ClinicalTrials.gov Guidance for PIs

RESPONSIBILITY:

The PI is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks

A. Obtain an Account:

Requests for a ClinicalTrials.gov account can be made by contacting the appropriate organizational ClinicalTrials.gov administrator. **GWU MFA's CT.gov Admin is Sarah Ford-Trowell (strowell@mfa.gwu.edu).** The requestor (PI) must provide full name and preferred institutional e-mail address.

Please note that the PI of the study will need to have a ClinicalTrials.gov account in order to approve and release the record. Once an account is created, you will be notified by the administrator and will receive an automated email from the Protocol Registration and Results System (PRS) with login instructions.

B. Determining Responsible Party:

For studies initiated and written by an investigator, the PI of the study should be listed as the Responsible Party, whether listed as "Principal Investigator" or "Sponsor-Investigator." The Responsible Party has the sole authority to approve and release the record; all records must be reviewed and released by the Principal Investigator. In the event that the PI leaves GWU, please contact the administrators to determine who should become the new Responsible Party.

C. Determining Study Registration Requirements:

The PI is responsible for determining if the study is an Applicable Clinical Trial (ACT), thus requiring registration and results information on ClinicalTrials.gov. To determine if a study is an applicable clinical trial per 42 CFR 11, please use the ACT checklist (PDF) available on the ClinicalTrials.gov website. In addition to federal requirements (42 CFR 11), NIH Policy, journals (i.e., ICMJE), funding sources, and insurance companies (i.e., Medicare/Medicaid) may require registration and submission of results information. Studies with approved consent language stating the study will be registered to ClinicalTrials.gov must register their study to ClinicalTrials.gov. Studies with human subjects that are not required per regulations or publication requirements may still be registered to ClinicalTrials.gov per the PI's discretion.

D. Create, Update, and Maintain Study Records:

PI's are responsible for creating, editing, reviewing, approving, and releasing a study record on the ClinicalTrials.gov website, but can delegate some of the tasks to qualified study coordinators.

E. Submit Results:

More detailed instructions for submitting results are available on the ClinicalTrials.gov website.

- Update the Protocol Section including the Study Status section, Completion Dates, and Enrollment.

- Enter the Results which include: Participant Flow, Arm/Group Information, Baseline Characteristics, Baseline Measurements, Outcome Measures, Adverse Events, and Statistical Analysis.
- Review and Release the Record

F. Timeline Requirements

Registration:

GWU MFA requests that all ACT be registered **BEFORE** the enrollment of a subject in the study, but no later than 21 days after the first subject has been enrolled. **Federal regulations** require that registration be complete no later than 21 days after the first subject has been enrolled. **ICMJE** requires that registration be complete prior to the first subject's enrollment. A study is considered registered once the responsible party releases the record to PRS for review.

Actively Enrolling Studies:

Every 6 months, the study registration should be updated and verified. Even if no changes are being made, the record must still be verified.

Studies Closed to Enrollment, Pending Results:

Annually, the study registration should be updated and verified. Even if no changes are being made, the record must still be verified.

Change in the Study Status:

Study registration must be updated within 30 days where there is a change in study status.

Results Submission:

Study Registration must be updated no later than 1 year after the primary completion date. Delayed submission of results is permitted in certain circumstances. See 42 CFR 11.44 for details.

G. Protocol Record Management:

1. The Responsible Party (the PI) is ultimately responsible for ensuring the studies are registered with ClinicalTrials.gov and updated appropriately at required intervals and released to the public database. Refer to Section F above for timeline requirements for updates.
2. The PI and protocol Record Owner should be contacted by the appropriate ClinicalTrials.gov administrator if their protocol record is delinquent and needs to be updated.
3. If you are confused what a section is asking for or the terminology is unfamiliar, there are definition tabs on every screen that can explain what is being asked.

H. Transferring a Record:

1. If the Record Owner or Responsible Party is leaving the Institution, they should inform their ClinicalTrials.gov Administrator to ensure the record is appropriately monitored or transferred. The Record Owner or PI can either be reassigned to another Record Owner or PI within the university, or the record can be transferred to a new institution.

2. If the PI (Responsible Party) is moving studies from another institution please contact your designated ClinicalTrials.gov administrator to help facilitate the record transfer.

I. Penalties:

1. Under 42 CFR 11, civil and monetary penalties exist for noncompliance. Monetary penalties can be up to 13,000 US dollars a day.
2. Grant funding can be withheld until the required information has been submitted.
3. Journals can refuse to publish data from records that are noncompliant.
4. Noncompliance with GWU policies, 42 CFR 11, and other requirements could result in corrective actions that may include reporting of noncompliance to the IRB.