UW Madison and University Research Records

UW-Madison Records Management Program

2013

UW Archives and Records Management
What are University Records?

Records are documents which:

• Contain recorded information;
• Are produced or received in the initiation, conduct or completion of an activity;
• Are retained as evidence of that activity, or because they have other informational value.
• The recorded information may be in any form (e.g. text, image, sound) and the records may be in any medium or format, including three-dimensional objects.
Generally Accepted Recordkeeping Principles “The Principles”

1. Accountability
2. Transparency
3. Integrity
4. Protection
5. Compliance
6. Accessibility
7. Retention
8. Disposition

Overarching Principles for Best Practices in Records Management for University Records
The Creation and Maintenance of records is integral to the research process. Complete, Authentic and Reliable records are required to:

- demonstrate good research practice and strengthen the reliability of research evidence;
- safeguard researchers and institutions from allegations of research misconduct;
- demonstrate effective stewardship of resources to auditors and to research sponsors;
- protect individual and institutional intellectual property rights;
- demonstrate compliance with legislation, regulations and other requirements.
What makes up a Research Record?

1. Records which document the research process. *e.g.* research protocols; applications for regulatory approvals and approvals granted.

2. Records documenting research outcomes or products. *e.g.* technical reports; monographs.

3. Records documenting the management of the research process/project(s). *e.g.* applications for funding; contracts; purchase invoices; staff timesheets.

4. Research data in both “raw” and “analyzed” form. *e.g.* notes; completed questionnaires; audio/video recordings; photographs; instrument readings; databases; samples, lab notebooks.

RIM Questions to think about...

1. Who is responsible for management of the research records?

2. Where and how should research records be stored?

3. Who will have access to research records?

4. How long should research records be kept?

5. How should they be destroyed?
• Different formats
• Stored in many areas
  Onsite, State Records Center,
  Shared Drives, Personal Drives, and
  now Cloud storage such as Box.net

• Records Management plan
  at creation phase on how
  research records will be
  organized and filed both in
  paper and electronically.

• Use of consistent naming
  conventions for folders
  (accessibility and usable in
  the future.)

Retention schedules should be applied to the research record. What is the research value of the records created?

Do research records meet not only outside requirements, but are in keeping with WI Administrative Rule 12 for management of Electronic Records?
Electronic Records

- **CONTEXT** is the business activity at the time of creation
- **CONTENT** is the subject matter; the topics or matter treated in the work
- **STRUCTURE** is the form and relationships
- Creates a full & accurate record

Metadata

- “Data about data”
- Conveys content, context & structure

Examples of descriptive metadata:

- Title
- Date
- Creator
- Subject
- Description
- Format

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Classification and Naming (Accessibility)

Conventions

- Hierarchical
  - **Function Activity**
    - **Topic**
    - **Subtopic**

E.g. Financial Management – Acquisitions – Requisitions

- Often depicted as a directory or folder structure
- Controlled vocabulary

### Metadata Diagram

- Research Data - Raw and Analyzed
  - Audio Video recordings
  - Instrument Readings
  - Lab Notebook
  - Photographs
  - Questionnaires
  - Samples
  - Applications for funding
  - Contracts
  - Invoices
  - Staff Timesheets
- Research Outcome or Products
  - Technical Reports
- Research Process
  - Research Protocol, Approvals
Note about University E-Mail

E-mail may be a Public Record

An E-mail system is not a recordkeeping system

• Business Communications Records Schedule

• Electronic Communications Guidelines for University Employees
Retention and Disposition of Research Records and Data - End of the Records Lifecycle

University General or Departmental records schedules

http://archives.library.wisc.edu:2784/records/rda.html#general-records
UW-Madison Policies on Research Data & Tangible Research Property Policies

Policy on Data Stewardship, Access and Retention

The University of Wisconsin-Madison has established this policy on Data Stewardship, Access and Retention to assure that research data are appropriately maintained, archived for a reasonable period of time, and available for review and use under the appropriate circumstances. The policy also provides for transfer of data in the event a research leaves UW-Madison.

This policy applies to all University of Wisconsin-Madison faculty, academic staff, visiting scholars, postdoctoral fellows or other trainees, research technicians, and graduate or undergraduate students and any other persons at UW-Madison involved in the design, conduct or reporting of research at or under the auspices of UW-Madison, and it applies to all research projects on which those individuals work, regardless of the source of funding for the project.

Click here for pdf copy of Policy on Data Stewardship, Access and Retention

Policy on Tangible Research Property

The University of Wisconsin-Madison Policy on Tangible Research Property relates to ownership, access, and distribution of tangible research property. This policy is intended to address the university’s responsibilities relating to the management of tangible research property, including, but not limited to:
### Records Retention/Disposition Authorization

**Signature Page**

<table>
<thead>
<tr>
<th>Agency #</th>
<th>Agency Name</th>
<th>College</th>
<th>Department/Division</th>
<th>UDDS#</th>
</tr>
</thead>
<tbody>
<tr>
<td>285A</td>
<td>UW-Madison</td>
<td>Graduate School</td>
<td>Office of Research Policy</td>
<td>A340275</td>
</tr>
</tbody>
</table>

*This is a Campus-wide Schedule*

**List of Records Series:**

<table>
<thead>
<tr>
<th>RDA #</th>
<th>Title</th>
<th>Dates</th>
<th>Format</th>
<th>Volume</th>
<th>Retention</th>
<th>Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>01649</td>
<td>Research Data and Records</td>
<td>Present</td>
<td>All formats and media</td>
<td>--</td>
<td>EVT + 7 years EVT= Close of the research project.</td>
<td>Destroy Confidential may contain PII</td>
</tr>
</tbody>
</table>

**NEW GRS**

We the undersigned have reviewed the above records series and approve the outlined retention and disposition. Approval is contingent on restrictions on records destruction contained in S.19.35 (5), Wisconsin Statutes, (Open Records.
Human Research Protection Program: Policy

Maintenance of IRB Records

Adoption By: All Campus IRB
Adoption Date: November 10, 2005

Purpose: This document describes the record maintenance practices of the UW-Madison IRBs.

Policy

I. UW-Madison IRBs maintain a complete set of materials relevant to review of a research study in each protocol file. IRBs maintain both paper files and electronic files. All UW-Madison IRBs use an electronic protocol management system to track and store information about research protocols.

II. IRBs maintain records of the following:
   ✫ All research proposals reviewed.
   ✫ Scientific evaluations, if any.
   ✫ DHHS-approved sample consent documents.
   ✫ Progress reports submitted by investigators.
   ✫ Reports of injuries to participants.
   ✫ Minutes of IRB meetings.
   ✫ Records of continuing review activities.
   ✫ All correspondence between the IRB and the investigators.
   ✫ A list of IRB members.
   ✫ Procedures for the IRB.
   ✫ Statements of significant new findings provided to participants.
   ✫ Approval of waiver or alteration of HIPAA authorization.
   ✫ Veterans Administration Research and Development Committee approval of protocol.

III. IRB records for initial reviews and continuing reviews by an expedited procedure include:
   ✫ The specific permissible category.
   ✫ A description of the review.
   ✫ A description of action taken by the reviewer.
   ✫ Any determinations and protocol specific findings required under federal regulations.

IV. The IRB records for each study's initial and continuing review note the frequency (not to exceed one year) for the next continuing review in either months or other conditions, such as after a particular number of participants are enrolled.

V. IRB records for all exemption determinations include a citation to the specific regulatory category justifying the exemption.

VI. IRB records document protocol specific findings required by applicable regulations for:
   A. Waiver or alteration of informed consent.
   B. Waiver of consent documentation.
   C. Research involving pregnant women, human fetuses and neonates.
Human Research Protection Program: Policy

Retention of IRB Records

Adopted By: All Campus IRB
Adoption Date: November 10, 2005
Revised: March 1, 2012 by HRPP Advisory Committee

Purpose: This document describes the record retention practices of the UW-Madison IRBs.

Policy

I. The policy of UW-Madison is to keep protocol records for 7 years after research ends.
II. If a study is canceled without participant enrollment, IRB records are required to be maintained for seven years after cancellation.
III. IRB records not related to a specific protocol, including IRB meeting minutes and general correspondence, are kept for a minimum of 7 years.
IV. All records are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.
V. Requests by the public to see IRB records must go through open records request.

Procedure

VI. Social and Behavioral Science IRB (SBS IRB) active files are kept in IRB Office. Inactive SBS IRB files are kept in locked files cabinets in the IRB offices for one year and then archived. Inactive files are destroyed 7 years after archived.
VII. Education Research IRB (ER IRB) files are kept in IRB office. Inactive Education Research files are kept in locked files cabinets in the IRB offices for one year and then archived. Inactive files are destroyed 7 years after archived.
VIII. Health Sciences IRB (HS IRB) and Health Sciences Minimal Risk IRB (MR IRB) active files are kept in the IRB Office or within the ARROW, the online tracking and submission system. Inactive paper files are sent to State Archives and retained for at least 10 years and then a decision is made regarding whether the material is historically significant. If considered historically significant, the records are then retained by the University of Wisconsin-Madison indefinitely.
IX. Paper files
A. Records are stored safely.
B. Records are stored in a way that maintains confidentiality.
C. Researchers and research staff permitted to view selected portions of the file upon request and may receive redacted documents (e.g., removing internal comments or IRB reviewer names).
D. Others who are not listed as key personnel on an IRB file may only have access to file documents with explicit permission of the investigator.
Other Resources

Research Data Services - http://researchdata.wisc.edu/
Thank You

Contact me if you need assistance with development of a Research Record Retention Schedule for your department of unit.

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University Records Officer