How to Register a Study
It takes approximately 2 hours to enter registration information. The system offers the option to save data as you go, in case you do not have time to complete the entire process. It is possible to copy and paste information from the protocol into the data fields.

1. Log in to the ClinicalTrials.gov Protocol Registration and Results System using your login name and password. The Organization name is DukeUMC. Contact the DOCR ClinicalTrials.gov team to create an account or change your password.

2. To create a new record, select "New Record" from the Quick Links section at the upper-left corner of the page. The person who creates the new record will be designated as the Record Owner and is responsible for maintaining the registration. To change the Record Owner, contact the DOCR ClinicalTrials.gov team.

Institution-Specific Information to Enter

- **Unique protocol ID:** Use the Duke University Health System IRB number (ProXXXXXXX).
- **Secondary IDs:** Enter the grant number, funding agency number or other funding source number, if applicable.
- **Responsible Party:** Defaults to “Sponsor”. If the study is under an IND or IDE, choose "Sponsor-Investigator" from the drop down menu and choose the IND/IDE holder as the Sponsor-Investigator. Do not choose “Principal Investigator”.
- **Investigator Name:** Displays only if “Sponsor-Investigator” is chosen as the Responsible Party. If the IND/IDE holder’s name is not displayed in the drop down menu, contact the DOCR ClinicalTrials.gov team to create an account for the IND/IDE holder.
- **Board Information:**
  - Board Name: Duke University Health System Institutional Review Board
  - Board Affiliation: Duke University Health System
  - Board Contact: Phone: 919-668-5111
  - Email: power008@duke.edu
  - Address: 2424 Erwin Road, Suite 405; Box 2712 DUMC, Durham, NC 27705
- **Oversight Authorities:** Always include “United States: Institutional Review Board”. Only include “United States: Food and Drug Administration" if the study is under an IND or IDE.
3. When entry is complete, click the green “Entry Complete” button on the Record Summary page. The template will be forwarded to the Responsible Party, who will review it and release the approved content to ClinicalTrials.gov for quality assurance review. If ClinicalTrials.gov PRS reviewers find problems with the record, it will be returned to the Record Owner with PRS Comments. The issues will need to be addressed and the record re-released to ClinicalTrials.gov within 15 days for QA and subsequent posting. When ClinicalTrials.gov has accepted the record, the Record Owner will receive an email with the NCT#.

**Tips for Success**

- Always return to the Record Summary page and click the green Entry Complete button to submit the registration.
- “Errors” must be resolved before you can submit. “Notes” should be reviewed; however, revisions are not required for submission.
- Do not use first or second person (i.e. replace “we” and “you” with “the investigator” and “participants”).
- Check for spelling errors by clicking the spelling link on the Record Summary page before selecting the “Entry Complete” button.
- The most common reason ClinicalTrials.gov returns a record for revisions is issues with the Outcome Measures section. Review the Protocol Review Criteria, starting on page 2, for helpful hints.