

Office of Clinical Research (OCR)

Effective: January 2, 2018	Revised: March 8, 2019	Revision: 2.0
Responsibility: OCR		
Policy 1.6.1		

INSTITUTIONAL REQUIREMENTS FOR REGISTRATION OF CLINICAL TRIALS

1. **PURPOSE:** This policy establishes the process and procedure for registration of Clinical Trials as defined by the Food and Drug Amendments Act of 2007 (FDAAA) and the NIH Final Rule (implemented on January 18, 2017) which established a requirement for certain clinical trials to be registered at trial initiation and to report summary results after trial completion in the public registry and results database called ClinicalTrials.gov.

2. **POLICY:** The Office of Clinical Research (OCR) requires that UT Health San Antonio Principal Investigators of investigator-initiated clinical trials complete and maintain clinicaltrials.gov registration. Investigator-initiated applicable clinical trials -as defined by FDAAA and the NIH Final Rule- conducted by local principal investigators will be registered on ClinicalTrials.gov with an assigned NCT number before institutional activation of a study will be granted (unless there are special circumstances as determined by OCR).

3. **RESPONSIBILITY:** UT Health San Antonio Principal Investigators determined the [Responsible Party](#) are required to register any Clinical Trial that meets the FDAAA 801 or NIH Final Rule definition of an "applicable clinical trial" that was either initiated after September 27, 2007, or initiated on or before that date and was still ongoing as of December 26, 2007. Trials that were ongoing as of September 27, 2007, and reached the Completion Date (see [Primary Completion Date data element](#) on ClinicalTrials.gov) before December 26, 2007, are excluded.

4. PROCEDURE:

The OCR will designate at least one individual to manage the university's PRS account, create user accounts, and serve as the point of contact for PRS staff. The PRS administrator(s) will oversee the maintenance of the organization's records, verify that all Clinical Trials are registered on ClinicalTrials.gov, and that appropriate wording is included in the consent forms to notify subjects that information regarding the Clinical Trial that they are participating in will be available to the public. See Institutional Policy 1.1.1 PI Responsibilities.

PI Responsibilities:

i) The Responsible Party (sponsor or designated PI) for an Applicable Clinical Trial is required by law to submit the required clinical trial information no later than 21 days after enrollment of the first participant. For local investigators, registration will be required prior to institutional approval. The ClinicalTrial.gov record is required to include primary and secondary outcomes.

NOTE: In addition, the International Committee of Medical Journal Editors (ICMJE) and other journals require registration of clinical trials prior to enrollment of the first participant, as a condition of consideration for publication. ICMJE requires a data sharing element in the ClinicalTrial.gov record, with information regarding when the information will be shared. A reason is required if data is not shared.

- ii) All Expanded Access trials (the use of an investigational product, not approved by the FDA, outside of a clinical trial) will be submitted as a separate record on ClinicalTrials.gov, and the expanded access information will be supplied to study subjects. Only one expanded access record will be created for any given investigational product; new records should not be created if additional patients are treated with the same product.
- iii) Study records for active studies will be reviewed and modified, as needed, at least once every 12 months. Some data elements, such as **recruitment status, location, and contact information** are required to be updated sooner (e.g., within 30 days of a change) based on the requirements in Section 801 of FDAAA and 42 CFR 11.64 in order to provide accurate and timely information to patients and health care professionals. An updated Record Verification Date (in the Protocol section, Study Status module) will confirm that the record has been reviewed.
- iv) The responsible party is required by law to submit results not later than 12 months after the primary completion date, with a possible deadline extension of up to an additional 2 years for trials of unapproved products or of products for which initial FDA marketing approval or clearance is being sought, or approval or clearance of a new use is being sought. Failure to maintain the record and report results may delay in institutional activation of future studies or approval of amendments for the Responsible Party or Record owners.
- v) Responsible parties will be required to correct or address **within 15 calendar days for registration information and within 25 calendar days for results information**, any apparent errors, deficiencies and/or inconsistencies that are identified during the National Library of Medicine (NLM) quality control review process. See 42 CFR 11.64 (b). Responsible parties will also be required to correct or address any errors that they identify on their own, including after quality review by NLM is complete. Any amendment to the protocol, where changes made to the protocol affect the record in ClinicalTrials.gov, require an update to the ClinicalTrial.gov record.
- vi) Any investigator who transfers their clinical trial to UT Health San Antonio is required to transfer their record to the institution if funding is transferred. Assistance with this process will be provided by the Office of Clinical Research. The ClinicalTrial.gov record remains with the funded institution. On leaving the institution the Responsible party will notify the OCR, and update their ClinicalTrial.gov record with their new contact information. If the departing investigator's funding is transferring to their new institution, the ClinicalTrials.gov record owner is required to notify the administrator of ClinicalTrial.gov records at the new institution to request transfer of the clinical trial record to that institution.
- vii) In addition to the requirements above, a protocol and statistical analysis plan, with cover page attached, will be uploaded at the time results are reported for any Clinical Trial with a primary completion date on or after January 18, 2017. Results records are required to include baseline information on age and gender, where this data has been collected.

viii) Consent forms will be posted on the ClinicalTrials.gov website where applicable, after recruitment closes, but no later than 60 days after the last study visit by any subject for federally funded Clinical Trials. There are no restrictions on which version of the consent form should be posted.

6. REFERENCES:

Submit Studies: <https://clinicaltrials.gov/ct2/manage-recs>

Final Rule Info: <https://prsinfo.clinicaltrials.gov>

Questions: register@clinicaltrials.gov