TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER™
EL PASO

Office *of the* Vice President *for* Research

OVPR Guide for ClinicalTrials.gov

1. **Introduction**

   ClinicalTrials.gov is a Web-based resource that provides easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The National Library of Medicine (NLM) maintains the web site at the National Institutes of Health (NIH). Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of each clinical study. Studies are generally submitted to the Web site (that is, registered) when they begin, and the information is updated throughout the study. In some cases, results of the study are submitted after the study ends. This Web site and database of clinical studies is commonly referred to as a "registry and results database."

   Most of the records on ClinicalTrials.gov describe clinical trials (also called interventional studies). In a clinical trial, human volunteers are assigned to interventions (for example, a medical product, behavior, or procedure) based on a protocol (or plan) and are then evaluated for effects of the interventions on biomedical or health outcomes. ClinicalTrials.gov also contains records describing observational studies and programs providing access to investigational drugs outside of clinical trials (expanded access). Studies listed in the database are conducted in all 50 States and in 200 countries.

   ClinicalTrials.gov does not contain information about all the clinical studies conducted in the United States because not all studies are required by law to be registered (for example, observational studies and trials that do not examine a drug, biologic, or device). See FDAAA 801 Requirements for more information. However, the rate of study registration has increased over time as more policies and laws requiring registration have been enacted and as more sponsors and investigators have voluntarily registered their studies.

2. **TTUHSC El Paso Requirements**

   a. Studies that meet the following criteria must be registered at ClinicalTrials.gov prior to receiving approval by the IRB:
   - Investigator-initiated Applicable Clinical Trials
   - Some Humanitarian Use Devices
   - NIH-funded interventional clinical trials (when TTUHSC El Paso is the primary grant awardee)
   - Qualifying trials billing insurance (externally sponsored and TTUHSC El Paso Investigator-initiated)

   For more information on what an Applicable Clinical Trial is, please refer to the ACT Checklist.

3. **ClinicalTrials.gov Registration**

   a. How to Request a ClinicalTrials.gov Account
      i. Request an account with the ClinicalTrials.gov Protocol Registration System (PRS) by sending an email to the TTUHSC El Paso PRS Administrator with "ClinicalTrials.gov Protocol Registration" in the subject line.
      ii. Within 1-2 business days, you will receive an email directly from ClinicalTrials.gov containing your temporary password and log-in information. Log on to the Protocol Registration and Results System using your login name and password. The Organization name is **TexasTechElPaso**. From the Accounts drop down menu, select "Change Password." The temporary one should be updated to a unique password of your choosing as soon as possible.

   b. How to Register a Study
      i. It takes approximately 1 hour to enter registration information. The system offers the option to save data as you go, in case you do not have time to complete the entire process. It is possible to copy and paste information from the protocol into the data fields.
         1. Log in to the ClinicalTrials.gov Protocol Registration and Results System using your login name and password. The Organization name is **TexasTechElPaso**.

2. To create a new record, select "New Record" from the Quick Links section at the upper-left corner of the page. The person who creates the new record will be designated as the Record Owner and is responsible for maintaining the registration. To change the Record Owner, contact the [TTUHSC El Paso PRS Administrator](#).

    ii. Institution-Specific Information to Enter
1. Unique protocol ID: Use the TTUHSC El Paso IRB number (EXXXXX).
2. Secondary IDs: Enter the grant number, funding agency number or other funding source number, if applicable.
3. Responsible Party: Defaults to "Sponsor", change to "Principal Investigator" unless the study is under an IND or IDE. If the study is under an IND or IDE choose "Sponsor-Investigator" from the drop down menu and choose the IND/IDE holder as the Sponsor-Investigator.
4. Investigator Name: Displays either the "Sponsor-Investigator" as the Responsible Party or the "Principal Investigator". If the IND/IDE holder's name or the principal investigator's name is not displayed in the drop down menu, contact the [TTUHSC El Paso PRS Administrator](#) to create an account for the IND/IDE holder or the principal investigator.
5. Board Information:
   - Board Name: TTUHSC El Paso Institutional Review Board (IRB)
   - Board Affiliation: Texas Tech University Health Sciences Center El Paso
   - Board Contact: Phone: 915-215-4162
   - Email: myrna.arvizo@ttuhsc.edu
   - Address: 5001 El Paso Drive, Room 1005B, El Paso, TX 79905
6. Oversight Authorities: Always include "United States: Institutional Review Board". Only include "United States: Food and Drug Administration" if the study is under an IND or IDE.

c. Adding Personnel to the Access List:
    i. In order to add personnel to the access list so that they are able to work on a record, the [TTUHSC El Paso PRS Administrator](#) will need to be contacted to ensure that the personnel have accounts with ClinicalTrials.gov. The [TTUHSC El Paso PRS Administrator](#) can add the personnel to the study record, or anyone with access to the record can add personnel to the access list by going into the record and selecting the underlines blue text next to
"Access List" on the main record page. The personnel will be given immediate access to the record at this point.

ci. Completing an Entry
    i. When entry is complete, click the green "Entry Complete" button on the Record Summary page. The template will be forwarded to the Responsible Party, who will review it and release the approved content to ClinicalTrials.gov for quality assurance review. If ClinicalTrials.gov PRS reviewers find problems with the record, it will be returned to the Record Owner with PRS Comments. The issues will need to be addressed and the record re-released to ClinicalTrials.gov within 15 days for QA and subsequent posting. When ClinicalTrials.gov has accepted the record, the Record Owner will receive an email with the NCT#.

4. Record Maintenance After Registration

a. The study team update the Record Verification Date every 12 months until all required information on registration and results has been submitted, even if no other updates are required. The following fields must be updated within 30 days of a change, unless otherwise noted:
- Overall Recruitment Status
- Primary Completion Date
- Study Start Date
- Intervention names (must update to a non-proprietary name within 30 days after a non-proprietary name is established)
- Availability of Expanded Access (if TTUHSC El Paso is the manufacturer and sponsor of the ACT)
- Expanded Access Status and Expanded Access Type
- Individual Site Status
- Human Subjects Protection Review Board Status
- Study Completion Date
- Responsible Party and RP Contact Information
- Changes in the protocol that are communicated to subjects
- Device Product Not Approved or Cleared by U.S. FDA (update within 15 days after change in approval or clearance status)

  b. Remember: updating Completion date fields in a timely manner can prevent records from being flagged with errors.

5. Entering Results

  a. Results for ACTs and NIH-funded clinical trials are due within one year of the Primary Completion Date (the date the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome). For more information on results entry, visit the ClinicalTrials.gov page entitled: How to Submit Your Results.

6. Helpful Tips

- Always return to the Record Summary page and click the green Entry Complete button to submit the registration.
- "Errors" must be resolved before you can submit. "Notes" should be reviewed; however, revisions are not required for submission.
- Do not use first or second person (i.e. replace "we" and "you" with "the investigator" and "subjects").
- Check for spelling errors by clicking the spelling link on the Record Summary page before selecting the "Entry Complete" button.
- The most common reasons why ClinicalTrials.gov returns a record for revisions are for problems with the Outcome Measures section. Review the Protocol Review Criteria, starting on page 2, for helpful hints.

7. Maintaining a Record When a Principal Investigator Leaves TTUHSC El Paso

  a. Before the investigator leaves the following must be completed:
    i. Study Closure (when applicable)
      1. A study closure form must be submitted to the IRB through iRIS.
      2. Update the "Study Status" section on the ClinicalTrials.gov record to reflect that the study is closed, when it closed, and why it was closed.
        a. If results exist for this study, then results information must be entered onto the results section of the ClinicalTrials.gov record.
        b. If no subjects were recruited, ensure that this is explained on the "Study Status" section. No results will need to be reported under this circumstance.
        c. A volunteer from the principal investigator's research team will need to be added as the study record owner, in case ClinicalTrials.gov has any comments or flags items on the record after the principal investigator has already left TTUHSC El Paso.
    ii. Study Transfer (when applicable)
      1. If another investigator will be taking over the study, ensure that this change is submitted through iRIS.
      2. Once the request to change the principal investigator has been submitted to the IRB, the ClinicalTrials.gov record can be updated as well.
      3. Update the contact information and name of the principal investigator in each required section on the ClinicalTrials.gov record.
      4. Submit a request to the TTUHSC El Paso PRS Administrator in order to update the "Record Owner" to the new principal investigator for a study (if applicable).

  b. If the whole investigative team leaves the following must be completed:
    i. A request must be submitted to the TTUHSC El Paso PRS Administrator so that the department chair will be made the record owner for this circumstance.
      1. The department chair will be asked to close all studies if they have not been transferred to another investigator or if studies have not been closed yet.
        a. A study closure form must be submitted to the IRB through iRIS.
        b. Update the "Study Status" section on the ClinicalTrials.gov record to reflect that the study is closed, when it closed, and why it was closed.
          i. If results exist for this study, then results information must be entered onto the results section of the ClinicalTrials.gov record.
          ii. If no subjects were recruited, ensure that this is explained on the "Study Status" section. No results will need to be reported under this circumstance.
        c. The department chair will be asked to update and close the record on ClinicalTrials.gov.

8. TTUHSC El Paso Escalation Process for Non-Compliance

  a. Before the investigator leaves the institution

     i.   A first email attempt will be made by the TTUHSC El Paso PRS Administrator to the record owner and responsible party in order to encourage them to address problems, comments or errors with a record, and to have them complete a record.

    ii.   A second email attempt will be made by the TTUHSC El Paso PRS Administrator to the record owner and responsible party in order to encourage them to address problems, comments or errors with a record, and to have them complete a record.

   iii.   A third attempt to contact phone call will be made by the TTUHSC El Paso PRS Administrator to the record owner and responsible party in order to encourage them to address problems, comments or errors with a record, and to have them complete a record.

   iv.   The TTUHSC El Paso PRS Administrator will send an email notification to the record owner and responsible party that the situation is being escalated to the department chair and the department chair will be contacted.

    v.   The department chair may then reach out to the record owner and responsible party in order to encourage them to address problems, comments or errors with a record, and to have them complete a record.

   vi.   The TTUHSC El Paso PRS Administrator will send an email notification to the record owner, responsible party, and department chair that the situation is being escalated to the Vice President for Research.

   vii.   The Vice President for Research will then reach out to the record owner and responsible party in order to encourage them to address problems, comments or errors with a record, and to have them complete a record.

b.   After the investigator leaves the institution

    i.   A first email attempt to contact will be sent by the TTUHSC El Paso PRS Administrator to the record owner and responsible party in order to encourage them to address problems, comments or errors with a record, and to have them complete a record.

    ii.   A second email attempt to contact will be sent by the TTUHSC El Paso PRS Administrator to the record owner and responsible party in order to encourage them to address problems, comments or errors with a record, and to have them complete a record.

   iii.   A third attempt to contact phone call will be made by the TTUHSC El Paso PRS Administrator to the record owner and responsible party in order to encourage them to address problems, comments or errors with a record, and to have them complete a record.

   iv.   The TTUHSC El Paso PRS Administrator will send an email notification to the record owner, responsible party, and department chair that the situation is being escalated to the Vice President for Research.

    v.   The Vice President for Research will then contact the responsible party's institutional VPR in order to encourage them to address problems, comments or errors with a record, and to have them complete a record.

The IRB and the ClinicalTrials.gov PRS administrators may take up to a month to respond to submissions. It is important that these steps are initiated and followed a couple of months prior to leaving the institution if possible.

TTUHSC EP Decision Flow Chart to Determine Applicable Clinical Trials That Must be Registered on ClinicalTrials.gov

Are you planning to publish your clinical trials with journals that follow ICMJE guidelines?
**Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.

Yes → **You will need to register your study before the enrollment of your first subject.**

No ↓

You do not need to register your study unless it meets the other guidelines listed below.

Is your clinical trial fully or partially funded by the NIH?

Yes → **Did your clinical trial begin on or after January 18, 2017?**

Yes → **You will need to register your study no later than 21 days after enrollment of your first subject.**

No (from NIH question) ↓

You do not need to register your study unless it meets the other guidelines listed below.

No (from January 18, 2017 question) ↓

You do not need to register your study.

Is your clinical trial interventional?

Yes → **Is your study a Phase 1 trial of a drug and/or biological product or is your study a device feasibility study?**

No → **Does your study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)?**

No → **You do not need to register your study.**

No (from interventional question) ↓

You do not need to register your study.

Yes (from Phase 1 question) ↓

You do not need to register your study.

Yes (from FDA question) ↓

Do ANY of the following apply (is the answer "Yes" to at least one of the following sub-questions: a, b, OR c)?
a. Is at least one study facility located in the United States or a U.S. territory?

b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)?

c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country?

Yes → **You will need to register your study no later than 21 days after enrollment of your first subject.**

No → **You do not need to register your study.**

For questions or to request a user account with ClinicalTrials.gov please contact:
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