ClinicalTrials.gov

ClinicalTrials.gov Registration and Reporting

ClinicalTrials.gov is a **website** and **online database** of clinical research studies and information about their results. The purpose of ClinicalTrials.gov is to provide information about clinical research studies to the public, researchers, and health care professionals. The U.S. government does not review or approve the safety and science of all studies listed on this website.

ClinicalTrials.gov:

- Relies on sponsors or investigators to submit and update information about studies
- Lists up-to-date information on clinical research studies and their results with new studies added almost every day
- Includes studies that take place in all 50 states and over 200 countries
- Supports laws, regulations, and policies that require sponsors and investigators to publicly share information about clinical trials, including results

Most interventional studies with health outcomes must be registered, and may be required to report results, in ClinicalTrials.gov. Those responsible for conducting a clinical trial must ensure that they are in compliance with these requirements for:

- All NIH-funded trials including phase 1 studies and clinical trials of behavioral or non-FDA-regulated interventions (Registration and Results required)
- Clinical trials involving FDA-regulated drug, biologic and device products (Registration and Results required).
- Studies that will bill routine costs to Medicare or any other insurer (Registration required)
- Clinical trials intended for publication in a journal recognized by the ICMJE (Registration required).
- Informed Consent Statement

Registration may be required by law and/or policy if any one (or more) of the following is true:

Required by Law

Required by Your Funding Source

Required for Journal Publication

Required for Billing

The CTSI Office of Regulatory Affairs (ORA) offers assistance to UCLA investigators for registration and/or results reporting of investigator-initiated clinical trials (IITs):

- **ClinicalTrials.gov Protocol Registration:** ORA to perform registration entries in the Protocol Registration System (PRS) for ClinicalTrials.gov in compliance with Protocol Registration Quality Control Review Criteria

https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf, and update/verification as needed through study duration (minimum annually)

- **ClinicalTrials.gov Results Reporting – Option #1:** ORA will provide fillable tables or lists specifying results data required, to be completed and returned via email, and ORA will perform data entry. ORA will respond to reviewers' comments, with information provided by PI/statistician as needed.
- **ClinicalTrials.gov Results Reporting – Option #2:** ORA will meet with PI/statistician via one or two ZOOM meetings to (1) explain PRS data entry requirements for results reporting, (2) guide through data entry process for results reporting and statistical analyses (if applicable), (3) Review and provide feedback prior to submission on entries likely to violate review criteria.

Registration and Results Reporting (Direct Costs)	ClinicalTrials.gov Protocol Registration	ClinicalTrials.gov Results Reporting – Option #1	ClinicalTrials.gov Results Reporting – Option #2
Fee Classification	Required Pass-Thru	Required Pass-Thru	Required Pass-Thru
Per Study	Per Study	Per Study	Per Study
Fee	$1,500	$2,500	$1,000

If you have questions or need assistance, please contact the CTSI Office of Regulatory Affairs.

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