

Research Data Policies



Researcher Handbook

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6g. Data Management: Research Records

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1. What are Research Records?

Typically, research records refer to any type of records or materials that document your research effort. These can be electronic or hard copy as in various forms of logs, notebooks, correspondence, videos, computer databases, audio or digital records, or even the actual products of experiments.

In addition to maintaining accurate and complete research records for data analysis, all records relating to the conduct of the project are important including those that document the management of the research funds and the intellectual property.

Although not an inclusive list, research records typically include:

- Laboratory research: lab notes, notebooks, computer databases, microscopic slides, gels, images, photos, videos, laboratory equipment printouts, and records of statistical and other data analysis.
- Animal research: protocol binders with IACUC- approved protocols with all approved modifications, animal health records, surgical or treatment records, breeding records, drug records, research data files.
- Clinical trials: regulatory binders which include CHR approvals, protocols, informed consent documents, monitoring reports, adverse event reports, and other documents pertaining to sponsors, drugs and devices. Other clinical records can include records for research data, data analysis, audio and video tapes of subjects, images of subjects and any other type of record that can identify persons that data were collected from.
- Funding: records and correspondence relating to the grant financial records, purchasing records, scope of work, budgets, and service records.
- All correspondence with granting agencies, institutions, and collaborators.

The University of Iowa Operations Manual includes description of UI's [Records Management Program](#) which provides definitions for different types of UI documents and records.

2. What points should I consider when managing my data?

The integrity of your data is dependent upon having and using a system of data management. When determining how data will be collected, recorded, and stored, you should consider the following:

- Are the research records legible, accurate, and complete? Are they in sequence and dated? Is the researcher identified in the records?
- Are there reasonable plans for retention, retrieval and storage of the data?
- Have you managed the data so it can be shared if required by funding agencies?
- Would an audit of the research records support your claims in your publications?
- Could co-investigators confirm the accuracy of the manuscript from the laboratory or research notebooks?

Your research records are the source documents for verification of your research by governmental or University investigations and audits. Clear, permanent records of research are crucial for clarifying any challenges to your data authenticity, authorship and intellectual property.

3. What am I responsible for?

As the PI, you should observe sound practices for the maintenance, oversight, and storage of data as you have the final responsibility for the following:

- Validity and quality of the data and manuscripts.
- Fulfilling all departmental and University research standards, policies, and procedures.
- Training and monitoring the performance of your students, research fellows, residents, and staff to assure that each has the knowledge, information, and skills necessary to meet these standards.

At Iowa, researchers are encouraged to retain research data and records for a period of at least five years following publication to provide verification of the validity of the reported results, according to [27.6 c of the University of Iowa Operations Manual](#).

In addition to institutional responsibilities, a growing number of U.S. funding agencies such as the National Science Foundation, the National Institutes of Health, and National Endowment for the Humanities-Office of Digital Humanities require researchers to supply detailed, cost-effective plans for managing research data, called Data Management Plans. These plans typically detail:

- What data will be kept and for how long
- How data will be formatted and described for reuse and interpretation
- Policies around data access, use, and attribution/copyright, and preservation

4. Who can help?

UI researchers can seek assistance in developing data management plans from various sources. The [DMP Tool](#) helps researchers create and manage data management plans. The [University of Iowa Libraries subject liaisons](#) and its [Digital Research & Publishing unit](#) also provide advice on developing data management plans and long-term archiving and preservation for small sets through [Iowa Research Online](#).

5. What are the relevant policies and procedures?

University of Iowa Policy, Procedures, and Resources:

- [The University of Iowa Operations Manual 17.3 Records Management Program](#)
- [The University of Iowa Guidebook on Records Management](#)
- [Guide for Human Subjects Research at the University of Iowa](#) (guidance on records management can be found in Section F. Record Keeping)
- [UI Information Technology Services – Research Services](#)
- The [Iowa Social Science Research Center](#) offers data access and management services to UI social science researchers.

Partial list of Federal Policies, Procedures, and Resources:

**JOHNS HOPKINS UNIVERSITY
POLICY ON ACCESS AND RETENTION
OF RESEARCH DATA AND MATERIALS
January 2, 2008**

INTRODUCTION

The following policy paper contains parameters for Research Data and Materials Management (hereafter to be referred to as Research Data). In recent years, the amount of scrutiny and inquiry into Research Data has increased from a variety of sources, which has prompted efforts at Johns Hopkins and elsewhere to evaluate and update their Research Data Management practices.

The purpose of this policy is to protect researchers and the university. These measures are designed to address compliance requirements for researchers while diffusing some of the burden associated with Research Data Management. At Johns Hopkins, the department, research administration, divisional and university administration and the researcher are partners in managing and protecting the Research Data produced at the university.

This policy provides an umbrella approach to Research Data Management across the university. Divisional and other policies may also apply but are not to conflict with the overarching policy. This policy has been carefully designed to serve the best interests of our researchers and the university in management of Research Data. This policy is designed to complement, not supersede, other policies of the Johns Hopkins University including (but not limited to) protection of human subjects, HIPAA, intellectual property, financial management, etc. This policy does not apply to academic issues.

1. DEFINITIONS

RESEARCH DATA AND MATERIALS: Research Data is defined as information recorded in physical form, regardless of form or the media on which it may be recorded. For the purposes of this policy, Research Data is further defined as including any records that would be used for the reconstruction and evaluation of reported or otherwise published results. Research Data also includes materials such as unmodified biological specimens, environmental samples, and equipment. Examples of Research Data and Materials include laboratory notebooks, notes of any type, photographs, films, digital images, original biological and environmental samples, protocols, numbers, graphs, charts, numerical raw experimental results, instrumental outputs from which Research Data can be derived and other deliverables under sponsored agreements.

PRIMARY RESPONSIBLE INVESTIGATOR: The individual who bears primary responsibility for technical, programmatic, fiscal, and administrative requirements of the project.

2. **APPLICABILITY OF POLICY:** This Policy on Access and Retention of Research Data and Materials shall apply to all Johns Hopkins University faculty, staff, postdoctoral fellows, students and any other persons, including consultants, involved in the design, conduct or reporting of research performed at or under the auspices of the University.
3. **OWNERSHIP OF RESEARCH DATA:** The University owns all Research Data generated by research projects conducted at or under the auspices of the Johns Hopkins University regardless of funding source, unless specific terms of sponsorship, other agreements or University policy supersede these rights.

This policy does not attempt to determine relative rights of researchers and issues surrounding collaborative efforts such as authorship.

4. **RETENTION AND ARCHIVING:** The Primary Responsible Investigator of a research project is responsible for selection of an appropriate method of storing and archiving Research Data, and for determining what needs to be retained in sufficient detail and for an adequate period of time to enable appropriate responses to questions about accuracy, authenticity, primacy, and compliance with laws and regulations governing the conduct of research. The Primary Responsible Investigator is responsible for educating all participants in the research project of their obligations regarding Research Data, and for protection of the University's rights and ability to meet obligations related to the Research Data. The Primary Responsible Investigator should also consult with University officials regarding the development of any contingency plans.
5. **RIGHTS TO ACCESS:** The Primary Responsible Investigator will have access to the Research Data generated by the project. Any other faculty, staff, student or person involved in the creation of Research Data may have the right to review that portion of the Research Data that he or she created. The University will have access to the Research Data as necessary for technology transfer, compliance and other purposes. The University also has the option to take custody of the Research Data as determined by the appropriate University official. Such option will not be invoked without cause and subsequent notification of the Primary Responsible Investigator. In some instances, a research sponsor has a legal right of access or access may be requested through the sponsoring agency under the federal Freedom of Information Act (FOIA). Such requests will be coordinated through the Office of the General Counsel and/or the appropriate Research Administration Office.

6. **DESTRUCTION OR REMOVAL:** Research Data must be maintained for the periods required by law, University policy and sponsored agreement terms (See Appendix V). Thereafter, Research Data must not be destroyed without prior approval of the appropriate University official. With respect to removal of the Research Data, the University recognizes the importance of Research Data to the future research and career of its faculty. Therefore, should removal of Research Data be approved, for example, because of the transfer of the investigator to another institution, the following requirements apply:

- I. Researchers may receive approval to remove original Research Data. The University may retain copies.
- II. Research Data generated during the Researcher's employment at the University will be maintained in accordance with Johns Hopkins policy
- III. Research Data that are integral to the ongoing research of another Johns Hopkins employee or student will continue to be made available for that purpose
- IV. The researcher bears full responsibility for making original Research Data available to Johns Hopkins or federal and legal entities upon request.

Others involved in the project may remove copies (but not originals) of the Research Data with permission of the Primary Responsible Investigator.

7. **MAINTENANCE AND REVISION OF THE RESEARCH DATA:** The Primary Responsible Investigator of the research project is the person directly responsible for maintenance of Research Data created on that project. In order to support the project's credibility and the University's rights and ability to meet obligations related to the Research Data, should any revisions to final Research Data be contemplated, the Primary Responsible Investigator must notify the appropriate offices in the University and the originator of the information. The Primary Responsible Investigator must retain the original Research Data. See also Appendix IV.

APPENDICES, WEB LINKS, AND/OR FORMS:

- I. [RESPONDING TO REQUESTS FOR ACCESS BY NON-HOPKINS ENTITIES UNDER FOIA](#) (Policy and Cost Reimbursement Form)
- II. [TRANSFER OF RESEARCH DATA FROM JHU CUSTODIANSHIP](#) (Optional Approval Form)
- III. [LINK TO UNIVERSITY POLICIES](#) (<http://jhuresearch.jhu.edu/policies.htm>)
- IV. [APPROVED METHODS OF ARCHIVAL](#)
- V. [TIME MINIMUMS FOR ARCHIVAL](#)



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REGULATION ON THE CONDUCT OF RESEARCH

4. RESEARCH DATA

- 4.1** A Researcher shall collect Data concerning human and animal subjects in accordance with the Regulatory Framework governing the use of such subjects.
- 4.2** A Researcher shall respect the laws governing access to personal information and privacy in his or her collection and use of Data.
- 4.3** A Student may engage in Research in which use of certain kinds of Data, in the custody of a government or Person, is restricted provided that:
- (i) the eventual publication of Research based on the Data is permitted; and
 - (ii) subject to section 4.3.1, any delay in publication does not exceed one (1) year.
- 4.3.1** A request by a third party for a delay in publication of Research undertaken by a Student for his or her thesis that exceeds one (1) year may be agreed to only in exceptional cases and shall require:
- (i) the written consent of the ~~S~~-Student; and
 - (ii) the written approval of:
 - (a) the Vice-Principal (Research and International Relations); and
 - (c) the Dean of Graduate and Postdoctoral Studies.
- 4.4** A Researcher shall not use or publish Data which he or she knows to be, or has reasonable grounds to believe are, false or of unknown provenance unless it is so identified.
- 4.5** A Researcher shall organize his or her Data in a manner that allows for its verification by third parties.
- 4.6** ***Retention of Research Data***
- 4.6.1** A Researcher shall retain Data in conformity with best practice in his or her discipline and for:
- (i) the period specified by the Agency supporting the Research; or
 - (ii) in the absence of an Agency specification, a period of seven (7) years from publication of the Data.
- 4.6.2** Each department or research unit shall establish procedures appropriate to its needs for the retention and recording of Data.
- 4.6.2.1** Data shall be retained by a Principal Investigator or the department or research unit in which they were generated as agreed to by the Principal Investigator and his or her Chair.
- 4.6.2.2** A Researcher who ceases to be a member of the University shall deposit his or her Data with the department or research unit where the Data were generated unless alternative written arrangements are made with his or her Chair.
- 4.6.3** In the event that Data obtained from a limited access database or under a Research Related Agreement cannot be retained by a Principal Investigator, the Principal Investigator must provide the Chair in writing with the location of the Data or the limited-access database.
- 4.7** ***Access to Research Data***
- 4.7.1** Subject to exceptions based on a duty of confidentiality and the laws respecting intellectual property and access to information, a Researcher shall make his or her Data available after publication to an Agency or established scientific or scholarly journal presenting a reasonable and legitimate written request to examine the Data.

- 4.7.2** Where there is a disagreement between the Researcher and the Agency or journal requesting the Data, the disagreement shall be referred for resolution:
- (i) first to the Chair;
 - (ii) then, if necessary, to the Dean; and
 - (iii) finally, if necessary, to the Office of the Vice-Principal (Research and International Relations).

4.8 Collaborative Data

- 4.8.1** Research collaborators, at the commencement of their collaboration, shall make all reasonable efforts to reach agreement, preferably in writing, that is consistent with the law and the Regulatory Framework relating to intellectual property, on their rights to, and future use of, Data.
- 4.8.2** In the absence of an agreement between Research collaborators, their rights to and future use of the Data shall be governed by the law and the Regulatory Framework relating to intellectual property.
- 4.8.3** In the event that a dispute should arise between Research collaborators concerning rights to and future use of the Data, the University shall assist in facilitating the resolution of dispute in accordance with section 6.5.

Research Data Policy

1. Objectives

Research Data are a valuable asset to The University of Tennessee (the University). This policy protects the faculty's and University's property rights by addressing definition, responsibility, control, and distribution of Research Data produced during activities supported by the University; supported by external sponsors; or produced with University facilities, resources, or other personnel.

This policy is applicable to Research Data developed by University employees in performing the duties of their employment by the University or through substantial use of funds and facilities provided by the University. This policy assures that Research Data are adequately recorded, archived, retained, and accessible for sufficient time to support the associated research that produced the data and any intellectual property developed by that research. This policy supports the academic freedom for free and broad dissemination of Research Data, consistent with University policy and needs.

2. Definition of Research Data

For purposes of this policy, Research Data includes all records necessary for the reconstruction and evaluation of reported results of research and the events and processes leading to those results, regardless of form or media. Research Data may include laboratory notebooks, databases documenting research, and other compilations of information developed during research.

Research Data are distinct and separate from, but may be associated with, other intellectual property such as patentable or copyrightable works, and trademarks. Intellectual property is subject to a separate policy (see The University of Tennessee Statement of Policy on Patents, Copyrights, and Other Intellectual Property), as is Tangible Research Property (see Tangible Research Property Policy).

3. Responsibility for Research Data

The University is ultimately responsible for the accuracy and sufficiency of research records, the cornerstone of rigorous research. Therefore, the University is responsible for Research Data developed by University personnel in performing the duties of their employment by the University or through substantial use of facilities or funds provided by the University. Such responsibility applies to research funded by external sources and managed by the University, unless the University agrees to another arrangement in a grant, contract, or other agreement.

The University's responsibility for the scientific record for projects conducted at the University, under University auspices, or with University resources is based upon (a) United States Office of Management and Budget Circular A-110, Sec. 53, (b) the University's need to assess and defend charges of intellectual dishonesty, (c) the University's need to support and commercialize the management of intellectual property, and (d) the University's mission to develop and disseminate new knowledge.

4. Control of Research Data

The University supports the principle of openness in research. Free dissemination of data, processes, and results of research and other sponsored activity is crucial to a vibrant and healthy academic environment. The University promotes the prompt and open exchange of Research Data with scientific colleagues outside the investigator's immediate laboratory or department, subject to relevant grants, contracts, other agreements, or applicable law.

In the case of externally sponsored research involving a grant, contract, or other agreement, the Principal Investigator (PI) is responsible for controlling storage, use, and distribution of Research Data arising from the research activity, subject to provisions of the applicable grant, contract, or other agreement, or University policy, or applicable law. The PI, or laboratory/department head is responsible in situations where the research is performed without a grant, contract, or other agreement, such as institutionally sponsored research. The PI or laboratory/department head is responsible for the following:

- a) Collection of Research Data, including production of defensible laboratory notebooks;
- b) Management of Research Data ensuring efficient and effective retrieval by the PI, other personnel within the research group, or appropriate administrative personnel or research sponsors;
- c) Development of a formal Research Data plan and procedures where appropriate;
- d) Consideration of a system for preserving Research Data in the event of a natural disaster or other emergency;
- e) Retention of Research Data for the requisite period of time (see below); and
- f) Documented communication of the management system and description of the data managed to members of a research group and to the Chief Research Officer.

Control of Research Data, however, remains at all times subject to the other provisions of this policy.

5. Retention of Research Data

The PI or laboratory/department head must preserve Research Data for a minimum of three (3) years after the final project close-out, with original data retained where feasible. The following circumstances may require longer retention:

- a) Where data supports a patent, such data must be retained as long as the patent and any derivative patents are valid;
- b) If allegations of scientific misconduct, conflict of interest, or other charges arise, data must be retained until such charges are fully resolved;
- c) If a student is involved, data must be retained at least until the degree is awarded or the student has unambiguously abandoned the work; and
- d) Data must be retained if required by the terms of a grant, contract, or other agreement, or applicable law.

Beyond these periods, destruction of the research record is at the discretion of the PI or the laboratory/department head. Research Data will normally be retained in the administrative unit where generated. Research Data must be retained on a University facility unless specific permission to do otherwise is granted by the Chief Research Officer.

6. University Responsibilities

University responsibilities with respect to Research Data include the following:

- a) Ensuring the academic freedom of the faculty in pursuit of the University's mission of developing and disseminating new knowledge;
- b) Securing and protecting intellectual property rights for Research Data and commercialization of such data where appropriate and feasible;
- c) Protecting the rights, including those of access to data, of faculty, postdoctoral scholars, students, and staff;
- d) Avoiding undue interference with appropriate dissemination of Research Data in an academic community;
- e) Complying with the terms of a sponsored grant, contract, or other agreement;
- f) Facilitating the investigation of charges of scientific misconduct, conflict of interest, and similar charges or disputes; and
- g) Ensuring the appropriate care of animals, human subjects, recombinant DNA, radioactive materials, controlled substances and the like.

7. Research Data Transfer When a PI Leaves the University or a Grant is Transferred

If a PI leaves the University and a research project is to accompany the PI to a new institution, ownership of the data may be transferred with the approval of the Chief Research Officer and with written agreement from the PI's new institution that ensures: (1) its acceptance of custodial and other responsibilities for the data; (2) the University

and any sponsors have access to the data when necessary and upon reasonable notice; and (3) protection of the rights of human subjects.

8. Resolving Disputes Concerning Research Data Ownership or Policy

Questions of Research Data ownership or other matters pertaining to the Research Data policy will be resolved by the Chief Research Officer in conformance with applicable University policies.

9. University Access

When necessary to assure access to Research Data, the University has the option to take custody of the data in a manner specified by the Chief Research Officer.