NUCATS Clinical and Translational Sciences Institute

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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 – Bishop C. Knight (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. Determine if you have an Applicable Clinical Trial (ACT) which requires 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 spelling and to see that all acronyms are expanded using the "Spelling" feature
   F. Check for any "Errors" or "Warnings"
   G. Have the RP approve and release the record for review by a ClinicalTrials.gov PRS Reviewer
   H. Submit a complete and timely response to any comments from the ClinicalTrials.gov PRS Reviewer

3. RESULTS REPORTING
   A. Determine if you have an Applicable Clinical Trial (ACT) which requires results reporting
   B. Start preparing early as results reporting can be a time-consuming and rigid process
   C. Enter the required and optional data elements and submit prior to the 12-month timeline
   D. Contact clinicaltrials.gov@northwestern.edu for any questions

4. TIPS, TRICKS AND TIMELINES
   - ICMJE requires trials registry at or before first patient enrollment as a condition for publication
   - Set calendar reminders:
     □Records must be updated every 12 months
     □If Overall Recruitment Status or completion date changes, then update record within 30 days
     □Enter and submit basic results no later than 12 months after the Primary Completion Date
   - Contact clinicaltrials.gov@northwestern.edu if the PI leaves the institution
   - Contact clinicaltrials.gov@northwestern.edu for any questions