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1. PURPOSE

- 1.1. The purpose of this procedure is to describe the registration process for clinicaltrials.gov.
- 1.2. This procedure begins when a registration record is started in clinicaltrials.gov.
- 1.3. This procedure ends when the registration record receives a National Clinical Trial (NCT) number and is publicly posted on the clinicaltrials.gov website.

2. POLICY

- 2.1. The Principal Investigator as Responsible Party¹ must ensure the timely, complete and accurate entry of information into the clinicaltrials.gov Protocol Registration and Results System (PRS) and ensure the timely resolution of any PRS issues preventing the submission or posting of the trial on the clinicaltrials.gov website.

3. RESPONSIBILITY

- 3.1. The Responsible Party must ensure the timely, complete and accurate registration of clinical trials, including: entry of information into the clinicaltrials.gov PRS system, release of the record for PRS review, resolve any issues or errors in the record during the registration process and timely response to any PRS comments or issues.
- 3.2. The Responsible Party may designate a study team member or similar to perform administrative entry into the PRS system; However, ensuring the timely, complete and accurate registration and submission remains with the Responsible Party.
- 3.3. The UMass Medical School (UMMS) local PRS administrator is available for consultation and guidance, and performs verification that errors and warnings are resolved.

4. PROCEDURE

4.1. Registration

- 4.1.1. The Responsible Party must ensure the timely and complete registration of the study in Clinicaltrials.gov.
 - 4.1.1.1. The Responsible Party, or Responsible designee, must enter all required information into the PRS system, using the Registration Entry Guide for assistance and guidance on UMMS-specific record requirements.
 - 4.1.1.2. Once the entry is complete, the Responsible Party or Designee routes the record for UMMS administrative review by selecting "Entry Complete"
 - 4.1.1.3. Once the UMMS PRS administrator has reviewed the record, and has selected "Approved" in the system, the Responsible Party must log in to select "Release" to release the record for PRS review.
- 4.1.2. If the record is complete, and PRS review does not detect any errors or other major issues, the record will receive an NCT number and will be publicly posted on clinicaltrials.gov
- 4.1.3. If there are major issues with the registration, the Clinicaltrials.gov PRS administrators will return the record, with comments, for correction. The Responsible Party and Designee repeats the steps in 4.1.1.2 and 4.1.1.3., above.
- 4.1.4. A record is not considered "registered" until it has been assigned an NCT number, and the record will not receive an NCT number until the issues are resolved and the record clears PRS Administrator review.

¹ See CTGov-002 for designation of Responsible Party

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5. REFERENCES

- 5.1. <https://clinicaltrials.gov/ct2/manage-recs/how-register>
- 5.2. FDA
 - 5.2.1. 42 U.S.C. 282
 - 5.2.2. 42 CFR 11.