

RESEARCH RECORDS RETENTION
January 2008
Policy 7.1.08

Policy:

Research Records are to be retained by the University of Kansas Medical Center (KUMC) for a period of not less than 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 other regulation.

Data collected as a part of research is the property of the University of Kansas Medical Center (KUMC). KUMC compensates researchers and allows students to produce work; as a result, the work/data becomes the property of the university. Thus, researchers may not copy, remove, or destroy data without the explicit written permission from the Vice Chancellor for Research. For example, if a researcher leaves the university, a copy of the data may not be taken without the written permission from the Vice Chancellor for Research.

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

Purpose:

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, and supporting regulations;
- 2) ensure the protection of intellectual property;
- 3) fulfill contractual obligations and sponsored project agreement requirements;
- 4) support issues of scientific integrity;
- 5) support issues of human subject and animal use;
- 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.

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 his/her direct reports 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 or in a network-based electronic file with access limited to authorized personnel.
- 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.
- 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 terms of the Contract/Agreement shall supersede this policy, if more conservative. Adequate funding must be available to pay for storage prior to agreeing to a contract that specifies how long records are to be maintained.
- If the research involves 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 at an appropriate KUMC-approved storage facility.
- If the research involves pediatric subjects then the records shall be retained for a minimum of 25 years after completion or termination of the study.
- An investigator involved in the research of drugs, devices, or biologics being in tested in humans for FDA approval shall retain records "for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified [sic]" 21CFR312.62.c. *Please note: this length of time can be much greater than 2 years. Written confirmation should be received from the sponsor and/or FDA granting permission to destroy the records.*
- When research results in an invention assigned to the KU Medical Center, and made available for commercialization, the original research lab log book that verifies the original discovery must be forwarded to the Research Institute. It will be archived in a fireproof locked safe for security purposes. This archive becomes the responsibility of the Vice Chancellor for Research.

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.
- 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 the original of all Research Records and data with the KUMC.
- Before transferring the a grant and a copy of the 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 archiving 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.

Destruction of Data

- When the Research Records have met the applicable retention guidelines, the documents will be shredded and the following recorded: 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, the sponsor will be contacted and written permission obtained to destroy the documents.
- Records/data cannot be destroyed until the institutional requirements for data destruction are met.

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.

Definitions:

HSC: Human Subjects Committee.

Human Subject: As defined by the Code of Federal Regulations Title 45 Part 46.102, means a living individual about whom an investigator (whether professional or student) conducting research obtains 1) Data through intervention or interaction with the individual, or 2) Identifiable private information.

IACUC: Institutional Animal Care and Use Committee

Research: A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

Research Records: Information needed 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, specimens, vouchers, computer files or other electronic data, video tapes and audio tapes.

Sponsor: Individual, company, institution or organization taking responsibility for initiation, management and financing of study.

Tangible Research Product: A wide range of tangible property resulting from the conduct of research, as distinct from copyrightable expressions and patentable inventions. Tangible Research Products include but are not limited to items and products that may confer a public benefit through commercial licensing and may include biological materials, such as cell line and plasmids; chemical compounds; electrical schematic diagrams; mechanical design drawings; and more abstract products such as detailed descriptions or compilations of laboratory procedures, analytical methods, or other such "know-how".

Responsible Parties:

This policy shall apply to all University of Kansas University 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 and Links:

KUMC Faculty Handbook, <http://www2.kumc.edu/aa/fa/>

KUMC Human Subject Committee, <http://www2.kumc.edu/researchcompliance/human.htm>

KUMC Information Resources Policies and Operational Protocols <http://www2.kumc.edu/ir/policy/>

KUMC Record and Retention Schedule <http://www.kumc.edu/Pulse/policy/recordretention.html>

21 CFR § 312.62 – Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trails

21 CFR § 812.140 – Investigator Record Keeping and Record Retention for Device Trails

ICH Guideline for Good Clinical Practice, Part 4.9,

<http://www1.va.gov/oro/apps/compendium/Files/good%20clinical%20practice.htm#contents>

OMB Circular A-110, §.50 Retention and access requirements for records.

<http://www.whitehouse.gov/omb/circulars/a110/a110.html>

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 <http://www.kslegislature.org/legsrv-statutes/getStatuteInfo.do>

National Institutes of Health (NIH) Office of Extramural Research, <http://grants1.nih.gov/grants/oe.htm>

Final NIH Statement on Sharing Research Data, Notice NOT-OD-03-032, Released February 26, 2003

<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

NIH Grants Policy Statement (3/01) Part II, Subpart A

http://grants.nih.gov/grants/policy/nihgps_2001/part_ii_a_6.htm

NIH Guide, Volume 25, Number 23, July 12, 1996: 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>

National Science Foundation (NSF) Grant Policy Manual (NSF 02151) § 734. Dissemination and Sharing of Research Results.

<http://www.nih.gov/science/models/sharing.html>

Contacts:

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