

	GUIDANCE ON CLINICALTRIALS.GOV REGISTRATION			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	4.07	02.08.2020	5.31	03.25.2019

A. ClinicalTrials.gov

ClinicalTrials.gov is a web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The website is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). This website and database of clinical studies is commonly referred to as a "registry and results database." Trial registration, therefore, serves to promote the public good by ensuring that the existence and design of clinically directive trials are publicly available.

Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study. Most of the records on ClinicalTrials.gov describe interventional studies but the site also contains records describing observational studies and programs providing access to investigational drugs outside of clinical trials (expanded access).

B. Regulations and Other Requirements

1. The *Food and Drug Administration (FDA) Amendments Act of 2007* (FDAAA or U.S. Public Law 110-85) requires registration of “**applicable clinical trials**” that are subject to FDA regulations by a “**responsible party**”.

An **APPLICABLE CLINICAL TRIAL (ACT)** is a study that:

- Prospectively assigns human subjects to intervention and at least one concurrent control or comparison groups;
- Uses a drug, biologic, or device as the intervention or control/comparison; and
- Studies the safety, efficacy, or cause-and-effect relationship between an intervention and a health outcome.

The registration requirement **DOES NOT APPLY** to:

- The use of FDA-approved, marketed products used in the course of medical practice;
- Phase I clinical investigations of drugs or biologics;
- Small clinical trials to determine the feasibility of a device, or clinical trial to test prototype devices in which the primary outcome measure relates to feasibility and not to health outcomes;
- FDA-required pediatric post-marketing surveillance of devices; and
- Purely observational studies, meaning those studies in which the assignment of the intervention is not at the discretion of the investigator.

The **RESPONSIBLE PARTY** is the sponsor of the clinical trial, meaning the person who initiates a clinical investigation:

- For investigator-initiated trials, the lead Principal Investigator is responsible for initiating, conducting, and coordinating the overall clinical trial for registration;
- For sponsor-initiated trials, the sponsor is responsible for registration;

- For trials sponsored or funded wholly or in part by the NIH, the grantee is responsible for registration; **as grantee, LSUHSC-NO designates the principal investigator of the trial as the responsible party;**
- For trials associated with Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications with the FDA, the IND/IDE holder is responsible for registration; and
- For trials associated with Biologics License Applications (BLA), the person who has submitted the application is responsible for registration.

The sponsor, grantee, contractor, or awardee may designate the Principal Investigator of a clinical trial as the responsible party, provided that the Principal Investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for submitting information under the law. ***If it is unclear who is responsible for registering an applicable clinical trial, investigators should consult with the sponsor, funding agency, and/or other study investigators to define who the responsible party will be.***

2. Effective January 18, 2017, *The National Institutes of Health (NIH) Policy on Dissemination of NIH-Funded Clinical Trial Information*, requires registration at ClinicalTrials.gov for **all clinical trials funded wholly or partially by NIH**. NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. This includes Phase 1 clinical trials, and trials that do not involve any FDA-regulated products (such as trials involving only behavioral interventions).
 - To determine if a competing application, contract proposal, funded grant, or awarded contract supports a clinical trial which requires registration, follow the decision tool located [here](#).
 - Competing applications that include studies that are required to be registered must include as part of the Human Subjects Section of the Research Plan a statement that reads, "This application includes a trial that requires registration in ClinicalTrials.gov." The study would then need to be registered at the site.
 - Non-competing continuation applications (1.e., "progress reports") that include studies that are required to be registered must include as part of the Human Subjects Section of the Progress Report the following items:
 - A statement that reads, "This application includes a trial that requires registration in ClinicalTrials.gov,"
 - The National Clinical Trial (NCT) number (i.e., the ClinicalTrials.gov number),
 - Brief Title as listed in ClinicalTrials.gov, and
 - The name of the individual or entity responsible for registering the study (responsible party) for each study being conducted under the application. (As grantee, LSUHSC-NO designates the lead investigator of the trial as the responsible party.)
 - If a Competing or Non-Competing Application does not include studies that are required to be registered, the Human Subjects Section of the Research Plan should

include a statement that reads, "This application does not include a trial that requires registration in ClinicalTrials.gov."

3. Under FDA regulation 21 CFR 50.25(c), the following statement must be reproduced word-for-word in informed consent documents for **Applicable Clinical Trials**: *"A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."*
4. The International Committee of Medical Journal Editors (ICMJE) Initiative requires investigators or sponsors to register clinical trials in the Protocol Registration System (PRS) of ClinicalTrials.gov as an a priori condition for publication.

C. Step by Step Instructions for Registering a Study at ClinicalTrial.gov

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, Kadie Rome, at krome@lsuhsc.edu.
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. **Enter requested information** - 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.

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 **Responsible Party** for "Approval" and "Release" of the record to PRS staff for review.
9. **PRS Staff review the record** - PRS Staff review the record for apparent errors, deficiencies, and/or inconsistencies. If PRS Staff find any potential issues with the record, they will add comments to the record and send an email notification. The **User** 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 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.
11. **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.
12. **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>.

D. Additional Resources

1. [ClinicalTrials.gov](https://clinicaltrials.gov)
2. [Food and Drug Administration \(FDA\) Amendments Act of 2007](#)
3. [The National Institutes of Health \(NIH\) Policy on Dissemination of NIH-Funded Clinical Trial Information](#)
4. [International Committee of Medical Journal Editors \(ICMJE\) Initiative](#)
5. [PRS User's Guide](#)