UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE CHATTANOOGA INSTITUTIONAL REVIEW BOARD CRITERIA FOR IRB APPROVAL OF NEW RESEARCH APPLICATIONS

I. PURPOSE

This document outlines the criteria for approval of studies reviewed by the University of Tennessee Health Science Center Institutional Review Board.

II. SCOPE

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

Personnel Responsible:

UTCOMC IRB administrative staff and IRB members.

III. BACKGROUND

General criteria for IRB review and approval of research are stipulated in the Common Rule at 45 CFR 46.111. Identical criteria for IRB review and approval of FDA-regulated research are provided at 21 CFR 56.111. Numerous additional guidance documents for interpreting and applying these criteria are provided by the Office for Human Research Protections of the Department of Health and Human Services, the Food and Drug Administration, and other federal departments and agencies involved in conducting or supporting research with human subjects. These guidance documents are supplemented by various codes of research ethics, such as the Declaration of Helsinki of the World Medical Association and the guidelines for biomedical research involving human subjects of the Council for International Organizations of Medical Sciences.

In Accordance With:

45 CFR 46.111; 21 CFR56.111

OHRP Guidance on Written IRB Procedures
https://www.hhs.gov/ohrp/regulations-and-

policy/guidance/institutionalissues/institutional-review-board-written-procedures/index.html

Institutional Review Boards Frequently Asked Questions – Information Sheet
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.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. The following criteria are utilized by the UTCOMC IRB in determining whether applications to conduct research can be approved: a. Risk(s) to subjects are minimized.
   i. The study uses procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk. ii. The investigators are competent in the area being studied. iii. When appropriate, the study uses procedures already being performed on the subjects for diagnostic or treatment purposes. iv. Appropriate screening and monitoring procedures are utilized to protect the subjects from harm.
   b. Risk(s) to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
   i. The risk-benefit profile of any treatment intervention evaluated in the study is not known to be significantly more or less favorable than any available alternative treatment. ii. Non-therapeutic interventions used in the study do not involve more than minimal risk or a modest increase over minimal risk. iii. The value of the knowledge to be gained in the study justifies any increment of risk to subjects resulting from participation in the research. This assessment requires a review of the scientific validity of the protocol and scientific rationale (including results of previous animal and human studies) for conducting the study.
   iv. In evaluating the risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in research.)
   v. The IRB shall not consider possible long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.
   c. Selection of subjects is equitable.
   i. Recruitment will be open to all prospective subjects who may benefit from study participation, without regard (as appropriate) to gender,

sexual orientation, religion, race or ethnicity, taking into account the purposes of the research and the setting in which it is conducted.

ii. The IRB will be cognizant of special problems associated wih the use of populations that are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision making capacity, or economically or educationally disadvantaged persons.

iii. The IRB will not permit the involvement of vulnerable subjects, without scientific justification, in research that does not offer the prospect of direct benefit to subjects.

d. Unless the requirement is waived, the investigator will obtain the legally effective informed consent of the subject or the subject's legally authorized representative before the subject's participation in research.

i. The consent form must contain the required elements of information as specified in the federal regulations and must include the information that a reasonable person would want to have in order to make an informed decision about whether to participate in the study.

ii. The information that is given to the subject or the legally authorized representative shall be in a language understandable to the subject or the representative. The IRB will consider the demographic profile of the study population in gauging the readability of the consent disclosure.

iii. The language of the informed consent form should be one in which the subject or the subject's legally authorized representative is fluent.

iv. A consent interview will be conducted with the prospective subjects or legally authorized representative, which involves presentation of the main elements of information required for informed consent and the opportunity for them to discuss that information.

v. The investigator plans to seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. vi. The consent of the subject or the legally authorized representative will be appropriately documented, as specified in IRB SOP: Informed Consent.

e. Where appropriate, the research plan makes provision for monitoring the data to insure the safety of subjects.

i. The IRB will determine that the plan for monitoring the study data and subject safety is appropriate to the degree of risk associated with participation. ii. The IRB will determine if a DSMB is required for the study. If so, the IRB will require the investigator or sponsor to submit DSMB reports for the study to the IRB in a timely fashion. iii. The IRB may ask the investigator for copies of monitoring reports for the investigative sites.

iv. The IRB may perform site audits (See IRB SOP: Auditing of Research Studies).

f. Where appropriate, there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data/specimens.
   i. Methods for identifying, screening, interacting with, and securing research data from subjects must respect privacy rights.
   ii. Methods for storing and transmitting private information and biospecimens ensure the confidentiality of the data/specimens is protected. iii. For more information on privacy and security, see IRB SOP: Privacy and Confidentiality in Human Subject Research Participation.

g. For the purposes of conducting the limited IRB review required by the broad consent exemption at 45 CFR 46.104(d)(7) in the revised Common Rule, the IRB is able to make the following determinations:
   i. Broad consent for storage, maintenance, and secondary research use of identifiable information or identifiable biospecimens is obtained in accordance with the requirements of 45 CFR 46.116(a)(1)-(4), (a)(6), and (d) in the revised Common Rule; ii. Broad consent is appropriately documented, or waiver of documentation is appropriate, in accordance with 45 CFR 46.117 in the revised Common Rule; and
   iii. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

h. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision making capacity, or economically or educationally disadvantaged persons, additional safeguards have been considered where necessary to protect the rights and welfare of these subjects.

i. The IRB shall make a determination of the approval period, as well as the need for additional supervision or oversight on a project-by-project basis. The IRB will take into consideration the following factors when deciding on an appropriate interval for continuing review, when continuing review is required:
   i. the nature of and risks posed by the clinical investigation;
   ii. the degree of uncertainty regarding the risks involved;
   iii. the vulnerability of the subject population;
   iv. the experience of the clinical investigator in conducting clinical research;

v. the IRB's previous history with the investigator and/or sponsor; and
vi. whether the study involves novel therapies.

2. The decision of UTCOMC IRB to disapprove a research protocol may be appealed by the investigator. See IRB SOP: Appeal of IRB Decisions.

3. Institutions in which studies approved by the UTCOMC IRB will be conducted have the right to prohibit, suspend, or terminate such studies, or to require alteration of such studies as a condition of their performance at the institution. Any alterations in such studies required by the institution must also be approved by the IRB prior to their implementation.