To define the procedures necessary to obtain a waiver, partial waiver, or alteration of individual research authorizations to use or disclose Protected Health Information (PHI) in the research context.

REVISIONS FROM PREVIOUS VERSION

1. Effective date: 11/9/2006
2. Revision #1 date: 6/12/2014
3. Revision #2 date: 5/6/2020

SCOPE

This procedure applies to:

1. Investigators of a covered entity or acting on behalf of the covered entity:

    a. Who intend to seek a waiver or partial waiver of the requirement to obtain individual authorization for the use of PHI in research activity; or

    b. Who have the need to seek an alteration of the authorization granted by the individual who is the subject of such PHI.

2. Health care providers who are included in the USF covered component (the College of Medicine (COM), Physical Therapy School, College of Pharmacy, University Medical Services Association (UMSA) / Medical Services Support Corporation (MSSC), USF Student Health Services, the Johnnie B. Byrd, Sr. Alzheimer's Center and Research Institute, the USF College of Behavioral and Community Sciences Department of Communication Sciences and Disorders, USF St. Petersburg Family Study Center, Infant Family Center, and certain administrative units to the extent those units engage in covered functions involving use/disclosure of PHI):

    a. W

Prior to using PHI in the research context, USF investigators and/or health care providers must ensure that, in the absence of individual authorization, the USF IRB (which serves as the USF Privacy Board) has approved a waiver, partial waiver, or alteration of authorization.

PROCEDURES

For qualifying research studies, investigators may submit an application for a waiver or alteration of the authorization requirement to the USF IRB/ Privacy Board. For more information on determining whether a research study qualifies for a waiver or partial waiver of the authorization requirement, refer to HRP-056b - SOP - Evaluating a Research Study for HIPAA Compliance on the HIPAA Research Compliance Program website.

The Privacy Board is a Board established pursuant to the Privacy Rule to review and act upon waivers, partial waivers, and alterations of subject authorizations upon reviewing the effect of a research protocol on the privacy rights and related interests of individual research subjects.

As an alternate member of the IRB, the HIPAA Research Privacy Officer or their designee reviews and approves the requests for HIPAA waivers, partial HIPAA waivers, and alterations of authorizations for those studies using HRP-441 - CHECKLIST - HIPAA Waiver of Alteration of Authorization. The IRB Chair, Vice Chair, or fully convened IRB also reviews the completed HRP-441 - CHECKLIST - HIPAA Waiver of Alteration of Authorization and issued waiver, partial waiver, or alteration.

Investigators must obtain documentation that a waiver, partial waiver, or alteration of authorization for release of PHI has been approved by the USF IRB/Privacy Board.

The documentation required of the USF IRB/Privacy Board when granting approval of a waiver, partial waiver, or alteration of authorization for the use/disclosure of PHI must include:

1. A statement identifying the USF IRB/Privacy Board that approved the action, and the date of such approval;

2. A statement that the USF IRB/Privacy Board has determined that the waiver, partial waiver, or alteration of authorization satisfies all of the following criteria:

    a. The use or disclosure of an individual's PHI involves no more than minimal risk to the privacy of individuals, based on at least the following elements:

        - An adequate plan to protect an individual's identifying information from improper use or disclosure;

- An adequate plan to destroy an individual's identifying information at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

- Adequate written assurance that the particular PHI will not be reused or disclosed to (or 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 particular PHI would be specifically permitted under the Privacy Rule.

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

c. The research could not practicably be conducted wThe ry pr [(under)0.P Tcrot pra 0 Tdy 3Gf .Htt22