
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

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This month the Program in Research Integrity Education (P.R.I.E.) newsletter focuses on *Records Retention*. Below is general information regarding records retention taken from the on-line encyclopedia, *Wikipedia*. Following that is specific information regarding records retention at the University of Arizona, authored by Richard King, Director of the University of Arizona Records Management & Archives in the Department of Records Management. The University of Arizona's records (including research records) are controlled by State and Federal law as well as funding agency rules and regulations. Principal investigators should gain a clear understanding of these regulations when they sign a contract or accept a grant. The links at the end of Mr. King's item will also be helpful in this regard.

Records Management

From Wikipedia, the Free Encyclopedia
http://en.wikipedia.org/wiki/Records_management

Records management is the practice of identifying, classifying, archiving, and sometimes the controlled destruction of records. There is an International Standard on records management, ISO 15489: 2001. This defines records management as, "The field of management responsible for the efficient and systematic control of the creation, receipt, maintenance, use and disposition of records, including the processes for capturing and maintaining evidence of and information about business activities and transactions in the form of records." The International Organization for Standardization (ISO) defines records as "information created, received, and maintained as evidence and information by an organisation or person, in pursuance of legal obligations or in the transaction of business." The International Committee on Archives (ICA) Committee on Electronic Records defines a **record** as, "a specific piece of recorded information generated, collected or received in the initiation, conduct or completion of an activity and that comprises sufficient content, context and structure to provide proof or evidence of that activity." While the definition of a record is often identified strongly with a document, a record can be any tangible object, or digital information which

has value to an organization. For example, birth certificates, medical x-rays, museum artifacts, ordinary office documents, databases and application data and e-mail are all examples of records.

Practicing Records Management

The practice of records management involves all of the following activities:

- Creating, approving, and enforcing records policies, including a classification system and a records retention policy
- Developing a records storage plan, which includes the short and long-term housing of physical records and digital information
- Identifying existing and newly created records, classifying them, and then storing them according to standard operating procedures
- Coordinate the access and circulation of records within and even outside of an organization
- Executing a retention policy to archive and destroy records according to operational needs, operating procedures, statutes, and regulations

Often, a records management system helps to aid in the capture, classification, and ongoing management of records throughout their lifecycle. Such a system may be paper based (such as index cards as used in a library), or may be a computer system, such as an electronic records management application.

ISO 15489:2001 states that records management includes:

- setting policies and standards;
- assigning responsibilities and authorities;
- establishing and promulgating procedures and guidelines;
- providing a range of services relating to the management and use of records;
- designing, implementing and administering specialized systems for managing records; and
- integrating records management into business systems and processes.

Managing Physical Records

Managing physical records involves a variety of diverse disciplines, diversity that may surprise the layperson. At its simplest, physical records must be organized and indexed. In more complex environ-

ments, records management demands expertise in forensics, history, engineering, and law. Records management then resolves to being a coordination of many experts to build and maintain the system.

Records must be identified and authenticated. In a business environment, this is usually a simple matter of filing signed contracts and other important business documents. However, in many environments, records must be identified and handled much more carefully.

- **Identifying records.** If an item is presented as a record, it must be first examined as to its relevance, and it must be authenticated. Forensic experts may need to examine a document or artifact to determine that it is not a forgery, or if it is genuine, that any damage, alterations, or missing content is documented. In extreme cases, items may be subjected to a microscope, x-ray, radiocarbon dating or chemical analysis to determine their authenticity and prior history.
- **Storing records.** Records must be stored in such a way that they are both sufficiently accessible and are safeguarded against environmental damage. A typical contract or agreement may be stored on ordinary paper in a file cabinet in an office. However, many records file rooms employ specialized environmental controls including temperature and humidity. Vital records may need to be stored in a disaster-resistant safe to protect against fire, flood, earthquakes and even war. In extreme cases, the item may require both disaster-proofing and public access, which is the case with the original, signed US Constitution. Even civil engineers must be consulted to determine that the file room can effectively withstand the weight of shelves and file cabinets filled with paper; military ships are designed to take into account the weight of their operating procedures on paper as part of their ballast equation. In addition to on-site storage of records, many organizations operate their own off-site records centers or contract with commercial records centers.
- **Circulating records.** Records are stored because they may need to be retrieved at some point. Retrieving, tracking the record while it is away from the file room, and then returning the record, is referred to as circulation. At its simplest, circulation is handled by manual methods such as simply writing down who has a particular record, and when they should return it. However, most modern records environments use a computerized records management system that includes the ability to employ bar code scanners for better accuracy, or radio-frequency identification technology (RFID) to track move-

ment of the records from office to office, or even out of the office. Bar code and RFID scanners can also be used for periodic auditing to ensure that unauthorized movement of the record is tracked.

- **Disposing of records.** When physical records are disposed, the records must be authorized for destruction by law, statute, regulation, and operating procedure. Once approved, the record must be disposed of with care for risk of discovery. Some documents may be simply be discarded as any other refuse, however most business environments use paper shredding or incineration to some degree.

Managing Electronic Records

The general principles of records management apply to records in any format. Digital records however raise specific issues. It is more difficult to ensure that the content, context and structure of records is preserved and protected when the records do not have a physical existence. Guidance on the management of electronic records can be found on the websites of National and State Archives authorities.

Unlike physical records digital records cannot be read without a computer or other machine. Functional requirements for computer systems that can be used to manage electronic records have been produced by the US Department of Defense, DoD 5015.2, the UK National Archives, and the European Union, MoREQ.

Particular concerns exist about the ability to retain and still be able to access and read digital records over time. Digital records require a particular combination of software version and operating system to be accessed and are at risk because technological changes occur at that rate they do. A considerable amount of research is being undertaken to address this issue.

Current Issues in Records Management

As of 2005, records management has increased interest among corporations due to new compliance regulations and statutes. While government, legal, and healthcare entities have a strong, historical records management discipline, general record-keeping of corporate records has been poorly standardized and implemented. In addition, scandals such as the Enron/Andersen scandal, and more recently records-related mishaps at Morgan Stanley, have renewed interest in corporate records compliance, litigation preparedness, and issues. Statutes such as the US Sarbanes-Oxley Act have created new concerns among corporate “compliance officers” that result in more standardization of records management practices within an organization.

Privacy, data protection, and identity theft have become issues of interest for a records manager. The role of the records manager to aid in the protection of an organization's records has often grown to include attention to these concerns. The need to ensure that certain information about individuals is not retained has brought greater focus to records retention schedules and records destruction.

Records Management at The University of Arizona

by Richard G. King, Director
Records Management & Archives

All records of the University are managed under State and Federal laws, rules and regulations or by contract stipulations. This applies regardless of whether the records are centrally managed by the University's Records Management and Archives (RMA) Department or are held by departments or individual principal investigators (PIs). Under State law, each record (for a definition of what a *record* is, please see the RMA web site at: <http://web.arizona.edu/~records/index.htm>) produced or received by the University must be scheduled with the State of Arizona for retention and disposition.

Retention periods are governed by State and Federal Law, agency rules and regulations, contract, and best business practice. Retention periods for research related records may depend on many factors such as patentability of the research, inclusion of human subjects, longitudinal studies that may continue for many years, requirements of granting and contracting entities, etc. Some of these retention periods have been negotiated by the Sponsored Projects office with the University's audit agencies.

Since there is no single source of information on these retention requirements, PIs should get a clear written understanding of records requirements from their granting or contracting agency for the retention of both financial and research documentation. RMA will work with departments and PIs to set these retention periods for stored documents based upon the current understanding of the various laws, rules, and regulations. However, it is up to the storing department or PI to inform RMA of changes in the retention periods due to changes initiated by the sponsoring agency, audit requirements, or litigation holds. Please call RMA (889-5666) for further information or see our web site for links to other sources of information.

The University of Arizona's Records Center

currently houses 8,000 boxes of research related records from departments and PIs. The provision of storage boxes, transportation to and from the Center, storage, retrieval and disposition is provided at no direct cost to departments or researchers. Records remain under the custody of the storing entity and are never accessed by second parties. If needed, a records retrieval service is provided and files are returned to campus on a daily basis.

The University of Arizona Records Center is located at 250 E. Valencia Road, Building 3301. For more information, please contact Richard King, Director, Records Management and Archives at: 889-5631, or email Richard at kingr@u.arizona.edu.

Web sites of interest:

<http://records.web.arizona.edu/>

http://www.fso.arizona.edu/fso/records_mgmt/

<http://web.arizona.edu/~records/retention.html>

<http://web.arizona.edu/~records/state.htm>

<http://206.151.87.67/docs/DataRetentionIntroduction.htm>

Missing Research Records Thwart Misconduct Investigations

Keeping in line with the focus of this month's P.R.I.E. newsletter, *Records Management*, the December 2005 issue of the *Office of Research Integrity (ORI) Newsletter* highlighted the fact that, "poor data management practices and the failure to sequester research records created serious problems in four misconduct investigations conducted by institutions and reviewed by ORI in 2005." This problem is addressed in the new Public Health Service (PHS) regulation, 42 CFR 93.106 (b)(1): <http://ori.dhhs.gov/policies/QA-Reg-6-05.shtml>. ***This regulation states the conditions under which institutions or the ORI might consider the destruction of, absence of, or the respondent's failure to provide research records as evidence of research misconduct.***

"HHS grant regulations also require institutions to maintain research records for three years after the final annual or expenditure report is submitted to the funding agency," said Alan Price, Director, Division of Investigative Oversight. He also said that in these cases research records should have been available, but were not. He mentioned that it would seem sensible for institutional officials to make their scientists aware of these HHS record-keeping requirements, which may be needed to support their research whether or not it is challenged with allegations of research misconduct."

**UNIVERSITY OF ARIZONA
RESEARCH SUPPORT SERVICES GROUP
(RSSG)**

**Important Research
Security Update**
from the Office of the
Vice President for Research

It has come to our attention through national research sources, that the University of Arizona may be targeted for protests and demonstrations by Animal Rights Activists this year during the month of April, which is known as World Laboratory Animal Liberation Month. This year, the week of April 23-30 has been designated World Week for Animals in Laboratories (WWAIL) with April 24th as World Day for Laboratory Animals. Many of us remember the days when April was a very active month for animal rights activities such as break-ins, sit-ins, building take-overs, etc. Therefore, it behooves us all to be particularly vigilant during April to ensure the safety of ourselves, our laboratories and animal facilities.

If you would like to view the *Coalition for Animals and Animal Research (CFAAR) Arizona Newsletter*, or if you would like to obtain contact information, please visit the following web site: http://www.swaabr.org/cfaar/newsletters/2006/Mar_06_news.pdf

**HUMAN SUBJECTS
PROTECTION PROGRAM**

≡Highlights≡

Clinical Trial Websites*

This article provides guidance regarding the requirement of the Institutional Review Board (IRB) to review information provided to potential research subjects through clinical trial websites. It specifically focuses on describing the circumstances for which IRB review of clinical trial websites is not required.

In addition to the use of printed materials and media advertisements, it has become common practice for investigators and institutions to recruit subjects via websites. In some cases, the information provided to potential subjects constitutes the earliest form of informed consent.

However, websites may only be clearly documenting basic information about the clinical trial. According to recent guidance received from the

Office for Human Research Protections (September 20, 2005) posting of **basic** information on a website does not require IRB review. Basic information includes:

- Title
- Purpose of the study
- Protocol summary
- Basic eligibility criteria
- Study site location(s); and
- Information for contacting the study site.

Information posted on a clinical trial website that goes beyond directory listings with basic descriptive information is considered part of the informed consent process and requires IRB review and approval. Types of information that would require IRB review include but are not limited to risks and potential benefits, solicitation of identifiable information or incentives (if any) which are being offered to prospective subjects.

Clinical trial websites that provide only directory listings with basic descriptive information about clinical trials in general (as listed above) do not need review and approval by an Institutional Review Board. Examples of clinical trial listing services that do not need IRB review and approval include the National Institutes of Health (NIH) ClinicalTrials.gov website, the NIH National Cancer Institute's cancer clinical trials listing (Physician Data Query [PDQ]), and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).

*Department of Health and Human Services, Office for Human Research Protections (2005). [Guidance on Institutional Review Board Review of Clinical Trial Websites](#), Access date 26 March 2006.

<http://www.hhs.gov/ohrp.policy/clinicaltrials.html>.

*Food and Drug Administration (Sept, 1998). [IRB Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators](#), Access date 26 March 2006.

<http://www.fda.gov/oc/ohrt/irbs/toc4.html>.

Also,

**New Journal Focuses on
Human Research Ethics**

The inaugural issue of a journal that aims to improve ethical problem solving in research on humans by publishing empirical studies on such research hit the journal shelves in libraries in March, 2006.

Joan E. Sieber, California State University –East Bay, is the editor-in-chief of the *Journal*

of *Empirical Research on Human-Research Ethics*. This new journal will be published quarterly.

For information and subscription rates see: <http://www.csueastbay.edu/JERHRE/>.

University of Arizona – Animal Care Quality Care for Research Animals



New Waste Vendor

Recently, the University has contracted with a new vendor for the disposal of biological and pathological wastes generated by UA laboratory activities. As part of this new contract, the decision was made to separate this waste stream into two disposal options; incineration and autoclaving. Autoclaving of contaminated laboratory wastes is much more cost-effective than incineration.

In the past, all waste materials were incinerated. Under the new disposal contract the majority of generated biologically contaminated waste materials will be autoclaved and eventually land filled, post treatment. Only animal carcasses and anatomical parts are candidates for the more costly incineration disposal option.

We need your help in preserving the new biohazard waste disposal contract. As noted in University Animal Care (UAC) training, all animals and carcasses MUST be returned to UAC at AHSC or the Central Animal Facility (Building 101) for proper disposal. Please DO NOT dispose of animal waste in the biohazard containers located in cold rooms throughout campus. These red containers are for contaminated laboratory wastes ONLY.

Failure to properly segregate wastes could result in forfeiture of the disposal contract.

Specific animal disposal questions should be directed to Casey Kilcullen-Steiner, Assistant Director or Cheryl Johnson, Husbandry Supervisor at UAC (626-6702). Please direct questions regarding the biohazard waste program to Risk Management & Safety (Jeff Christensen, 621-5861).



News from HIPAA.....

HIPAA Enforcement Rule

The Department of Health and Human Services has announced the comprehensive enforcement for

all of the HIPAA Rules (e.g. Privacy Rule, Security Rule, Code Set Rule). The purpose of this Enforcement Rule is to unify the existing rule and regulations governing the different parts of HIPAA.

To better understand the DHHS enforcement and compliance policy, the Office for Civil Rights (OCR), under the direction of the Department of Health and Human Services, is responsible for enforcing the HIPAA Privacy Rule. The Center for Medicare and Medicaid Services (CMS) is responsible for enforcing the HIPAA Security and Code Set Rules. Rules governing the investigative procedures for the Privacy Rule are already in place including the procedures for investigation and impositions of civil monetary penalties. The Enforcement Rule brings together and extends all of these rules to the other parts of HIPAA, as well as supplements them with additional provisions. The result is a comprehensive and unified policy on enforcement and compliance which would apply to all parts of HIPAA, and all of the enforcing agencies.

The present compliance and enforcement was primarily complaint based and responsive in nature. This will continue in addition to HHS audits for adherence to the Privacy Rule. HHS states that they will try to resolve a Covered Entity's noncompliance through "informal means" before resorting to monetary penalties.

If you have comments or questions, please contact Jeniece Poole, UA Privacy Officer, at jpoole@email.arizona.edu.



Radiation Control



Reception Honoring Mel Young's Retirement

After 30 years of service to the Radiation Control Office and the University of Arizona, Dr. Melvin C. Young will retire on April 11, 2006. We are grateful for his many contributions and dedication to safety and service.

Please join us at the Radiation Control Office for a retirement reception for Mel on Wednesday, April 5, 2006, 12:00 - 2:00 p.m., at the Babcock Building, 1717 E. Speedway, Suite 1201, on the second floor in building 1.

 **Good Laboratory Practices
(GLP)**

Quality Assurance Professionals in Good Laboratory, Good Clinical and Good Manufacturing Practices, please join us for the **22nd SQA Annual Meeting and Preconference Training**

Sunday - Thursday, 23 - 27 April 2006
at the

Pointe South Mountain Resort Phoenix, Arizona

The theme of the 22nd SQA Annual Meeting is "SQA on the Rise: Increasing Awareness of the QA Profession and Raising Expectations of the QA Professional." The Conference will include training and concurrent sessions dedicated to promoting and advancing the principles and knowledge of quality assurance essential to human, animal and environmental health worldwide.

Preconference Training will be offered Sunday - Monday, 23 - 24 April 2006, consisting of full-day and half-day workshops. Please check back regularly for a list of workshop titles.

The Conference will be held Tuesday - Thursday, 25 - 27 April 2006. Three days of plenary and concurrent sessions will explore hot topics and the latest regulatory interpretations in the field. Meeting topics, sessions and posters will be selected from abstract submissions by an SQA program committee. Abstracts have been received from professionals around the globe who are committed to quality in GCP, GLP and GMP related fields.

Day registration and preconference training space is still available www.sqa.org

Please contact Marilyn M. Marshall, QAO (621-1469), or Alice C. Langen, Director of Compliance (621-5196) for information.

Institutional Biosafety Committee



The University of Arizona Institutional Biosafety Committee (IBC) web site contains a wealth of information regarding agency guidelines and links to important web sites. You may access the IBC web site at: <http://www.ibt.arizona.edu/>.

Upcoming Conferences/Workshops

Teaching Research Ethics -
A Workshop at Indiana University

Thirteenth Annual Workshop, May 10-13, 2006

The thirteenth annual Teaching Research Ethics Workshop will be held at Indiana University from May 10-13, 2006. Session topics include an overview of ethical theory, trainee and authorship issues, conflicts of interest, using human subjects in clinical and non-clinical research, and responsible data management. Information and registration are available at <http://poynter.indiana.edu>.

July 24-25, 2006

[Mentoring and Supervision for the Responsible Conduct of Research](#)

St. Louis, MO

Co-sponsor: Washington University School of Medicine

September 14-15, 2006

Statistics, Images, and Perceptions of Truth: Detecting Research Bias and Misconduct

Birmingham, AL

Co-sponsor: University of Alabama School of Medicine

October 16-17, 2006

Fourth Annual RCR Expo

Quebec City, Canada

Contact: LNguyen-Khoa@osophs.dhhs.gov

December 1-3, 2006

[Research Conference on Research Integrity](#)

Tampa, FL

Co-sponsors: Association of American Medical Colleges, American Association for the Advancement of Science

Abstracts due: April 28, 2006 (see ORI web site for details on submitting abstracts and to obtain a conference schedule: <http://ORI.hhs.gov>).

Questions should be addressed to Nick Steneck at nsteneck@umich.edu.

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*The P.R.I.E. newsletter is researched
and compiled by Ruth Kurash Daniels.*

Words of Wisdom:

*"A teacher affects eternity; he can never
tell where his influence stops."*

~ Henry Brooks Adams