Institutional Handbook of Operating Procedures Policy 11.03.02	
Section: Research Policies	Responsible Vice President: Provost and Dean, School of Medicine
Subject: Clinical Research	Responsible Entity: Office, department, body, or individual designated by the responsible vice president to develop and implement the policy.

I. Title

Registration of Clinical Trials in ClinicalTrials.gov

II. Policy

Scope

This policy applies to all UTMB principal investigators conducting clinical trials/studies as defined by the Food and Drug Administration (FDA), International Committee of Medical Journal Editors (ICMJE), National Institutes of Health (NIH), or when submitting qualified research billing claims to the Centers for Medicare and Medicaid Services (CMS). It is the responsibility of the principal investigator (PI) to ensure compliance with this policy's requirements.

Background

The registration of clinical trials is required by the FDA, NIH, ICMJE, and CMS in ClinicalTrials.gov (http://www.clinicaltrials.gov), a public registry aimed at increased transparency and public awareness of research. The ClinicalTrials.gov Protocol Registration System (PRS), a web-based data-entry system, provides the public access to a directory of clinical trials that test the effects of drugs, biologics, devices, and procedures on medical diseases and conditions.

Which Studies Must be Registered and Submit Results on ClinicalTrials.gov?

1. Clinical trials funded in whole or in part by NIH, only when the NIH application/proposal or IRB approval is received on or after January 18, 2017.

2. The ICJME requires, as a condition of consideration for publication, registration of a clinical trial at or before the onset of patient enrollment. This requirement applies to any clinical trial starting enrollment after July 1, 2005. Click here for further information and frequently asked questions regarding the ICJME clinical trial registration requirements.

3. Applicable Clinical Trials (ACT), which include:
   a. Studies initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007;
   b. Interventional studies or studies that involve a pediatric postmarket surveillance of a device;
   c. Studies involving a U.S. FDA regulated drug, biologic, or device product;
   d. Studies that do not include Phase 1 (drug and biologic product);
   e. Studies where the primary purpose is not device feasibility (device products); and
   f. Studies where any of the following apply: (1) Trial site has one or more locations in the United States; (2) trial is conducted under an FDA investigational new drug

application or investigational device exemption, or (3) trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research.

Who is Responsible for Registration and Results Reporting?

A single Responsible Party must be designated to register and submit results information via the ClinicalTrials.gov website. For UTMB Principal Investigator (PI)-initiated studies, regardless of funding source, and studies involving an application where the PI is the holder of an IND or IDE, the UTMB PI is the Responsible Party who must register an applicable clinical trial on ClinicalTrials.gov and submit results and data as required. For industry-sponsored trials or multi-site trials, the industry sponsor or lead site is generally the Responsible Party for registration and results submission on ClinicalTrials.gov. Note that it is the responsibility of the UTMB PI to verify that the Responsible Party will be the sponsor on a sponsored trial or the lead-site PI on a multi-site trial.

What are the Registration and Results Reporting Requirements?

	FDA	ICMJE	NIH-funded	CMS
When to Register	At trial initiation (no later than 21 days of enrollment of the first subject); update at least every 12 months.	Prior to first subject enrollment	At trial initiation (no later than 21 days of enrollment of the first subject); update at least every 12 months.	Before a claim is submitted to Medicare.
Results Reporting	No later than 12 months after the Primary Completion Date (the last subject, last visit).	Not required.	No later than 12 months after the Primary Completion Date (the last subject, last visit).	Not required.

Penalties for Noncompliance

Regulation/Policy	Penalty for Noncompliance
FDA	Initial $10,000 and $10,000 per day thereafter for the duration of the violation, withholding or loss of funds, and other sanctions
NIH	Initial $10,000 and $10,000 per day thereafter for the duration of the violation, withholding or loss of funds, and other sanctions.
ICMJE	Inability to publish in prominent journals
CMS	Submitted claims will not be paid
UTMB	Sanctions up to and including termination of employment.

III. Procedures

For guidance on how to comply with ClinicalTrials.gov requirements and this policy, please contact the Office of Clinical Research.

IV. Definitions

For additional information and guidance, including relevant definitions, see the ClinicalTrials.gov information webpage on the Office of Clinical Research website.

V. Relevant Federal and State Statutes

1. Food and Drug Administration Amendments Act of 2007 (FDAAA 801).
2. National Institutes of Health Final Rule (January 18, 2017).
3. ClinicalTrials.gov PRS Log-in Site
4. ClinicalTrials.gov Training Materials

VI. Dates Approved or Amended

Originated: 08/15/2018	
Reviewed with Changes	*Reviewed without Changes*

VII. Contact Information

Office of Clinical Research
(409) 772-1978