Touro University Nevada

Instructions for ClinicalTrials.gov registration and administration

The instructions provided online are quite comprehensive, so this document provides some basic information and links that would usually be needed to meet the requirements.

Who needs to register a study, and why?

1. Why?
    a. Required by FDA (FDAAA801 and human subjects research laws (42 CFR Part 11), plus many funding agencies (check requirements)
    b. Required for publication in any journal associated with the International Committee of Medical Journal Editors (ICMJE)
2. Brief overview of scope of studies that must be registered and timing of registration:
    a. What: The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention *and* a health outcome.
    b. Intervention: Drug, Biological, Device, surgical procedure, behavioral intervention, educational intervention
    c. When: "at or before the time of first patient enrollment" (ICMJE)
3. References: https://clinicaltrials.gov/ct2/manage-recs/background ; http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

Mechanics and details of registration

1. Obtaining a PRS account. Email Dr. Vanier (cvanier@touro.edu) to request an account. The system will send an email to you to complete the process after you are entered.
    a. **Organization**: TouroUN
    b. **TUN ClinicalTrial.gov administrators**:
        i. Cheryl Vanier (cvanier@touro.edu)
        ii. Drew Ehlert (dehlert@touro.edu)
2. Landing page for ClinicalTrials.gov:
    a. https://register.clinicaltrials.gov/prs/app/action

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3. User Guide for the Protocol Registration and Results System (PRS) used by ClinicalTrials.gov
    a. https://prsinfo.clinicaltrials.gov/prs-users-guide.html
4. Help: https://clinicaltrials.gov/ct2/manage-recs/how-apply

Help with entering information

5. How to determine responsible party and applicable clinical trial
    a. https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf
6. Details and definitions to help fill out the PRS information
    a. https://prsinfo.clinicaltrials.gov/definitions.html
7. Quality control review criteria (for checking the submission)
    a. https://prsinfo.clinicaltrials.gov/ResultsDetailedReviewItems.pdf

ClinicalTrials.gov FAQ: https://clinicaltrials.gov/ct2/manage-recs/faq#42CFRPart11