PRIVACY 14.0 **USE AND DISCLOSURE FOR RESEARCH AND REVIEWS PREPARATORY TO RESEARCH**

Scope: All workforce members (employees and non-employees), including employed medical staff, management, and others who have direct or indirect access to patient protected health information (PHI) created, held or maintained by any subsidiaries of Universal Health Services, Inc., including facilities and UHS of Delaware Inc. (collectively, "UHS"), including UHS covered entities ("Facilities").

Purpose: To assure that when research is conducted or reviews preparatory to research are performed involving the use or disclosure of PHI this is done in accordance with applicable HIPAA requirements.

Definitions:

Terms not defined in this Policy or the *HIPAA Terms and Definitions* maintained by the UHS Compliance Office will have the meaning as defined in any related State or Federal privacy law including the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA") and regulations promulgated thereunder by the U.S. Department of Health and Human Services ("HHS") at 45 CFR Part 160 and 164, Subparts A and E ("Privacy Regulations" or "Privacy Rule") and Subparts A and C ("Security Regulations" or "Security Rule"), the Health Information Technology for Economic and Clinical Health Act ("HITECH") privacy and security provisions of the American Recovery and Reinvestment Act (Stimulus Act) for Long Term Care, Public Law 111-5, the American Recovery and Reinvestment Act of 2009 ("ARRA"), Title XIII and related regulations.

Policy:

UHS is committed to complying with the legal requirements for the use and disclosure of PHI for research and reviews preparatory to research.

Procedure:

Facilities may use or disclose PHI for research under any of the following circumstances, provided these requirements are followed:

1. Disclosure Pursuant to Patient Authorization

Facilities may use and disclose PHI for research pursuant to an authorization, if the subject of the PHI has granted specific written permission through a valid authorization that complies with UHS Privacy 3.0 *Use and Disclosure Requiring Authorization* ("authorization").

2. Board Approval of a Waiver of the Authorization Requirement

For research use and disclosure of PHI, an institutional review board ("IRB") may approve a waiver or an alteration of the authorization requirement in whole or in part as follows:

- A complete waiver of the authorization requirement -- when the IRB determines that no authorization will be required for a Facility to use and disclose PHI for a particular research project.

- A partial waiver of the authorization requirement -- when an IRB determines that a covered entity does not need authorization for all PHI use and disclosure for research purposes, such as disclosing PHI for research recruitment purposes.

- An IRB may also approve a request that removes some PHI, but not all, or alters the requirements for an authorization (an "alteration").

The waiver or alteration of authorization must be documented by the Facility as follows:

1. Include a statement identifying the IRB that made the approval and list the date of approval.

2. Include a statement that the IRB has determined that the waiver or alteration of authorization, in whole or in part, satisfies all of the following criteria:

    a) The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements:

        - An adequate plan to protect health information identifiers from improper use and disclosure.

        - An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so).

        - Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

    b) The research could not practicably be conducted without the waiver or alteration.

c) The research could not practicably be conducted without access to and use of the PHI.

3. Include a brief description of the PHI for which use or access has been determined to be necessary.
4. Include a statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures of the IRB, which must follow the requirements of the Common Rule in the federal regulations.
5. The documentation must be signed by the IRB chair or other member designated by the chair.
6. The documentation must be retained for six (6) years from the date of its creation or the date it was last in effect, whichever is later.

3. Reviews Preparatory to Research

For activities involved in preparing for research, the Facility may use or disclose PHI to a researcher without an individual's authorization and without obtaining a waiver or alteration of authorization or a data use agreement. However, the Facility must obtain from the researcher representations that:

- The use or disclosure is requested solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research,
- The PHI will not be removed from the Facility in the course of the review, and
- The PHI for which use or access is requested is necessary for research purposes.

4. Identifying Research Participants

The Facility may use or disclose PHI to researchers to aid in research study recruitment. The Facility may allow a researcher, either within or outside the Facility, to identify to the Facility (but not contact) potential study participants. However, before permitting this activity, the Facility must receive proper representation, as described in subsection 3 above, from the researcher. No PHI may leave the Facility.

5. Contacting Research Participants

The Facility may use and disclose PHI to researchers to aid in study recruitment. UHS may allow a researcher to identify to the Facility, but not contact, potential study participants. A researcher may contact study participants without authorization from the individual only under the following circumstances:

- If the researcher is a workforce member, the researcher may contact the potential study participant, if authorized by the Facility as part of the Facility's health care operations, for the purposes of seeking authorization only.
- A treating provider may discuss treatment alternatives, which may include participating in a clinical trial, with the patient as part of the patient's treatment or the Facility's health care operations.
- The Facility may contract with a Business Associate—who may be a researcher—to assist in contacting individuals on behalf of the Facility to obtain the patient's authorizations.
- If the Facility obtains documentation that an IRB (either at the Facility or another facility) has partially waived the authorization requirement to disclose PHI to a researcher for recruitment purposes, the Facility may disclose to the researcher only that PHI necessary for the researcher to contact the individual.

6. Research on Decedents' PHI

To use or disclose PHI of the deceased for research, a Facility is not required to obtain Authorizations from the personal representative or next of kin, a waiver or an alteration of the authorization requirement, or a data use agreement. However, the Facility must obtain from the researcher who is seeking access to decedents' PHI the following:

- oral or written representations that the use and disclosure is sought solely for research on the PHI of decedents,
- oral or written representations that the PHI for which use or disclosure is sought is necessary for the research purposes, and
- documentation, at the request of the Facility, of the death of the individuals whose PHI is sought by the researchers.

7. De-identified Data

PHI that has been de-identified may be used for research in accordance with UHS Privacy 8.0 *De-Identification of Protected Health Information (PHI)*.

8. Limited Data Set

PHI may be used for research in accordance with UHS Privacy 7.0 *Limited Data Sets and Data Use Agreements.*

References:

45 C.F.R. §§ 164.508 - 164.512(i)

Related UHS Policies:

UHS Privacy 8.0 *De-Identification of Protected Health Information (PHI)*

UHS Privacy 7.0 *Limited Data Sets and Data Use Agreements*

UHS Privacy 3..0 *Use and Disclosure Requiring Authorization*

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