Policy on HIPAA Compliant Research
HIPAA Policy: Privacy 10

Summary: Outlines the rules for using protected health information from HIPAA covered entities in research.

Affected Individuals: Researchers intending to use protected health information, members of the UM Institutional Review Board, staff at HIPAA covered entities, patients at HIPAA covered entities

1.0 PURPOSE

The purpose of this policy is to guide University of Mississippi (UM) employees and students, who are involved with research, in obtaining an authorization for the use and disclosure of protected health information and/or a waiver in whole or in part of such authorization as required through the Health Insurance Portability and Accountability Act (HIPAA).

2.0 SCOPE

The UM Policy on HIPAA Compliant Research applies to any UM employee or student involved in obtaining an authorization or waiver for research purposes.

3.0 STANDARDS

Research conducted pursuant to an authorization from the participant – It is UM policy that investigators of research studies involving human participants obtain a HIPAA compliant authorization from the participant upon enrollment in the study. The authorization may be combined with other types of written permissions, including the informed consent document for the study, but all core elements and statements, as listed in section 3.1 below must be included.

Research conducted pursuant to a waiver in whole or in part of the authorization requirement – It is UM policy to allow investigators to seek a waiver, from the UM Institutional Review Board (IRB), in whole or in part of the authorization requirement. The primary investigators seeking such a waiver should follow the waiver request procedures as listed in section 3.2.

Research using a limited data set – It is UM policy that in some cases, researchers seeking PHI from UM can perform the research without an authorization from the participant or a HIPAA waiver from the IRB, if he/she plans to use a limited data set. The researcher may simply request PHI from the covered entity with only limited identifying information on it. If the researcher wishes to do this, then he/she must enter into a data use agreement with UM. A data use agreement assures appropriate use of the PHI by the researcher and that the researcher will not identify the information or contact the individuals. See section 3.3 below for more information on what identifiers must be removed before the PHI will be considered a limited data set.

3.1 Authorizations – Research authorizations should be signed by each participant that enrolls in a study, unless the IRB grants in whole or in part a waiver to the authorization requirement. The authorization should provide the researcher the permission needed to use and disclose PHI for the research project. The authorization must contain the following core elements and statements:

- A description of the information to be used and/or disclosed that identifies the information in a specific and meaningful fashion.

  NOTE: Psychotherapy (psychiatric) information can be disclosed only if such information is specifically requested in the authorization. For more detailed instructions on how to handle the release of psychotherapy notes, see section 3.6 of Access, Uses & Disclosures of PHI Policy;
- The name or other specific identification of the person(s), or class of persons, authorized to make requested disclosure;
- The name or other specific identification of the person(s), or class of persons, to whom UM may make the requested disclosure – this should include all person(s) or entities to whom UM may disclose the PHI created through the research project. For example: an authorization form for a multi-center study should list all entities who are participating in the study and may therefore have access to the PHI during the research study;
- A description of each purpose of the use or disclosure;
- An expiration date or a description of an event upon which the authorization will expire must be on the authorization; if applicable. It is allowable for the authorization to simply state "the end of the study". If the primary investigator decides that the research project will not have an expiration date or event, then the authorization must state this fact. This allows the researcher to use the information after the research study has ended;
- Signature of the individual and date; and
- If the authorization is signed by a legal representative (personal representative), or guardian of the individual, a description of such representative's or guardian's authority to act for the individual must be provided or noted.

Required Statements:

- A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization. Although a patient can revoke his/her authorization, the researcher can still use and disclose that information collected prior to receiving the revocation, to the extent necessary to preserve the integrity of the research study.
- A statement that treatment, payment, and enrollment will be conditioned upon obtaining the signature of the participant and that refusal to sign the consent will prohibit the participant from participating in the study; and

- A statement that information used or disclosed pursuant to the authorization may be subject to re-disclosure by the recipient and may no longer be protected by this rule.

The authorization may be a separate document or it may be combined with any other type of written permission for the same research study, such as the informed consent or another authorization for the same research study. When combined it must be clear to the participant the component of the research for which authorization is required (conditioned) in order to participate, versus the components of the research that are optional (unconditioned). It must be clear to the participant that participation in the unconditioned component is optional.

An authorization for research involving psychotherapy notes can only be combined with other authorizations to use or disclose psychotherapy notes.

Authorizations including a statement for future research must adequately describe such purposes such that it would be reasonable for the participant to expect that his/her PHI could be used or disclosed for future research.

As is currently done with the informed consent, the authorization must be included in the material submitted to the IRB for approval before it can be used. Where authorization is required, no research should be conducted prior to obtaining authorization from the participant.

3.2 Waivers – It is the policy of UM to allow researchers to seek a waiver in whole or in part of the authorization requirement. To qualify for such a waiver, the researcher must obtain approval from the IRB. The documentation must show the three defined waiver criteria, as listed in bullets below, have been sufficiently met by the researcher. The researcher must describe in as specific detail as possible how he/she plans to meet each of the waiver criteria below. If the IRB agrees that the researcher has met the criteria, the IRB must document as such.
Waiver criteria:

- The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on at least the presence of the following elements:
    - An adequate plan to protect the identifiers from improper use and disclosure;
    - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law;
    - Adequate written assurances that the PHI will not be reused or disclosed to 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 PHI would be permitted;
- The research could not practicably be conducted without the waiver or alteration; and

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

3.3 Research using a limited data set – To be considered a limited data set, the following information must be removed from the PHI, before it is disclosed to a researcher:

Names	Account numbers
Postal address information, other than town or city, state and zip code	Certificate/license numbers
Telephone numbers	Vehicle identifiers and serial numbers, including license plate numbers
Fax numbers	Device identifiers and serial numbers
Electronic mail address	Web universal resource locators
Social security numbers	Internet protocol address numbers
Medical record numbers	Biometric identifiers, including finger and voice prints
Health plan beneficiary members	Full face photographic images and any comparable images

3.4 Disclosures of PHI to a researcher for purposes of developing a research protocol or to be used by the researcher for research that will be conducted on only decedents' information – Certain representations, as described in bullets below, must be received from the researcher, before the disclosure can occur.
These representations should be made by completing a data use agreement and submitting the information to the area from which the information is being sought.

3.5 Creation of Research Databases – Databases created specifically for research purposes can be created with an authorization from each patient included in the database, pursuant to a waiver in whole or in part to the authorization requirement.

- Databases compiled pursuant to patient authorization:
  - Authorization is for use and disclosure of PHI to create a database or to manipulate PHI to create a database or to bank tissue for future research;
  - Authorization is not for use or disclosure for a specific protocol.
- Databases created under a waiver of authorization from the IRB:
  - Waiver can only be granted if the researcher represents to the IRB that the database is solely for the manipulation or storage of the PHI, not for use in a specific protocol.

4.0 CONTACT INFORMATION

For questions about the UM Policy on HIPAA Compliant Research or for more information, call the Institutional Review Board at 662-915-7482 or the Office of General Counsel at 662-915-7014.