

## How to Register a Study

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The <u>"Guidance for Registering in the ClinicalTrials.gov Registry"</u> document provides guidance for UCLA investigators, plus selected tips on how to initiate a new record. Please review the <u>UCLA Creating a New Study Record</u> document. Detailed instructions, examples, data entry tips and a review checklist are also available by logging in to your PRS user account and selecting <u>Help > Protocol Data Entry.</u>

The Clinical and Translational Science Institute (CTSI) Office of Regulatory Affairs (ORA) assists investigators conducting non-oncology related research with the process of registering trials with clinicaltrials.gov. Please contact the <u>UCLA PRS Administrator</u> for more details.

The <u>JCCC Office of Regulatory Compliance (ORC)</u> assists investigators conducting oncology related research with the process of registering trials with clinicaltrials.gov.

### Timelines & Deadlines

#### **Registration:**

- Not later than 21 calendar days after enrollment of the first participant (Applicable Clinical Trials under FDAAA 801 and NIH-funded clinical trials)
- Prior to enrollment of the first participant (for publication in journals adhering to ICMJE standards).

#### Required Updates:

- Within 30 days of a change to Recruitment Status, or Completion Date data elements
- Within 15 calendar days of a change to Device Approval Status
- General updates to the record (or verification of no changes) must be made at least every 12 months

#### Correction of errors, deficiencies:

- Registration: 15 calendar days after Review Comments
- Results: 25 calendar days after Review Comments

#### **Results:**

• Not later than 12 months after Primary Completion Date (The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated.)



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