UNIVERSITY OF WISCONSIN - MADISON

RECORDS RETENTION AND DISPOSITION SCHEDULE
FOR
UW-Madison Institutional Review Board (IRB) Records

2014

1765, 1766, 1767
1768, 1769
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 Law) and that no records are destroyed if litigation or audit involving these records has commenced.

Michelle Cobr
Dean/Department Chair/Administrative Officer

 Nichelle CoBR
Dean/Dept. Chair/Admin. Officer--PLEASE PRINT

John C. Denney
University Legal Counsel

Margaret E. Enser
University Records Officer

Dale S. Prewitt
University Archivist

State Archivist

G. Thompson

Executive Secretary - PRB

APPROVAL SUBJECT TO 10-YEAR SUNSET. RESUBMITAL REQUIRED PRIOR TO August 2024

5/30/14
Date

6/6/2014
Date

6/6/2014
Date

AUG 2 1 2014
Date

9/8/14
Date
I. INTRODUCTION AND PURPOSE
This retention schedule represents the official University of Wisconsin-Madison policy with regard to the retention and disposition of records and information and has the approval of the University Records Management Advisory Group (URMAG) and the Wisconsin Public Records Board (PRB). The PRB is the statutory body with the responsibility to safeguard the financial, legal, administrative, and historical interests of the State in the disposition of records through the review of records schedules prepared by State agencies.

This retention schedule also provides guidance to University of Wisconsin-Madison employees regarding what does and does not comprise a public record. The UW-Madison campus must manage all records to ensure systematic control from creation or receipt through processing, distribution, maintenance, retrieval, retention and final disposal.

II. SCOPE:
This schedule pertains to the records and information arising from currently understood UW-Madison record policies and procedures. It applies to all such records regardless of format or media. While an attempt has been made to describe the records in commonly used terms, there may be instances in which the schedule does not reflect the exact title or name used by a given department. If offices or departments cannot determine by the descriptive information provided on each item whether a given departmental record is covered or not, they should contact the University Records Officer. An attempt has been made to include all records commonly required or used within the University campus. However, as processes change, forms may be modified and new ones created, and documentation requirements may also change.

This schedule will be reviewed periodically to ensure that it is kept as up-to-date as possible. This schedule applies to all organizational units of the University of Wisconsin-Madison and any attached entities that are required to follow UW-Madison policies.

III. SUSPENSION OF THE RECORDS RETENTION SCHEDULE
Records may be delayed from disposition/destruction only under the following conditions:

1. Particular records have been identified as needed for a financial or performance audit.

2. Records that are required for legal proceedings are held under a "litigation hold" for an actual or imminent legal proceeding. Imminent meaning legal action is anticipated or there is reasonable expectation thereof.

3. An open records request has been received and not completed.

4. The Wisconsin Open Records Law, § 19.35(5), Wis. Stats, forbids the destruction of any record after an inspection or copying request until the request is granted, or at least 60 days after the date that the request was denied. Court orders and litigation may extend this time...
period. The agency's legal custodian of records can provide advice. For the University of Wisconsin Madison the legal custodian is the Chancellor's Office.

It is the responsibility of the office holding the record to determine if an audit, litigation, or an open record request is pending, before disposing of the records.

IV. UTILITY AND FUNCTION OF INFORMATION PROVIDED WITHIN THIS DOCUMENT

a. Minimum Retention Established and Permanent Retention Procedure. The records retention schedules included within this document establish minimum retention periods for each type of record. The disposition of each record is assumed to be destruction after its minimum retention period or transfer to the UW Archives.

b. Materials That Comprise Public Records. Under Wisconsin law, many materials comprise public records performing the transaction of public business on behalf of the University Campus. Under Wis. Stats. § 16.61, Public records are defined as "all books, papers, maps, photographs, films, recordings, optical disks, electronically formatted documents or other documentary materials, regardless of physical form or characteristics, made, or received by any state agency or its officers or employees in connection with the transaction of public business".

c. Materials That Do Not Comprise Public Records. Under Wisconsin law, many materials do not comprise public records. Therefore, non-records should be retained only so long as they are useful as a resource for performing the transaction of public business on behalf of the University Campus. Thereafter, in the interest of efficiency and proper resource management, they should be destroyed. Under Wis. Stats. § 16.61, the definition of "Record" does not include: duplicate copies of materials the original copies of which are in the custody of the University and which are maintained only for convenience or reference and for no other substantive purpose; materials in the possession of a library or museum made or acquired solely for reference or exhibition purposes; notices or invitations received by the University that were not solicited by the University and that are not related to any official action taken, proposed or considered by the University; drafts, notes, preliminary computations and like materials prepared for the originator's personal use or prepared by the originator in the name of a person for whom the originator is working; and routing slips and envelopes.

d. Preservation of Historical Documents. Historically, University records have been preserved in paper files. Presently, however, advances in technology are beginning to present a viable alternative to paper records: electronic data stored in many electronic systems. Because of the potential for electronically-preserved information to be lost over time as electronic systems degrade or become obsolete, electronic systems should be used as the primary manner of preserving historical documents only if measures are implemented to ensure appropriate updates to the electronic storage systems are consistently purchased, installed, and maintained, and to ensure the appropriate migration of the electronically-stored information as electronic systems become obsolete and are replaced by new technologies.

Because of the consequences of failing to appropriately maintain electronic information technology systems, records storage within an electronic information system must comply with the legal requirements set forth in Board of Regents Policy Document 3-2: University of Wisconsin-Madison Retention and Disposition Schedule for Institutional Review Board (IRB) Records 2014.
Please carefully review these documents prior to storing official copies of public records upon information systems and if you have questions or concerns, then please seek assistance from the University Records Officer.

Using the Schedule

- Use the table to locate the record series item.
- Identify whether you are the holder of the official, department, or copy of the record.
- Implement the retention and disposition noted at the level of record you hold.
- If you are uncertain about the records series item or your responsibility for it, contact the Records Officer for clarification.
- Retention periods and disposition methods outlined in this document have been reviewed and approved by both University (CRRG) and State Public Records Board.
UNIVERSITY OF WISCONSIN- MADISON
Institutional Review Boards (IRB)

Federal regulations and UW-Madison policy mandate review of non-exempt research involving human subjects by an Institutional Review Board (IRB). UW-Madison has pledged that the institution and all investigators will follow the US Department of Health and Human Services (DHHS) regulations (Title 45 CFR 46.115), also known as the "Common Rule," for protecting human research subjects in the case of federally support human subjects research and Food and Drug Administration (FDA) investigational drug and device regulations (21 CFR Parts 56.115) for FDA-regulated research.

The Associate Vice-Chancellor for Research Policy in the Graduate School serves as UW-Madison's Institutional Official for human subject protections.

UW-Madison currently has 3 IRBs, supported by two offices. The Education and Social/Behavioral Science IRB are supported by one office while the Health Sciences and Minimal Risk IRBs are supported by a second office. Each IRB maintains standard operating procedures, research protocol files, correspondence with study teams and meeting minutes.

The campus IRB offices maintain the official protocol file for each study to meet the University's regulatory obligations for recordkeeping. The campus IRB offices maintain the official REGULATORY OVERSIGHT file for each study to meet the University's regulatory obligations for recordkeeping.

Investigator records are considered the official research file and are not covered in this schedule. The IRB office only maintains copies of documents sent to the investigator. It is the investigators responsibility to maintain adequate documentation of research procedures/process. In case of a request to review the file all information must be readily available to be reviewed by the appropriate individuals in a reasonable manner.

NOTE: There is some overlap between the University and the VA: All IRB records and study team records that fall under the VA will be transferred from UW custody once the research study has been completed to the custody of William S. Middleton Memorial Veterans Hospital and subject to follow the VA policy for retention of records.

This Schedule covers the following record series:

- IRB Minutes
- Applications for IRB Review
- IRB Exempt Research
- IRB Initial Review Applications – Not Approved or Incomplete
- IRB Oversight Documentation
*ACCESS REQUIREMENTS:

Access is limited for all series. Contact UW-Madison Office of Legal Affairs for access as documents maintained by the IRB which may contain trade secret information subject to non-disclosure obligations, certain employee personnel records, information protected by the attorney-client privilege, as well as confidential information relating to research materials, facilities and personnel. Trade secrets may be kept confidential under Wis. Stats. § 19.36(5) and certain intellectual property records may be kept confidential under the balancing test. Certain information regarding staff may be kept confidential under Wis. Stats. § 19.36(10), and the balancing test. Records directly related to students may be kept confidential under Wis. Stats. § 19.36(1), where disclosure of information is prohibited by the Family Educational Rights and Privacy Act, 20 USC 1232g and 34 CFR Part 99, and under the balancing test. Certain information pertaining to research activities, such as the security measures for specific research facilities and the location of hazardous materials or controlled substances, is exempt from disclosure per Wis. Stats. § 19.36(1), where disclosure is prohibited by federal law, such as the Public Health Security and Bioterrorism Preparedness and Response Act, 42 USC 262a, and the balancing test. Minutes of IRB Committee meetings may contain attorney-client privileged information. These records must be reviewed by IRB, and confidential information redacted, prior to public release.

Other Requirements:
21CFR 56.115 IRB Record requires Completion of Research + 3 years. Record series retentions exceeds these requirements per university Human 45 CFR 46.115 BASIC HHS POLICY FOR PROTECTION OF HUMAN RESEARCH SUBJECTS

University Faculty Policy II-314 on Misconduct in Scientific Research mandates a minimum of 7 years for research records.

Retention of IRB Records Policy March 1, 2012 by HRPP Advisory Committee

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<tr>
<th>Record Series ID Number</th>
<th>Record Series Title</th>
<th>Record Series Description</th>
<th>Retention</th>
<th>Media Type</th>
<th>Disposition</th>
<th>Office of Record</th>
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<tr>
<td>GRS01765</td>
<td>IRB Minutes</td>
<td>This record series consists, but is not limited to IRB minutes, attachments, agendas and meeting announcements and may reference protocols.</td>
<td>Retention: EVT + 3 Years EVENT = After All protocols referenced in the minutes are closed. Copies: Destroy when no longer needed, but not longer than the Originals. Confidential: Yes or PII: May contain PII and Proprietary and Intellectual property. *See Access Requirements page 7</td>
<td>Paper or Electronic</td>
<td>Destroy Confidential</td>
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<td>GRS01766</td>
<td>Applications for IRB Review</td>
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<td>This records series consists of all available documentation related to the IRB application review and associated correspondence, continuing reviews, amendments, and reportable events (noncompliance and unanticipated problems). This application review consist of one of the following:</td>
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<td>- Expedited Review</td>
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See Record Series GRS01767 for applications that are Exempt and GRS01768 for applications that are not approved or incomplete.

| Retention: | Paper or Electronic |
| EVT + 7 Years | Destroy Confidential |
| EVENT = Date of the Study is Closed. | IRB Office |

Copies: Destroy when no longer need, but not longer than the Originals.

Confidential: Yes or PII: May contain PII and Proprietary and Intellectual property.

*See Access Requirements page 7
<p>| GRS01767 | IRB Exempt Research | This record series consists of IRB determinations that a research project does not fall under IRB purview pursuant to 45 CFR 46. See Record Series GRS01768 for applications that are not approved or incomplete. | Retention: EVT + 5 Years EVENT = Date of Final IRB Determination | Copies: Destroy when no longer need, but not longer than the Originals. | Confidential: Yes or PII: May contain PII and Proprietary and Intellectual property. | Paper or Electronic | *See Access Requirements page 7 |</p>
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<th>GRS01768</th>
<th>IRB Review Applications – Not Approved or Incomplete</th>
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<td>This records series consists review applications of any type submitted to the IRB that were never approved or never completed the formal review process (e.g., were withdrawn) and all available documentation related to the submitted IRB Initial Review Application which were not approved and associated correspondence. This review consist of one of the following:</td>
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<td>- Full Review</td>
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<td>EVENT = Date not approved or closed by the IRB</td>
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<td><strong>IRB Office</strong></td>
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| GRS01769 | IRB Oversight Documentation | This record series consists of documents related to IRB function, such as rosters, external audits, and IRB reporting. | Retention: EVT + 7 Years
EVENT = Date of the report or when document superseded by an updated version. |
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