1. PURPOSE

1.1. The purpose of this procedure is to describe the mechanisms by which UMMS manages the clinicaltrials.gov program to maintain and secure compliance with clinicaltrials.gov requirements.
1.2. This procedure begins with the activities described in 4.1.1.
1.3. This procedure ends with the completion of activities described in 4.1.3.

2. POLICY

2.1. Given the importance of compliance with clinicaltrials.gov requirements to the Principal Investigator as Responsible Party[1] and Institution, UMMS has established administrative processes and escalations to support ongoing compliance with clinicatrials.gov requirements.

3. RESPONSIBILITY

3.1. The UMMS PRS Administrator collaborates with the IRB, Office of Sponsored Programs and Office of Clinical Research to identify studies which may require registration on clinicaltrials.gov and monitors the UMMS PRS account to support ongoing compliance with clinicaltrials.gov requirements.
3.2. The Responsible Party must ensure the timely and accurate completion of all requirements associated with clinicaltrials.gov.

4. PROCEDURE

4.1. Administrative Program Management

4.1.1. At least once a week, the UMMS PRS administrator:

4.1.1.1. Reviews the PRS problem list and contacts Responsible Parties and study teams regarding outstanding issues
4.1.1.2. Escalates outstanding issues as needed.

4.1.2. At least once a month, the UMMS PRS administrator:

4.1.2.1. Reviews the PRS Planning Report in clinicaltrials.gov and advises Responsible Parties and study teams on upcoming actions.
4.1.2.2. Prepares metrics on UMMS compliance with clinicaltrials.gov requirements and training for review by leadership.

4.1.3. At least annually, the UMMS PRS administrator:

4.1.3.1. Reviews clinicaltrials.gov education and training needs, and adjusts as needed;
4.1.3.2. Reviews clinicaltrials.gov SOPs and support materials and makes any necessary updates and clarifications;
4.1.3.3. Consults with Office of Sponsored Programs, Office of Clinical Research and other impacted areas for input on program enhancements.

4.2. Escalation and Actions for Failure to Comply with Required Actions

4.2.1. If the Responsible Party does not respond/fails to attend to required actions with relation to a registration record, the following steps may be taken:

4.2.1.1. First overdue notice: Notification to Responsible Party

[1] See CTGov-002 for information about Responsible Party designation

4.2.1.2. Second overdue notice: Notification to Responsible Party, placement on restricted status

4.2.1.3. Third overdue notice: Notification to Responsible Party, with cc to division chief/department chair or departmental dean for research and Institutional Official. Continued restricted status.

4.2.1.4. Fourth overdue notice: Referral to Institutional Official for consideration of further action.

4.2.2. The escalation process may vary depending on the responsiveness of Responsible Party and the nature and type of deficiency.

5. REFERENCES

5.1. N/A