POLICY REGARDING THE CREATION, USE AND DISCLOSURE OF LIMITED DATA SET INFORMATION (LDS) UNDER HIPAA

This revised policy:

a. Incorporates formatting changes; and
b. Introduces a new Compliance section.

I. PURPOSE

The purpose of this policy is to ensure that all George Washington University (GWU) researchers (defined below) involved in human subject research involving Limited Data Set information (LDS) comply with applicable Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provisions regarding LDS.

II. SCOPE

This policy applies to all GWU researchers, including GWU, Medical Faculty Associates (MFA), and GWU Hospital faculty, staff or students, who create, use, or disclose LDS for research purposes.

III. POLICY STATEMENT

GWU researchers (defined above) may create, use and/or disclose LDS for research purposes if GWU (not the principal investigator) enters into a data use agreement (DUA) as follows:

A. With a non-GWU recipient requesting access to LDS maintained by GWU (including MFA and/or GWU Hospital); or

B. With a non-GWU individual/entity, i.e., data source, offering to provide a GWU researcher with access to LDS maintained by the data source. Please be advised that a GWU researcher requesting access to LDS maintained by a non-GWU individual/entity, e.g., another hospital, will be asked to follow the non-GWU individual/entity’s policies and procedures for granting access to LDS.

LDS is protected health information (PHI) that does not directly identify the subject, but contains certain potentially identifying information. As such, disclosures of LDS are exempt from the HIPAA requirements for Accounting of Disclosures of PHI.

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LDS use and disclosure must be limited to that which is reasonably necessary to achieve the purpose of the disclosure.

Because a GWU researcher requesting access to LDS maintained by a non-GWU individual/entity must follow the non-GWU individual/entity’s policies and procedures for granting access to LDS, the remainder of this Policy focuses on the procedures that are required for a GWU researcher to be able to convert GWU maintained PHI into LDS and provide the newly converted GWU LDS to a non-GWU recipient, i.e., disclose such information outside of GWU.

IV. PROCEDURES

Before a GWU researcher can convert GWU maintained PHI into LDS and disclose the newly converted GWU LDS to a non-GWU individual/entity (i.e. recipient), the GWU researcher must complete steps A, B, and C below. Alternatively, if a GWU researcher simply wishes to access already converted LDS, the GWU researcher only needs to follow Step C below.

A. Obtain GWU IRB Approval of a Waiver of Research Subject Authorization Before Converting PHI into LDS

If a GWU researcher wants to access GWU maintained PHI, convert it into LDS, and disclose the newly created LDS to a non-GWU researcher/entity/individual, the GWU researcher must first obtain GWU IRB approval of a Waiver of Research Subject Authorization before accessing the PHI to convert it into LDS. A Waiver of Research Subject Authorization Request Form is available at http://www.gwumc.edu/research/forms.htm

B. Create LDS from PHI

In order to create LDS from PHI, the GWU researcher must remove the following 15 direct identifiers of the individual, or of relatives, employers, or household members of the individual:

1. Names (initials do not have to be removed);
2. Telephone numbers;
3. Fax numbers;
4. Electronic mail addresses;
5. Social security numbers;
6. Medical record numbers;
7. Health plan beneficiary numbers;
8. Account numbers;
9. Certificate/license numbers;
10. Vehicle identifiers and serial numbers, including license plate numbers;
11. Device identifiers and serial numbers;
12. Web Universal Resource Locators (URLs);
13. Internet Protocol (IP) address numbers;
14. Biometric identifiers, including finger and voice prints; and
15. Full face photographic images and any comparable images.

Thus, LDS contains dates, addresses, including town, city, state and five-digit zip code but not the street address, and unique identifying numbers, characteristics, or code-links of the individual, or of relatives, employers, or household members of an individual.

C. Execute a DUA

GWU researchers may not disclose LDS until a DUA is executed between GWU and the non-GWU recipient requesting access to the LDS maintained by GWU. In order to successfully execute a DUA, the research much complete the following:

1. Obtain a copy of the GWU Data Use Agreement Template from the Office of Health Research, Compliance and Technology Transfer (OHRCTT), located in Ross Hall, Room 712. Pursuant to the HIPAA Privacy Rule, a DUA agreement must:
   a. Establish the permitted uses and disclosures of the LDS by the recipient of, consistent with the purpose of the research;
   b. Limit who can use or receive the data;
   c. Provide that the recipient will:
      • Not use or further disclose the information other than as permitted by the DUA or as otherwise required by law;
      • Use appropriate physical, technical and administrative safeguards to prevent use or disclosure of the LDS other than as provided for in the DUA;
      • Report to GWU any use or disclosure of the information not provided for by the DUA of which the recipient becomes aware;
      • Ensure that any subcontractor to whom it provides the LDS agrees to the same restrictions and conditions that apply to the LDS recipient with respect to such information;
      • Not identify the information or contact the individuals; and
      • Not use or further disclose the information in a manner that would violate HIPAA requirements.
2. Complete the DUA in accordance with the protocol under IRB review;
3. Forward the draft DUA to OHRCTT for review;
4. Forward the OHRCTT reviewed DUA to the recipient for signature;
5. Upon receipt of a signed DUA, forward it to OHRCTT for GWU signature and execution.

6. Once signed, OHRCTT will provide the researcher with a copy of the executed DUA. The researcher should maintain a copy of the executed DUA in the applicable study file.

Before a GWU researcher can disclose LDS maintained by GWU to a non-GWU recipient or a GWU researcher can access LDS maintained by a non-GWU entity, GWU must have successfully executed a DUA. Thus, the principal investigator of a study involving LDS should begin the DUA process at the same time the investigator initiates the IRB review process.

V. COMPLIANCE

Whenever a GWU researcher discovers any pattern of activity or practice by an LDS recipient that is a material breach or a violation of the signed DUA, the GWU researcher must report such breach or violation to the GWU IRB. The GWU IRB will then take reasonable steps to cure the breach or end the violation, as applicable. If such steps are not successful, the GWU IRB will revoke its approval of the disclosure of PHI to the recipient and report the problem to the Secretary of the Department of Health and Human Services.