IFAR Record Retention Policy

Institutional Policy

Title:	IFAR Record Retention Policy
Responsible Officer:	Kathy Tasker
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Approved By:	

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1 Purpose

The Institute for Aging Research (IFAR) at Hebrew SeniorLife (HSL) and its researchers have legal, institutional and ethical obligations to manage and retain records of research conducted at HSL. These obligations arise from express provisions in agreements with federal and other research sponsors, overarching regulatory requirements relating to funded research, and fundamental precepts of research integrity. The purpose of this policy is to outline proper record retention practices within IFAR.

2 Scope

The policy covers Sponsored Award and Fiscal Records, Human Research Records (investigator/study files and IRB files), Other Non-Human Research or Project Records, and IFAR Personnel Files.

3 Definitions

Term: Sponsored Award

This includes all funding arrangements in which HSL is providing a return benefit to, or agrees to provide a defined deliverable or complete a set of activities for, the sponsor in exchange for the funds, regardless of whether the funding instrument is designated a contract, cooperative agreement, grant, consortium agreement, subcontract, subgrant or otherwise. This category includes all sponsored contract or sponsored "grant" funding from federal or nonfederal sources, including foreign entities or international organizations, whether pursuant to a contract or sponsored "grant." Sponsored awards most often support research activities, but in some cases, may be provided for non-research, demonstration, service or capital projects.

Term: Research

Systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and Clinical Research, including applied research and product development.

Term: Research with Human Subjects

Research is considered to involve human subjects when an investigator conducting research obtains (1) data through intervention or interaction with a living individual, or (2) identifiable private information about a living individual.

Term: Research Records

Research records are recorded research information, data and materials (including photographs, videos, website content, electronic mail, budgets, databases and datasets, etc.) that are created or acquired in the process of performing research, regardless of sponsorship. Research records include documents, materials, information and written correspondence that relate to the administration and financial management of research, reporting of research results, or sponsored award applications, as well as the record of all data or results that embody the facts resulting from scientists' inquiries, including, but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, presentations, and journal articles at all stages of development. This includes, but is not limited to, financial, administrative, cost or pricing, or other management information that has been gathered or used to apply for or support specific research activities, such as grant proposals, progress reports, and communications with funders.

Term: Research Data and Materials

Research Data and Materials include recorded, tangible, or intangible research information, regardless of form or the media on which it may be recorded, that is created or collected in the process of performing research, whether supported by HSL resources or by external funders. Research Data and Materials include, but are not limited to, computer software (computer programs, computer databases, and documentation thereof), materials such as unmodified and modified biological specimens, new or modified chemical entities, laboratory notebooks, notes of any type, materials submitted to and/ or approved by IRB, IACUC, or other research oversight committees (e.g., applications, outreach/ advertising materials, consent forms, survey routines/ questionnaires and debriefing scripts), photographs, films, audio recordings, digital images, original or modified biological and environmental samples, gels, spectra, cell lines, reagents, protocols, algorithms, graphs, charts, numerical raw experimental results, instrumental outputs, other deliverables under sponsored agreements; intangible data such as statistics, findings, conclusions, other deliverables under sponsored agreement; and any other records of, or in any form that could be used for, reconstruction and evaluation of reported or otherwise published results of research.

4 Policy Statement

This policy establishes guidelines and expectations of IFAR faculty and staff to ensure that Research Records and Research Data and Materials, as defined above, are appropriately documented, maintained, retained, and accessible to HSL/IFAR or auditors.

Research Records normally should be maintained in the office or department where they are created and used, or otherwise on HSL premises or in HSL-approved vendor storage, or in electronic computing systems maintained by HSL. Principal Investigators and staff who direct, lead, or administer research projects are responsible for maintaining an orderly system for recording, retaining, accessing, and storing their research records, and for communicating such systems and their proper use and access to the members of their research teams and other appropriate administrative or department personnel.

Research Data and Materials in particular must be stored in compliance with the IFAR Research Sensitive Data Security Policy and, in the case of research data and materials relating to research with human subjects, in a manner that complies with all applicable IRB requirements, and with any relevant contracts, data use agreements and federal regulations.

Research Records should be retained, generally, for a period of **no fewer than seven (7) years after the end of a research project or activity.*** For this purpose, a research project or activity

should be regarded as having ended after (a) final reporting to the research sponsor, (b) final financial close-out of a sponsored research award, or (c) final publication of research results, or (d) cessation of academic or scientific activity on a specific research project, regardless of whether its results are published, whichever is later. Please note that research related financial and administrative records need only to be kept for 7 years from the final filing of the final financial close-out report. Investigators who wish to store records on-site for longer than the required period of time may be subject to storage fees or cost sharing fees.

***The seven (7) year period is based on the six (6) year period within which the federal government may seek to reclaim federal grant funds and to assess possible additional penalties for misuse of federal funds, plus a one year period to assure that any annual records destruction would not unintentionally include records during the sixth year of their existence.*

Examples of materials to be retained, include:

1. **Sponsored award and fiscal records,** including, for example:
   Grant applications, renewal applications, quarterly reports/progress reports/status reports, notice of grant awards, invoices, accounts receivable, A133 audit reports, any emails that address budget issues, any emails that address the scope of the work, and grant agreements and any amendments.

2. **Human Research Records**, including, for example (for a more comprehensive list, see the HSL IRB SOPs, section 14):
   Regulatory documents (including all IRB-related materials and IRB-approved materials), correspondence with study sponsor/funding agency/regulatory agencies/research collaborators, financial disclosure forms submitted by staff responsible for the design, conduct and reporting of the research, study management logs, study staff qualifications, correspondence/communications with collaborating sites, FDA-related documentation, individual subject files (e.g. consent materials), etc. The scope of the correspondence that should be retained should be sufficient to enable an independent party reviewing that correspondence to identify and understand primary findings, major events, and major strategic decisions or judgments made in the course of the research.

3. **Other Research or Project Records** (not involving human subjects)
   HSL/IFAR staff and faculty engage in intellectual activities that may result in research or other projects, that, if they wish to publish or patent or claim intellectual property, may require retention practices similar to those required of financial or human research records.

HSL/IFAR staff who create such research or projects should plan accordingly and keep these records for as long as they find necessary or consult with the HSL IP policy, or with the HSL General Counsel and Compliance Office.

4. Personnel Files

IFAR administration and project directors often maintain their own personnel files, including those of volunteers. Documentation contained in personnel files (including occupational health reports, immunization records, etc.) should be maintained according to the same 7-year retention period.

Note: This policy is subject to change, depending on changes to HSL corporate policies, federal and state policies surrounding record retention.

5 Reference Materials

- IFAR Data Retention and Destruction Policy http://thehslhub/~/media/HSLNet/P_P/IFAR/IFARPPSensitiveDataRetentionandDestruction.ashx
- IFAR Sensitive Data Security http://thehslhub/~/media/HSLNet/P_P/IFAR/IFARPPSensitiveDataSecurity.ashx
- HSL IRB SOPs http://thehslhub/~/media/HSLNet/Docs/IFAR/IRB/IRB_SOP.ashx
- Harvard University Policy of Research Data and Materials http://osp.finance.harvard.edu/retention-research-data-and-materials
- Partners Human Research Committee Recordkeeping and Record Retention Requirements http://navigator.partners.org/ClinicalResearch/Recordkeeping_and_Record_Requirements.pdf

6 Appendix

Principal Investigator Attestation Form for Destruction of Research Records

7 Document Properties

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