University of Kentucky Data Retention & Ownership Policy

Contents

Policy Scope

This policy applies to all University faculty, staff, postdoctoral appointees, students, and any other people involved in the conduct of Research using University of Kentucky facilities and resources and it applies to all Research on which those individuals work, regardless of funding source. The policy also applies to research undertaken in third-party facilities.

In particular, this policy will:
1. clarify responsibilities and accountability with respect to Research Data management,
2. aid in decision making with respect to acceptable practices for management of Research Data,
3. promote coordination between support providers to ensure that services meet the Research needs of the University research community, and
4. help researchers and the University assure compliance with applicable laws and regulations requirements (both internal and external) with respect to Research Data management practices, data storage, data security, sharing, and dissemination of Research Data.

Definitions

- <u>Human Subjects</u> – Human Subjects refer to living individuals about whom an investigator (whether professional or student) conducting Research obtains (a) Research Data through intervention or interaction with the individual, or (b) identifiable private information (DHHS 46.102).
- <u>Institutional Animal Care and Use Committee (IACUC)</u> – IACUC is responsible for the oversight of the University of Kentucky's animal program, facilities, and procedures. Part of this responsibility includes the review and approval of all vertebrate animal activities involving Research, education, and testing.

- Institutional Review Board (IRB) – The IRB reviews and approves activities that meet either (a) the Department of Health and Human Services (DHHS) definition of both "Research" and "Human Subjects," or (b) the Food and Drug Administration (FDA) definitions of both "clinical investigation" and "human subjects."
- Material Transfer Agreement (MTA) – An MTA sets forth the conditions under which materials (usually Biological materials) are given to another party. By the terms of these agreements, University personnel may be either the recipient or the donor.
- Non-Sponsored Research – Non-Sponsored Research is funded by internal, rather than external, funding sources. This includes, but is not limited to, salary and start-up funds.
- Principal Investigator (PI) – A PI is the primary individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research. The PI has primary Stewardship of Research Data on behalf of the University and bears primary responsibility for the overall conduct of the Sponsored Research or scholarly activity.
- Research – Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (DHHS 46.102).
- Research Data – Research Data is comprised of the raw data and any other data necessary for the reconstruction and evaluation of reported results created in connection with the design, conduct, or reporting of Research performed or conducted at or under the auspices of the University, as well as the events and processes leading to those results, regardless of the form or media on which they may be recorded, including sponsored and non-sponsored research. Research Data may differ among disciplines, but the term does not include information incidental to Research administration, such as financial, administrative, cost or pricing, or management information. Research Data are created at the University of Kentucky by faculty, staff, students, post-doctoral fellows, scholars, and visiting scientists in the course of their scholarly activities.
- Research Data Management (RDM) – RDM covers all of the decisions made during the Research lifecycle to handle Research Data, from the planning stage of a project to the long-term Preservation of the Research Data. Planning ahead for RDM helps to ensure Research Data quality, minimize risks, save time, and comply with legal, ethical, institutional, and funder requirements.
- Scholarly Activities – Scholarly Activities include both Sponsored and Non-Sponsored Research.
- Sponsored Research – Sponsored Research is funded by external funding sources designated specifically for the purpose of supporting Research.
- Stewardship – Encompasses the responsibilities and accountabilities associated with managing, collecting, viewing, storing, sharing, disclosing, or making use of Research Data

Ownership & Stewardship of Research Data

The University of Kentucky owns Research Data resulting from Scholarly Activities. The PI is responsible for Stewardship of the Research Data on behalf of the University.

The PI is responsible for complying with any applicable data sharing plan. In the absence of a specific data sharing plan, the PI is generally expected to make Research Data available to collaborators, including students.

Students own Research Data that they generate or acquire in the course of independent Research, unless the Research Data are a) generated or acquired within the scope of their employment at the University; b) generated or acquired through use of substantial University resources, c) generated as a part of a sponsored project, or d) subject to other agreements and regulations that supersede this right, e.g. IRB requirements. If there are questions about student ownership of data, inquiries should first be directed to the department. If there are further questions, the Office of Research Integrity should be contacted.

The University may waive ownership rights of Research Data if a specific condition in the sponsored project's grant, contract, or cooperative agreement prohibits university ownership or if the activity is considered to be the unrestricted property of the author as defined in the University of Kentucky Administrative Regulations, which defines traditional products of scholarly activity.

Data Management Responsibilities

The data management responsibilities of the PI include, but are not limited to, responsibility for:
- ACCESS: Ensure timely access to Research Data as deemed appropriate for the type of data, requirements of the funding agency, and applicable laws and regulations;
- COMPLIANCE: Comply with University and funding agency requirements regarding data Access and retention;
- COMMUNICATION: Communicate this policy and the data management plan to all members of the Research team, including appropriate administrative personnel;
- DISASTER PREPAREDNESS: Establish and maintain procedures, particularly for long-term Research projects, for the protection of essential records in the event of a natural disaster or other emergency, and securing such records should such an event occur.
- DOCUMENTATION: Ensure that sufficient records are kept to document the experimental methods, processes, and accuracy of data collection, as well as the methods, processes, and accuracy of data interpretation;
- INTELLECTUAL PROPERTY: Assure that in the event the data are associated with inventions or tangible Research property that the University wishes to commercialize through licensing or other means, the University can access the underlying data;
- INVESTIGATION: Facilitate the investigation of allegations, such as Research misconduct or conflict of interest;
- MANAGEMENT: Identify, collect, manage, and retain Research Data on behalf of the University;
- ORGANIZATION: Adopt an orderly and dated system of data organization;
- PRESERVATION: Manage activities necessary to ensure continued Access to analog and digital Research Data for as long as deemed necessary. This includes determining

what data needs to be retained in sufficient detail and for an adequate period of time to enable appropriate responses to questions about accuracy, authenticity, and primacy of the Research Data, and compliance with laws and regulations governing the conduct of Research, e.g. IRB, IACUC, state and federal regulations;

Retention of Research Data

Research Data must be retained by the Principal Investigator for a period of five years after publication of the results or submission of the final report on the project for which the data were collected. If the retention requirements specified in other statutes or external agency regulations are longer, those requirements will apply.

During the retention period and under the appropriate circumstances, e.g. conflicts of interest, audit compliance, infraction of regulation(s), etc. Research Data must be immediately provided to relevant administrators upon request. Questions related to requests for Research Data should be directed to the Office of Research Integrity. Research Data must also be available to representatives of external sponsors or designated governmental officials, as appropriate.

Certain Research circumstances may arise that prompts the University to require a longer retention period for Research Data. Examples include, but are not limited to, the following:
- If any intellectual property resulting from the work has been or is likely to be commercialized by UK, Research Data must be kept for as long as deemed necessary to protect it;
- If any charge, audit, claim or litigation regarding the Research arises, such as allegations of research misconduct or conflict of interest, data must be retained for (7) years after the completion of the proceedings adjudicating such charge, audit, claim or litigation is fully resolved and final action is taken; and
- If a student is involved, data must be retained at least until the degree is awarded or it is clear that the student has abandoned the work.

Transfer of Research Data

If a Principal Investigator transfers to another institution, the original data may be transferred to the new institution unless University administration objects to the transfer. Before any Research Data is removed from a University Research facility, the PI should complete the Departing Investigator Memorandum of Understanding (MOU) hosted by the Office of Sponsored Projects Administration. A Material Transfer Agreement (MTA) through the Office of Technology Commercialization may also be required. Principal Investigators should note that many contractual agreements require the sponsor's consent before data are transferred or removed. Before transferring the original data, the principal investigator should ensure that any special conditions stated in the grant, contract, or cooperative agreement are met.

Prior to transfer, the Principal Investigator may be asked by University administration to leave copies of original data with the institution. Other investigators, including students, associated with the project may make copies of data, unless restricted by the terms of any contractual agreements or regulations that may apply, including MTAs.

Departing investigators who transfer original data are obligated to hold original data in trust for the University of Kentucky for the five-year retention period or in accord with the applicable funding/regulatory agency requirements, whichever is longer. The original Research Data must be returned to the University, if requested. If the PI is unable to hold the Research Data in trust for the University for the required data retention period for any reason, the data must be returned to the University.

Disputes regarding requests for original data, copies of data, or transfer of data will be resolved by the Vice President for Research or his/her designee.

Resources

While the PI is ultimately responsible for direction and oversight of data management, resources are available on campus to assist with compliance with RDM requirements. Management of Research Data is a shared responsibility among the Office of the Vice President for Research; Office of the Chief Information Officer; Office of the Chief Information Officer of UK HealthCare; University of Kentucky Healthcare; University of Kentucky Libraries; University of Kentucky colleges, schools, departments, centers, & institutes; and the Principal Investigator (PI).

Information on the various types of support available for Research Data Management at the University of Kentucky can be found on the UK Data Management Support page of the Research Data Management at UK Research Guide.