SECTION 3: USES & DISCLOSURES OF PHI

3.13 Limited Data Sets and Data Use Agreements

POLICY

1. Scope: The University of Florida (UF) is permitted by law to use or disclose a Limited Data Set (LDS) of protected health information (PHI) only for the purposes of research, public health, or health care operations.

2. HIPAA Data Use Agreements: Use of LDSs is strictly controlled and must be approved before a person or entity within UF enters into any agreements. After approval, a LDS may be used or disclosed only if a formal Data Use Agreement (DUA) is established with a recipient.
   a. Whenever a LDS is to be used or disclosed for research, public health, or health care operations purposes, UF requires the use of UF’s approved DUA template. The limited uses and disclosures of the PHI will be defined in detail by the purpose statements in the DUA.
   b. A LDS created by UF may include a link field to allow re-identification of individuals included in the data set. The link field may incorporate portions of direct identifiers; for example, initials plus a sequence number or an encrypted portion of a social security number.
   c. The LDS is not subject to disclosure accounting, but it is subject to the Minimum Necessary Rule (see 3.10 Minimum Necessary Rule).

3. Creating a HIPAA Limited Data Set:
   a. If an outside entity creates a LDS on UF’s behalf, using PHI received from UF, it must have first signed a Business Associate Agreement with UF.
   b. If a UF employee creates the LDS, that employee, will, for that purpose, be a member of the UF HSC workforce, and shall complete appropriate HIPAA training and follow applicable UF policies regarding privacy of PHI.

4. Non-HIPAA Data Use Agreements
   a. DUAs are a common “tool” often used for the transfer of data, where the data is nonpublic or is otherwise subject to some restrictions on its use.
   b. Many federal and state agencies publish DUA templates. For example, CMS, NIH, and AHCA have DUA templates. These documents are treated similar to any other legal document – signature authority restrictions and review by appropriate UF staff apply.

DEFINITIONS

1. Data Use Agreement: An agreement or contract that establishes the uses and disclosures of PHI by the recipient of a limited data set.

2. Limited Data Set: PHI that excludes all direct identifiers, as defined by the HIPAA Privacy Rule, except for dates and postal address information, other than town or city, State, and zip code, related to the patient or to relatives, employers, or household members of the patient.

REQUIREMENTS

1. Data Use Agreement Required: A Covered Entity (CE) may use or disclose a LDS only if a DUA is established stating that the recipient will only use or disclose the PHI for limited purposes.
2. **Contents:** A DUA between the CE and the Limited Data Set recipient must:
   a. Establish the permitted uses and disclosures of such information by the recipient. The DUA may not authorize the recipient to use or further disclose the information in a manner that would violate federal privacy regulations;
   b. Establish and define who is permitted to use or receive the LDS; and
   c. Provide that the LDS recipient will:
      i. Not use or further disclose the information other than as permitted by the agreement or as otherwise required by law;
      ii. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the agreement;
      iii. Report to the CE any use or disclosure of the information not provided for by its DUA of which it becomes aware;
      iv. Ensure that any agents, including subcontractors, to whom it provides the LDS agree to the same restrictions and conditions that apply to the recipient; and
      v. Not identify the information or contact the patients.

3. **Compliance:** The CE is required, if a pattern of activity or practice of a LDS recipient were discovered, that constituted a material breach or violation of the DUA, to take immediate reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:
   a. Discontinue disclosure of PHI to the recipient; and
   b. Report the problem to the Secretary of Health and Human Services.

**PROCEDURES**

The Privacy Office shall:
   c. Direct persons or entities requesting to use a LDS to contact the UF Division of Sponsored Programs, Office of Research and/or the UF HSC Office of Contracts and Related Services to apply for a DUA.
   d. Notify persons or entities considering a LDS to not attempt to compose or initiate a DUA without authorization and assistance.
   e. Give final approval for the terms of officially sanctioned Data Use Agreements.

**REFERENCES**

1. HIPAA Regulations: 45 CFR §164.502(b) General Rules: Minimum Necessary; §164.514(e) Limited Data Sets;

**EXHIBITS**

None