

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
HIPAA AUTHORIZATION FOR THE USE OF
PROTECTED HEALTH INFORMATION IN RESEARCH**

I. PURPOSE

To provide guidance to investigators for securing subject authorization for use of protected health information (PHI) in human research studies.

II. SCOPE

This SOP applies to IRB members and investigators.

Personnel Responsible:

Institutional Review Board staff, members, investigators.

III. BACKGROUND

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that persons provide authorization for the use of PHI for specific purposes other than treatment, payment or health care operations. Specific authorization is generally required for the use and disclosure of PHI in research studies. The IRB requires incorporation of HIPAA authorization language in the body of the informed consent document.

The basic elements of information that must be provided in writing to prospective subjects in securing their authorization for the research use of their PHI are specified in the privacy regulations. They include the following elements:

1. a description of the information to be used or disclosed that identifies the information “in a specific and meaningful fashion”;
2. the name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;
3. the name or other specific identification of the person(s), or class of persons, to whom the covered entity is permitted to make the requested use or disclosure;
4. a description of each purpose for the requested use or disclosure;
5. an expiration date or an expiration event that relates to the purpose of the use or disclosure; the **expiration date may be specified as “end of the research study”, or as “none” in the event that the PHI will be used for an indefinite period as part of a research database or repository;**

6. a description of the individual's right to revoke the authorization in writing, including limitations on this right, and an explanation of how the individual may revoke the authorization; in explaining limitations on the right to revoke the authorization, investigators must indicate that the Privacy Rule permits the continued research use and disclosure of PHI obtained from the subject prior to the time when the authorization is revoked;
7. an explanation that the investigator may condition research participation on the provision of the authorization and that subjects who revoke the authorization may be withdrawn from the study;
8. the potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer protected by the Privacy Rule; and
9. when the research includes evaluation of a treatment, a statement that the **subject's access to PHI will be temporarily suspended as long as the research is in progress, but will be reinstated upon completion of the research; this ground for the denial of access does not apply to research in which treatment is not evaluated.**

Several other regulatory requirements for authorizations must also be noted. First, the authorization must be signed and dated by the subject or the **subject's** legally authorized representative. Second, if the signature is secured from the **subject's** legally authorized representative, then a description of the **representative's authority to act on the individual's behalf must also be provided.** This latter provision requires that, for studies in which personal representatives may be providing consent or permission for some subjects, a separate line must be inserted in the signature section of the research consent form for describing the relationship of the representative to the subject. Third, when the authorization is included in the consent form for the research study, a copy of the consent form **must be provided to the subject or the subject's** legally authorized representative. Finally, signed consent forms including the authorization must be retained for at least six years.

In Accordance With:

45 CFR 160, 164; <http://www.hhs.gov/ocr/hipaa>

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. PROCEDURES

1. When a study is submitted for full board or expedited review, the confidentiality section of the project descriptors must specify the plan for securing the HIPAA authorization of prospective subjects as part of the informed consent process.
2. The following HIPAA authorization language must be inserted at the appropriate location in the confidentiality section of the consent document. The material in block form is the required authorization language. The *italicized* material in parentheses provides directions for including material that may or may not be relevant for particular studies. The italicized material should not be retained in the authorization language as it appears in the consent form.

“Under federal privacy regulations, you have the right to determine who has access to your personal health information (called “protected health information” or PHI). PHI collected in this study may include your medical history, the results of physical exams, lab tests, x-ray exams, and other diagnostic and treatment procedures. Basic information about you such as age, race, where you live or other similar information may be collected and is considered PHI.

By signing this consent form, you are authorizing the researchers at the *(insert the name of the institution)* to have access to your PHI collected in this study *(if the study will use PHI in the possession of another covered entity, add)* and to receive your PHI from *(either)* your physician *(and/or)* facilities where you have received health care. *(If any of the following individuals or entities will also be reviewing the PHI collected or received for the study, then add the following sentence.)* In addition, your PHI may be shared with other persons involved in the conduct or oversight of this research, including *(if the study is multi-institutional, add)* researchers at *(name of the institutions)*; *(if a cooperative group study, add)* the *(name of the cooperative group)*; *(if the research involves an FDA-regulated drug, device or biologic, add)* the Food and Drug Administration (FDA); and *(if claims for some of the procedures performed during the study will be submitted to third party payers, add)* your medical insurance carrier. *(If the research is sponsored, add)* Your PHI may also be shared with *(name of sponsor)*, which sponsors and provides funds for this research; *(name of CRO, if applicable)* which has been hired by the sponsor to coordinate the study; and a Data and Safety Monitoring Committee *(if applicable)*. *(If the previous sentence was used, add the following sentence as well.)* However, these latter organizations may not have the same obligations to protect your PHI.

The Institutional Review Board (IRB) at the University of Tennessee Health Science Center may review your PHI as part of its responsibility to

protect the rights and welfare of research subjects. Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies, or for other research for which the use and disclosure of your PHI has been approved by the IRB. Your PHI will be used only for the research purposes described in the introduction of this consent form.

Your PHI will be used (*either*) until the study is completed (*or if the research is FDA regulated*) for as long as the sponsor reports study data to the FDA (*or if the research is without a foreseeable end-point, such as a repository or a registry*) indefinitely.

You may cancel this authorization in writing at any time by contacting the principal investigator listed on the first page of the consent form. If you cancel the authorization, continued use of your PHI is permitted if it was obtained before the cancellation and its use is necessary in completing the research. However, PHI collected after your cancellation may not be used in the study. If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study.

Finally, the federal regulations allow you to obtain access to your PHI collected or used in this study. (*If the research study includes treatment of subjects, add the following sentences.*) However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. When the study is completed, your right of access **to this information will be reinstated.**"

3. In general, the language in the HIPAA authorization template should be precisely followed. Minor changes to the template, inserted at the request of study sponsors, are permissible with the review and approval of the IRB and the legal department of the institution in which the research is conducted. Use of sponsor recommended HIPAA authorization templates in place of or in addition to the IRB template is not permitted.
4. The HIPAA authorization template must be placed in the confidentiality section of all consent forms unless the investigator has received IRB approval to use PHI in research without the authorization of the subject.
5. **Investigators must maintain documentation that subjects have provided a HIPAA authorization for the research use of their PHI for at least 6 years. If the sponsor, governmental regulatory agency, IRB or institution requires that research documents/materials be retained for longer than 6 years, then the longer period of retention prevails.**

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