Clinicaltrials.gov Record Update and Maintenance

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 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