1. PURPOSE

1.1. The purpose of this procedure is to describe how to determine (1) which clinical trials must be registered in the Clinicaltrials.gov Protocol Registration and Results (PRS) system and (2) the Responsible Party for the registration record.
1.2. This procedure begins when a Principal Investigator initiates a new Clinical Trial.
1.3. This procedure ends when the trial is registered in the PRS system.

2. POLICY

2.1. The Principal Investigator is responsible for determining (1) if his/her study must be registered in the Clinicaltrials.gov Protocol Registration and Results System (PRS) under one or more of the categories outlined, below, and (2) whether s/he meets the definition of Responsible Party and is responsible for registration of the trial in the PRS system of Clinicaltrials.gov.
2.2. The Principal Investigator/Responsible Party on a Clinicaltrials.gov registration record must be the same as the Principal Investigator on the IRB submission/approval.

3. RESPONSIBILITY

3.1. The Principal Investigator must determine if his/her study meets the definition of clinical trial which requires registration in the clinicaltrials.gov PRS system, and for serving as the Responsible Party as Principal Investigator or Sponsor-Investigator.

4. PROCEDURE

4.1. Registration Determination

4.1.1. The Principal Investigator must assess whether his/her study meets one or more of the categories, below to determine if registration in clinicaltrials.gov is required:

4.1.1.1. Any study meeting the World Health Organization (WHO) definition of Clinical Trial which is intended for publication in a journal adhering to **International Conference of Medical Journal Editors (ICMJE) policy**:
4.1.1.2. Any study funded in whole or in part by the National Institutes of Health (NIH) which meets the NIH definition of a Clinical Trial (**National Institutes of Health (NIH**) **policy)**
4.1.1.3. Any study which meets the definition of “Applicable Clinical Trial” as defined by Food and Drug Administration Amendments Act of 2007 **(FDAAA 801)**
4.1.1.4. Any study which meets the definition of Qualifying Clinical Trials as outlined in **Center for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) 310.1** and which intends to bill Medicare for Routine Costs **(NCD 310.1)**

4.1.2. The Principal Investigator can opt, at Investigator’s discretion, to voluntarily register their study even if it does not meet one or more of the categories listed in 4.1.1 to 4.1.4

4.2. Responsible Party Determination

4.2.1. For UMMS single-site studies: the Principal Investigator is the Responsible Party and will identify as such in the registration as either the Principal Investigator or Investigator-Sponsor.

4.2.1.1. If the Principal Investigator is the holder of the IND/IDE, the Principal Investigator is the "Investigator Sponsor" for clinicaltrials.gov registration.

4.2.1.2. If UMMS is receiving external funding via sponsored research agreement to conduct the research, select "Principal Investigator" with sponsor UMass Worcester for clinicaltrials.gov registration.

4.2.1.3. If UMMS is not receiving external funding via sponsored research agreement to conduct the research, select "Sponsor-Investigator" for clinicaltrials.gov registration.

4.2.2. For Multi-Site Studies: the Responsible Party is:

4.2.2.1. The holder of the IND or IDE (Sponsor-Investigator)

4.2.2.2. The overall Principal Investigator for the study, and/or the Investigator who meets all requirements of "Responsible Party" as outlined in FDAAA 801

4.3. Registration

4.3.1. The Responsible Party must ensure the timely and complete registration of the study in Clinicaltrials.gov.

4.3.1.1. The Responsible Party, or Responsible designee, must

4.4. If the Responsible Party is arriving at UMMS and has active registration records at their prior institution

4.4.1. Contact the UMMS PRS Administrator as the Responsible Party may need a UMMS account and may need to transfer registration record(s) to UMMS. Transfer depends on IRB review, grant ownership, study status and status of Responsible Party as Investigator-Sponsor.

5. REFERENCES

5.1. ICMJE

5.1.1. http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html#one

5.1.2. http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/

5.2. NIH

5.2.1. https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

5.3. FDA

5.3.1. 42 USC 282(j)

5.3.2. 42 CFR 11.4

5.3.3. 42 CFR 11.10

5.3.4. 42 CFR 11.22

5.4. CMS National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)