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1. PURPOSE

- 1.1. The purpose of this procedure is to describe when clinicaltrials.gov records must be reviewed and updated.
- 1.2. This procedure begins when there is a change to the study which requires update to the record or at least annually.
- 1.3. This procedure ends when the registration record is updated and/or reviewed.

2. POLICY

- 2.1. The Responsible Party must ensure the timely update and routine review of clinicaltrials.gov registration records.

3. RESPONSIBILITY

- 3.1. The Responsible Party must ensure the timely update and routine review of clinicaltrials.gov registration records.
- 3.2. The UMass Medical School (UMMS) local PRS administrator reviews the list of records due for annual review, and notifies the Responsible Party and designated individuals.

4. PROCEDURE

4.1. Record Update

- 4.1.1. The Responsible Party must ensure that registration records are updated within 30 days of:
 - 4.1.1.1. Study Activation or Completion
 - 4.1.1.2. Change to Study Recruitment Status
 - 4.1.1.3. Change to Approval Status
 - 4.1.1.4. Change in Responsible Party, or Responsible Party affiliation
- 4.1.2. It is also expected that the registration record will be updated within 30 days of any change to study outcomes, arms, procedures and inclusion/exclusion criteria.
- 4.1.3. With all changes, update the Record Verification Date to the current month and year.
- 4.1.4. Route the record to the UMMS PRS administrator by selecting "Entry Complete".
- 4.1.5. Once the UMMS PRS administrator completes review, the Responsible Party must release the record for final PRS review.

4.2. Record Maintenance

- 4.2.1. At least every 12 months, the Responsible Party must review the registration record to ensure it remains accurate. Key items include:
 - 4.2.1.1. Study contact information
 - 4.2.1.2. Study personnel
 - 4.2.1.3. Funding or sponsorship
 - 4.2.1.4. Any changes in 4.1.1.1 to 4.1.1.4. not previously made
- 4.2.2. Once the record has been reviewed and all applicable changes have been made, update the Record Verification Date to the current month and year.
- 4.2.3. Once the UMMS PRS administrator completes review, the Responsible Party must release the record for final PRS review.

5. REFERENCES

- 5.1. 42 CFR Part 11
- 5.2. <https://clinicaltrials.gov/ct2/manage-recs/how-register>