SOP: Evaluating a Research Study for HIPAA Compliance			
NUMBER	DATE	APPROVED BY	PAGE
HRP-056b	5/6/2020	Julie Moore	1 of 4

PURPOSE

To provide guidance to investigators and health care providers on evaluating the HIPAA implications of a proposed use/disclosure of health information for research.

REVISIONS FROM PREVIOUS VERSION

1. Effective date: 9/18/2003
2. Revision #1 date: 6/12/2014
3. Revision #2 date: 5/6/2020

SCOPE

This procedure applies to investigators who seek to comply with the requirements of HIPAA when using and disclosing Protected Health Information (PHI) for research.

RESPONSIBILITIES

Investigators who intend to use health information in their research studies should apply the criteria outlined herein to evaluate whether the health information is PHI and if so, which process for HIPAA compliance (e.g. authorization, waiver, partial waiver, review preparatory to research, etc.) will best serve the needs of the Investigator while ensuring that the Investigator's obligations under HIPAA are met.

PROCEDURES

The Investigator should determine whether health information to be used in a proposed research study is PHI.

1. Does the proposed research study use or reference individually identifiable health information about human subjects (living or deceased) or health information that can be linked in any manner to the identity of the subject?

    a. If yes, proceed to Question 2.

    b. If no, then the use is not subject to the USF standard operating procedures governing HIPAA compliance.

2. Is the individually identifiable health information created, or maintained by, or received from a hospital or health care provider that engages in electronic billing transactions (physician; community clinic; social services agency; practitioner in psychology, psychotherapy, or social work), health insurer, Health Maintenance Organization (HMO), health plan, and/or health care clearinghouse?

    a. If yes, proceed to Question 3.

    b. If no, then the use is not subject to the USF standard operating procedures governing HIPAA compliance.

3. Is the PHI being created or maintained by or received from a USF covered component?

    a. If yes, the use is subject to the USF standard operating procedures governing HIPAA compliance. Proceed to Question 4.

    b. If no, is the PHI being created or maintained by or received from a USF affiliate (Moffitt, TGH, JAHVA, Empath Health, Bayfront, or TeamHealth)?

        i. If yes, the use is subject to the USF standard operating procedures governing HIPAA compliance; however, authorizations obtained for use of this information in research must also be approved by the privacy or compliance officer for the USF affiliate source.

        ii. If no, then the individually identifiable health information used in the study <u>is PHI</u> but is not the property of the USF covered entity or a USF affiliate covered entity. As a recipient of PHI, an Investigator may have certain responsibilities under HIPAA which are not governed by these USF standard operating procedures. In order to ensure compliance with HIPAA, investigators need to contact the privacy or compliance officer for the entity disclosing the information to determine whether that entity has any procedures or requirements for recipients of PHI. Failure to comply with the HIPAA procedures or requirements of the disclosing entity can result in the termination of your relationship with that entity as a recipient of their PHI.

The Investigator should determine what, if any, exceptions apply to the fundamental requirement under HIPAA that subjects' authorization must be obtained prior to use of their PHI for research purposes. If the research involves psychotherapy notes, refer to HRP-056e - SOP - Obtaining Authorizations to Use PHI on the HIPAA Research Compliance Program website.

1. Can the research be conducted with de-identified data? For more information about de-identifying data sets, see HHS's Guidance Regarding Methods for De-Identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

    a. If yes, refer to HRP-056i - SOP - Use and Disclosure of De-Identified Data for Research Purposes on the HIPAA Research Compliance Program website.

    b. If no, can the research be conducted with the only identifying information linking the subject's identity to the health information being one or all of the following: admission and discharge dates; birth dates; county, city, or state of residency; or zip codes?

        i. If yes, the PHI would constitute a limited data set HRP-056c - SOP - Limited Data Sets is available on the HIPAA Research Compliance Program website.

2. Is the proposed use of PHI necessary for the purpose of preparing a research protocol or for a similar purpose associated with preparatory activities for research (e.g. reviewing the clinical and demographic information of a population to determine if it supports the development of a research question)?

    a. If yes, refer to HRP-056f - SOP - Preparatory to Research on the HIPAA Research Compliance Program website.

3. Is the review or use of the PHI primarily to recruit research subjects from a population that does not consist of the Investigator's own patients?

    a. If yes, refer to HRP-056g - SOP - Study Subject Recruitment on the HIPAA Research Compliance Program website.

4. Does the research involve PHI related only to deceased subjects where the focus of research does not involve any living relative of the decedent?

    a. If yes, refer to HRP-056h - SOP - Use and Disclosure of Decedents' PHI for Research Purposes on the HIPAA Research Compliance Program website.

5. Is use of the PHI necessary to the research study, yet will it be difficult or impossible to obtain the subjects' authorizations?

    a. If yes, will the use or disclosure of the subject's PHI involve greater than minimal risk to the privacy of the subject? [NOTE: The research study must also be a minimal risk study where the IRB has agreed to waive the requirement of informed consent.]

        i. If yes, refer to HRP-056e - SOP - Obtaining Authorizations to Use PHI on the HIPAA Research Compliance Program website.

        ii. If no, you must apply to the USF IRB/Privacy Board to obtain a waiver, partial waiver, or alteration of authorization, whichever is appropriate. Refer to HRP-056d - SOP - Obtaining a Waiver, Partial Waiver, or Alteration of Authorization to Use PHI.

Researchers who have questions regarding the process of evaluating a research study for HIPAA compliance should contact the USF Research Integrity & Compliance HIPAA Research Privacy Officer at hipaa-research@usf.edu.

REFERENCES

45 CFR 164.508

45 CFR 164.512(i)