Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Record Retention

Record Retention

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Approved By: Michele Kennett, JD, MSN, LLM
Associate Vice Chancellor for Research

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1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the requirements for record keeping.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

IRB Records

General information - The IRB will prepare and maintain adequate documentation of IRB activities per 45CFR46.115 and 21CFR56.115. The IRB utilizes an all-electronic submission and record keeping site called eCompliance. The IRB records are kept indefinitely as a result of the paperless system and kept no less than three years following the completion of a study.

1. *IRB Documentation*: All available documents related to a research study including, but not limited to:
    a. IRB Application
    b. Protocol
    c. Scientific evaluations, when provided by an entity other than the IRB
    d. Grant Proposal
    e. Investigator's Brochure
    f. Consent Form(s)
    g. Progress reports submitted by the Principal Investigator (PI)
    h. Recruitment and advertisement materials
    i. Reports of unanticipated problems and statements of significant new findings provided to participants
    j. Reports of injuries to participants
    k. Data safety monitoring reports
    l. Amendments
    m. Noncompliance

2. *Minutes*: Minutes and reviewer checklists become part of the permanent IRB record (see Minutes SOP for detailed information)

3. *Continuing Review*: Records of Continuing Review activities including all supporting documentation. (See CRR SOP for detailed information.)

4. *Correspondence*: Copies of all correspondence between the IRB and PIs will be filed in the relevant protocol file.

5. *IRB Members:*
    a) Membership Lists: A list of committee members identified by:
        - Name
        - Earned degrees
        - Representative capacity
        - Indications of experience such as board certifications, licenses, etc. sufficient to describe each members chief anticipated contributions to IRB deliberations

- Any employment or other relationship between each member and the IRB (e.g. full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).

b) Resume for each IRB member

Investigator Records

Investigator records are considered the official research file. 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.

Under the University of Missouri policy, research records must be retained by the investigator for at least seven years after completion of the research. (See University of Missouri Record Retention Guide)

Additional requirements for records retention may apply depending on the language in the contract or the type or sponsor of the research (see section on "special circumstances" below). For studies that are sponsored, it is common that after data collection is completed at this site the records are shipped off to the sponsor for records storage and data analysis. The sponsor, then, is required to adhere to all regulations regarding records storage. The university maintains policies regarding the storage of research records (see Records Management for more information).

Ownership

Any record that is determined to be a University Record is property of the University of Missouri. This includes research records created, developed, or otherwise maintained under the auspices of employment, contract, or grant with the University. Original research records must remain at the University even if the researcher has left the institution. The researcher's department must provide a means of securing and storing the research records in connection with all applicable rules relating to this and Records Management policies. A researcher may, however, make copies of the original research records to take with them if they leave the institution for continued analysis and future research.

Special Circumstances

Additional requirements for records retention may apply depending on the type and/or sponsor of the research. Below are some possible additional requirements to consider when determining whether records may be removed or destroyed.

VA Research Records

All records as outlined in this policy will be kept in addition to correspondence between the IRB and the VA R&D committee. Records retention by investigators either using or who are part of the Truman VA Memorial Hospital may have additional records retention requirements other than stated in the above policy. All records pertaining to the VA must

also comply with any VA policies as outlined in the HS IRB SOP "VA Hospital Research - Special Considerations"

FDA Regulated Research

Records retention by investigators for FDA regulated trials may have additional requirements regarding maintaining records. All records pertaining to FDA regulated trials must also comply with any FDA record retention policies.

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