UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
INFORMED CONSENT

I. PURPOSE

This document outlines the procedures for University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) concerning informed consent and its documentation.

II. SCOPE

This SOP applies to all IRB administrative staff, board members, and investigators.

Personnel Responsible:

UTGSM IRB members and administrative Staff

III. BACKGROUND

The fundamental purpose of IRB review and approval of the consent process and document is to protect the rights and welfare of human subjects. Investigators may not generally involve a human subject in clinical research without the legally effective informed consent of the subject or the subject's legally authorized representative. The informed consent disclosure must be presented in language understandable to the subject, with all required elements of information as specified in the regulations and local IRB policy. Investigators may seek consent only under circumstances that provide the subject sufficient opportunity to consider whether to participate in the study and that minimize the possibility of coercion or undue influence. In addition, no consent disclosure may contain exculpatory language through which the subject or the subject's legally authorized representative waives or appears to waive any of their legal rights, or releases or appears to release the investigator, sponsor, institution or its agents from liability for negligence. The informed consent document is the written summary of the information provided to the subject in the informed consent interview, and the subject's signature on the consent form documents the prior informed and voluntary agreement of the subject to participate in the study.

UTGSM IRB is responsible for ensuring that procedures are in place to appropriately provide the subject or legally authorized representative with the elements of information needed by a reasonable person to make a decision about research participation. UTGSM IRB also has the authority to audit (SOP IRB #030) investigators and / or observe the informed consent process to assure that consent is

obtained and documented, and that records are maintained, in accordance with this standard operating procedure.

This policy is not intended to limit the authority of a physician to provide emergency medical care or to preempt any applicable local, state or federal laws which require additional information to be disclosed in order for informed consent to be legally effective.

In Accordance With:

45 CFR 46.109; 45 CFR 46.111; 45 CFR 46.116; 21 CFR 50.20, 50.25 and 50.27; 21 CFR 56.109 and 56.111; and applicable state and local laws.

Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators, 1998:

http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/guidancesinformationsheetsandnotices/ucm113709.htm

A Guide to Informed Consent:
http://www.fda.gov/regulatoryinformation/guidances/ucm126431.htm

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

IV. PROCEDURES

1. General requirements for adequate informed consent and documentation of consent include the following:
   a. No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative (SOP IRB # 006). No informed consent disclosure, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
   b. UTGSM IRB requires the investigator to detail the process for obtaining consent and securing written documentation of consent in the informed consent section of the project descriptors. This section must also specify who has the authority to

obtain informed consent. If the study will involve accrual of subjects for whom consent must be secured from the legally authorized representative, this plan must be explained and justified in this section as well.

c. Scientific and technical terms must be adequately explained or substituted with common terms. Complex concepts should be described in a manner easily understood by the population being consented.

d. The process of obtaining informed consent must normally involve an informed consent interview conducted in person. Inviting the subject to read and sign the consent form is not sufficient for securing informed consent. Any alteration of this process must be requested as an alteration of informed consent under 45 CFR 46.116(d), with a justification that establishes that the conditions for approving an alteration under the regulations are satisfied.

e. Investigators are responsible for assessing the subject's capacity to consent.

e. When prospective subjects lack adequate decision making capacity, investigators may not involve them in clinical research without the legally effective informed consent of the subject's legally authorized representative (LAR). Identification of the LAR for a subject incapable of making an autonomous decision is governed by state law. The LAR must be an adult who has exhibited special care and concern for the subject, who is familiar with the subject's personal values, who is reasonably available, and who is willing to serve. No person who is identified in a protective order or other court order that directs that person to avoid contact with the subject shall be eligible to serve as the subject's LAR. Identification of an LAR should normally be made using the following order of descending preference: conservator; guardian; attorney-in-fact; subject's spouse, unless legally separated; the subject's adult child; the subject's parent; the subject's adult sibling; any other adult relative of the subject; or any other adult who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve as LAR.

f. Securing informed consent by telephone is generally not allowed. It is acceptable to send the informed consent document to the subject or legally authorized representative by facsimile and conduct the consent interview over the telephone when the subject or legally authorized representative can read the consent form as it is discussed. If the consent is signed, it may be sent back to the investigative site by facsimile. The consent with the original signatures must be mailed or brought to the investigative site at the earliest opportunity. Any alteration of this process for securing consent by telephone must be requested as an alteration of informed consent under 45 CFR 46.116(d), with a justification that establishes that the conditions for approving an alteration under the regulations are satisfied.

g. The UTGSM IRB may approve an alteration or waiver of informed consent under 45 CFR 46.116(d) provided that the IRB finds and documents the following conditions. Satisfaction of these conditions must be established by the principal investigator in the informed consent section of the project descriptors:

    i. the research involves no more than minimal risk to the subjects;

ii. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
iii. the research could not practicably be carried out without the waiver; and
iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

h. The UTGSM IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
   i. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
   ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

   In cases in which the requirement for written documentation of consent is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
i. UTGSM IRB requires at a minimum the following signatures to be obtained and dated by the signatory on the informed consent document:
   i. Subject or legally authorized representative (as described in (1e) of this section)
   ii. The person obtaining consent who is informed and knowledgeable about the study and study requirements, and authorized in the approved application to conduct the informed consent interview.
   iii. Principal or collaborating investigator who attests to the best of his/her knowledge that the informed consent process has been properly conducted.
j. The UTGSM IRB requires the signature of the principal or collaborating investigator within 72 hours of the subject's entry into the study.
k. Consent revisions for studies initially approved by the full Board will be reviewed by the full Board unless the changes satisfy criteria for expedited review.
l. Any IRB approved revisions to the informed consent document that might relate to the subjects' willingness to continue participation in the study will necessitate the re-consent of all current subjects (active or in follow-up) in the clinical study. Subjects who have completed the study may be mailed a copy of the changes to the consent document. UTGSM IRB does not require re-contacting subjects who have completed their active participation if the revisions do not involve issues pertinent to their health, safety, or well-being. UTGSM IRB does not require re-consent of subjects who are still actively participating when the revisions will not affect their willingness to continue participation in the study.
m. UTGSM IRB will affix a stamp on the approved informed consent form along with a date of expiration. Only the current stamped, unexpired consent form may be used to secure written documentation of informed consent.

n. UTGSM IRB requires that the investigator place a copy of the signed informed consent document in the research records for the study. A copy of the consent form must also be provided to the subject or the subject's legally authorized representative at the time of consent to participate in the study.
o. For non-English consent procedures, see SOP IRB # 006.
p. For Pediatric Assent, see SOP IRB #13.
q. Investigators are required to report to UTGSM IRB any deviations from or violations of the consent policies.
r. UTGSM IRB has the right to observe the consent process.
s. A copy of any approved current consent form will be kept in the IRB files for the study.

2. UTGSM IRB will review each informed consent document and revisions to the document to assure that the information contained in the document includes the following elements as required by federal regulations:
    a. A statement that the study involves research;
    b. An explanation of the purposes of the research;
    c. The expected duration of the subject's participation;
    d. Description of the procedures to be followed;
    e. Identification of any procedures that are experimental;
    f. A description of any reasonably foreseeable risks or discomforts for the subject, including their probability, magnitude, duration and reversibility;
    g. A description of any benefits to the subject or to others that may reasonably be expected from the research. Named benefits should refrain from any unproven claims of effectiveness or certainty of benefit. Overly optimistic representations are misleading and violate FDA regulations concerning the promotion of investigational drugs [21 CFR 312.7] or investigational devices [21 CFR 812.7(d)] as well as the requirement to minimize the possibility of coercion or undue influence [21 CFR 50.20].
    h. A disclosure of appropriate alternative procedures or courses of treatment (if any) that may be advantageous to the subject;
    i. A statement describing the extent to which the confidentiality of research records identifying the subject will be maintained;
    j. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
    k. An explanation of whom to contact for answers to pertinent questions *(include names and phone number)*:
        i. about the research (the principal investigator)
        ii. about the subject's rights (the IRB Chairman)

iii. whom to contact in the event of a research-related injury (this should be a number where an investigator on the study team can be reached 24 hours a day);

l. A statement that participation is voluntary;
m. A statement that refusal to participate will involve no penalty or loss of benefits to which the subjects is otherwise entitled;
n. A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; subjects should also be informed that they might be asked to permit follow-up if they withdraw;
o. A statement that the particular treatment or procedure may involve risks to the subject that are currently unforeseeable;
p. A statement that the particular treatment or procedure may involve risks that are currently unforeseeable to an embryo or fetus, if the subject is or may become pregnant, and specific language regarding contraception (including information for male and female participants if applicable);
q. A statement of anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
r. Any additional costs to the subject that may result from participation in the research, including a statement that some insurance and / or other reimbursement plans may not fund or cover care that occurs in a research context;
s. Information concerning payment to subjects, including the amount and schedule of payments;
t. Incorporation of the HIPAA subject authorization template;
u. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
v. A statement that significant new findings that develop during the research and that may relate to the subject's willingness to continue participation in the study, will be provided to the subject;
w. A statement that subjects will be provided a copy of the consent form;
x. Dated signature lines to permit verification that consent was obtained prior to participation in any study related procedures; and
y. UTGSM IRB may require additional information be given subjects when such information would enhance protection for the rights and welfare of the subjects.
z. The consent document should provide subjects with accurate information about the training and education of the individuals who will be serving as investigators and study staff. Titles should be used uniformly throughout the document listing name, and degree. examples: *Bill Jones, M.D., Bill Jones, PhD, Bill Jones, RN*

3. Requirements for the formatting of informed consent documents include the following:
    a. The consent form must normally be prepared in accord with the UTGSM IRB general consent template. If the study involves a specimen repository, then a separate consent form must be prepared according to the UTGSM IRB consent template for repositories (Appendix 06). This consent may be attached to the main study consent, but must have a separate signature section. If the study involves genetic analysis, then the consent form must be prepared according to the UTGSM IRB template for consent to research involving genetic analysis (Appendix 05).
    b. Number pages 1 of 5, 2 of 5, etc.
    c. Insert a line for the research subject's initials ( ) at the bottom of all pages except the signature page.
    d. Insert a brief title and study number (if applicable) at top of all pages starting on pg 2.
    e. Add to either the top or bottom of each page of the consent form a "Version date ". (This date changes whenever a revision is made to the consent form.)
    f. The document must be written in language understandable to the subjects (for most studies, this would be approximately an 8th grade readability level).
    g. Consent forms must be written in the 2nd person (you), except for the section entitled "Consent of Subject" which should be written in the l st person (I).
    h. UTGSM IRB requires the following signature lines on the informed consent document:
        i. Signature, printed name, date and time of consent for the subject or subject's legally authorized representative; if a legally authorized representative is used, then a line must also be included for specifying the relationship of the legally authorized representative to the subject;
        ii. Signature, printed name, and date for the person obtaining informed consent;
        iii. Signature, printed name and date for the principal or collaborating investigator; and
        iv. Signature, printed name and date for the assent of child subjects (if applicable)