table that links to a file of standard operating procedures (SOPs) to guide investigators in doing GLP-compliant work.



News from HIPAA.....

Frequently asked questions on Privacy.....

Question:

May physician's offices or pharmacists leave messages for patients at their homes, either on an answering machine or with a family member, to remind them of appointments or to inform them that a prescription is ready? May providers continue to mail appointment or prescription refill reminders to patients' homes?

Answer:

Yes. The HIPAA Privacy Rule permits health care providers to communicate with patients regarding their health care. This includes communicating with patients at their homes, whether through the mail or by phone or in some other manner. In addition, the Rule does not prohibit covered entities from leaving messages for patients on their answering machines. However, to reasonably safeguard the individual's privacy, covered entities should take care to limit the amount of information disclosed on the answering machine. For example, a covered entity might want to consider leaving only its name and number and other information

necessary to confirm an appointment, or they may ask the individual to call them back.

A covered entity also may leave a message with a family member or other person who answers the phone when the patient is not home. The Privacy Rule permits covered entities to disclose limited information to family members, friends, or other persons regarding an individual's care, even when the individual is not present. However, covered entities should use professional judgment to assure that such disclosures are in the best interest of the individual and limit the information disclosed. See 45 CFR 164.510(b)(3).

In situations where a patient has requested that the covered entity communicate with him in a confidential manner, such as by alternative means or at an alternative location, the covered entity must accommodate that request, if reasonable. For example, the Department considers a request to receive mailings from the covered entity in a closed envelope rather than by postcard to be a reasonable request that should be accommodated. Similarly, a request to receive mail from the covered entity at a post office box rather than at home, or to receive calls at the office rather than at home are also considered to be reasonable requests, absent extenuating circumstances. See 45 CFR 164.522(b).

EXHIBIT SPACE FREE AT RCR (Responsible Conduct of Research) EXPO 2004

The RCR Expo 2004 will be held October 25th and 26th in conjunction with the Society of Research Administrators (SRA) International 2004 Annual Meeting in Salt Lake City, Utah. The Expo will be held in the luxurious Grand America Hotel, situated in a high-traffic space within the conference area. With over 1,200 top research administrators attending the SRA meeting, this event will be an excellent opportunity for institutes and businesses to showcase their RCR educational materials, videos, training tools, web sites, and/or programs.

Exhibit space is free to the 25 exhibitors selected to participate. Those interested in becoming an exhibitor at the RCR Expo 2004 should contact Loc Nguyen-Khoa (LNguyen-Khoa@osophs.dhhs.gov) and include your name, institution, and description of your product or program.

For more information about the Society of Research Administrators International 2004 Annual Meeting, visit <http://www.srainternational.org>.

**INTRO RCR TEXT MAILED;
REVISION UNDERWAY**

Single copies of the ORI Introduction to the Responsible Conduct of Research were mailed in January 2004 to the responsible institutional official at the 4,000 institutions that have a misconduct policy assurance on file with ORI.

The publication is currently being revised because some illustrations, case studies, and the ISBN number were dropped, and format and style errors were made during the production process of the initial printing. Publication content, however, is accurate. A PDF version of the missing material is available on the ORI web site at <http://ori.hhs.gov>.

The revised publication is expected to be available for purchase from the Government Printing Office this Spring. Please see <http://bookstore.gpo.gov>. It will be posted on the ORI web site later this year for on-line reading or downloading.

**RCR SUMMIT SET FOR MICHIGAN STATE
UNIVERSITY IN JUNE**

Responsible conduct of research (RCR) instructors and program coordinators are urged to participate in a national dialogue on future directions in RCR education that will be held at Michigan State University (MSU) on June 28-29, 2004.

A web site for *The RCR Summit: A National Dialogue on Future Directions of RCR* will be available shortly on the MSU and ORI web sites. "We would like to see a substantial turnout for this conference," Larry Rhoades, Director, Division of Education and Integrity, ORI, said, "Because we would like to begin developing a collaborative effort that would be helpful to us all."

The conference will develop basic information on the structure of RCR programs created across the country, discuss the content and pedagogical approaches being used, and suggest directions for the further development of the RCR education program.

**CONFERENCE, WORKSHOP,
AND MEETING PROPOSALS
DUE OCTOBER 1, 2004**

ORI is seeking proposals from institutions, scientific societies, and professional associations that wish to collaborate with ORI in developing conferences, workshops, symposia, colloquiums, seminars, and annual meeting sessions that address the responsible conduct of research, research integrity, or research misconduct. ORI will provide up to \$20,000, depending on the event proposed.

The next target date for receipt of application is October 1, 2004. Proposal instructions and an application form are available on the ORI web site at <http://ori.dhhs.gov/html/programs/conf-workshops.asp>.

Please submit your proposal electronically to cfassi@osophs.dhhs.gov. Dr. Carolyn Fassi may be reached at 301-443-5300.

UA Human Subjects Program

»Highlights«

**Human Subjects Protection Program
Periodic Review**

The Institutional Review Board (IRB) approval process is not a one-time step in the life of the research project. Rather IRB approval is a temporary authority that is based on the degree of risk to which study subjects are exposed. For example high risk studies might be given a three month approval period, whereas minimal risk studies might be given an annual approval period. An annual review is the greatest amount of time an IRB can grant approval for a project. Initial IRB review is based on the Principal Investigator's best estimate about the anticipated risks, benefits, and study procedures to be conducted.

At periodic review, the IRB determines whether this estimate is reasonable and whether the project can continue. Continued monitoring of approved research is as important as the initial review and approval. Only after the research has begun can actual risks and benefits to the subjects be assessed and preliminary results of the study used to determine an evaluation of risk/benefit. Collaborative efforts between the investigator and the IRB will result in the best protection for study subjects.

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

**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 can be accessed 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 web site: <http://poynter.indiana.edu/sas/lb/>. You may also contact Kara Lochridge at: (812) 856-4968, or klochrid@indiana.edu.



ALTERNATIVE TRAINING MATERIALS:

Alternative training materials are available for individuals conducting Social/Behavioral Science research. A [test](#) based on Federal regulations, the Human Subjects Protection Program Manual of Procedures, and Planning Ethically Responsible Research by Joan E. Sieber, can be downloaded and submitted to the Human Subjects Protection Program office for training certification. Planning Ethically Responsible Research is available for purchase at the UA Bookstore and will be available soon on reserve (24-hour checkout) at various UA Library locations.

Note: Individuals who choose to complete or have previously completed training based on the text, Protecting Study Volunteers in Research (Rochester test), have met the training requirement to conduct medical or social/behavioral science research involving human subjects at the UA. No additional training is necessary at this time.

**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.

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**

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

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

October 23-27, 2004

RCR Expo

Salt Lake City, UT

Co-Sponsor: SRA International

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

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

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

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

Words of Wisdom:

"Nearly all men can stand adversity, but if you want to test a man's character, give him power."

— *Abraham Lincoln*