

Staff Changes and Data Access Policy

Institutional Policy

Title:	Staff Changes and Data Access Policy
Responsible Officer:	Director, Research Informatics and Director, IRB
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Approved By:	<i>Kathryn Tasker</i>

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1 Purpose

This policy is intended to ensure strict access to sensitive data or data that were provided through a formal Data Use Agreement (DUA) or Data Sharing Agreement (DSA) such as with the Centers for Medicare and Medicaid Services (CMS).

2 Scope

All HSL employees including research faculty and staff working on projects involving sensitive data (SD) including data obtained through formal data use or data sharing agreements.

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

Projects involving sensitive data must be reviewed by the HSL IRB or ceded by the HSL IRB to another duly appointed IRB (the Reviewing IRB). As a result, the following conditions apply.

- IRB approval includes review of personnel working on the protocol, confirming appropriate qualifications to conduct the research and human subject protection trainings.
- IRB policies require that staffing changes receive approval prior to work commencing on the protocol.

It is the policy of HSL that SD projects include obtaining IRB approval prior to staffing changes, and informing the DUA/DSA contractor (e.g. CMS) within 30 days of staffing changes. Access rights to data must be restricted within 8 hours and ideally prior to any staffing change.

5 Procedures

5.1 Planned Staff Changes

- When a planned staffing change occurs, principal investigators or their project directors must inform the HSL IRB and/or other reviewing IRBs, and DUA/DSA contractor (e.g. CMS) in advance of the change and provide details regarding their data access restriction.

5.2 Unplanned Staff Changes

- When unplanned staffing changes occur, principal investigators or their project directors must inform the HSL IRB, and/or other reviewing IRB, within the timeline outlined in the relevant IRB

policies and DUA/DSA contractor (e.g. CMS) as appropriate within 30 days of the staffing change.

- When an unplanned staffing change occurs, the principal investigator and/or project director must inform the IFAR Informatics Director within 8 hours
 - Access restrictions must be enacted immediately by emailing the HSL Help Desk to deactivate applicable network credentials.

5.3 Data Access Changes

- Principal investigators and project directors must follow HSL corporate policy regarding granting physical or electronic access to sensitive data locations. These include following prerequisite HR procedures for staff changes (hiring, termination, etc.) as well as IT procedures for network access requests (activating and deactivating accounts). Proof of this correspondence should be printed and given to the institution's Office Manager to be retained in the personnel file.

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 any time, without notice.

- HSL - IRB Policies and Procedures (Section 3 – Investigator and Research Personnel Requirements)
- HSL - Termination Policy
- HSL - Use of Information Technology Resources Policy

7 Reference Materials

NA

8 Appendix

NA

9 Document Properties

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