

Frequently Asked Questions regarding ClinicalTrials.gov Reporting

When is a University of Texas at Austin researcher a Responsible Party under HHS and ICJME guidelines?

Generally, a University of Texas at Austin researcher is the Responsible Party when:

- The PI is the PI of record for an ACT.
- The PI is the PI of record for an NIH funded clinical trial.
- The PI wishes to publish in an ICJME journal.
- The PI holds the IND or IDE.
- The PI drafted the protocol and is the PI of record for an FDA-regulated IND-exempt clinical investigation of a drug or biologic.
- The PI drafted the protocol for an FDA-regulated clinical investigation of 1) a non-significant risk device or an 2) IDE-exempt device.
- A foundation, cooperative group, or group of investigators wrote the protocol and a University of Texas at Austin investigator has been delegated this responsibility in an agreement.

When is a University of Texas at Austin researcher not responsible for registration and resulting reporting?

Generally a University of Texas at Austin researcher is not the Responsible Party when:

- The manufacturer of a clinical investigation of a drug, biologic, or medical device wrote the protocol and is the sponsor.
- A University of Texas at Austin researcher is a sub-recipient of a contract or grant from another organization or institution, unless a University of Texas At Austin researcher has been assigned this responsibility in the award agreement.

What if the University of Texas at Austin is not the IRB of record for a study?

A University of Texas at Austin researcher may still be the Responsible Party even if the University of Texas at Austin does not serve as the IRB of record, e.g.—the study is at a Central IRB or UT is relying on another institution's IRB.

What if my protocol is an expanded access protocol for a drug or biologic?

Expanded access protocols should be registered on ClinicalTrials.gov by the manufacturer of the drug or biologic. Single patient INDs (i.e., single use compassionate or treatment use) do not require registration. Single patient IDE projects are not applicable device clinical trials and do not require registration. This scenario will typically be limited to Dell Medical School researcher physicians.

Is there a charge for listing a study on ClinicalTrials.gov?

No. There is no fee for listing.

My study is not yet approved by the IRB. Can I still enter it on ClinicalTrials.gov?

Most studies require approval from a human subjects review board. If your study requires approval, you may register your study on ClinicalTrials.gov prior to getting approval if the Overall Recruitment Status of the study is “Not yet recruiting” within PRS.

If a study requires human subjects review board approval, approval must be obtained before the study's Overall Recruitment Status is changed to “Recruiting.” When board approval is obtained, please update the Protocol Section of the study record in PRS and “Release” (submit) the study for processing.

Are clinical studies with no external sources of funding required to be registered on ClinicalTrials.gov?

Unfunded studies that otherwise meet the requirements of this policy (e.g., falling under the definition of an ACT or for publication purposes) must register with ClinicalTrials.gov and otherwise meet the requirements stated above.

How do I upload studies with a large dataset to ClinicalTrials.gov?

A new feature in the eRA Human Subjects System in the PRS allows study records to be exported as an XML file, with upload fields that will be captured directly into ClinicalTrials.gov PRS. More information (and a video) is available here:

<https://nexus.od.nih.gov/all/2019/03/07/uploading-studies-to-clinicaltrials-gov-just-got-easier/>.

What if I leave the University of Texas at Austin?

If a researcher who serves as a Responsible Party leaves the University of Texas at Austin, the study must be assigned a new University of Texas at Austin responsible party or the study record transferred to the ClinicalTrials.gov system at the researcher's new institution.

More information is available at <https://clinicaltrials.gov/ct2/manage-recs>, including FAQs at <https://clinicaltrials.gov/ct2/manage-recs/faq>.