Guidelines on Retention of Research Data, Materials, and Records  
October 1, 2013

Introduction

Partners institutions and their investigators, research staff and administrators share responsibility for the retention of research data, materials, and records (collectively “Research Information”) in accordance with sponsor and regulatory requirements. Research sponsors are the primary source of these requirements through the grant or contract agreement that provides the funding. Federal, state and local governments are also a source of minimum retention requirements through individual agency policies or regulations or, in the case of federal awards, through requirements (OMB Circular A-110) that apply to all federally-funded research projects. Additional obligations may be imposed by journals as a condition of publication. Research Information sometimes needs to be retained longer than the minimum retention period set forth in these Guidelines for business operations or possible legal actions.

All Research Information arising from research conducted at a Partners hospital or institution is the property of the hospital or institution. It is the Investigator’s responsibility to ensure that the Research Information is collected, organized, and stored securely in accordance with Partners and hospital policies for recordkeeping and data security. In addition, Research Information must be made available to Partners or the hospital to respond to inquiries, investigations, audits, litigation, and other appropriate requests from sponsors or federal, state or local government agencies and for internal reviews or investigations.

These Guidelines apply regardless of the medium containing the Research Information. Independent of making back-up copies of digitized research data, there is no Partners requirement to retain duplicate records in different media. For example, if a grant application or research proposal was originally prepared in paper format, but has been scanned and retained electronically, the paper version does not need to be kept.

While these Guidelines specify the minimum length of time Research Information should be retained, research staff should also consider how to retain them in a secure manner that is consistent with regulatory requirements, such as HIPAA, and sponsor expectations, such as confidentiality. Investigators are encouraged to establish a written Research Information data management plan that describes how research data, records, and materials will be collected, maintained, shared and retained throughout the research project. Ideally the plan should be developed before the start of the research project, although established studies that do not already have one would also benefit from the creation of a management plan.
Research Data, Materials, and Records Covered by these Guidelines

Research Data: There is no uniform definition of research data across federal agencies. Thus, for federal projects, investigators should be knowledgeable of the sponsoring agency’s definition of the term “research data.”

- OMB Circular A-110/2CFR 215 defines research data “as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analysis, drafts of scientific papers, plans for future research, peer reviews or communications with colleagues.”

- The NIH Grants Policy Statement (GPS) defines data as “recorded information, regardless of the form or medium on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data.”

- The Federal Acquisition Regulations (FAR) refers to “recorded information, regardless of form or the media on which it may be recorded,” and includes technical data and computer software.

- The Department of Defense Acquisition Regulations (DFARS) defines “technical data [as] recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation but not software programs.”

- The Environmental Protection Agency (EPA) defines raw data as “any laboratory worksheets, memoranda, notes or exact copies thereof that are the result(s) of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study.”

- NASA defines “data [as] recorded information, regardless of form, the media on which it may be recorded, or the method of recording, created under the grant. The term includes...data of a scientific or technical nature, and any copyrightable work in which the recipient asserts copyright, or for which ownership was purchases, under the grant.”

Generally, for the purposes of these Guidelines, research data mean any and all materials that are created or collected in the process of performing research.

Research Materials: Research materials encompass all types of materials generated and used in research. These include, but are not limited to, materials such as unmodified and modified biological specimens; new or modified chemical entities; original or modified biological samples; gels; spectra; cell lines; reagents; protocols; algorithms; graphs, charts, numerical raw experimental results; instrumental outputs; other deliverables under sponsored agreements; statistics; findings; conclusions; computer programs, databases and documentation; laboratory
notebooks and notes of any type; materials submitted to and approved by the IRB, IACUC, IBC, ESCRO or other research oversight committees (e.g., applications, outreach/advertising materials, sample consent forms, survey routines/questionnaires); signed consent forms; and any other records or source documentation in any form necessary for reconstruction, evaluation or replication of reported or otherwise published results.

Research Records: These are records and correspondence associated with new, continuing, and renewal grant applications, cooperative agreement applications, contract proposals and the resulting awards, or that document compliance with Partners, sponsor and/or federal, state or local government requirements. See the end of this document for a listing of typical research records.

Expired Research Information: Expired Research Information is all research data, materials, and records that

i. Are older than the minimum retention period(s) set forth in these Guidelines;

ii. No longer have a KNOWN and IDENTIFIED business purpose; and

iii. Are not subject to a legal hold.

Retention and Disposal

Partners has established a retention period for all Research Information of no fewer than seven (7) years after the end of a research project or activity. In this context, a research project or activity should be considered ended after submission of (whichever is later)

- Final technical report to the sponsor;
- Final financial close-out of a sponsored research award (i.e., submission of final financial report and close-out documents);
- Final publication of research results;
- Termination of activity on a research project regardless of whether results are published;
- Any end date otherwise defined in the research / sponsorship / data use agreement (if any) governing the project

Departments should develop procedures for promptly disposing of Expired Research Information and designate an individual responsible for implementing these procedures.

Confidential paper-based data should be shredded before discarded. Locked containers are located throughout Partners hospitals and institutions for disposal of paper-based records. Items in these bins are shredded by an outside vendor and discarded. Confidential information stored on portable media, such as a flash-drive or disk may be disposed of in specially marked bins throughout the hospitals. Partners Research Computing should be contacted to remove confidential information from devices that should not be destroyed such as computers.

Regardless of any applicable retention period, you are required to retain, in accordance with any legal hold instructions from the Office of General Counsel, Research Information that is covered by a subpoena, civil investigative demand or that Partners is otherwise obligated to produce to a government agency in the context of legal or investigative proceedings. In the case of pending or anticipated litigation, internal or external investigation, or internal audit, all relevant Research
Information must be maintained. This applies to Research Information older than the minimum retention period. Destruction of Research Information to avoid disclosure in a legal proceeding is a criminal offense.

In addition to situations involving pending litigation or investigative proceedings, there are other situations where retention of Research Information beyond seven years may be required. These include:

- Protecting intellectual property that is the subject of patent applications. Research Information associated with a patent application should be kept the longer of seven years, until the application is rejected, or the patent is expired.
- Research Information needed in connection with pending internal investigation and other proceedings related to sponsored research. For example, review of a research misconduct allegation. The records must be retained until the allegation is resolved, even if the process extends beyond the seven year period.

Standard hospital medical records, employment records, and business records should be kept in accordance with the appropriate Partners policy.

In keeping with the accepted practice of their specialty or research area and consistent with the terms of the sponsored research agreement or material transfer agreement, Investigators may dispose of certain types of tangible research materials prior to the end of the seven year retention period. Early disposal is limited to research animals, biological specimens, cell lines and samples, and does not apply to other forms of research data, materials or records. Materials identified for early disposal must be maintained a minimum of three years prior to disposal.

If tangible research materials are destroyed before the end of the seven year retention period, Investigators are required to document the characteristics of the materials that were destroyed, why they were destroyed early, the date and circumstances of the destruction, and maintain this information in their records. Research animals, biological specimens, cell lines and samples necessary to replicate data reported in scholarly publications may not be destroyed prior to publication and at a minimum must be retained in accordance with the journal’s or publisher’s retention policy.

**Material Transfer Agreements (MTA) and Data Use Agreements (DUA):** If research data or materials are obtained under a MTA or DUA that specifies that the materials/data must be kept for a period shorter than the period required by these Guidelines, the materials/data should be kept for the minimum time period required under these Guidelines. If research data or materials are obtained under a MTA or DUA that specifies that the materials/data must be kept for a period longer than the period required by these Guidelines, then the terms of the MTA or DUA shall govern.

**FDA Requirements-Disposition of Investigational Drugs:** Investigators are required to maintain adequate records of the disposition of investigational drugs, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued or completed, the investigator is required to return unused supplies of the drug to the sponsor or dispose of unused supplies in accordance with sponsor instructions.
FDA Record Retention: The Partners seven-year retention period also applies to retention of records associated with an FDA investigational new drug or device application. The retention period begins following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is filed or if the application is not approved for such indication, the retention period begins upon discontinuation of the investigation and notification of FDA.

Questions

Questions about retention of Research Information should be referred to your hospital’s Research Compliance or Corporate Compliance Office or Partners Research Compliance. Questions about retention of FDA-related materials should be referred to the Partners IRB/QI Office.
Standard Research Records

Institutional Animal Care and Use Committee (IACUC) Records

Records: Minutes; records of attendance; applications, records pertaining to protocol approval; amendment suspension, etc; semi-annual IACUC reports/recommendations; reports/recommendations forwarded to Institutional Official; accreditation records.

Regulatory/Policy Citation:
OMB Circular A-110
Animal Welfare Act 9 CFR 2.35
NIH Institutional Animal Care & Use Committee Guidebook
Partners Document Retention Policy (12/18/96)

Institutional Biosafety Committee (IBC)

Records: Minutes; records of attendance; applications, records pertaining to protocol approval; amendment suspension, etc; reports/recommendations forwarded to Institutional Official.

Regulatory/Policy Citation:
OMB Circular A-110
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
Partners Document Retention Policy (12/18/96)

Conflict of Interest (COI) Records

Records: Records of all financial disclosures, institution’s review of and response to such disclosures (whether or not a disclosure resulted in a determination of FCOI), and all actions under the institution’s policy or retrospective review, if applicable.

Regulatory/Partners Policy Citation:
OMB Circular A-110
42 CFR 74.53 (b); 92.42 (b); 94.4(i)
Partners Document Retention Policy (12/18/96)

Records Relating to Agreements (federal, state or local government; not-for-profit; and industry) Awards and Contracts

Records: All financial and administrative records (e.g., applications, proposals, progress reports) pertinent to the award (grants, contracts and cooperative agreements) that pertain to contract/agreement negotiation, award administration, expenditures, scope of work, compliance, and financial and other reporting to sponsor.
**Regulatory/Partners Policy Citation:**
OMB Circular A-110,
NIH Grants Policy Statement
45 CFR 74.48; 92.36
Federal Acquisition Regulation (FAR)
Partners Document Retention Policy (12/18/96)

**Institutional Review Board (IRB) Records**

**Records:** Reviewed research protocols; scientific evaluations; approved sample consent documents; progress reports; reports of unanticipated problems involving risks to subjects or others; minutes of IRB meetings; records of continuing review activities; copies of all correspondence between IRB and investigators; list of IRB members; written IRB procedures; and statements of significant findings provided to new subjects

**Regulatory/Partners Policy Citation:**
21 CFR 56.115
45 CFR 46.115
Partners IRB Policy
Partners Document Retention Policy (12/18/96)

**Research Misconduct Records**

**Records:** All records, documentation, correspondence, etc., related to research hearings, findings, and correspondence with sponsor or regulatory agency.

**Regulatory/Partners Policy Citation:**
21 CFR 312.62
Partners Procedures for Handling Allegations of Scientific Misconduct
Partners Document Retention Policy (12/96)

**Food and Drug Administration (FDA) Records**

**Records:** Records related to the disposition of drug or device, investigator financial disclosure, subject case histories, correspondence with sponsor, monitor, IRB, or another investigator, and any other document that FDA requires to be maintained by regulation or specific requirement.

**Regulatory/Partners Policy Citation:**
21 CFR 312.57
21 CFR 312.62
21 CFR 812.140
Partners Document Retention Policy (12/96)