SOP: Evaluating a Research Study for HIPAA Compliance			
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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 r

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.

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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.]

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