

**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) (http://jhuresearch.jhu.edu/policies.htm)
- IV. [APPROVED METHODS OF ARCHIVAL](#)
- V. [TIME MINIMUMS FOR ARCHIVAL](#)

APPENDIX IV

Approved Methods of Archival for Research Data

1. Requirements for the recording and storage of Research Data and material will vary by discipline. Primary Responsible Investigators should always adhere to guidance provided by funding bodies, professional guidance where available, any principles set out on the division level as well as the University's recommendation as outlined below and in records management policies endorsed by the Chief Information Officer (CIO).
2. Research Data should be stored using a method that permits a complete retrospective audit if necessary. Unless ethical/professional/local or funding body guidance requires otherwise, Research Data should be archived in a durable form and in a secure location that is immune to subsequent tampering and falsification for a minimum period of 5 years after the date of any publication upon which it is based. It is recommended good practice that evidence for research based on clinical samples or relating to public health should be retained as required by the funding agency, federal laws, or other policies of the University.

APPENDIX V

Time Minimums for Research Data Archival

Research Data	Laws, Policies and Regulations	Time Periods
Proposals not funded	Not defined, but may contain proprietary information	Not defined
Expired Grants and Contracts	- Office of Management and Budget (OMB) Circular A-110* - Grants Policy of Funding Agency	OMB - Three years after completion of the entire research project Federal - follows OMB Private – Varies--see specific policy
Clinical Trials (All relevant records)	Food and Drug Administration (FDA) Notice: “Good Clinical Practices: Consolidated Guidelines”	At least two years after the last approval of a marketing application or at least two years after formal discontinuation of clinical development of the investigational product or longer if required by contract, but in no instance less than three years after the completion of the Clinical Trial
- Patent files - Data in support of patent	U.S. Patent Law	17 years from the date of the patent application
Research Data which supported enactment of a federal, state or local law	Not defined	Indefinite

* = OMB Circular A110 Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations”

NOTE: If a sponsored agreement exists, see specific archival requirements contained therein.