UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE 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 investigator

Personnel Responsible:

University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) 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. UTGSM 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 personal representative. Second, if the signature is secured from the subject's personal 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 personal representative. Finally, signed consent forms including the authorization must be retained for at least six years.

General information for investigators on the requirements of the HIPAA regulations are available in the UTGSM IRB guidance document entitled, "HIPAA Privacy Regulations and Medical Research: UTGSM IRB Guidance and Procedures".

In Accordance With:

45 CFR 160, 164: 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.

   "All reasonable efforts will be made to keep your protected health information (PHI) private and confidential. PHI is health information that is, or has been, collected or maintained and can be linked back to you. Using or sharing ("disclosure") such information must follow federal privacy guidelines. By signing the consent document for this study, you are giving permission ("authorization") for the uses and disclosures of your personal health information. A decision to participate in this research means that you agree to let the research team use and share your PHI as described below.

   As part of the study, Dr. *[PI]* and *[HIS/HER]* study team may share the results of your study and/or non-study related *[INCLUDE STUDY SPECIFIC INFORMATION: E.G. LABORATORY TESTS, X-RAYS, ETC.*], as well as portions of your medical record, with the groups named below:

   - Representatives from the Federal Government Office for Human Research Protections
   - The University of Tennessee Graduate School of Medicine Institutional Review Board
   - *[ADD OTHERS AS APROPRIATE, E.G., FOOD AND DRUG ADMINISTRATION, NATIONAL INSTITUTES OF HEALTH, REPRESENTATIVES OF {SPONSOR NAME}, CROs, IBC, SRC, INSURANCE COMPANIES FOR BILLING PURPOSES, ETC]*.

   Federal privacy regulations may not apply to these groups; however, they have their own policies and guidelines to assure that all reasonable efforts will be made to keep your personal health information private and confidential. [OPTIONAL: The sponsor may give your personal health information, not containing your name, to others or use it for research purposes other than those listed in this form. In handling your personal health information, the sponsor, Dr. _____ and associated staff wi

keep your information in strict confidence, and shall comply with any and all applicable laws regarding the confidentiality of such information.]

The study results will be retained in your research record for at least six years after the study is completed. At that time, the research information not already in your medical record will be *[INFORM PARTICIPANT WHAT WILL HAPPEN TO THE RECORD AT THAT TIME]*. Any research information entered into your medical record will be kept indefinitely.

Unless otherwise indicated, this permission to use or share your PHI does not have an expiration date. If you decide to withdraw your permission, we ask that you contact Dr. [PI] in writing and let *[HIM/HER]* know that you are withdrawing your permission. *[HIS/HER]* mailing address *is [ADDRESS]*. At that time, we will stop further collection of any information about you. However, the health information collected prior to this withdrawal may continue to be used for the purposes of reporting and research quality.

[OPTIONAL: You have the right to see and copy your personal health information related to the research study for as long as the study doctor or research institution holds this information. However, to ensure the scientific quality of the research study, you will not be able to review some of your research information until after the research study has been completed.]

Your treatment, payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to participate. You will receive a copy of this form after it is signed."

3. In general, the language in the HIPAA authorization template should be precisely followed. Minor additions to the template, inserted at the request of study sponsors, are permissible with the review and approval of the IRB. Use of sponsor recommended HIPAA authorization templates in place of the UTGSM IRB template is not permitted. Use of sponsor recommended HIPAA authorization templates, in addition to the UTGSM IRB template, is also 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. (See IRB SOP #10).

5. Investigators must maintain documentation that subjects have provide a HIPAA authorization for the research use of their PHI for at least 6 years.