

RESEARCH ADVISORY COUNCIL

Policy on Research Records Retention and Access

The preparation and retention of appropriate records is an essential component of a research endeavor. The KFSH&RC, its members and its trainees have a common interest and a shared responsibility to assure that research is appropriately recorded, archived for a reasonable length of time, and available for review under appropriate circumstances. Original research records are essential to protect intellectual property rights, to answer ongoing questions regarding management of a research program, and to address possible questions that may arise regarding the propriety of research conduct.

Definition of Research Records

Research records include (but are not limited to) material contained in research notes, laboratory notebooks, case report forms, data collection forms, and in other media such as computer and compact disks, videotapes and machine printouts. Research materials or products generated by the research may also become archived research records. Consent Forms are an essential part of the record of research involving human subjects.

Retention of Research Records

The principal investigator has the obligation to insure that, for all aspects of his/her research program, sufficient records are kept to document the experimental methods and accuracy of data collection as well as the methods and accuracy of data interpretation. The principal investigator has an obligation to discuss the responsibilities of data management and retention with other members of his/her research team. This policy does not create an obligation to retain the research records of an **unfunded** project unless it results in publication or involves the use of animals or human subjects.

Research records should be archived for a minimum of five years after final reporting or publication of a project. The records archived should be the originals whenever possible. In addition, the records should be kept for as long as may be required to protect any patents resulting from this work or required by an external funding source. If any questions regarding the research are raised during the five year retention period, the records should be kept until such questions are fully resolved. In the event a principal investigator leaves the KFSH&RC for any reason, he/she must notify the Research Advisory Council and his/her supervisor of the designated custodian and location of research records covered by this policy.

Access to Research Records

The Research Advisory Council has the right of access to the supporting records for all research at the KFSH&RC or supported by KFSH&RC-sponsored funds provided such access to the records shall be for reasonable cause, at reasonable times and after reasonable notice. The KFSH&RC's right of access to the data shall continue regardless of the location of the responsible investigator. Extramural sponsors providing support for research at KFSH&RC may also have the right to review the data and records resulting from that extramural support. Co-investigators and trainees who are an integral part of a research project have the right to review all records and data which are part of those projects.