REGISTERING A STUDY AT CLINICALTRIAL.GOV

Step by Step Instructions

1. **Determine if a study requires registration -** Use this checklist to determine if a clinical trial or study is an **Applicable Clinical Trial** requiring registration at ClinicalTrial.gov. If the study meets the definition of an ACT and was initiated after January 18, 2017, then proceed to Step 2.

2. **Identify the Sponsor Organization (SO) -** Studies must be registered under the SO's account. For example, if you are a Principal Investigator designated to be the Responsible Party for a study and you work for University X, but the SO for the study is University Y, the study must be registered under University Y, and you should set up your PRS account through University Y. The steps described below are specific for LSUHSC-NO as the Sponsor Organization but generally applicable for all SOs.

3. **Create User and/or Responsible Party accounts -** Studies are registered using the Protocol Registration and Results System (PRS). In this system, a **User** is any account holder who is authorized to enter information into the PRS, including investigators or research assistants. A **Responsible Party**, typically the Principal Investigator, is responsible for verifying the accuracy of a study record and releasing it to ClinicalTrials.gov. If you will serve in the role of an **User** and/or **Responsible Party** and do not have an account under LSUHSC-NO in PRS, **request a username and password** from the LSUHSC PRS Administrator at CTO@lsuhsc.edu.

   The LSUHSC PRS Administrator is the contact for requesting a username and password only. For details regarding protocol registration, see instructions below and/or contact ClinicalTrials.gov Staff for additional help at register@clinicaltrials.gov.

4. **Go to the** Protocol Registration and Results System (PRS) webpage at the ClinicalTrials.gov website.

5. **Under Organization name, enter "LSU" -** Then enter your username and password.

6. **Create a Record** - A clinical trial is registered in the ClinicalTrials.gov system by creating a "protocol record". Click on the "Create" link under Protocol Records on the Main Menu and fill in a series of data entry screens. For detailed instructions on protocol data entry, click here or access the PRS User's Guide here.

   Data is saved as each screen is filled in, so that you can "Quit" at any time, saving the record for later completion using the "Updating…" instructions provided below.

7. **Review data entries -** After filling in the last data entry screen, the "Edit Protocol" screen appears with all of the information provided. Review the information for accuracy and completeness, and address "ERROR" messages, if any. "Alert" messages should also be addressed (and must be for trials that are not under U.S. FDA IND/IDE application).

8. **Submit the study record for PRS review -** When the record is ready, click on the "Next Action: Complete" link near the top of the Edit Protocol screen. An email will be sent to the **LSUHSC PRS Administrator** for "Approval" and "Release" of the record to PRS staff for review.

9. **PRS Staff review the record** - PRS Staff reviews the record for apparent errors, deficiencies, and/or inconsistencies. If PRS Staff finds any potential issues with the record, they will add comments to the record and send an email notification. The **User/Responsible Party** must log in to PRS to view the comments. He or she then edits the study record to address the comments and resubmits the record for PRS Review, using the same procedures described above.

10. **Record is registered and posted** - Once the study record passes PRS Review, an email notification will be sent to the **User/Responsible Party** with the ClinicalTrials.gov Identifier (NCT number), indicating that the study is registered. Once registered, a study record becomes a permanent part of ClinicalTrials.gov and cannot be removed.

    The record is generally registered on the site within 2-5 business days after correction of all errors and deficiencies. If the record is not available within 10 days of completion, and you have not heard from the PRS quality assurance review personnel, please contact CTO@lsuhsc.edu.

    Updating clinical trial registrations – It is the investigator's responsibility to ensure that protocol records for active trials are reviewed and modified in a timely manner. Once created, a protocol record can be modified at any time. Click on the "Modify" link under Protocol Records on the Main Menu. A selection list of all records owned by you appears, with status information for each record. Click on the "Edit" link next to the record that you wish to update. The Edit Protocol screen appears. The record status is automatically reset to "In progress". Use the "Edit" links on the left to modify the desired portion(s) of the record. Remember to mark the record as Complete when finished editing. Your PRS Administrator will approve and release the modified record as described above.

    - Unless there have been no changes, registration information must be updated no less than once every 12 months.

    - If recruitment status for the study changes (e.g., recruitment suspended), the registration must be updated within 30 days.

    - If the trial is complete (whether concluded or terminated prior to conclusion), registration must be updated within 30 days.

11. **End of study** - For certain clinical trials subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801), Responsible Parties must submit scientific and administrative information about the results of the trial to the ClinicalTrials.gov results database. The following items must be posted on the site:

    - **Participant Flow:** A tabular summary of the progress of participants through each stage of a study, by study arm or comparison group. It includes the numbers of participants who started, completed, and dropped out of each period of the study based on the sequence in which interventions were assigned.

    - **Baseline Characteristics:** A tabular summary of the data collected at the beginning of a study for all participants, by study arm or comparison group. These data include demographics, such as age and gender, and study-specific measures (for example, systolic blood pressure, prior antidepressant treatment).

    - **Outcome Measures and Statistical Analyses:** A tabular summary of Outcome measure values, by study arm or comparison group. It includes tables for each pre-specified Primary Outcome and Secondary Outcome and may also include other pre-specified outcomes, post hoc outcomes, and any appropriate statistical analyses

    - **Adverse Events:** A tabular summary of all anticipated and unanticipated serious adverse event and a tabular summary of anticipated and unanticipated other adverse events exceeding a specific frequency threshold.

    - **Administrative Information:** This consists of the study results point of contact and any agreement between the sponsor and principal investigator (PI) restricting the ability of the PI to discuss the results after the completion of the study.

    Detailed information of the FDAAA 801 requirements and instructions for submission of study results may be obtained on the clinicaltrials.gov Protocol Registration and Results System webpage at https://clinicaltrials.gov/ct2/manage-recs/how-report

Online Resources

- ClinicalTrials.gov Home Page
- Checklist to Determine if a Clinical Trial is an Applicable Clinical Trial Requiring Registration
- How to Submit Your Results
- Protocol Registration and Results System (PRS) User's Guide