Record Retention

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Approved By: Robert Hall, PhD
Associate Vice Chancellor, 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 Health Sciences Institutional Review Board.
3.0 Policy/Procedure

IRB Records

General information - The HS IRB will prepare and maintain adequate documentation of IRB activities per 45CFR46.115 and 21CFR56.115, including the following:

1. Protocols: All available documents related to a research study including, but not limited to, the IRB application, protocol, scientific evaluations, grant (if applicable), Investigator’s Brochure (if applicable), consent form(s), progress reports submitted by the Principal Investigator (PI), recruitment and advertisement materials, reports of unanticipated problems and statements of significant new findings provided to participants.

2. Minutes: Minutes of the committee meetings that document the:
   • Attendance at meetings
   • Actions taken by the Committee
   • Vote on these actions (including the number of members voting to approve, disapprove, and abstaining).
   • Basis for requiring modifications or disapproving the research, and a summary of controverted issues and their resolution.

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. VA Studies: All records as outlined in this policy and in addition, correspondence between the IRB and the VA R&D committee.

6. 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

Changes in IRB membership shall be reported to OHRP in accordance with 45CFR46.103(a).

IRB records will be accessible for inspection and copying by authorized representatives of the OHRP, FDA and other federal agencies at reasonable times and in a reasonable manner. As outlined in the HS IRB SOP “VA Hospital Research – Special Considerations”, VA R&D and other authorized representatives of the VA will be provided with complete access to records pertaining to VA-specific research for inspection and copying.

IRB records in paper format will be retained for 5 years after the research is completed, terminated, withdrawn, cancelled prior to enrollment, or otherwise closed, and all other records will be retained for 5 years.
VA research records (all records normally retained under the HS IRB policy and all correspondence between the HS IRB and the R&D Committee) in paper format will be retained for a minimum of 5 years after the completion of the study and in accordance with VHA Records Control Schedule (RCS10-01), applicable FDA and DHHS regulations or as required by outside sponsors, and all other records will be retained for 5 years.

With the implementation of the electronic IRB system (eIRB) in 2004, all IRB records (including VA research) from that date forward are now electronically retained in the eIRB system indefinitely.

The HS IRB office routinely sends IRB records to Records Management in accordance with University policy regarding retention of records. Records relating to research which are completed, terminated, withdrawn, cancelled prior to enrollment, or otherwise closed are maintained in the IRB office for a period of one year. After one year, the IRB office transfers all study records to Records Management. The records continue to be retained according to HSIRB policy and VA policy.

**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, including VA records, must be retained by the investigator for at least seven years after completion of the research. (See University of Missouri policy) [http://www.umsystem.edu/ums/departments/fa/management/records/guide/academic/01801.shtm](http://www.umsystem.edu/ums/departments/fa/management/records/guide/academic/01801.shtm)

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: [http://www.umsystem.edu/ums/departments/fa/management/records/](http://www.umsystem.edu/ums/departments/fa/management/records/)).

**Ownership**
Any record that is determined to be a University Record (see definitions above) is property of the University of Missouri. This includes research records created, developed, or otherwise maintained or created 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
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 records retention policies.