ClinicalTrials.gov Registration Quick Guide

Instruction: This quick guide supplements ClinicalTrials.gov online help.
Take a few minutes to familiarize yourself with this document, which summarizes requirements and gives entry tips.

- Keep this guide open while you enter information in each section of the registration
- The registration should summarize basic information about a study in lay language
- Registration information is in the Protocol Section — the Document Section can be left empty.

Tips for success:

1. Initiate registration before eIRB study submission. Registration may take up to 10 hours. eIRB study activation (Greenlight) will be held until registration is completed

2. PI, Co-I, experienced research staff to do "Study Design Module", "Arms and Intervention Module" and "Outcome Measures Module" as these sections require basic statistical & epidemiological knowledge

3. Add study coordinators in the *Access List* to help with registration. Record owner/Department PRS Administrator manage user access to the study record

4. Use resources in the Protocol Registration and Results System (PRS)

Screen Tips	Look for short definitions in blue text under the data element on the screen **Example** * Primary Completion Date: Month: June Day: 01 Year: 2017 Type: Actual Final data collection date for primary outcome measure.
Data Element Definitions and Help (*top of screen*)	Help Definitions Click Help for entry tips for the different modules of the *Protocol Section* (each module has a separate *Help* page)
Requirements indicators (*bottom of screen*)	In general, a red asterisk means that entry is required Save Cancel * Required * § Required if Study Start Date is on or after January 18, 2017 [*] Conditionally required (see Definitions)
Validation Messages (*throughout the record*)	**NOTES**: Check if there is a problem with the entries – maybe there is, maybe not **WARNINGS**: It's likely there is a problem (possible there is not), check these carefully **ERRORS**: Fix these—records cannot be released when they contain errors

5. Tips for passing ClinicalTrials.gov QC review
   - Complete all required data elements in the Protocol Section
   - Each outcome measure must describe WHAT will be measured, WHEN the measurement(s) will be made (time frame)
   - Aims (or objectives) are broader goals (e.g., "to assess...", "to evaluate...") that CANNOT be presented as outcome measures, which are specific measurements taken at specific times
   - Only one assessment and time frame may be included in a given outcome measure

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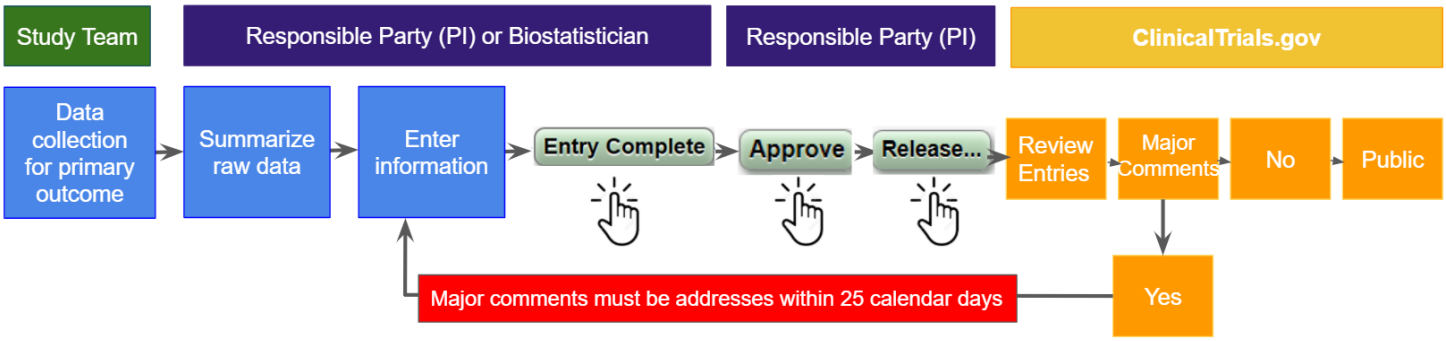
Implementation Date 07/01/20
Adapted from Stanford CRQ

6. Always complete the ClinicalTrials.gov submission cycle

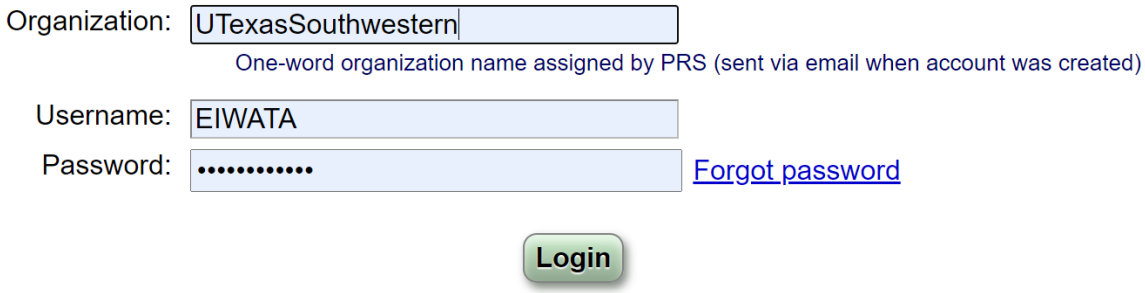


Getting Started:

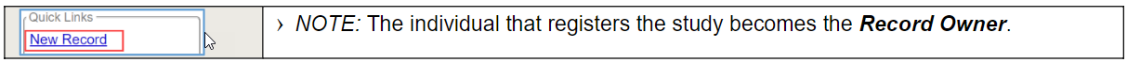
- Log into PRS at https: https://register.clinicaltrials.gov

  Organization: UTexasSouthwestern

  Don't have an account? email at ctgov@utsouthwestern.edu



- To begin a new registration, click **New Record** on the PRS Home Page (login landing page)



UTSW Specific Information & Entry Tips:

This section follows the order of the 13 modules of the Protocol Section of the study record

Study Identification Module	
Organization's Unique Protocol ID	UTSW eIRB STU number (e.g., STU-2020-1234)
Brief Title	Short, in language for lay audience (8th grade level)
Official Title	Should match the title of the protocol
Secondary ID	NIH Grant/contract award number, and any other identifiers

Study Status Module	
Record Verification Date	Current date
	NOTE: The record must be updated at least once a year while the study is active, even if no changes are required (at a minimum, the Record Verification Date must be updated and the record released)
Overall Recruitment Status	Recruitment status best applies to the CURRENT status of the study
Study Start Date	Enter your anticipated/actual start date
	NOTE: Study Start Date is the date of the first signing of informed consent, unless time of enrollment is otherwise specified in the clinical protocol document
Primary Completion Date	Enter Anticipated/Actual Final date when data for the primary outcome measure(s) will be collected - NOT analyzed
Study Completion Date	Enter Anticipated/Actual Final date when data for all outcome measures will be collected - NOT analyzed

Sponsors/Collaborators Module	
Responsible Party	Select Principal Investigator from the Responsible Party drop down menu. In the Investigator Name drop-down menu, select the responsible party name Enter the person's official title (e.g., "Professor of Medicine")
	NOTE: If PI is unresponsive then Sponsor (UTSW) becomes RP temporarily. If trial gets fined, PI be responsible for the FDAAA fines ($12, 103 per day, per study)
Sponsor	Enter University of Texas Southwestern Medical Center. The regulatory sponsor, not the funding institution.
Collaborators	Organizations (not individuals) that provide support (funding, data analysis, etc.)

Oversight Module	
U.S. FDA-regulated Drug Product	Select Yes IF the clinical study is studying and-regulated drug/biologic
	NOTE: A drug/biologic intervention can be included in a study but not be under evaluation
U.S. FDA-regulated Device Product	Recruitment status best applies to the CURRENT status of the study
	NOTE: A device intervention can be included in a study but not be under evaluation
Unapproved/Uncleared Device ***This data element appears if 'U.S. FDA-regulated Device Product' (above) = Yes**	Indicate whether the device product has been approved or cleared by FDA
Post Prior to U.S. FDA Approval or Clearance **This data element appears if 'Unapproved/Uncleared Device' (above) = Yes**	Select Yes to protect ability to publish the results in a journal (allows CTgov to publicly post the information)
Pediatric Postmarket Surveillance	Select Yes **only** if the study is an FDA-ordered pediatric postmarket surveillance study of a device product
Product Exported from U.S.	Refers only to FDA-regulated drug, biologic, or device products. Leave unselected unless the study has no U.S. locations (study sites)
U.S. FDA IND/IDE	Yes IF studying a drug or biologic product with an Investigational New Drug (IND) Application, or a device product with an Investigational Device Exemption (IDE)
FDA Center	Select the FDA center handing the IND or IDE CDER: Center for Drug Evaluation and Research CBER: Center for Biologics Evaluation and Research CDRH: Center for Devices and Radiological Health
IND/IDE number	Enter the IND or IDE number assigned by the FDA center
IND serial number	4 digit number entered on the IND application, Form 1571 (if any). Not applicable to IDEs
Human Subjects Protection Review: Board Status *IRB information *Board status and information is not made public	**Board Status**: In general, select Request not yet submitted until the eIRB study is submitted, then continue to update as status changes **Approval number and contact information:** **Non-UTSW IRB**: If the study relies on another IRB (reliance study), enter information for the approving IRB **UTSW IRB**: if the study relies on the UTSW IRB, enter the following information: -Approval Number: eIRB STU number -Board Name: University of Texas Southwestern Medical Center Institutional Review Board (IRB) -Board Affiliation: University of Texas Southwestern Medical Center -Phone: 214-648-3060 -Email: HRPP@UTSouthwestern.edu -Address: 5323 Harry Hines Blvd Dallas, TX 75390
Data Monitoring Committee	Select Yes IF there is an independent committee to monitor "safety and scientific integrity" of the study
FDA-Regulated Intervention	Leave unselected (legacy field)

Study Description Module	
Brief Summary	Enter the hypothesis/primary and secondary aim(s)/objective(s)of the study **TIP**: -Remove all pronouns (e.g., "I", we, "our" becomes "the investigator", "the study team"; "you", "your" becomes "the participant(s)") -Make sure all acronyms are expanded on their first use -Remove all parenthetical citations -Correct all spelling and grammatical errors
Detailed Description	Not required .In general, the information in the Brief Summary is sufficient. -If primary or secondary outcome measures are listed in this section, but not in the Outcome Measures module, ClinicalTrials.gov may comment following QC review -Check outcome measures for consistency with the clinical protocol document **TIP**: to create a bulleted list in free-text fields, begin each line with a space-hyphen-space. Additional hyphens indent the bullet (2 hyphens = bullet level 2, etc.)

Conditions (& Keywords) Module	
Conditions	Enter primary disease or condition being studied
Keywords	Enter words (e.g., children, pregnant women) or phrases that describe the study

Study Design Module	
Study Type	Interventional or Observational
Primary Purpose	Select the option that best fits this study
Study Phase	If the answer to “U.S. FDA-regulated Drug” is Yes (Oversight module), then a phase number must be entered, otherwise enter N/A
Interventional Study Model	Select the option that best fits this study
	Single Group: Clinical trials with a single arm
	Parallel: Participants are assigned to one of two or more groups in parallel for the duration of the study
	Crossover: Participants receive one of two (or more) alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study
	Factorial: Two or more interventions, each alone and in combination, are evaluated in parallel against a control group
	Sequential: Groups of participants are assigned to receive interventions based on prior milestones being reached in the study, such as in some dose escalation and adaptive design studies
Number of Arms	Enter the total number of arms/groups for this study
Masking	Indicate who (if any) is being masked in this study
Allocation	Select the method by which participants are assigned to arms in a clinical trial. Select N/A if only a single-arm study
Enrollment	Number of participants that are consented on the protocol
	Note: This maybe larger than the number of participants who actually "start" the study (e.g., assigned to a study arm)

Arms and Interventions Module	
	Arms
Arm Title	Should be descriptive but brief (e.g., “Drug A 200 mg” is a better arm name than “Arm 1”) Differentiate groups if more than one (e.g., “Drug A 200 mg” and “Drug A 50 mg”)
Arm Type	Select the option that applies to each arm
Arm Description	Enter detailed description describing the cohort, include the intervention to be administered. (e.g., Participants will take Drug A for 12 weeks, with study visits in clinic for physical and laboratory assessments at weeks 3, 6, and 12.)
Study Phase	If the answer to “U.S. FDA-regulated Drug” is Yes (Oversight module), then a phase number must be entered, otherwise enter N/A
	Interventions
Intervention Type	Select the category that applies to each intervention
Intervention Name	Enter the same name that has been described in the Arm Description (e.g., Drug A 200mg) **Note**: -Drug studies: use the generic name if available -Include all interventions in the study, including placebo
Other Intervention Names (if any)	Enter the brand name or other name(s)used to publicly identify the intervention(if any)
Intervention Description	Should include details about how the intervention is administered (e.g., Drug A 200mg tablet taken orally once daily. Six therapist-led 50- minute Cognitive Behavioral Therapy (CBT) sessions

Outcome Measure Module	
Outcome measures are clinical endpoints and must be specific and measurable **Required: all primary and secondary outcome measures** **Not required: other outcomes of interest, exploratory or tertiary outcome measures** **If the same outcome is assessed at different time points, a separate outcome measure must be created for each time point**	
Title	Describe **WHAT** is being measure (parameter) and how (metric) and time points Examples: • Safety, as measured by number of subject with at least one adverse event as assessed by CTCAE v4.0 • Mean change from baseline in systolic blood pressure at 6 Months • Mean change from baseline in pain scores on the Visual Analog Scale (VAS) at 6 weeks • Mean change from baseline in lesion size at 24 months • Biomarker, as measured by number of participants with XXXXX • Maximum tolerated dose of Drug A in patients with breast cancer • Number of hospitalizations at 24 months
Description	Describe **HOW** each outcome measure, quantitative data, will be reported in detail. If scale will be used, include full unabbreviated name of the scale, what it measures, range of possible scores, and meaning of scores Examples: • Lesion size in millimeters will be measured by ultrasound, at baseline and week 2 • The Hamilton Depression Rating Scale is used for rating the severity of depressive symptoms. Scores range from 0 to 50, with higher scores indicating greater severity of depression. • Scores are measure on a 100 mm VAS. The VAS ranges from 0 to 100 with 0 indicating no pain and higher scores indicating greater pain. • Number of participants who experience adverse events >= Grade 3, as defined by Common Terminology Criteria for Adverse Events by CTCAE v4.0
Time Frame	Describe **WHEN** or how long it will take to assess the outcome measure in a participant Examples: • Week 12 (for single assessment) • Day 1 post intervention • Changes from baseline to 12 weeks (for change measures, 2 time points) • Through end of study (for change measures, continues) • 0, 1, 2, 3, 4, 6, 8, 24 hours post-dose (for pharmacokinetic measure) • From date of randomization until the date of first documented progression or date of death from any cause, whichever came first, up to 100 months (Time to event measure)

Eligibility Module	
Sex	Indicate biological sex of eligible participants
Gender Based	Indicate if participant eligibility is based on self-representation of gender identity.
Age Limits	Specify the eligible age range in (weeks/months/years)
Accepts Healthy Volunteers	Indicate "yes/no"
Eligibility Criteria	Enter criteria in bulleted format. Within this PRS system, a bullet level 1 is typed as "-", a bullet level 2 is typed as "--". When saved, it will convert to a bullet level 1 and bullet level 2

Contacts/Locations Modules	
	Overall Contacts
Central Contact Person	Complete this information only if using a single contact for a multi-center trial. Enter name, or title (e.g., “Study Coordinator”), or group name (e.g., “Study Team”)
Central Contact Backup	Not required
Overall Study Officials ***At least 1 entry is required by publishers**	Enter names and title of the researchers conducting the study In general, this will be the Principal Investigator(s) and Sub-Investigator(s)
	Locations
Facility Information	For each participating facility in the study Click Add Location to enter each study site separately (e.g., UTSW, Parkland, etc...)
Site Recruitment Status	Enter the status for each individual location Must be kept up to date while the Overall Recruitment Status (Study Status module) is Recruiting
Facility Contact	If not using a Central Contact, a facility contact must be provided for each location. Enter name, or title (e.g., “Study Coordinator”), or group name (e.g., “Study Team”)
Investigators	Not required. In general, the information in the Brief Summary is sufficient. Enter Site Principal Investigator(s) and/or Site Sub-Investigator(s)

IPD Sharing Statement Module	
Plan to Share IPD ***Required by publishers in the original registration**	Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study). Select one. Yes: There is a plan to make IPD and related data dictionaries available. No: There is not a plan to make IPD available. Undecided: It is not yet known if there will be a plan to make IPD available.

References Module	
Citations	References that can be linked online; in general indexed by PubMed ID, citation text can also be entered (PRS will still try to match to PubMed)
Results Reference	Select No for any citations entered at the time of registration, (Yes would means the reference contains results of the study being registered)
Links	Provide links to educational, research, government, and other non-profit web pages
Available IPD/Information	If the answer to Share Data is Yes in the IPD Sharing Statement, this area appears for entering links to documents/meta data associated with data sharing. In general, this information is provided at the time when data sharing commences (after study completion) This data element is not related to the study documents that are included in ClinicalTrials.gov results submissions