SDSU | HealthLINK Center

ClinicalTrials.gov

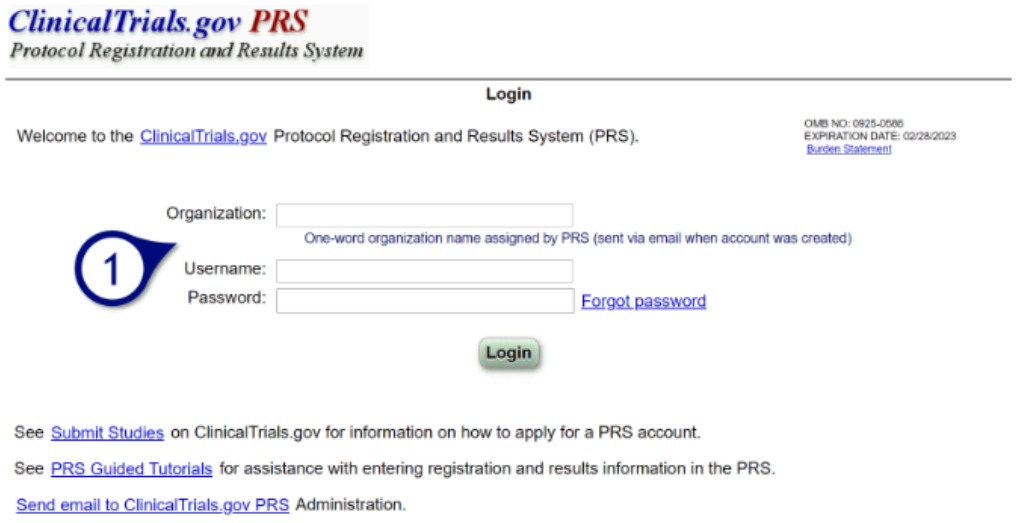
- ☐ Research Projects conducting clinical trials research must register with ClinicalTrials.gov within 21 days of first participant enrollment in the trial
- ☐ Minimally, once per year, the project leader/delegate must ensure ClinicalTrials.gov entries are up to date and consistent with information reported on your organization's RPPR
- ☐ Once enrollment in the trial is completed, researchers should review and complete any applicable updates and final reporting requirements in ClinicalTrials.gov, including study records that must be updated to reflect enrollment status. Report results, Adverse events (AEs), and participants' flow, and updated changes may need to be submitted within 12 months of the primary completion date.
- ☐ Review the Helpful Tips & Frequently Asked Questions Section below

Helpful Tips & Frequently Asked Questions

- **What is ClinicalTrials.gov?**
  A database maintained by the US National Library of Medicine at NIH. It provides information on publicly and privately funded clinical studies conducted around the world.

- **Is there a charge for listing studies on ClinicalTrials.gov?**
  No, there is no charge for listing studies on ClinicalTrials.gov. ClinicalTrials.gov is a free service of the National Institutes of Health, provided through the National Library of Medicine.

- **How can I register my clinical trial on ClinicalTrial.gov?**
  1. Create a record:
     Step 1: If you have not created a record before or have not been added to the Access List for a record, no records will be displayed in your Record List.
     Request a Protocol Registration and Results Sysytem and Results System (PRS) account via your organization's administrator

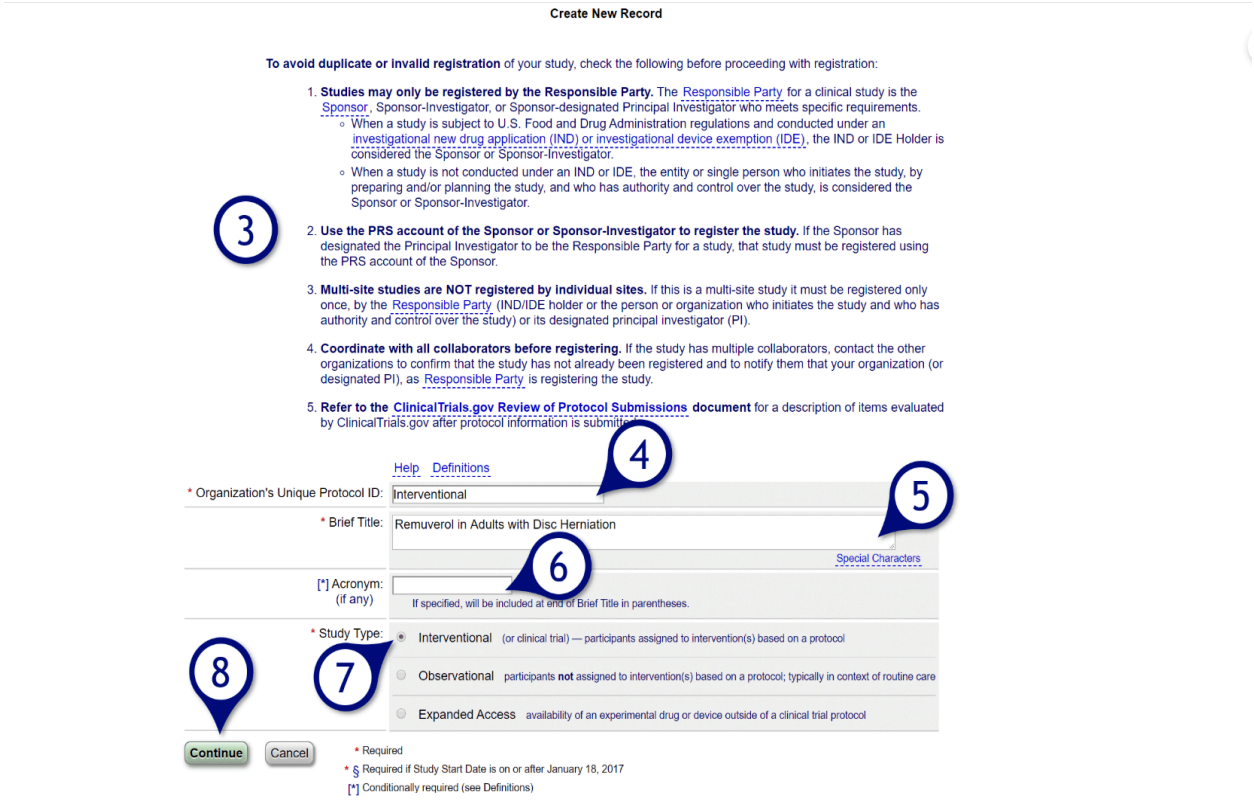


Step 2

From the PRS home page, click on the **New Record** Quick Link or select **New Record** from the Records dropdown menu.

Step 3

To avoid duplicate or invalid registration of your project, review the on-screen tips (1—5) before proceeding to create a new record.



Step 4

On the Create New Record page, you will enter project identification information, which consists of numbers and titles that identify your project information that will appear on ClinicalTrials.gov. Enter the unique protocol identification number used by your organization for the study. If you have not been assigned a Protocol ID by your organization, please use your IRB approval number, or any combination of 30 letters/numbers that can serve as a unique identifier for your record.

Step 5

Enter a Brief Title, using terms easily understandable to the public (use clear language, avoid using overly technical or alarming language to the audience, such as cure, miracle, or guaranteed results). The Brief Title is a short and simplified version of the official title. The title should inform readers of the condition and treatment being studied. This title must be unique within the organization sponsoring the PRS account.

Step 6

Enter an acronym for the project, if applicable.

Step 7

Select the appropriate radio button option for Study Type. Data Elements differ based on the Study Type selected.

Step 8
Click on the **Continue** button.

For more information, you can visit ClinicalTrial.gov tutorials, check the link below
https://cdn.clinicaltrials.gov/documents/tutorial/content/index.html#/lessons/oFLwOJiplbZ2D44Fl-Z6uTTr16GJu4r-

1. Fill Out Trial Information
    a. Enter your project title, description, design, and eligibility criteria.
    b. Add your strategies (treatments) and define outcome measures (what you are measuring).
    c. Provide details on trial locations and sponsors.
2. Add Key Dates
    a. Provide start date, primary completion date (is when the data collection is completed for the primary outcomes of the study, it marks the point at which all the participants have completed their final visit related to the primary outcomes, and study completion date (this is the date when all the data collection ends for the entire study, including secndary outcomes and safey data, it is later date than the primary completion date.
3. Submit the Registration
    a. Review your entries and submit the trial for approval.
4. Update Information

If anything changes, such as:

- Changes in the recruitment status.
- Updated study locations or contacts.
- Reviewing outcome measures.
- Updates to enrollment numbers or key data.
- Any protocol amendments, update the registration with new details.

5. Report Results
    a. Submit trial results within one year of completing the trial (if applicable).

- **Is my Study a clinical trial?**
  Use this Checklist for evaluating whether a clinical trial or project is an Applicable Clinical Trial (ACT) under CFR 11.22(b) for clinical trials initiated on or after January 18, 2017.

- **Why register my Clinical Trial?**
  Registering your trial in ClinicalTrials.gov became a requirement for all NIH-funded clinical trials as of 2007. Most journals will require your ClinicalTrials.gov registration number before accepting your manuscript for potential review and publication in the journal. Even noninvasive approaches may be required to register for clinical trials. See FR 42.CFR part 11.

- **Who is the responsible party to register the Clinical Trial?**

When registering a project, your organization (**San Diego State University)** is designated as the **Responsible Party**. As the study sponsor, SanDiegoSU assumes responsibility for ensuring compliance with all applicable registration and reporting requirements, including the accuracy and completeness of trial information in ClinicalTrials.gov.

- **What information should I register on ClinicalTrial.gov before and after enrolling Participants?**
  Before enrolling participants: Basic Information, Eligibility Criteria, Trial Locations, Interventions, Primary and Secondary Outcomes, Sponsors and Collaborators, Trial Start and Completion Dates, Contact Information, Funding Source

  After Enrolling Participants (Results Reporting): Outcome Measures, Participant Flow, Adverse Events, Statistical Methods, Results Summary, Study Outcomes, Limitations and confounding factors, Publications and presentations, Protocol amendments.

- **When will the NCT Number for my study be assigned?**
  The NCT Number, also called the ClinicalTrials.gov Identifier, is assigned after the protocol information has been released (submitted) by the Responsible Party (PP Leader or delegate) and passed review by ClinicalTrials.gov staff. At that time, an email notification containing the NCT Number is sent to the PP Leader. The record, including its NCT Number, will typically be available on ClinicalTrials.gov within 2–5 business days after it is released.
  See How to Register Your Study for more information.

- **Why can't I find my project on ClinicalTrials.gov?**
  If you are unable to find your project on ClinicalTrials.gov, it might not have been released (submitted) to ClinicalTrials.gov for processing. After a record has been entered into PRS (or modified) and marked as complete, it must be approved and released by the Responsible Party (see Responsible Party data element on ClinicalTrials.gov).

  The study might also be undergoing review. After the Responsible Party releases (submits) information to ClinicalTrials.gov, that information undergoes a manual review to identify possible errors, deficiencies, or inconsistencies that are not detected automatically during data entry. The Responsible Party will be notified of any issues that need correction, usually within a few days after release of the protocol information. The review of results information may take longer (up to 30 days).
  See How to Register Your Study and How to Submit Your Results for more information.

- **What are the penalties for failing to register?**

For extramurally-funded awards, penalties may include the withholding or recovery of funds. Failing to register may also result in the automatic rejection of manuscripts by a journal that requires compliance with registration of clinical trials.

For more information, visit those links below:

NLM Webinar: Introduction to the Modernized Protocol Registration and Results System

PRS User's Guide | ClinicalTrials.gov

Protocol Registration Data Element Definitions for Interventional and Observational Studies | ClinicalTrials.gov

Frequently Asked Questions | ClinicalTrials.gov

SDSU | Research Support Services

Customized ClinicalTrials.gov Checklist

This checklist is tailored to ensure smooth registration and compliance for your clinical trial.

Pre-Registration Checklist

1. **Determine Need for Registration**
   - Does the study meet NIH/FDA requirements for registration?
   - Is the trial federally funded, involve FDA-regulated products, or required by institutional policy?

2. **Assign the Responsible Party**
   - When registering a study, **San Diego State University (SanDiegoSU)** is designated as the **Responsible Party**. As the study sponsor, SanDiegoSU assumes responsibility for ensuring compliance with all applicable registration and reporting requirements, including the accuracy and completeness of trial information in ClinicalTrials.gov.

3. **Gather Study Information**
   - Study title and brief summary.
   - Study type (e.g., interventional, observational).
   - Key dates (study start, anticipated completion).
   - Interventions (name, type, dosage).
   - Primary and secondary outcome measures (specific and measurable).
   - Eligibility criteria (inclusion/exclusion details).
   - Site locations and contact information.

4. **Secure PRS Access**
   - Request a Protocol Registration and Results System (PRS) account via SDSU administrator.

Research Support Services
Division of Research and Innovation
5250 Campanile Drive
San Diego, CA 92182-1933
Tel: 619/594-5938
Email: RSS@sdsu.edu

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Registration Checklist

1. **Log into PRS Account**
   - Use your individual PRS account.

2. **Create a New Record**
   - Enter:
     - **Study Identification**: Title, unique protocol ID, study phase, and brief description.
     - **Sponsor/Collaborators**: Responsible Party and funding sources.
     - **Study Design**: Masking, allocation, intervention model.
     - **Outcomes**: Clearly define primary and secondary outcomes.
     - **Recruitment Info**: Status, location, and contact details.
     - **Eligibility**: Age, sex, inclusion/exclusion criteria.
     - **Intervention Details**: Drugs, devices, or other interventions.

3. **Validate the Record**
   - Use the PRS validation tool to identify and fix errors or missing fields.

4. **Submit for Review**
   - Submit the record to ClinicalTrials.gov for review and approval.

Post-Registration Checklist

1. **Update Information Regularly**
   - Recruitment status (e.g., enrolling, completed, terminated).
   - Protocol changes (update within 30 days).

2. **Respond to ClinicalTrials.gov Feedback**
   - Address reviewer comments promptly to avoid delays in approval.

3. **Keep Records Consistent**
   - Ensure registration matches the IRB-approved protocol.

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Results Reporting Checklist

1. **Gather Results Data**
   - Primary and secondary outcome measures.
   - Participant flow and baseline characteristics.
   - Adverse events (serious and other).

2. **Input Results in PRS**
   - Use the Results Section in PRS to report:
     - Participant flow.
     - Baseline demographics.
     - Outcome measures.
     - Adverse events.

3. **Validate Results**
   - Use PRS validation to identify and fix any errors or incomplete fields.

4. **Submit Results**
   - Results must be submitted **within 12 months** of the primary completion date.

Additional Tools and Reminders

- **Templates**: Use PRS templates for consistency.
- **Deadlines**: Set calendar reminders for key dates (updates, results reporting).
- **Help Desk**: For assistance, contact the SDSU Clinicaltrials.gov administrator, Eric Morgan, at ejmorgan@sdsu.edu.
- **Training**: Attend webinars or review PRS Tutorials.

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SanDiegoSU CLINICALTRIALS.GOV Review Checklist

PROTOCOL ID	RECORD OWNER	REVIEWER	❑ Registration ❑ Update status ❑ Results *(add Results checklist)*	❑ pACT/ACT ❑ Non-ACT
NCT#				

DATE RELEASED	COMMENTS DATE	REPLY DATE	DATE PUBLISHED

GENERAL REVIEW ITEMS	NOTES
❑ No monetary value (e.g. compensation, food voucher) should be entered anywhere in the protocol ❑ Record Owner is the PI or Coordinator – Admin Only ❑ Contact info for Record Owner is up-to-date ❑ PI on record matches IRB PI: _____ ❑ NCT# included in IRB "Clinical Trials Information" section ❑ All Warnings/Errors addressed ❑ All parenthetical citations have been removed ❑ All acronyms have been expanded on their first use ❑ Spell-check complete ❑ Free-text fields are blank if there is no information to report, and do not contain text such as "TBD," "Pending," "N/A," "None"	

PROTOCOL SECTION

STUDY IDENTIFICATION

- ❑ Unique protocol ID is the IRB#
- ❑ Brief Title does not include study type (e.g., Phase I, Randomized…)
- ❑ Official title should match what is in the IRB (or grant application if applicable)
- ❑ Secondary IDs include NIH grant #s (verify in IRB)

STUDY STATUS

- ❑ Record Verification Date is the current month/year
- ❑ Overall Status matches IRB
- ❑ Study start date verified with enrollment date
- ❑ Completion Dates Actual/Anticipated have been evaluated for accuracy
- ❑ If timeframes for outcomes are the same the primary and study completion dates are identical

SPONSOR/COLLABORATORS

- ❑ Responsible Party: Sponsor
- ❑ All sources of support identified in IRB "Support Information" section included as Collaborators
- ❑ Full Name used and if not recognized, "Recognize" is selected

OVERSIGHT

- ❑ IND/IDE information completed (if applicable)

Verify Human Subjects Review

- ❑ Board Status verified
- ❑ Approval Number is a valid IRB number
- ❑ Board Name: San Diego State University IRB
- ❑ Board Affiliation: San Diego State University
- ❑ Phone: 619-594-6622 Email: irb@sdsu.edu
- ❑ Address: 5500 Campanile Drive, San Diego CA 92182

STUDY DESCRIPTION

- ❑ Brief Summary does not unnecessarily duplicate information provided for other data elements
- ❑ Brief Summary clearly states the study's hypothesis or the purpose (for interventional and observational)
- ❑ Brief Summary and Detailed Description are written in complete sentences with no formatting errors
- ❑ **Record does not use personal pronouns: "I, my, we, our, us" – becomes "the investigator(s)"; "you, your, they, them, their" – becomes "the participant(s)"**

CONDITIONS

- ❑ Conditions/Focus of study are discrete and does not use verbs or complete sentences
- ❑ Keywords are not numbered or bulleted, each condition and keyword is listed individually, one per line

STUDY DESIGN

- ❑ All required fields are completed
- ❑ Verify Study Design based on protocol in IRB
- ❑ "Allocation" marked as "N/A" for single-arm interventional studies
- ❑ Enrollment number Actual/Anticipated verified

ARMS/INTERVENTIONS

- ❑ Arm Title or Group/Cohort Label is brief and informative (even if there is only 1 arm)
- ❑ Interventions and intervention descriptions are entered correctly (drug or device names should be added to title and description)
- ❑ Arms/interventions are cross-referenced appropriately

OUTCOME MEASURES

- ❑ Title is "outcome neutral", specific and states WHAT is being measured, only 1 variable must be assessed per outcome measure (unless it is a composite)
- ❑ Description explains WHAT is being measured, not WHY it is being measured
- ❑ Scoring scale name, score range, significance of upper and lower limits specified (if applicable)
- ❑ Unit of measure specified
- ❑ Time frame specified as a single time point or change between 2 time points (if unsure of duration, add up to the duration team is willing to follow each participant for that outcome measure e.g. "up to 1 year")
- ❑ Time points written in full e.g. 5 hours not 5hrs, 60 minutes not 60mins, 2 years not 2yrs
- ❑ Time frame is not the whole duration of study if outcome measure specifies a duration for the assessment of that measure which is less than whole duration of study

  INCORRECT: "Safety and Toxicity", Description: "Safety of study drug."
  CORRECT: *"Safety as assessed by number of participants experiencing adverse events"* Description: *"Number of participants experiencing adverse events grade 3 or higher, as defined by Common Terminology Criteria for Adverse Events version 5.0 (CTCAE v5.0)"*

ELIGIBILITY

- ❑ Age Limits are consistent with the Eligibility Criteria and with other parts of the record
- ❑ Eligibility criteria is divided into Inclusion/Exclusion criteria in bulleted format

CONTACTS/LOCATIONS

- ❑ Central Contact Person specified and accurate
- ❑ Study Officials match IRB
- ❑ All study sites specified matches CRMS
- ❑ Recruiting status for each study site accurate (if at least one study site is recruiting then Study Status reflects "Recruiting")
- ❑ Each facility is listed in a separate field

IPD Sharing Statement

- ❑ The Plan to Share IPD selection is consistent with the IPD Sharing Plan Description.

REFERENCES

- ❑ Each citation is listed in a separate field (if applicable)

Add results checklist if results entry submitted.

RESULTS SECTION

PARTICIPANT FLOW

- ❑ Protocol Enrollment refers to total number of subjects who consented to protocol (including withdrawals, etc.)
- ❑ Recruitment details (optional) explains any specifics used at time of recruitment
- ❑ Pre-assignment details explains (in detail) what happened to subjects who signed consent but were not assigned to an arm/intervention (i.e., how many screen failures, withdrawals, etc.)
- ❑ Arms and arm descriptions specified consistent with protocol section
- ❑ Number of Participants Started refers to total number of participants assigned to each arm
- ❑ Number of Participants Completed refers to total number of participants who completed study intervention
- ❑ Reason(s) for Not Completed provided (optional)
- ❑ Divided into periods/milestones appropriately
- ❑ Total number of participants started cannot be greater than enrollment number
- ❑ Total number completed is equal to or less than "started"

BASELINE CHARACTERISTICS

- ❑ Overall Number of Baseline Participants should match Number of participants Started (from Participant Flow)
- ❑ Baseline Analysis Population Description explains if there is a discrepancy between Overall & Started numbers
- ❑ Arm titles/descriptions are consistent with participant flow and/or protocol section
- ❑ Data is presented per arm or all participants together for crossover design
- ❑ If "number of participants" is reported, make sure Measure Type is "Count of Participants"
- ❑ Measure description is specified for all Study-specific measures

OUTCOME MEASURES

- ❑ Titles/descriptions/time frame meet the criteria (as specified on prior checklist)
- ❑ Results are reported per arm or by intervention for crossover design
- ❑ Analysis Population Description includes reason why Number of Participants analyzed is different than total number of participants completed (if applicable)
- ❑ Type and Number of Units analyzed is indicated, if other than "number of participants" (i.e., # of Lesions)
- ❑ Unit of measure matches what is stated in Outcome Title/Description
- ❑ Sum of all results entered for each arm equals overall number of participants analyzed
- ❑ Verify true data is entered and there are no placeholders
- ❑ Time frame specified should not be more the duration of the study
- ❑ Statistical Analysis portion is optional (if entered, review for accuracy)

ADVERSE EVENTS

- ❑ Time frame specified
- ❑ Collection Approach specified
- ❑ Arm titles/descriptions consistent with other sections in the record
- ❑ Data presented per arm
- ❑ All-cause mortality specified (cross-check with number "not completed due to death" from participant flow and any mortality measures in outcome section, if applicable)
- ❑ Total Number "At Risk" must be equal to total number of participants who started the study

LIMITATIONS AND CAVEATS

- ❑ Information here should only be about limitations, unvalidated data or any reason why data entered cannot be totally reliable. It should not contain any discussion of results or any other information.

CERTAIN AGREEMENTS

- ❑ Principal Investigators are employed by the organization sponsoring the study

RESULTS POINT OF CONTACT

- ❑ Information is correct and valid email address/phone number entered

DOCUMENT SECTION

- ❑ Protocol (required for primary completion date after January 18, 2017)
- ❑ Statistical Plan (required for primary completion date after January 18, 2017)
- ❑ Informed Consent Form (required for studies approved on or after January 21, 2019)
- ❑ Each Document must have a Cover Page that includes the following:
  - ❑ Record (NCT) Number
  - ❑ Study Title
  - ❑ PI Name
  - ❑ Date of Document (must match date within actual document)
- ❑ Additional Documents: _____
- ❑ Uploaded document(s) does not include a publication

REFERENCES

- ❑ Links are verified (if applicable)