

ClinicalTrials.gov

This guide has been created for Principal Investigators and study teams to effectively use ClinicalTrials.gov

1. CREATE AN ACCOUNT

Contact the appropriate Protocol Reporting System (PRS) Administrator

- Northwestern University – Tomek Wojtasik (clinicaltrials.gov@northwestern.edu)
- Shirley Ryan Ability Lab – David Zembower (dzembower@sralab.org)
- Robert H Lurie Comprehensive Cancer Center – Ashlee Drawz (a-stephens@northwestern.edu)

2. REGISTRATION

A. Check whether your study requires registration, registration is required if:

- The study meets the requirements for an Applicable Clinical Trial (ACT) [Definition of an ACT](#)
- Is partially or wholly NIH funded (for other federal agencies/departments, confirm requirements with your grant officer)
- You are planning to publish in a journal requiring registration

B. Log-on to PRS: <https://register.clinicaltrials.gov/>

C. Enter the required and optional data elements

D. Assign the PI as the Responsible Party (RP)

E. Check for any “Errors” or “Warnings” and use the “Spelling” feature to proofread and ensure that all acronyms are expanded

F. Have the RP approve and release the record for review by a ClinicalTrials.gov PRS Reviewer

G. Submit a complete and timely response to any comments from the ClinicalTrials.gov PRS Reviewer

3. RESULTS REPORTING

A. You are required to submit results within 12 months of your primary completion date if:

- Your study is an ACT or probable-ACT
- Your study is partially or wholly NIH funded (for other federal agencies/departments, confirm requirements with your grant officer)
- You are planning to publish in a journal requiring ClinicalTrials.gov results submission

B. Start preparing early and consult the tutorial [Results Tutorial](#) as reporting can be a time-consuming and rigid process

C. Submit prior to the 12-month timeline and address any comments from the ClinicalTrials.gov PRS Reviewer

D. Contact clinicaltrials.gov@northwestern.edu for any questions

4. TIPS, TRICKS, AND TIMELINES

- ICMJE requires trial registry at or before first patient enrollment as a condition for publication, for ACTs the deadline is within 21 days of first patient enrollment
- Set calendar reminders:
 - Records whose status is not “Completed”, “Terminated”, or “Withdrawn” must be updated every 12 months
 - Update the Overall Recruitment Status and Completion or Start dates as soon as they change.
 - As soon as the Start Date or Completion Dates pass, change them from “Anticipated” to “Actual”
 - As soon as you change the status to “Completed”, “Terminated”, or “Withdrawn”, change the number of participants enrolled from “Anticipated” to “Actual” and enter the accurate enrollment number.
 - Enter and submit basic results no later than 12 months after the Primary Completion Date
- Contact clinicaltrials.gov@northwestern.edu with any questions or if the PI leaves the institution