PURPOSE

To define the procedures necessary to recruit study subjects in compliance with the HIPAA privacy regulations.

REVISIONS FROM PREVIOUS VERSION

1. Effective date: 10/31/2003
2. Revision #1 date: 6/12/2014
3. Revision #2 date: 5/6/2020

SCOPE

This procedure applies to all investigators who recruit subjects and to health care providers who are included in the covered components of the University of South Florida (USF) covered entity who use or disclose Protected Health Information (PHI) for recruitment purposes.

RESPONSIBILITIES

Investigators may recruit study subjects only in accordance with the procedures stated herein. USF health care providers must adhere to the procedures stated herein prior to disclosing PHI for recruitment purposes.

PROCEDURES

USF Health Care Providers with a Direct Treatment Relationship - USF health care providers and their staff who have a direct treatment relationship with a potential study subject may review PHI of that potential study subject for research protocols in which the USF health care provider is participating, provided that the USF health care provider and his/her staff understand that:

1. The sole purpose of the review is to identify potential study subjects;
2. The information reviewed must be limited to that necessary to identify potential study subjects; and
3. No patient records or other PHI can be copied or removed from the premises of the USF covered component.

USF health care providers and their staff who have a direct treatment relationship with the potential study subject may contact the potential study subject as part of the USF covered entity's healthcare operations for recruitment purposes, or may discuss a clinical research study opportunity with a patient as a treatment alternative as part of the patient's treatment and as part of the USF covered entity's healthcare operations without having to obtain a HIPAA authorization or a waiver of HIPAA authorization. USF health care providers and their staff may *not* disclose PHI (including a patient's identity) to anyone else for purposes of recruitment in a research study without obtaining authorization or a waiver of authorization.

USF Investigators who are Part of the Workforce but are Non-Treating Health Care Providers or Staff - If the Investigator is part of the workforce of any of USF's covered components but is a non-treating health care provider or staff, the Investigator may use PHI obtained from the USF covered entity via a preparatory to research authorization for preparatory to research activities and recruitment purposes, **so long as**:

1. The sole purpose of the review of PHI obtained from the USF covered entity is to identify potential study subjects;
2. The information reviewed is necessary to identify potential study subjects;
3. No patient records or other PHI will be copied or removed from the premises of the USF covered component; and
4. Potential study subjects are not contacted until the USF IRB has approved the related study protocol.

A USF Investigator who is part of the workforce of a USF covered component but is a non-treating health care provider or staff may also obtain PHI from the USF covered entity for recruitment purposes by applying for and receiving a partial waiver of HIPAA authorization from the USF IRB/Privacy Board. If the IRB has partially waived the HIPAA authorization, the USF Investigator who is part of the workforce of the USF covered component but is a non-treating health care provider or staff may contact the potential study participant through a USF health care provider who has a direct treatment relationship with that potential study subject or upon specific authorization from the IRB. USF investigators who disclose PHI obtained pursuant to this SOP must maintain a record of all PHI disclosed pursuant to a partial waiver, such record to include the dates on which the PHI was disclosed, the name of the entity or person who received the PHI, and if known, the address of such entity or person, a description of the type of information that was disclosed (e.g. date of birth, medical record number, telephone number, etc.), and a brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure. This information should be kept on the "Accounting Log of Disclosures of PHI," a template of which can be found on the HIPAA Research Compliance Program website.

Investigators who are not part of a USF Covered Component – An Investigator who is not part of the workforce of a USF covered component may obtain PHI from the USF covered entity after applying to and receiving from the USF IRB/Privacy Board a partial waiver of HIPAA authorization to obtain PHI for preparatory to research activities or for recruitment purposes, and may not begin any preparatory to research activities or recruitment until the Privacy Board/IRB has granted that partial waiver *and* the IRB has approved the recruitment method. An Investigator who is not part of the workforce of the USF covered entity may contact the potential study subject through the USF health care provider who has a direct treatment relationship with that potential subject after receiving a partial waiver or upon specific authorization from the IRB. USF investigators who use PHI obtained pursuant to this paragraph must maintain a record of all PHI disclosed to them pursuant to a partial waiver, such record to include the dates on which

the PHI was disclosed, the name of the entity or person who received the PHI, and if known, the address of such entity or person, a description of the type of information that was disclosed (e.g. date of birth, medical record number, telephone number, etc.), and a brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure.

This information should be kept on the “Accounting Log of Disclosures of PHI,” a template of which can be found on the HIPAA Research Compliance Program website.

REFERENCES

45 CFR 164.508

45 CFR 164.512

Template: Accounting Log of Disclosures of PHI