

CLINICALTRIALS.GOV QUICK GUIDE

Clinical Trials.gov is a publicly available registry and results database of clinical studies of human participants. The purpose of ClinicalTrials.gov is to disclose to the public key information about clinical trials that are currently underway or that have been conducted. ClinicalTrials.gov captures summary level protocol information and adverse event information before, during, and after clinical trials. Federal laws require registration of clinical trials. Many journals also require evidence of registration of clinical trials before accepting manuscripts for publication.

A clinical trial is defined by ClinicalTrials.gov as follows:

A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

The National Institutes of Health define a clinical trial as follows:

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

For Study Record Managers: There is a really nice little tutorial about clinical trials.gov on their website (<https://clinicaltrials.gov/ct2/manage-recs/present>). Anyone from TWU who is doing a clinical trial (doctoral students included) should enter their study into this database and keep it current. As a study record manager, you'll add new users, review the TWU protocols, approve protocols for release, and assist faculty and students in getting their protocols entered.

To begin:

Notify ORSP that you need to register a clinical trial. You will receive an email when an account has been created for you.

Go to the Protocol Registration and Results System (PRS): <https://clinicaltrials.gov/ct2/manage-recs/register>

If you don't have an account, create one using the link on the page. Once you have an account, you log in for Texas Woman's University. Our organization name is TexasWU.

Enter your study information, making sure that you answer all of the questions clearly. If you are a first time user, please plan to complete the tutorial (<https://clinicaltrials.gov/ct2/manage-recs/present>). Once you've completed the entry, click "submit". TWU ORSP will receive a notification a new submission from TWU. We will review the submission and, assuming everything is complete, we will release the record. If there are elements missing, we will notify you and ask you to address any missing elements. Once the record is complete, we will release the record.

A ClinicalTrials.gov staff member will review the study record after it is released (submitted) and before it is published on ClinicalTrials.gov. This review will focus on apparent validity (when possible), meaningful entries, logic and internal consistency, and formatting. You may be asked to clarify items or make corrections to the record before publication. Please note that the review process may take up to a few days. Ensuring that the record is consistent with the ClinicalTrials.gov protocol review criteria (PDF) before releasing it will expedite publication on the site.

After you release a record and it is accepted by review staff for publication, the record, including its NCT Number, will be available on ClinicalTrials.gov within 2–5 business days.

Submitting Your Results

You are responsible for regularly updating your record and for submitting results when the study is complete. To submit results, log back into the system, enter your results, and submit the record. Again, the website has excellent instructions about how to enter your results. You must click “submit” for ORSP staff to be notified that there is a new update. We will review the record and release it.

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After submitted results are accepted by review staff, the Results Section will be displayed with the corresponding registered Protocol Section under different tabs in a single study record on ClinicalTrials.gov.

After the Results Section has been initially posted, the record may be updated and edited at any time. The most recent version of a study record is displayed on ClinicalTrials.gov. A history of changes made to a study record is available on the ClinicalTrials.gov archive site. You will need the ClinicalTrials.gov Identifier (NCT Number) for the record in order to view its history. The NCT Number can be found at the top of every study record. You can also click on the History of Changes link at the top of a record to see its earlier, archived versions.