Lifespan Office of Research Administration	**Subject:** Record Retention Policy	**File Under:** ORA Gen 009
Issuing Department: Lifespan Office of Research Administration		**Latest Revision Date:**
Original Policy Date: 12/1/10		**Approved By:** Peggy McGill, MA, CRA Administrative Director; Peter J. Snyder, Ph.D. Vice President for Research

I. Purpose

Lifespan is committed to full compliance with applicable federal and state laws and regulations regarding retention of research records generated at Lifespan and its affiliates.

II. Eligibility

This policy applies to all Lifespan Employees and all Lifespan Professional Staff members.

III. Policy

Each responsible party must retain the research records relating to their scope of responsibilities. In instances of shared responsibilities (e.g., subrecipient invoice review), all responsible parties retain research records related to these shared responsibilities.

Research records are subject to access by the IRB, Internal Audit, federal and state authorities, sponsors, and other authorized individuals as appropriate to ensure proper performance of the study. The right of access is not limited to the required retention period but shall last as long as the records are retained.

IV. Procedure

4.1 Roles and Responsibilities

All Lifespan employees and Professional Staff members must retain all research records related to their area of responsibility in compliance with sponsor requirements and this policy. ***A longer record retention period may be required if the term of a contract/agreement supersedes this policy or if any litigation, claim, or audit is started before the expiration of retention period. The records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.***

Responsible Party	Type of Research Records	Retention Period
Principal Investigator (PI) or designee Records include, but are not necessarily limited to, all technical data, documentation involving the methods used to conduct research, results of the research, and progress/performance reports.	Human subjects or human subject materials, including IRB and regulatory records	6 years after termination. A longer period may be required if the study is FDA regulated. FDA requires 3 years of record retention after approval of the investigational product.
	Basic research (research not involving human subjects)	3 years from the date of submission of the final expenditure report or for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, as authorized by the federal awarding agency.
Grants and Contracts Office Records include, but are not necessarily limited to, pre- and post-award materials related to research grants and contracts.	e.g., budget information, proposal, notice of award or sponsor agreement, correspondence with the sponsor, sub-recipient monitoring	3 years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, as authorized by the federal awarding agency.
	Equipment and real property records	3 years after final disposition.

Research Finance Records include, but are not necessarily limited to, financial documents.	e.g., Federal Financial Reports (FFR), Payment Management System Reports (PMS), journal entries, financial reports, invoices, copies of checks, and miscellaneous financial information	3 years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, as authorized by the federal awarding agency
	Indirect cost and fringe benefit rate proposals, cost allocation plans, and supporting records	3 years from the date of submission
Research Protection Office Records include, but are not necessarily limited to, copies of all research protocols with supporting documentation.	e.g., minutes of Committee meetings, documentation of continuing review activities, any significant new findings to be provided to participants, and correspondence involving administration, investigations, and any appropriate federal and/or state agency	3 years after termination. Records not associated with research or for protocols cancelled without participant enrollment must also be retained for at least 3 years after termination

4.2 Transfer of Research Records

A. Lifespan must retain all patient/subject information. All patient/subject records require appropriate patient/subject authorization for use and disclosure to another entity. De-identified patient/subject information is allowable for transfer under an approved Data Use Agreement.

B. All original research records pertaining to legal matters, including, but not limited to patents, litigation and disciplinary actions will remain at Lifespan under the applicable administrative office.

C. If a grant or contract is being transferred to another institution with the PI, then PI is responsible for leaving a complete copy of all research records with the Chief of Department or replacement PI approved by Lifespan and sponsor.

D. Before transferring the original research records, PI must ensure that any special conditions stated in the grant or contract are met.

E. The PI's Department is responsible for archiving of the research records (or copies where allowable) for a period not less than 6 years following the transfer of the PI or the term of the grant or contract, whichever, is longer.

F. Prior to the removal of any tangible research product from Lifespan, the recipient/institution must execute a material transfer agreement (MTA) with Lifespan.

4.3 Record Storage and Destruction

This policy applies to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper document, images, and other electronic media. Electronic storage systems must be stable, reliable, and maintain the integrity of the information. When storing electronic images of paper documents, the system must also include a full, complete, and accurate representation of the original, including all official approvals.

Research records must be retained in locked filing cabinet(s) and/or locked room(s) with controlled access within each responsible party's area or at a secured archived off-site location.

After retention period, research records must be shredded or otherwise destroyed so as to not be retrievable.

V. Related Lifespan Policies and Federal Regulations:

- Lifespan System-Wide Policy CCPM-25: Documentation and Retention Standards Policy
- Lifespan System-Wide Policy CCPM-72: Litigation Hold Directive Standards
- Lifespan Corporate Policy IS-209: Confidential Information – Data Protection Controls Policy
- Lifespan Corporate Policy IS-210: Electronic Records Management Standards
- Lifespan Human Research Protection Program Policy and Procedure Manual
- Lifespan System-Wide Policy ORA RRC 002: Lifespan Institutional Animal Care and Use Committee (IACUC) Policy and Procedure Manual
- OMB Circular, A-110, Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations, Subpart C.53
- The Department of Health and Human Services (HHS) Grants Policy Statement, Part II: Terms and Conditions of Award, Reporting and Record Retention
- NIH Grants Policy Statement, Part II: Terms and Conditions of NIH Grant Awards, Record Retention and Access
- 45 CFR 74.53 and 92.42 for grant-related records
- 45 CFR 74.48 and 92.36 for contracts under grants