

Access to Closed and Archived Research Records

Institutional Policy

Title:	Access to Closed and Archived Research Records
Responsible Officer:	Director, IRB and Director, Research Informatics
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1 Purpose

The purpose of this policy is to promote compliance with applicable regulations (45 CFR 46 and 21 CFR 56) and related institutional policies.

2 Scope

This policy applies to all faculty and staff of Hebrew SeniorLife Marcus Institute for Aging Research (Marcus Institute) including principal investigators as well as project, research and administrative staff.

3 Definitions

Term: Sensitive Data

Any data which contains Social Security Numbers or other personal identification numbers, confidential personal or financial information, protected health information, student educational records, proprietary customer data or information that is otherwise deemed to be protected by HSL corporate policy, state, federal, or international laws, statutes, or regulations or explicitly identified in a contract.

4 Policy Statement

Completed and closed research records stored by the institution (physical or electronic) and containing sensitive data may ordinarily be accessed only under the following circumstances:

1. A protocol is being re-opened, and IRB approval has been granted for the re-opened research
2. The Investigator would like to assess whether there are adequate data for a new grant proposal or research project, and no identifiable information will be extracted from the files
3. An authorized auditor (government, sponsor, IRB, etc.) has requested access to the files

5 Procedures

5.1 General Rule

Faculty and staff are required to store project related data including sensitive data in electronic or paper format to secure network storage or in preapproved physical storage locations. See the Sensitive Data Security policy regarding preapproved locations for storing data.

Closed and archived research records may be accessed in the following circumstances (see 5.2.1 for more details):

1. If a protocol is being re-opened;

2. If an Investigator is assessing whether there are adequate data for a grant proposal or research project;
3. If the research records are requested as part of an authorized audit.

5.1 Project Closeout

All investigators and project directors should develop and execute project closeout activities. This process should be executed at the end of primary data analysis and before IRB authorization expires. Specific closeout activities vary by project, but investigators are encouraged to create de-identified data sets and isolate sensitive data within project archives to avoid record access violations.

5.2 Record Archives

If sensitive data are moved to the institute's electronic or paper archives then the following procedures must be followed.

5.2.1 Accessing Record Archives

Access to institutional electronic and paper record archives is strictly prohibited and controlled by the Director of Research Informatics.

Investigators who rely on the institution to retain records of completed and closed research protocols containing identifiable patient or resident information, and would like access to those records, must submit a formal request to the Director of Research Informatics.

The Director of Research Informatics will review the application and authorize access if the request meets the requirements of the policy. As such,

4. If a protocol is being re-opened, documentation of current IRB approval, or the approval of the IRB office, will be required;
5. If the Investigator is assessing whether there are adequate data for a grant proposal or research project, the Director of Research Informatics/designee will assign personnel from Data Management to oversee access to the records to verify that no material containing patient or resident identifiers are removed or copied;
6. If the records are requested as part of an authorized audit, the Director of Research Informatics/designee will verify for Data Management (with input from Research Administration, the IRB office, the Investigator, and/or General Counsel, as appropriate) the appropriate records to provide to the auditor, and to assure confidentiality of the records when not in use by the auditor.

Requests for access to stored records should allow sufficient time for the Director of Research Informatics/designee to review, authorize, and assign staff to fulfill the request. Last minute and 'rush' requests may be accommodated, depending on staff availability.

5.3 Policy Exceptions

Any requests that fall outside of this Policy require authorization from Research Informatics, Research Administration, the IRB Office, and/or General Counsel, as appropriate.

6 Related Policies

The document author(s) have attempted to identify policies that may be applicable or related to this policy. This is not an exhaustive list. All HSL employees are expected to abide by all active policies of the organization at all times. As such, employees are encouraged to review any and all potentially applicable policies regardless of whether they are identified below. HSL reserves the right to modify, cancel, or enact new policies at anytime, without notice.

- HSL Policy: Record Management, Retention, Disposition & Destruction Guidelines
- HSL IRB Policies and Procedures: see Principal Investigator Responsibilities (Section 3.1) and Record Management (Section 14)

7 Reference Materials

NA

8 Appendix

NA

9 Document Properties

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