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

PURPOSE: To ensure that all GWU researchers involved in human subject research involving LDS comply with applicable Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provisions regarding Limited Data Set information (LDS).

SCOPE: This policy applies to all GWU researchers, including GWU, MFA, or UHS faculty, staff, or students and any research contractors, who create, use, or disclose LDS for research purposes.

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:

1. With a non-GWU recipient requesting access to LDS maintained by GWU (including MFA and/or UHS); or
2. 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 anon-GWU individual/entity, e.g., Washington Hospital Center, will be asked to follow the non-GWU individual/entity’s policies and procedures for granting access to LDS. Keep in mind, however, that pursuant to HIPAA if a researcher (who is also a covered entity) requests access to LDS, s/he cannot access such LDS unless the GWU researcher (recipient) has entered into a DUA agreement with the entity/individual providing him/her the LDS. Thus, a researcher should inquire into the non-GWU individual’s/entity’s policies/procedures regarding LDS to make sure that the researcher does not access LDS in violation of HIPAA.

LDS use and disclosure must be limited to that 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 provide LDS maintained by GWU to a non-GWU recipient (i.e., disclose such information outside of GWU).
PROCEDURES: Before a GWU researcher can disclose LDS maintained by GWU to a non-GWU individual/entity (i.e. recipient), the following steps must be completed.

A. Create LDS

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

B. Execute a DUA

GWU faculty, staff and students may not access or disclose LDS until a DUA is executed between GWU and either: (1) a non-GWU recipient requesting access to LDS maintained by GWU; or (2) a non-GWU individual/entity, i.e., data source, offering to provide a GWU researcher with access to LDS maintained by the non-GWU individual/entity. In order to successfully execute a DUA the researcher must do the following:

1. Download the GWU Data Use Agreement Templated from http://www.gwumc.edu/research/forms.htm
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 Office of Health Research, Compliance, and Technology Transfer (OHRCTT), located in Ross Hall, Room 712, 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. A copy of the executed DUA should be maintained by the researcher in the study files.

Again, please keep in mind that 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 individual/entity, GWU must have successfully executed a DUA, as outlined above. Thus, the principal investigator of a study involving LDS should begin the DUA process at the same time the principal investigator initiates the IRB review process.