



POLICY NAME (R*)

Management and Sharing of Research Data

POLICY NUMBER (O*)

To be determined

INITIAL ADOPTION AND EFFECTIVE DATE (R*)

To be determined

POLICY APPLICABILITY (R*)

This policy applies to all members of the University of Louisville (UofL) community including, but not limited to, faculty (including gratis faculty), staff, and trainees; visiting scholars, scientists, student investigators, residents, fellows, and postdoctoral fellows; and any other persons at the UofL involved in the design, conduct, or reporting of research at or under the auspices of UofL. This policy applies regardless of the source of support for the research project/activity and therefore does not distinguish between funded and unfunded efforts, except where specific sponsor requirements prevail.

REASON FOR POLICY (O*)

UofL has developed this policy to protect the integrity of research data used in research conducted under the auspices of UofL. In conducting research as part of the UofL community, investigators are obligated to assist UofL in fulfilling its responsibilities to comply with applicable federal, state, and local laws, and sponsor requirements governing the conduct of research, including the management and sharing of research data while protecting the privacy of individuals' personal and identifiable information. The value of effective management and sharing of the data is reflected in the enhancement of discovery and increasing the visibility of research.

POLICY STATEMENT (R*)

The University of Louisville is the administrative organization ultimately responsible for all tangible and intangible research data resulting from research activities at the University. As such, the University has the responsibility to ensure the preservation and availability of research data and can be held accountable for the integrity of research data even after the creator(s) have left the University.



1. Introduction

1.1 Collection and generation of research data, including utilization of research data from other sources, are integral aspects of research activity at the University of Louisville and the University of Louisville Research Foundation, Inc. (collectively referred to hereinafter as "UofL"), whether the data are primary in nature or compiled, assembled, or otherwise derived. These data have several purposes: to serve as a record of the investigation, to form the basis on which conclusions are made, and to enable the reconstruction of procedures and protocols. In keeping with its commitment to promote integrity in the scholarly process, UofL's research data management practices should ensure open and timely access to and sharing of research data. Access, sharing, and retention are especially vital with respect to questions about compliance with legal or regulatory requirements governing the conduct of research, accuracy or authenticity of data, primacy of findings, and reproducibility of results.

1.2 UofL has developed this policy to protect the integrity of research data used in research conducted under the auspices of UofL. Investigators can choose the nature and the direction of their investigations, to use research data they generate to pursue future research, and to share their findings with scientific and academic communities. Such activities, however, are subject to compliance with laws and regulations, as well as contractual obligations that govern the conduct of research. In conducting research as part of the UofL community, investigators are obligated to assist UofL in fulfilling its responsibilities to comply with applicable federal, state, and local laws, and sponsor requirements governing the conduct of research, including the management and sharing of research data while protecting the privacy of individuals' personal and identifiable information. The value of effective management and sharing of the data is reflected in the enhancement of discovery and increasing the visibility of research.

1.3 UofL's responsibility for stewardship of research data, including access to data, derives from the Office of Science and Technology Policy (https://www.science.gov/docs/ostp_public_access_memo_2013.pdf) ("OSTP"). While this regulatory authority applies specifically to federally funded activities, the principle that it espouses informs good management practices with respect to all research activities undertaken at UofL. Further, each Federal agency with over \$100 million in annual conduct of research and development expenditures (e.g., National Science Foundation [NSF], National Institutes of Health [NIH]) is required by the OSTP to have a plan to support increased public access to the results of research funded by the Federal Government. These agencies have developed their own requirements for data management and data sharing, such as NIH's Policy on Data Management and Sharing (NOT-OD-21-013)



(<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html>) for sharing research data and disseminating research results.

1.4 In order to promote scientific data reusability and reproducibility, researchers are encouraged to follow discipline-specific guidelines for sharing data, including structured ontologies, providing the necessary data for reproducing results, and ensuring the data adheres to the FAIR principles – Findability, Accessibility, Interoperability, and Reusability (<https://doi.org/10.1038/sdata.2016.18>). The FAIR Data principles promote good data management and stewardship practices, resulting in scientific data that can be utilized by a wider range of stakeholders and constituents.

2. Scope

2.1 This policy should not be construed to limit the right of any member of the UofL community who is an Investigator on a project/activity to have access to and to work with the research data generated in that project/activity, nor should this policy be construed to constrain the practices that are particular to the field of inquiry of which the data are a part.

3. Intellectual Property and Data Ownership.

3.1 Ownership of research data is governed by UofL's Intellectual Property Policy and UofL's Ownership of Data Policy (<https://louisville.edu/policies/policies-and-procedures/pageholder/pol-ownership-of-data-1>).

4. Recording Research Data

4.1 Investigators shall record research data consistent with the standard practices of their discipline. In the absence of such standards, UofL's minimum standard is that research records are written/recorded, dated, and identified by the project title and name(s) of the individual(s) conducting the activity, experiment(s), or other investigation(s). Whatever the organizational system used, the Investigator should ensure that all personnel involved with the research project/activity, including any key administrative personnel, understand and adhere to the system.

5. Maintaining/Retaining Research Data

5.1 General principles:

5.1.1 Research data must be retained in sufficient detail and duration to allow appropriate response to questions about research accuracy, authenticity, primacy,



and compliance with laws and regulations governing the conduct of research and its associated research data.

5.1.2 The recordkeeping systems/practices used by Investigators should, upon request, allow access by UofL over their entire retention period. Of particular importance are instances in which an Investigator leaves UofL.

5.1.3 Primary Investigators of each research study are responsible for the physical storage and security of research data during collection and retention periods, consistent with the standard practices of their discipline and/or the terms of a sponsored agreement and in compliance with UofL's information security policies. Of particular importance are issues involving confidentiality and general management of data obtained from human subjects, security of research data against theft or loss, compliance with export control regulations, privacy law, and maintenance of backup or archival copies of research data that may be needed in the event of a disaster, as well as any software.

5.2 Data Retention Period. Except as noted below, UofL requires a data retention period of at least: (a) five years from the date of data collection, (b) five years from the termination of a sponsored agreement under which the data were collected (or longer if the agreement mandates), or (c) five years from the longer of the submission or publication of a paper based on the data. The longest term of the three options cited shall be the controlling period. Notwithstanding the preceding and any exceptions below, the controlling period shall be extended until the conclusion of any investigations/legal proceedings and any subsequent appeals should any investigation/legal proceeding regarding the research, or its research data begin prior to the end of the controlling period.

5.2.1 Data Retention Period Exceptions:

5.2.1.1 For Student Investigators, research data must be retained in an authorized manner until the pertinent controlling period (as provided above) has elapsed, the student's degree is awarded, or the research project/activity is closed or completed, whichever is longer. In addition, if the student's department requires a longer retention period, the latter would prevail.

5.2.1.2 When existing research data are relevant to an allegation of misconduct in scholarly activity or of financial conflict of interest, or to an open case of litigation, claim, or audit, the retention period must extend at least until the final, non-appealable resolution of the case and final action taken, comply with the retention requirements of the policy/regulation/law governing the case (e.g., seven years



after the conclusion of a research misconduct investigation), or the applicable controlling period (as provided above) has elapsed, whichever is longer.

5.2.1.3 Data relevant to intellectual property interests must be retained for as long as may be necessary to protect those interests, at minimum for the (above) three year controlling period. Individuals should consult the UofL technology transfer office for current guidance. (For example, data relevant to patent applications must be retained in accordance with US Patent and Trademark Office guidelines (<http://www.uspto.gov>)).

5.2.1.4 Data subject to specific federal, state, or local regulation must be retained for the period indicated by the regulation, or the applicable controlling period (as provided above), whichever is longer.

6. Accessing Research Data

6.1 Members of Research Groups. Reasonable access to research data should be available to any member of the research group in which the data were collected, when such access is not limited otherwise by written agreement, including research authorizations and/or informed consents, policy, law, or regulation. For unique materials prepared during the research, such as intermediates in chemical synthesis, cell lines, or reagents, items that can be proportioned should be divided among members of a research group at different locations under negotiated terms of a written Materials Transfer Agreement. If there is any possibility that a copyright or patent application might emerge from a group project or other collaborative effort, the PI, Other Investigator, or Sponsoring PI should promptly contact the technical transfer office within the Office of the Office of Research and Innovation for guidance.

6.2 UofL. There may be instances in which it is necessary for UofL to access research data in situations including, but not limited to, sponsor requests, patent disputes, allegations of data misuse, research misconduct proceedings, subpoena, or Freedom of Information Act, Right to Know law, or other open records law requests. To facilitate necessary, timely, and appropriate access to research data, UofL reserves the right to take physical possession of such data and/or make forensic copies as necessary.

6.2.1 With Prior Notification. Where there exists a legitimate official need to take physical possession of research data in situations not covered by existing UofL policies, the EVPRI, if permitted by law or if it will not impact the investigation/legal proceeding, will notify the Investigator in writing of such need. The EVPRI's request



will describe the data sought and set forth the legitimate official need(s) sufficient to justify the request.

7. Sharing Research Data

7.1 UofL recognizes the importance of data sharing in the advancement of innovation and education. Sharing research data can increase the visibility of related research and promote new discoveries.

7.2 Research data created by Investigators may be shared for research or scholarly purposes consistent with standard practices of their discipline with other individuals when such sharing is not limited by written agreement, policy, law, or regulation. Investigators shall make every effort to protect intellectual property rights as defined and governed by UofL Intellectual Property policies.

7.3 Certain external sponsors (e.g., the National Science Foundation and the U.S. Public Health Service) require that data gathered during research supported with their funds be shared broadly in a timely manner after the associated research results have been published or provided to the sponsor. When data sharing is not governed otherwise by another written agreement or an applicable policy or regulation (e.g., export control licenses), research data created by Investigators may be shared in a manner consistent with standard practices of their discipline. Tangible research materials (e.g., cell lines, technical data, manufactures of matter, or any unique material) shall be shared only by specific agreement with persons or entities outside UofL (or vice versa). Such specific agreements may include, but are not limited to, Material Transfer Agreements, Uniform Biological Material Transfer Agreements, License Agreements, Grants, and Contracts.

8. Disposition of UofL-owned Research Data when Investigator Permanently Leaves UofL and/or Ceases Involvement in Project or Activity

8.1 Faculty or Staff Principal Investigator (PI), Other Investigator, or Sponsoring PI.

8.1.1 The PI, Other Investigator, or Sponsoring PI shall come to a written understanding with each Student Investigator and/or member of the research group, specifying which parts of the research data may be copied and taken by the individual prior to or in conjunction with when they leave the group or cease involvement in the research project/activity. The written understanding should address research data generated both before and after the individual's departure from the research group or cessation of her/his involvement in the research project/activity. The original data must remain in the custody of the PI.



8.1.2 If/when the PI permanently leaves UofL and has indicated in writing their intent and plans to continue the research, this individual may take a copy of the research data for which they are custodian; provided originals are retained by the University. The PI may ask for an exception to this policy from their Dean/Director and the Office of Research and Innovation in order to take the original research data and leave the UofL a copy; however, they cannot do so if: (a) the data have been used for a patent application filed or pending filing by UofL, (b) the research data are relevant to an ongoing inquiry/investigation under UofL's relevant policies, or (c) the funding sponsor of the project/activity specifically requires UofL retain original data. Departing PIs are obligated to hold the data in trust for UofL and return the data when requested to do so. The data must not be disposed of within the controlling retention period (see section 5.2) without written permission of UofL's EVPRI.

8.2 Student Investigators. Upon departure from UofL, a Student Investigator may take a copy of UofL-owned data related to the Student Investigator's research project/activity (see section 5.2.1.1); however, they must leave the original research data, including laboratory notebooks, with PI.

9. Enforcement

9.1 Failure to comply with the requirements of this policy will be considered a deviation from accepted standards of conducting research at UofL. Funded PI's will follow guidelines of funding agency in developing and following data management plans and in curating and, in conjunction with the university, making data openly accessible.

9.2 UofL and the EVPRI (or their respective designees) will investigate alleged violations of this policy and will make recommendations for action. Breaches of policy include but are not limited to: Failure to maintain/retain research data as stipulated; and failure to provide sharing of UofL research data as outlined in Section 7.

RELATED INFORMATION (O*)

Include links to UofL related policies and links to laws and regulations that support the need for this policy.

UofL Policies: [HYPERLINK "https://louisville.edu/policies/policies-and-procedures/pageholder/pol-intellectual-property"](https://louisville.edu/policies/policies-and-procedures/pageholder/pol-intellectual-property)Policy Intellectual Property

[Policy Intellectual Property Policy](#)



[Policy Ownership of Data](#)

[Policy Classified or Sensitive Research](#)

UofL Resources: [Data Management \(Ekstrom Library Resources\)](#)

[Data Management \(Kornhauser Health Sciences Library Resources\)](#)

Federal: [Final NIH Policy for Data Management and Sharing \(2023\)](#)

[Executive Order -- Making Open and Machine Readable the New Default for Government Information \(2013\)](#)

[Dissemination and Sharing of Research Results - NSF Data Management Plan Requirements](#)

DEFINITIONS (O*)

Investigator: Principal Investigator (PI), Trainee Investigator, Other Investigator, and Sponsoring Principal Investigator.

Principal Investigator (PI): A faculty (including gratis faculty) or staff employee of UofL who holds primary responsibility for the research project/activity for which data will be collected or used.

Trainee Investigator: A postdoctoral fellow, clinical fellow, resident, graduate student, or undergraduate student involved in the design, conduct, data collection, or reporting of a research project/activity at or under the auspices of UofL.

Other Investigator: A visiting scholar, scientist, postdoctoral fellow, or other visiting person who holds primary responsibility for a research project/activity for which data will be collected or used at or under the auspices of UofL.

Sponsoring Principal Investigator (Sponsoring PI): The UofL faculty or staff advisor, instructor, or mentor on a student-initiated research project/activity serves as the Sponsoring PI for purposes of this policy.

Research: Investigation undertaken to gain knowledge and understanding, including that conducted in the classroom setting. An investigation may be conducted without any application or generalization in mind, for possible future application or generalization, or to address an immediate need.



Research Data: The recorded factual material commonly accepted in the relevant research community as necessary to validate and reproduce research findings, but not any of the following: preliminary analyses, drafts of manuscripts, plans for future research, peer views, or communications with colleagues. Research data may be in hard-copy form (including research notes, laboratory notebooks, or photographs) or in electronic form, such as text files, computer software, computer storage/backup, or digital images.

- Research Data encompass associated protocols, numbers, graphs, tables, and charts used to collect and reconstruct the data. Research data include numbers, field notes or observations, procedures for data analysis and/or reduction, data obtained from interviews or surveys, computer files and databases, research notebooks or laboratory journals, slides, audio/video recordings, and/or photographs.
- Research Data can have different formats and forms. Primary research data are gathered by the researcher and secondary research data are collected from existing sources.
- For purposes of this policy, Research Data do not include: unreported preliminary analyses of data, drafts of scientific papers, future research plans, peer reviews, or communications with colleagues; trade secrets, commercial proprietary information, or materials necessary to be held confidential by a researcher until they are published, or similar information protected under law; personnel, medical, and similar information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy or a violation of privacy law.

Research Materials: Tangible physical objects from which data are obtained such as environmental samples, biological specimens, cell lines, derived reagents, drilling core samples, or genetically altered microorganisms. While these are not considered to be research data, they should be retained or deposited in a broadly available resource consistent with disciplinary standards.

RESPONSIBILITIES (O*)

Authority and Responsibilities

The Executive Vice President for Research and Innovation (“EVPRI”) has the authority and responsibility for administering and enforcing this policy for UofL, including, but not limited to, the following:



- Communicating this policy to all members of the UofL community;
- Ensuring UofL complies with terms of sponsored agreements, including requirements to maintain and share research data;
- Protecting rights of faculty, staff, students, and other investigators to access data from projects/activities in which they participated as researchers at or under the auspices of UofL, while maintaining the privacy of any personal/identifiable research data;
- Securing UofL’s intellectual property rights, as covered by the existing UofL policy; and
- Facilitating investigation of charges, such as scientific misconduct or financial conflict of interest in research, as covered by existing UofL policy.

The PI and each member of the research group is responsible for following this policy.

The PI for a research project/activity is responsible for all aspects of: (1) procuring and maintaining research data, including collection and/or recording, and providing adequate accompanying documentation; (2) security during collection; (3) timely access to data, materials, and essential records; (4) sharing research data and results as required; and (5) retention while at the University. The PI for a research project/activity is responsible for carrying out these responsibilities in a manner consistent with the standard practices for their discipline and/or the terms of a governing sponsored agreement. They are also responsible for educating those supervised about these practices and associated rationale.

The University is responsible for creating and supporting infrastructure to ensure that research data is shared in line with FAIR data principles.

The Trainee Investigator is responsible for following this policy under the direction of their PI.

RESPONSIBLE AUTHORITY (R*)

Executive Vice President for Research and Innovation

RESPONSIBLE UNIVERSITY DEPARTMENT/DIVISION (R*)

Office of Research & Innovation



University of Louisville

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HISTORY (R*)

Revision Date(s):
Reviewed Date(s):

The University Policy and Procedure Library is updated regularly. In order to ensure a printed copy of this document is current, please access it online at <http://louisville.edu/policies>.

R* = Required O* = Optional