

Research Records Retention Policy

10/04

Policy

Research Records are to be retained by the University of Kansas Medical Center (KUMC) for a period of six (6) years after the submission of the final report and close-out procedures on the research project for which the Research Records were prepared, unless a longer retention period is specified by the sponsor, funding source, or regulation.

The retention of the original Research Records shall be the responsibility of the Principal Investigator on behalf of the KUMC, but at all times shall remain the property of the KUMC, unless otherwise specified by law, regulation or agreement.

Background

This KUMC policy assures that Research Records are appropriately archived and retained, and available for review under the appropriate circumstances. The Principal Investigator is responsible for the maintenance and retention of Research Records in accordance with this policy and this policy exists so the KUMC and Principal Investigator can 1) verify compliance with Federal, State, and local laws, supporting regulations, 2) to ensure the protection of intellectual property, 3) fulfill contractual obligations and sponsored project agreement requirements, 4) assure scientific integrity, 5) protect human and animal subjects, 6) assure appropriate use of recombinant DNA, etiologic agents, radioactive materials, etc., and 7) avoid disputes among researchers and protect the rights of all those participating in the research, including postdoctoral fellows, students, and staff.

Definitions

Principal Investigator or PI: The investigator, scientist, or scholar with primary responsibility for the overall design and conduct of the research, and retaining or ensuring retention of Research Records and providing access to it. The design responsibility is with person or sponsor that created and/or sponsored the research. Also referred to as the Project Director.

Research: Including, but not limited to, investigational studies of drugs or devices, laboratory studies, student research, behavioral, and outcomes research.

Research Records: Information recorded for the purpose of a research study, regardless of form or the media on which it may be recorded. Research Records may include technical data, computer software, laboratory worksheets, memoranda, notes or exact copies thereof that are the result of original observation and activities of a study, and any records that are necessary for the reconstruction and evaluation of reported results of the research and the events and processes leading to those results. Items which constitute research data under this policy include, but are not limited to: laboratory notebooks, samples of chemicals and materials synthesized during research, field specimens, voucher specimens, computer files or other electronic data, video tapes and audio tapes.

Sponsor: In clinical studies (human), a sponsor is a person or entity that initiates a clinical investigation of a study, including a drug or device manufacturer or the institution that developed the study and assumes the responsibility for compliance with applicable laws and regulations. The Sponsor does not actually conduct the investigation. A clinical investigator may serve as a sponsor-investigator. The sponsor assumes the responsibility for the study.

Procedures

Retention of Research Records

- The Principal Investigator is responsible for the collection, management, storage and retention of Research Records.

- Principal Investigators should adopt an organized system of data collection and record retention and ensure compliance by all under his/her direction regarding such data, including the use and retention of Laboratory Notebooks as appropriate.
- Research Records will be maintained in the department or division in which they were produced.
- Research records must be retained on the University campus or campus affiliate (including University approved long term storage facilities), unless specific permission to do so has otherwise been given by the Vice Chancellor for Research Administration.
- Principal Investigators must retain or otherwise archive Research Records for a minimum period of 6 years on research not involving human subjects and a minimum of 15 years on research involving human subjects or human subjects materials. If, however, the research is funded by contract, the term of the Contract/Agreement shall supersede this policy.
- If the research involved protected health information (PHI), the Principal Investigator must retain the permission to use the PHI for 6 years beyond the expiration date of the authorization (i.e. the consent form or authorization).
- Principal Investigator will maintain all documents involved in the study at the investigative site or appropriate KUMC approved storage facility.
- If the Research involves pediatric subjects or is in vitro, then the records shall be retained for a minimum of 25 years after completion or termination of the study.
- When the Research Records have met the applicable retention guideline, shred the documents and document the following: Principal Investigator name; Protocol identifiers such as Funding source or sponsor (when applicable), protocol number (when applicable), HSC, IACUC or Committee identifier; Date shredded ;Person shredding the documents and a Summary of documents shredded.
- If the study is an industry-sponsored study, prior to shredding documents or disposal of materials contact the sponsor and obtain written permission.
- When research results in an invention assigned to the KU Medical Center, and made available for commercialization, the original research lab log book which verifies the original discovery must be forwarded to the Research Institute and will be archived in a fireproof locked safe for security purposes. This archive becomes the responsibility of the Vice Chancellor for Research Administration.

Transfer of Research Records

- The Principal Investigator directing a research project may take copies of Research Records not involving human subjects, upon written approval of the Vice Chancellor for Research Administration.
- The Institution must retain all original Research Records and data. Any patient/subject records will require appropriate patient/subject authorization for use and disclosure to another entity.
- If a Grant is being transferred to another Institution with the Principal Investigator, then the Principal Investigator is responsible for leaving a complete copy of all Research Records and data with the KUMC.
- Before transferring the original Research Records, the Principal Investigator must ensure that any special conditions stated in the grant, contract, or cooperative agreement are met.
- The Department is responsible for archive of the Research Records for a period not less than six (6) years following the transfer of the Principal Investigator or the term of the grant or agreement, whichever, is longer.
- Prior to the removal of any tangible research product from KUMC, the recipient/institution must execute a material transfer agreement (MTA) with KUMC.

Access to Research Records

- Where necessary, the KUMC has the right to access all Research Records and to take custody thereof, in a manner specified by the Executive Vice Chancellor, or his/her designee.
- The Research Records shall be available to representatives of external sponsors of the research or designated governmental officials, when such access is appropriate.
- Any disputes regarding requests for original Research Records, copies, or transfer of Research Records will be resolved by the Executive Vice Chancellor or his/her designee.

Applicability

This policy shall apply to all University of Kansas Medical Center faculty, staff, postdoctoral fellows, students, trainees, and any other persons at KUMC or KUMC Research Institute involved in the design, conduct, or reporting of research at the KUMC, including all research projects on which those individuals work, regardless of funding source for the project.

Exemptions

None

Related Policies

- Faculty Handbook
- Humans Subjects Committee Policy and Procedure Manual
- KUMC Record and Retention Schedule, <http://www2.kumc.edu/finance/recordretention/>
- KUMC Policies and Procedures, <http://www.kumc.edu/guides/policyguide.html>
- 21 CFR §312.62 – Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials
- 21 CFR §812.140 – Investigator Record Keeping and Record Retention for Device Trials
- ICH Good Clinical Practice Guidelines – Part 4.9 Records and Reports
- OMB Circular A-110, §.53 [Retention and access requirements for records.](http://www.whitehouse.gov/omb/circulars/a110/a110.html)
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- Federal Acquisition Regulation (FAR) <http://www.arnet.gov/far/>
- 48 CFR Part 27 (For contracts awarded by the Federal government) §27.403 Data rights—general 52.227-14 Rights in Data – General (Clauses & Forms)
- Kansas Statutes Annotated §75-3504, on public records disposition Agreement Term + 5 years
- National Institutes of Health (NIH) Office of Extramural Research, <http://grants1.nih.gov/grants/oer.htm>
- Statement on Sharing Data Policy (Notice # NOT-OD-03-032; Released February 26, 2003) http://grants1.nih.gov/grants/policy/data_sharing/index.htm
- NIH Grants Policy, Part II Subpart A, Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical Research Resources, http://grants.nih.gov/grants/policy/nihgps_2001/part_ii_a_6.htm
- Public Health Service Policy Relating to Distribution of Unique Research Resources Produced with PHS. <http://grants.nih.gov/grants/guide/notice-files/not96-184.html>
- Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts. , <http://www.nih.gov/science/models/sharing.html>
- National Science Foundation (NSF) Grant Policy Manual (NSF 02151) §734. Dissemination and Sharing of Research Results http://www.nsf.gov/pubs/2002/nsf02151/gpm02_151.pdf

Contacts

Vice Chancellor for Research Administration: 913-588-1261

This policy shall not be construed to authorize or condone destruction of any document in contemplation of or in anticipation of, or during, any litigation or investigation. This prohibition of destruction is applicable regardless of whether the document is otherwise eligible for or past the point at which it may be destroyed. Questions regarding this requirement should be directed to the Office of the General Counsel.