PURPOSE

To define procedures necessary to obtain authorizations to use and 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 all investigators who generate, collect, use, or disclose PHI in research conducted at the University of South Florida (USF), or investigators utilizing the USF Institutional Review Board (IRB) as their IRB of record, and who are required to seek subject authorization.

RESPONSIBILITIES

It is the Investigator's responsibility to obtain authorization from human subjects enrolled in research studies prior to using or disclosing their PHI in research.

PROCEDURES

The Investigator must obtain written authorizations from human subjects enrolled in research studies that comply with HIPAA Privacy Rule Regulations. Template language for HIPAA authorizations can be found in the IRB informed consent templates (HRP-502x - TEMPLATE CONSENTS). Investigators from USF affiliate institutions who utilize the USF IRB can employ their institution's HIPAA authorization language and include the USF IRB as an entity authorized to use and disclose PHI. Alternatively, affiliate investigators can utilize the template language provided by USF.

The USF IRB requires the HIPAA authorization language to be compounded with the informed consent. Some USF affiliate institutions may have other requirements. The authorization must include:

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

2. The name of the covered entity, or class of entities or persons, authorized to make the requested use or disclosure;

3. The name of other specific identification of the person(s) or class of persons to whom the covered entity may make the requested use or disclosure;

4. Description of each purpose of the requested use or disclosure (e.g., a brief description of the clinical research study).

5. An expiration date. However, in authorizations granted for research purposes, statements such as “end of the research study,” “none,” or similar language is sufficient; signature of the individual or the individual’s legally authorized representative (LAR) with a description of the LAR’s authority to act on behalf of the individual;

6. Date of granting the authorization;

7. A statement in which the individual acknowledges the right to revoke the authorization in writing, and an explanation of the exceptions to the right to revoke, and a description of how the individual may revoke the authorization;

8. A statement in which the individual acknowledges that information used or disclosed to any entity other than a health plan or health care provider may no longer be protected by the Privacy Regulations; and

9. Unless the authorization is requested for clinical research that includes the delivery of health care, a statement that the covered entity will not condition treatment or payment on the individual’s provision of authorization for the requested use or disclosure.

In the event a need arises to amend authorizations already obtained, the Investigator must submit the amended authorization to the USF IRB via a modification application.

An individual may revoke his/her authorization at any time, provided that the revocation is in writing, **unless** the covered entity/Investigator has taken action in reliance upon the authorization and the use/disclosure as necessary to preserve the integrity of the research study. Under the reliance exception, the Investigator is not permitted to use and disclose PHI that was not already gathered at the time the individual revoked his/her authorization.

Instances where the covered entity/Investigator will be permitted to continue to use/disclose the PHI notwithstanding revocation by an individual are as follows:

1. To account for the individual’s withdrawal from the research study;

2. As necessary to incorporate the PHI as part of a marketing application submitted to the FDA; and/or

3. To conduct investigations of scientific misconduct or to report adverse events.

REFERENCES

45 CFR 164. 508

HRP-502x - TEMPLATE CONSENTS