# **Laboratory Data and Material Management and Processes**

As a researcher at the University of Kentucky, you have certain responsibilities related to the access and management of data and materials developed and/or maintained in University laboratories. These responsibilities apply to all University faculty, staff, postdoctoral appointees, students, visitors and any other people involved in the conduct of research using University of Kentucky facilities and resources and to all research on which those individuals work, regardless of funding source. These responsibilities also apply to research undertaken in third-party facilities. It is important you understand and comply with such responsibilities.

# **Ownership**

As stated in the University's <u>Data Retention and Ownership Policy</u>, the University of Kentucky owns Research Data resulting from both sponsored and non-sponsored research.

Research Data means: 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.

The University's Data Retention and Ownership Policy applies to all research disciplines and is not limited to scientific research. Research Data varies between disciplines, but includes any material used and analyzed for the purposes of research. For example, Research Data generated from scientific research may include laboratory notebooks, spreadsheets, or protein or genetic sequences, while Research Data generated from research within the humanities may include image files of archival items or artworks, oral history sound files and transcripts, or text files extracted from a corpus of texts by optical character recognition software.

The University's Data Retention and Ownership Policy also states that student researchers own Research Data that they generate or acquire in the course of their 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 or agreements like those discussed in this summary).

As stated in the University's <u>Administrative Regulation 7:6</u>, all intellectual property conceived, first reduced to practice, written, or otherwise produced by faculty, staff, or students of the University of Kentucky using University funds, facilities, or other resources shall be owned and controlled by the University.

Intellectual Property is defined in <u>Administrative Regulation 7:6</u> as: the tangible or intangible results of research, development, teaching, or other intellectual activity. Intellectual property may include the following categories:

- 1. Inventions, discoveries, or other new developments which are appropriate subjects of patent applications.
- 2. Written materials, sound recordings, videotapes, films, computer programs, computer-assisted instruction materials, works of art including paintings, sculpture, and musical compositions, and all other material which may be copyrightable.
- 3. Tangible research property such as biological materials including cell lines, plasmids, hybridomas, monoclonal antibodies, and plant varieties; computer software, data bases, integrated circuit chips, prototype devices and equipment, circuit diagrams, etc.; and analytical procedures, laboratory methods, etc. All such tangible research property may or may not be patentable or copyrightable.

The three categories above are not mutually exclusive; a given article of intellectual property may include aspects of all three categories.

Data management plans for research projects are highly encouraged by the University, and frequently required by funding agencies, to lay out information for the research team about the type(s) of data that will be collected, how the data will be stored, managed and analyzed, and what will happen to the data when the project is completed. Building policy compliance, including but not limited to the University's Data Retention and Ownership Policy, into the data management plan will make following policies easier and help avoid mistakes later in the research process. More information and guidance on creating a data management plan can be found on the University Libraries website.

If you are collaborating on a project with other researchers, the University highly encourages establishing an Authorship Agreement prior to commencement of the project to avoid potential scientific conflict between researchers. Authorship identifies those individuals who deserve primary credit and hold principal responsibility for a published work. Understanding each researcher's role and expectations in the project can help avoid plagiarism, intellectual property and authorship disputes. Additional information and guidelines can be found on the University's Research Misconduct webpage.

### Sharing

It is common for researchers to share data with other researchers—both within and outside of the University—involved in the same or similar field. Additionally, there is a long tradition in some fields of sharing research materials such as reagents, cell lines and purification media. The University of Kentucky encourages cooperation among researchers; however, University of Kentucky researchers must be aware of certain limitations on the sharing of data and materials developed and/or maintained within University laboratories.

The principal investigator is responsible for complying with any applicable data sharing plan. If you are not a principal investigator, you are responsible for complying with instructions given to you by the principal investigator regarding any applicable data sharing plan. It should be noted there may be additional data sharing plan requirements (outside the University's policies) if research is funded by the National Institutes of Health.

If you are interested in sharing Research Data or materials, <u>Administrative Regulation 7:6(VIII)</u> expects that the terms of such sharing be spelled out in a written agreement among the parties, such as a data use agreement (DUA), material transfer agreement (MTA), non-disclosure agreement (NDA) or other collaborative agreement. Contact the <u>Office of Technology Commercialization</u> (OTC) for further help putting such an agreement in place.

Researchers should also be aware of and comply with the University of Kentucky's <u>Ethical Principles and Code of Conduct</u>. University of Kentucky researchers are expected to be responsible stewards of University property and resources, which include research data and materials. Researchers are entrusted with protecting the property, equipment and other assets of the University and exercising responsible, ethical behavior when using the University's resources.

#### **Transfer**

Data and materials controlled by the University cannot leave the University without a transfer agreement. The University's Office of Technology Commercialization can help with inquiries regarding data and material transfer (DUAs/MTAs), as well as non-disclosure agreements (NDAs/CDAs). These agreements must be assessed by OTC, in consultation with the Office of Legal Counsel, and may only be signed by the appropriate authorized institutional signatory, which does not include the principal investigator or those working under the principal investigator.

Data and information owned and controlled by the University may not be presented or published without first discussing with the principal investigator. Sponsored research may have additional requirements for presentations and publications which must be followed.

Principal investigators leaving the University are required to complete the <u>Departing Investigator Memorandum of Understanding</u> hosted by the <u>Office of Sponsored Project Administration</u> (OSPA). Investigators who leave the University for another non-profit institution often want to transfer grants, equipment, supplies, materials acquired and research animals in order to continue their research. This Memorandum of Understanding documents specific agreements between the investigator and the University of Kentucky regarding these transfers as well as requirements for handling research records, intellectual property, hazardous materials that will be left behind, and the exit safety survey.

### **Export Control**

Research Data may be subject to federal export control regulations. These regulations control the shipment of both tangible items and technical data outside the United States, and prohibit access to export-controlled technical data, materials, or equipment to non-U.S. persons within the United States, known as a deemed export. Additionally, there are other federal limitations for interacting with or sharing certain data or other information with certain individuals or entities, including in certain countries and regions of the world. For more information, please contact OSPA's Export Compliance Official.

# Consequences

Any violation of local, state or federal law or regulation may be subject to criminal charges, fines or other penalties. Additionally, violations of University regulations and policies may lead to your relationship with the University as an employee, student or visitor subject to sanctions imposed including but not limited to termination. Researchers should also be aware there may be additional requirements imposed by the terms of research grants and/or contracts applicable to specific studies or projects or which control the use of information, material, data, inventions, discoveries or publications. Failure to comply with such requirements may be considered a breach of the applicable agreement which could include additional consequences for the University and the involved individuals, including but not limited to, revocation of research funding.

#### Resources

For more information, you can find the above-referenced University of Kentucky regulations and policies in their entirety by visiting University webpages, which are described and linked below:

The University of Kentucky's Data Retention and Ownership Policy may be found by navigating to the University's Office of Research Integrity website, clicking "Policies & Guidance" on the menu bar at the top of the page, then scrolling down and selecting "Data Retention & Ownership Policy." The full URL to navigate to the policy is: <a href="https://www.research.uky.edu/research-misconduct/data-retention-and-ownership-policy">https://www.research.uky.edu/research-misconduct/data-retention-and-ownership-policy</a>

University of Kentucky Administrative Regulation 7:6 may be found by navigating to the University's Office of Legal Counsel website, under "Regulations." The full URL to the Regulation is: <a href="https://regs.uky.edu/administrative-regulation/ar-76">https://regs.uky.edu/administrative-regulation/ar-76</a>

The University of Kentucky's Governing Regulation, Part XIV, Ethical Principles and Code of Conduct may be found by navigating to the University's Office of Legal Counsel website, under "Regulations." The full URL to the Regulation is: <a href="https://regs.uky.edu/governing-regulation/gr-xiv">https://regs.uky.edu/governing-regulation/gr-xiv</a>

The University of Kentucky's Office of Technology Commercialization should be the first contact before there is a sharing of data and/or materials to assure that the rights of the University and its researchers (and/or their sponsors and other parties with which they have a relationship) are properly protected and documented. More information and contacts for OTC, which can help put agreements such as Material Transfer Agreements, Data Transfer Agreements, Nondisclosure Agreements and others into place, can be found on its website at the following URL: <a href="https://www.research.uky.edu/office-technology-commercialization">https://www.research.uky.edu/office-technology-commercialization</a>

More information about administration of sponsored projects may be found at the University of Kentucky's Office of Sponsored Projects Administration website at the following URL: <a href="https://www.research.uky.edu/office-sponsored-projects-administration">https://www.research.uky.edu/office-sponsored-projects-administration</a>

The University offers a free electronic research notebook to University researchers in all disciplines which allows researchers to collaborate with their research team and add and organize

their data via a cloud-based method. More information can be found at the following URL: <a href="https://www.research.uky.edu/ERN">https://www.research.uky.edu/ERN</a>

Authorship and collaboration resources and further information may be found at the following URL: <a href="https://www.research.uky.edu/research-misconduct/authorship-and-collaboration">https://www.research.uky.edu/research-misconduct/authorship-and-collaboration</a>

To report concerns of potential mishandling of and/or access to data and materials, you may:

- Use the Office of Research Integrity's Research Misconduct reporting system, which can be found at the following URL: <a href="https://www.research.uky.edu/research-misconduct">https://www.research.uky.edu/research-misconduct</a>
- Use Corporate Compliance's Comply-Line or make an online report to Corporate Compliance, information for each of these may be found at the following URL: <a href="https://ukhealthcare.uky.edu/staff/corporate-compliance">https://ukhealthcare.uky.edu/staff/corporate-compliance</a>