Limited Data Sets and Data Use Agreements

Institutional Policy

Title:	Limited Data Sets and Data Use Agreements
Responsible Officer:	Director, Research Informatics
Original Effective Date:	3/24/2018
Revised Date:	2/8/2019
Renewal Date:	On or before 2024
Approved By:	*Kathryn Tasker*

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1   Purpose

The purpose of this policy is to promote compliance with applicable privacy regulations and institutional policies regarding the use of Limited Data Sets or data sets associated with third party Data Use Agreements.

2 Scope

This policy applies to all principal investigators, project and research administrative staff.

3 Definitions

Term: <u>Data Use Agreement (DUA)</u>

A written satisfactory assurance between the covered entity and a limited data set recipient (e.g., an investigator) requiring agreement by the recipient to various terms, including that the data will only be used or disclosed for specific purposes, that the limited data set will be protected, that the recipient will notify the covered entity of any unauthorized uses or disclosures of which it becomes aware, and that the recipient will not identify the information or contact the individuals whose information comprise the limited data set.

Term: <u>Limited Data Set (LDS)</u>

A limited data set is defined as Protected Health Information that excludes the following direct identifiers of the individual or of relatives, employers or household members of the individual: names; postal address information, (other than town or city, State and zip code); telephone and FAX numbers; electronic mail addresses; Social Security Numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plates; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address; biometric identifiers, including finger and voice prints; full face photos, and comparable images.

Limited Data Sets can include:

1. Geographic data: A limited data set can include town, city, State and zip code, but no street address.
2. Dates: A limited data set can include dates relating to an individual (e.g., birth date, admission and discharge date).
3. Other unique identifiers: A limited data set can include any unique identifying number, characteristic or code other than those specified in the list of 16 identifiers that are expressly disallowed.

Important requirements/restrictions for use and/or disclosure of limited data set:

1. Limited data sets may NOT be used to re-identify or contact an individual.
2. The "minimum necessary" standard applies to the limited data set, which means an Investigator must explain that the data elements requested are necessary for the research.

3. A Data Use Agreement must be signed by the covered entity and the recipient of the Limited Data Set, and in some circumstances, the Institutional Official at the recipient institution.

4. The requirement of accounting for disclosures of protected health information (PHI) does not apply.

Term: Protected Health Information (or PHI)

Individually identifiable health information transmitted or maintained in any form. PHI as used in this policy, consists of any information about an individual, including very basic information such as their name or their age, that (1) relates to the past, present, or future physical or mental health or condition of the individual, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, and (2) either identifies the individual, or could reasonably be used to identify the individual. Protected health information may be in any form, including spoken, written, or electronic form. Examples of protected health information include, but are not limited to, medical records, medical data on information systems, and applications for health or disability benefits.

4   Policy Statement

4.1   Limited Data Sets

HSL allows, absent individual HIPAA authorization, the use and disclosure for research purposes (as well as public health or health care operations) a Limited Data Set that includes a subset of the individual's protected health information that has been stripped of all direct identifiers, provided that all persons or entities using or receiving the Limited Data Set have signed a Data Use Agreement with HSL through which the individuals or organizations agree to protect the privacy of the information received.

A member of HSL's workforce (or a third party that has signed a Business Associate Agreement with HSL) may use HSL's PHI to create a Limited Data Set to be used in research without individual authorizations, because such an activity is considered to be part of HSL's health care operations (see HSL Corporate Policy "General Uses and Disclosures of PHI"). See Sections 5.2 and 5.3 for details.

4.2   Data Use Agreements

All data use agreements will be reviewed by the following officials, as appropriate and applicable, before corporate signatures are applied.

Reviewer	Purpose / Category
Director, Research Informatics	Technology, Data Transfer and Security Procedures

Chief Compliance Officer (or her designee)	Legal
Director, IRB (if applicable)	Human Subjects Protection
VP, Research Administration (or her designee)	Finance and Grant Administration Compliance

5   Procedures

5.1   LDS/DUA Requests

Data use agreements may be categorized as outgoing ("when HSL is the provider of the data") or incoming ("when HSL is the recipient of the data"). The following sections detail the procedures investigators must follow to execute institutional approvals for DUAs. Please take note of the rules for limited data sets below.

5.1.1   Notes:

- (1) Data Use Agreements are not ordinarily required for outside (non-HSL) research collaborators, presuming the research collaborator is listed on the HSL Investigator's research protocol as having access to the limited data set for that research project, and if a waiver of patient authorization has not been granted, is listed on the consent form/HIPAA authorization as having access to research subjects' PHI for the research project.
- (2) Investigators who are not members of the HSL workforce and not working as a collaborator with an HSL investigator as described above, may need to obtain prior approval from the HSL Privacy Officer prior to receiving any data.

5.2   When HSL is the provider of the data:

HSL has a Data Use Agreement (DUA) template for those who wish to disclose a "limited data set" to recipients. This template is available on the institution's Research Administration page via its Web site. When HSL is providing the limited data set, if any material change is to be made to this template form, or if another party's version of a data use agreement is to be used, the Director of Research Informatics, in consultation with those listed in section 4.2 above, must review and approve the terms of the agreement prior to engagement. Investigators, research staff, and data core personnel should check with the Director of Research Informatics to assure that all appropriate documentation is in place prior to sending research data external sources.

5.3   When HSL is the recipient of the data:

If a HSL Investigator is the recipient of a limited data set of PHI from a non-HSL source, the HSL Investigator will likely be asked to sign the other party's Data Use Agreement. In such instance, the IFAR Director of Research Informatics is responsible for reviewing the Data Use Agreement and determining if it complies in material terms with the HSL Data Use Agreement template. If the other party's Data Use Agreement differs materially from the HSL Data Use Agreement template, or if there is any uncertainty, the HSL General Counsel/Chief Compliance Officer must be consulted. Investigators, research staff, and data core personnel should check with the Director of Research Informatics to assure that all appropriate documentation is in place prior to receiving research data from external sources.

5.4   Investigator Responsibilities

- HSL Investigators are responsible for initiating and completing the agreement process. This may include completing form fields, responding to clarifications or supervising subordinates in the completion of these materials.
- The Investigator is responsible for ensuring that all parties sign the agreement before data are exchanged or work begins on the project.
- HSL Investigators are responsible for complying with all terms documented in data use agreements they have signed, or that have been signed on their behalf by HSL institutional officials.
- HSL Investigators are not permitted to continue to use data sets beyond an expiration date if specified in DUA. Investigators are responsible for obtaining extensions or updating DUA details such as staff changes, end-dates, scope change, etc.
- Investigators mentoring Jr. Faculty, Research Fellows, Graduate Students, or hosting Visiting faculty, Research Fellows or Students are also responsible for properly overseeing the execution of agreements and data used in research.

5.5   Internal Procedures (corporate agreements)

The following procedures apply to data use agreements with institutional oversight and signatures.

1. The Principal Investigator or her designee must email the agreement along with appropriate companying materials (e.g. CMS data management plan, letters of commitments, etc.) to the Director of Research Informatics.
2. A copy of all fully-executed data use agreements will be stored in a common share and recorded using a tracking system. Specifically, the DUA and its accompanying material (e.g. applications, IRB approvals, subcontract agreement, etc.) will be emailed to the address; Ifar-datause@hsl.harvard.edu

a. The common inbox will be established by the IT department and managed by the Research Informatics Core in connection with the tracking system.
b. There is no required list of accompanying materials as data use agreements vary in context, complexity and formality. The PI must include enough information to answer the following questions.
    i. Which PI is responsible for the DUA?
    ii. What project, grant or corporate initiative is associated with the DUA?
c. Draft versions of data use agreements will not be retained.
d. Agreements will be organized by PI last name in the share.
3. A copy of all formal DUA final actions (e.g. certification of destruction) will be stored in the share as well.
4. A copy of DUA renewals will be stored in the share and tracking system.
5. All agreements will be tracked in a system in parallel with the inbox. The fields listed in Appendix 8.1 will be tracked as part of operations.
6. The Research Informatics Core will generate a list of DUAs on request. A dashboard of all DUAs will be developed to facilitate continuous monitoring.
    a. If applicable, the designated PI by contract will be responsible for executing the termination or renewal of agreements including certifying the destruction of materials.
    b. Terminated and renewed agreements will be updated in the tracking system accordingly.

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: see section 11, Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule's Application to Research Activities
- HSL Corporate Privacy Act Policies

7   Reference Materials

NA

8 Appendix

8.1 Metadata Fields

The following list of attributes will be tracked for projects. It is important to note that this list may not be up-to-date and is provided for general reference only. This list is subject to change independent of policy or formal published procedures.   (Source: HSL Data Use Agreements, DATAUSE Jira Project)

Field Name	Title
tracking_id	Ticket or Tracking Number for Agreement Request
short_name	Project Common Name
pi_firstname	PI First Name
pi_lastname	PI Last Name
contract_startdate	Contract Start Date
contract_enddate	Contract End Date
project_comments	General Comments
status	Status of the agreement (in review, executed, terminated, etc.)
attachements	All related attachments to the inbox emails

9 Document Properties

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