Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

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1. PURPOSE

1.1. The ***Health Insurance Portability and Accountability Act (HIPAA***) protects the ***privacy*** of individually identifiable health information (referred to as protected health information or PHI). HIPAA also governs how PHI is used and disclosed for ***research*** purposes. Compliance with HIPAA, as well as other laws and regulations, must be determined by the University of Georgia Institutional Review Board (UGA IRB) during review of ***human subjects research***. This document describes the ***policy*** and ***procedures*** that the UGA IRB uses to ensure HIPAA compliance.

2. DEFINITIONS

2.1. ***Authorization:*** under HIPAA, is an individual's signed permission that allows a covered entity to use or disclose the individual's PHI for the purposes and to the recipient(s) as stated in the Authorization.

2.2. ***Business Associate:*** in general, is a person or organization, other than a member of a covered entity's workforce, who acts on behalf of, or provides certain services to, a covered entity that involves the use or disclosure of PHI.

2.3. ***Covered Entity:*** the organization that has to comply with HIPAA. A covered entity is a health plan, a health care clearinghouse, or a health care provider transmitting health information.

2.4. ***Disclosure (under HIPAA):*** means the release of PHI outside of the covered entity holding the information.

2.5. ***Privacy Board:*** is a committee established to review requests for a waiver or alteration of the Authorization requirement for uses and disclosures of PHI in a particular research study.

2.6. ***Protected Health Information (PHI)***: is health information that has one or more of the 18 identifiers associated with the individual, and is held or transmitted by a Covered Entity (or its Business Associate), in any form or media (electronic, paper, or oral). PHI is information, including demographic information, that identifies, or could be used to identify, an individual and relates to:

2.6.1. the individual's past, present or future physical or mental health or condition,

2.6.2. the provision of health care to the individual, or

2.6.3. the past, present, or future payment for the provision of health care to the individual.

For a list of these 18 identifiers, see *HIPAA FAQs, Q1*.

3. POLICY

3.1. The UGA IRB serves as the Privacy Board for PHI that will be obtained from UGA's Covered Units and for compliance with HIPAA requirements for research. Specifically, it will:

3.1.1. review and approve HIPAA Written Authorizations when they are combined with an ***Informed Consent*** document or stand-alone document;

3.1.2. approve and document determinations regarding requests for a waiver or alteration of the Authorization requirements;

3.1.3. review and approve requests to use PHI for work preparatory to research and research involving decedents; and,

3.1.4. address HIPAA ***non-compliance*** allegations.

3.2. Since the provision of health care is not UGA's primary function, UGA is permitted to designate itself as a "hybrid entity," which allows it to apply HIPAA only to those parts of UGA that, if standing alone, would be a Covered Entity. For a list of UGA's Covered Units, see *HIPAA FAQs, Q5*.

3.3. In order to utilize PHI for research purposes, researchers must perform **one** of the following:

3.3.1. obtain written authorization from the individual who is participating as a research subject in accordance with HIPAA standards,

3.3.2. obtain a waiver or alteration of the authorization requirement from the IRB in accordance with HIPAA criteria,

3.3.3. obtain approval for use as "preparatory to research,"

3.3.4. use a limited data set, or

3.3.5. notify the IRB of such use as research on decedents' information.

3.4. Depending upon the policies of individual health care providers or source of PHI, it may be necessary to obtain approval of the authorization, its waiver, or alteration from another Privacy Board or IRB. The UGA IRB will also accept the review and approval of the other Privacy Board of a stand-alone Authorization Form.

3.5. When UGA IRB is the Reviewing IRB for a study and the PHI will be obtained from a covered entity that does not have a Privacy Board, the UGA IRB will serve as the Privacy Board for purposes of reviewing compliance with all the requirements of the HIPAA Privacy Rule, such as the HIPAA Authorization, or a waiver or alteration of the authorization.

4. **PROCEDURES: Researchers**

On the Study Scope page of the IRB submission, the researcher identifies if PHI will be involved and, congruent with the information requested for in the submission form, provides all HIPAA-related information and supporting document(s). Researchers can perform HIPAA-compliant research if they perform **one** of the following:

4.1. Obtain Subject Authorization

4.1.1. The most common and preferred method is for researchers to obtain a signed Authorization from the individual.

4.1.2. The researcher may submit a separate or stand-alone Authorization Form or include the required information in the study's Informed Consent Form.

4.1.3. The IRB highly recommends the use of the HIPAA Authorization Form Template that already contains the required core elements and statements.

4.1.4. The participant, or the participant's ***Legally Authorized Representative***, must sign and be given a signed copy of the Authorization.

4.1.5. Signed copies of the Authorization must be retained by the ***Principal Investigator*** for at least six (6) years from the date of its creation or the date when it was last in effect, whichever is later.

4.2. Obtain a Waiver or Alteration of Authorization Requirements

4.2.1. For certain types of research, it is impracticable for researchers to obtain a written HIPAA Authorization from prospective participants. The researcher can then request a waiver or alteration (i.e., removes some, but not all required elements) of the Authorization from the IRB if specific criteria have been met. See *HIPAA FAQs, Q6.*

4.3. Obtain Approval for Activities Preparatory to Research

4.3.1. A researcher can request IRB approval for use or disclosure of PHI without Authorization for activities preparatory to research (e.g., preparing a research protocol, developing a research hypothesis, or identifying prospective research participants who would meet the eligibility criteria for enrollment into a research study) if specific criteria have been met. See *HIPAA FAQs, Q7.*

4.3.2. Under this provision, covered entities may use and disclose PHI to researchers to identify, but not contact, potential study participants. Under certain circumstances, however, a researcher may contact potential study participants without an Authorization:

4.3.2.1. If the researcher is a workforce member of a covered entity, the researcher may contact the potential study participant, as part of the covered entity's health care operations, for the purposes of seeking Authorization. Alternatively, the covered entity may contract with a researcher as a business associate to assist in contacting individuals on behalf of the covered entity to obtain their Authorizations.

4.3.2.2. If the covered entity obtains documentation that an IRB has partially waived the Authorization requirement to disclose PHI to a researcher for recruitment purposes, the covered entity could disclose to the researcher that PHI necessary for the researcher to contact the individual.

4.4. Use a Limited Data Set

4.4.1. The use or disclosure of PHI without Authorization is also permitted if a researcher will only use a limited data set (LDS). An LDS may be disclosed without an Authorization if specific criteria have been met. To determine what qualifies as LDS, see *HIPAA FAQs, Q8*. For criteria to use or disclose an LDS without an Authorization, see *HIPAA FAQs, Q9.*

4.5. Use of PHI About Decedents

4.5.1. To use decedents' PHI for research purposes, a researcher must meet **all** of the following:

4.5.1.1. that the use or disclosure is solely for research involving the PHI of decedents (i.e., and not also the living relatives of decedents);

4.5.1.2. that the PHI is necessary for the research; and,

4.5.1.3. documentation (at the request of the covered entity holding the PHI) of the death of the individuals whose PHI is sought.

4.5.2. Although use of decedents' PHI does not meet the regulatory definition of human subject research, the privacy rights of deceased individuals are still protected under the Privacy Rule. Such research does not require IRB review, but may require approval by a Privacy

Board (or by the UGA IRB, if acting as the Privacy Board).

5. **PROCEDURES: Institutional Review Board**
   - 5.1. During the review of a new submission, ***continuing review***, or ***modification*** to an approved study, the IRB confirms if PHI will be involved. If PHI is involved, the IRB will review and make a determination if the use or disclosure requires an Authorization, a waiver or alteration of Authorization, or meets other exceptions for Authorization in accordance with this policy. See *WORKSHEET: HIPAA Authorization* and *CHECKLIST: HIPAA Waiver of Authorization*.
   - 5.2. The IRB will review combined consent/Authorization documents to ensure that the language meets the HIPAA requirements. The IRB will review, approve, and date-stamp stand-alone HIPAA documents, to ensure that these contain the required elements and are consistent with the rest of the submission.
   - 5.3. For ***non-committee reviews***, the Designated IRB Staff will offer the Investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence.
   - 5.4. For committee reviews, the Designated IRB Staff will offer the Investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence that describes missing information or required modifications.
   - 5.5. The Designated IRB Staff will document determinations that the requirements of this policy have been met in the review history and/or meeting minutes by recording the motion to approve.

6. **MATERIALS**
   - 6.1. WORKSHEET: HIPAA Authorization
   - 6.2. CHECKLIST: HIPAA Waiver of Authorization
   - 6.3. HIPAA Authorization Template
   - 6.4. HIPAA FAQs

7. **REFERENCES**
   - 7.1. Office for Civil Rights Health Information Privacy, http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/
   - 7.2. NIH Institutional Review Boards and the HIPAA Privacy Rule, https://privacyruleandresearch.nih.gov/pdf/IRB_Factsheet.pdf

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