SOP 302: Record Retention

Terms and Abbreviations

FDA: Food and Drug Administration; the division of HHS that oversees drugs, medical devices, and food.
HHS: Health and Human Services; a department of the US government whose responsibility is the protection of the health of Americans
IRB: Institutional Review Board
IRB office staff: the IRB Manager, IRB Administrator, and any other IRB office staff, either collectively or individually
OHRP: Office of Human Research Protections; a division of HHS that oversees human subjects research
PI: Principal Investigator
SPI: Student Principal Investigator
UWM: University of Wisconsin – Milwaukee

Overview

The Principal Investigator and IRB must maintain and retain the appropriate records for each research study, consistent with federal regulations, Wisconsin open meeting laws, and UWM's records retention policies. Records must be maintained in a confidential and secure manner.

IRB records are generally subject to open records requests.

Exceptions:

- Minutes of closed session IRB meetings
- Student research projects
- Any other documents created by or related to a student

Details and Procedures

Principal Investigator Record Retention

Each Principal Investigator must retain records of all correspondence relating to the use of human subjects in research, as required by UWM procedures and federal regulations. This includes:

- All IRB application materials (initial, amendment, continuing review, etc.)
- All approval letters and important correspondence (initial, continuing review, and amendment approval letters; reportable event memos, etc.)
- All versions of approved informed consent forms

- Training records for research team members
- Research data, which must be stored according to the IRB approved protocol

Records of human subject research may be inspected by federal authorities, the IRB, and/or accreditation agencies.

Research records must be kept for a minimum of three years after completion of the study. For studies that involve drugs or devices seeking FDA approval, records must be kept for three years after the FDA has taken final action on the marketing application.

Other requirements for record retention may also apply. Funding agency, department, professional field, or other UWM requirements may be different. Records should be maintained in a manner compliant with the most stringent of all applicable requirements.

Researchers Leaving UWM
If a researcher leaves UWM, appropriate arrangements should be made for the care and retention of the records. This may include transfer of oversight of the data to another UWM faculty or staff member, de-identification or destruction of data, or transfer of the data to a new institution.

All actions related to transfer of data to another institution must be discussed with appropriate parties within both UWM and the receiving institution, including the IRBs of both institutions.

IRB Record Retention
The IRB maintains records of all protocols and correspondence submitted to the IRB and minutes from all full board meetings for a minimum of three years after completion of the study.

All records are accessible for inspection and copying by authorized representatives of OHRP, HHS, FDA, Sponsors, university officials, and internal auditors at reasonable times and in a reasonable manner.

References

45 CFR 46.115

21 CFR 56.115

Wis. Stats. §§ 19.21-19.39 (Wisconsin open records law)

Wis. Stats. §§ 19.81-19.98 (Wisconsin open meetings law)

Revision History

Version	Date	Summary of Changes
1	13 Feb 2020	Initial version