Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Record Retention

Record Retention

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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

The IRB will prepare and maintain adequate documentation of IRB activities per 45 CFR 46.115 and 21 CFR 56.115. 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.

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 printed form or electronically. 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**).**

Exceptions:

1. Since audio-recordings, video-recordings, and photographs are considered an original record, they must be kept for at least seven years following after completion of the research UNLESS the convened board determines the destruction of tapes after transcription further protects human subjects. Documentation of the IRB determination is placed in the board meeting minutes.

2. Investigators may remove identifying information from original research records if they have IRB approval to do so. Typically, this would be allowed if the removal of identifying information further protects the human subjects involved in the research.

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 record retention may apply depending on the type and/or sponsor of the research. 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 record storage and data analysis. The sponsor is then required to adhere to all regulations regarding record storage. The university maintains policies regarding the storage of research records (see Records Management for more information). 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 SOP "Truman VA Hospital Human Subject 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.

References:

Policy Revision Dates Prior to January 21, 2019:
August 1, 2004; May 25, 2006; December 1, 2006; June 10, 2010; July 1, 2011; March 1, 2015; July 1, 2015; January 29, 2016; June 8, 2017, May 3, 2018