

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 I

Responding to Requests for Research Data Directed to Johns Hopkins University by a Sponsoring Federal Agency Under the Freedom of Information Act

In 1999, the Office of Management and Budget (“OMB”) adopted amendments to Circular A-110 that under certain circumstances allow public access under the Freedom of Information Act (“FOIA”) to Research Data maintained in connection with federally sponsored research projects. This appendix sets forth the procedures regarding FOIA requests directed to JHU by a federal agency.

Applicability

The requirements in A-110 apply only to Research Data first produced under an award issued after the November 8, 1999 effective date of the amendments. Additionally, these requirements only apply to Research Data produced wholly or in part with federal support.

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. The term includes technical data and computer software. 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, software, numbers, graphs, charts, numerical raw experimental results, and instrumental outputs from which Research Data can be derived.

Federal Policy states that for FOIA requests the following are not included in the definition of research data and materials:

- preliminary analyses
- drafts of scientific papers
- plans for future research
- peer reviews
- communications with colleagues
- physical objects (e.g., laboratory samples, audio tapes, video tapes)
- trade secrets
- commercial information
- materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal
- information which is protected under the law (e.g., intellectual property)
- personnel and medical files and similar files, the disclosure of which would constitute unwarranted invasion of personal privacy

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- information that could be used to identify a particular person in a research study

FOIA Request Process

- The requestor makes a FOIA request to the sponsoring agency (e.g., NIH), which in turn is referred to the agency's FOIA coordinator. Typically, the sponsoring agency will require that the FOIA request include:
 1. The specific regulation or administrative order citing the Research Data being requested;
 2. The publication cited in the regulation or administrative order;
 3. The grant number under which the Research Data were produced;
 4. A specific description of the Research Data being sought;
 5. A statement that the Research Data are being requested under the amendment to Circular A-110 (45 CFR 74.36)
- The agency FOIA coordinator will notify the University and/or the Principal Investigator about the request. Any individual receiving such notification should immediately contact the divisional office responsible for sponsored research administration and/or the Office of the Vice President and General Counsel. Those offices will ensure that the agency provide a copy of the FOIA request in written form, and will coordinate with the Principal Investigator to provide a timely response.
- If the requested Research Data are already available to the public through an archive or other source, the A-110 requirements allows the FOIA coordinator to direct the requestor to the public source. In that event, the process stops here. However, if the Research Data are not publicly available, the process continues as follows.
- The A-110 requirements provide for a reasonable fee to cover costs incurred in responding to the request. The fee will include both the costs to the sponsoring agency and the costs incurred by the grantee institution, which are to be accounted for separately.
- To accomplish this, in consultation with the agency FOIA coordinator, the University must estimate the cost of providing the Research Data by completing the attached "Reimbursement Form for FOIA Requests." The University may recover reasonable costs, including labor costs and copying and mailing charges.
- The agency FOIA coordinator will notify the requestor of the estimated cost of producing the Research Data. The agency may also require pre-payment in the event the requestor has a history of non-payment or if the estimated cost is over a set amount (approximately \$250 or more).
- Under the A-110 requirements, the grantee institution and the investigator are required to provide Research Data that are consistent with the definition of Research Data (see

definitions above) and deemed responsive to the request. Determinations as to what Research Data should or should not be provided shall be made in consultation with the Office of the Vice President and General Counsel and the divisional office responsible for sponsored research administration.

- Prior to sending the Research Data to the appropriate FOIA coordinator, the University and the investigator must redact the Research Data to remove personal identifiers and other information in accordance with amended A-110 definitions (see above) and FOIA procedures. The Office of the Vice President and General Counsel will provide guidance and assistance for compliance with this requirement.
- Once responsive Research Data has been appropriately compiled and redacted, the University shall transmit the Research Data to the FOIA coordinator with an accounting of all associated costs (as documented on the “Reimbursement Form for FOIA Requests”). Agency questions as to the adequacy or scope of the responsive Research Data provided may be directed to the Office of the Vice President and General Counsel.
- The agency will provide the responsive Research Data to the requestor and issue a final invoice for the fees.
- All funds remitted by the requestor through the funding agency must be deposited in accordance with applicable University procedures.

Attachment: Reimbursement Form for FOIA Requests

1. **Copy Costs:**

Number of copies _____ x \$.10 per page \$ _____

2. **Actual Mailing Costs:** \$ _____

3. **Labor Costs:**¹

Labor Rate: \$ _____

Search Time: _____

Examination Time: _____

Separation Time: _____

Duplication Time: _____

Total Time: _____

Labor Rate x Total Time: \$ _____

Total Cost: \$ _____

¹Determine through use of hourly wage rate for person(s) retrieving and processing information necessary to comply with the request.

APPENDIX II

The Johns Hopkins University Original Research Data Transfer Approval

1. Name of person making request: _____

2. Description of Research Data: _____

3. Reason for Proposed Transfer:

4. Original Research Data or Copies of Research Data will be left at JHU in the custody of: _____

If Original Research Data are being transferred, please identify name and address of person in possession of Original Research Data. If a university or corporate entity, please provide name and address of its legally responsible representative:

I understand that original Research Data are owned by JHU. I agree to honor sponsor or JHU requirements for protection or sharing of this Research Data which were effective as of the date of this request. If this request pertains to original Research Data, I will maintain the original Research Data in compliance with JHU's Policy on Data Management which is incorporated as part of this agreement. I further agree to make original Research Data available to JHU upon reasonable notice.

(Signature)

Name and Title

Date

APPROVAL(S):

For the Johns Hopkins University:

**Primary Responsible Investigator:
*(If different from requestor)***

(Authorized Signature)

(Authorized Signature)

Name and Title

Name and Title

Date

Date

Attachments: JHU Policy on Access and Retention of Research Data and Materials

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.