Institutional Handbook of Operating Procedures Policy 11.01.03	
Section: Research Policies	Responsible Vice President: EVP, Provost and Dean of Medicine
Subject: General Research	Responsible Entity: Research Services

I. Title

Conduct of Clinical Research

II. Policy

Clinical Research is an important part of UTMB's academic mission. A clinical investigation requires an understanding of such issues as study design, statistical validity, human subjects' protections, privacy rights, and ethics of clinical investigation and the standards of research data integrity in addition to professional clinical training.

UTMB requires that a qualified Principal Investigator (PI) direct all clinical investigations. Therefore, student initiated projects must be conducted under the supervision of a qualified PI. It is the responsibility of the Department Chair, or designee to verify the proposed investigator's qualifications and the suitability of the research to UTMB and the department. If the Department Chair is the proposed Investigator or otherwise has a conflict of interest in the research project, the Dean of the School of the proposed researcher's primary appointment will be responsible for verifying the investigator's qualification and suitability of the proposed research. PI's qualifications are further demonstrated by (1) the successful completion of all UTMB required trainings and (2) the IRB's approval of a study protocol.

The Principal Investigator is solely responsible for the conduct of the clinical investigation. He or she may delegate various tasks to the study team, but he or she remains accountable for, and responsible for, the conduct of the study. It is imperative that the PI defines for the research team the roles and the delegated tasks for each person. The PI should also practice strong management of the research team, assuring compliance with institutional policies, Federal and State regulations, and good standards of research data integrity.

Violation of this policy may result in disciplinary action up to and including termination for employees; a termination of employment relationship in the case of contractors or consultants; or suspension or expulsion in the case of a student. Additionally, individuals might be subject to loss of access privileges and civil and/or criminal prosecution.

Other Requirements for the Conduct of Clinical Research

1. All clinical protocols must be reviewed by UTMB's IRB (or UTMB-approved central IRB) or must be determined to be exempt by the IRB. PI's conducting clinical research studies that they consider to be exempt under the IRB regulations, must obtain the IRB's independent confirmation. PI's are expected to be familiar with and follow the IRB's *Policies and Procedure Manual* found at this link: IRB Policy and Procedures.
2. Studies should be conducted according to the description of the research protocol.
3. Studies should be conducted to conform to the "Common Rule" regulations governing the Protection of Human Subjects found in the Code of Federal Regulations (CFR) (45 CFR 46). The PI should complete all required training and assure that members of the research team have completed the required training. The PI should also refer his or her team members to additional

training as he or she deems appropriate. The current institutional training requirements for clinical research teams can be located at the Research Services web site found here: Training Policy.

4. The PI and those with significant delegated study-related responsibilities should be familiar with and follow all applicable institutional policies governing clinical research. Current policies can be found on the research services website. Office of Clinical Research Standard Operating Procedures.
5. To the extent that a clinical study is governed by FDA regulations, PI's should conduct their studies in accordance with applicable FDA regulations found in the CFR governing clinical research with device, pharmaceutical, biologic or supplement including regulations for Electronic Records (21 CFR 11), Protection of Human Subjects (21 CFR 50), Financial Disclosures (21 CFR 54), IRB oversight (21 CFR 56), Investigational New Drugs (21 CFR 312) and Investigational Device Exemptions (21 CFR 812) and with FDA Good Clinical Practices..
6. PI's conducting investigator initiated research on applicable clinical trials are required to register and report results on the clinicaltrials.gov website in accordance with US Public Law 110-85 Title VIII, Section 801 of the Federal Food and Drug Administration Amendments Act of 2007 or FDAAA.
7. The PI may have additional obligations outlined in a clinical trial agreement with the study sponsor or funding agency, the PI is obligated to ensure all research is conducted in accordance with any and all legally binding agreements or federal award specifications for their project.

III. Definitions

Clinical Research: (aka Clinical Investigation): a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge that uses either data (1) obtained through intervention or interaction with a living individual or (2) by accessing identifiable private information.

Clinical Trial Agreement: A legally binding contract between the sponsor of a clinical trial and the investigational site.

Code of Federal Regulations (CFR): The codified regulations of the Federal government based on the final agency regulations published in the Federal Register.

Principal Investigator: scientist or health care professional that has accepted full responsibility for the scientific, administrative, ethical, legal, technical, operational and fiscal aspects for the management of a clinical investigation conducted at UTMB.

Institutional Review Board (IRB): An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.

Research Protocol: A formal description and design for a specific research project. A protocol involving human subject research must be reviewed and approved by an Institutional Review Board (IRB) if the research is not exempt, and by an IRB or other designated institutional process for exempt research.

IV. Relevant Federal and State Statutes

US Public Law 110-85 Title VIII, Section 801
21 CFR 11
21 CFR 50
21 CFR 54
21 CFR 56

21 CFR 58
21 CFR 312
21 CFR 812
45 CFR 46
Guidance for Industry, E6 Good Clinical Practices: Consolidated Guidance
https://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/guidancesinformationsheetsandnotices/ucm219488.htm

V. Related UTMB Policies and Procedures

IRB Policy and Procedures
Research Services
Research Services Training Policy

VI. Dates Approved or Amended

Originated: 11/30/2011	
Reviewed with Changes	*Reviewed without Changes*
	07/03/2018

VII. Contact Information

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