Procedure Name: ClinicalTrials.gov	**Number:** SOP 17 v1.0
Subject: Clinical Research	**Effective Date:** February 01, 2023
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** February 01, 2023

PURPOSE:
To establish the GW Medical Faculty Associates (MFA) procedure outlines the responsibilities of the research team members when using ClinicalTrials.gov

SCOPE:

This procedure applies to all research team members responsible for conducting clinical research at the MFA.

RESPONSIBILITY:

It is the responsibility of the Principal Investigator to ensure registration and results reporting are completed and updated, and in the timeframes required, by **FDAAA**, **NIH**, **CMS** and/or **ICMJE.** It is the Principal Investigator's responsibility to upload the required documents per the Final Rule for Clinical Trials Registration and Results Information Submission and the 2018 Common Rule. The PRS Admins within the Office of Clinical Research will reach out to the PI to register the trial after IRB approval and 6 months after study completion to remind the PI to report their results. The PRS Admins will also reach out to the PIs if there are any problems within the record that need to be addressed and if the trial needs to be updated.

PROCEDURES:

AGENCY REQUIREMENTS:

Studies registered on ClinicalTrials.gov must be registered through the GWUnivertsity organization account.

Principal Investigators are responsible to register clinical trials on ClinicalTrials.gov within required time frames, as follows:

- **GWU MFA:** We require the Principal Investigator to register their clinical trial on ClinicalTrials.gov BEFORE subject enrollment- preferably once the study is IRB approved. There are timeframes from governing bodies (below) that allow the PI to enter the trial after subject enrollment, but as best practice and GWU MFA policy, the trial should be entered into the system before any subject have been enrolled to ensure regulatory compliance and to

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avoid any deadlines. It is university policy that studies be entered once the IRB is approved or NO later than 21 days after the subject enrollment.

- **Under FDAAA:** The Principal Investigator must register and input required clinical trial information through the Protocol Registration System (PRS) on the ClinicalTrials.gov website no later than 21 days after enrollment of the first participant.

- **Under NIH:** The Principal Investigator must register and input required clinical trial information on the ClinicalTrials.gov website no later than21 days after enrollment of the first participant

- **Under CMS:** The Principal Investigator must register and input required clinical trial information and obtain an NCT# at the ClinicalTrials.gov website before submitting claims for such services to CMS.

- **ICMJE:** The Principal Investigator must register with an ICMJE qualified publicly-accessible registry at or before the first patient is enrolled in the study as a condition for publication in a participating journal

UPDATING RECORDS:

Principal Investigators are responsible to update clinical trial records, review the record for accuracy and verify that data-entry occurs within the required time frames, as follows:

FDAAA, NIH, CMS and **ICMJE** require the following:

- Registration information must be updated no less than **once every six months;**

- Recruitment/enrollment status changes (such as suspending recruitment or enrollment closed) must be input **within 30 days of any change;**

- Trial closure (regardless of the reason for closure—completion, low enrollment, etc.) must be input **within 30 days of trial closure.**

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RESULTS REPORTING:

Principal investigators are responsible to ensure data-entry occurs within required timeframes, as follows:

•**FDAAA and NIH:** Aggregate results and adverse event reporting on ClinicalTrials.gov must occur within 12 months of the Primary Completion Date;

• **CMS and ICMJE:** If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur within 12 months of the Primary Completion Date. If the study does not qualify as a clinical trial under FDAAA or NIH, results reporting is voluntary.

If the trial is covered by multiple applicable entities, registration and results reporting must occur within the timeframe set by the applicable entities, whichever is sooner.

OTHER CLINICALTRIALS.GOV SITE RESPONSIBILITIES:

Principal Investigators are responsible for the following:

As required per the Final Rule:

• Uploading the IRB-approved protocol and statistical analysis plan in a timely manner to ClinicalTrials.gov.

• Responding to registry reviewer requests for information or changes, as applicable, in a timely fashion.

• Submitting everything within the timeframes mentioned above

TRANSFER OF PRINCIPAL INVESTIGATOR (PI) RESPONSIBILITIES:

During the course of a clinical trial, the PI may relocate to another institution or otherwise be unavailable to fulfill his/her role responsibilities as PI. Before leaving the University, the PI must work with the University PRS Admin to ensure an orderly transition of his/her responsibilities to the new PI at the University or to initiate transfer of the registry account/record(s) and PI responsibilities to the new institution.

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If a clinical trial remains at the University and there are continuing registry reporting obligations without a named PI, then the PRS Admin must appoint a PI to serve and assume any remaining reporting obligations.
NOTE: If the PI fails to transfer the trial record and the trial is closed and results have been reported, the admin has the responsibility to try and contact the PI and if they do not ultimately respond, the university PRS Admin has the power to release the record.

COMPLIANCE WITH THE CLINICALTRIALS.GOV POLICY:
The University requires compliance with clinical trials registration and results reporting.

Review and Revision The SOP Review Committee shall review this SOP every 2 years. This SOP may be reviewed more frequently if it does not reflect current operations.

REFERENCES:

- FDAAA 801
- Clinical Trials Registration and Results Information Submission (Final Rule)
- NIH Elaboration Document of Responsible and Applicable Clinical Trial
- NIH Policy & Compliance ClinicalTrials.gov and FDAAA: FAQs
- ClinicalTrials.gov website
- 2018 Common Rule
- 2018 Common Rule – Clinical Trial Informed Consent Form Posting
- ICMJE FAQ
- CMS Medicare Clinical Trial Policies
- Center for Medicare and Medicaid Services (CMS):
  - Medicare Clinical Trial Policies
  - Routine Costs in Clinical Trials
- Final Rule (42 CFR Part 11)
- GWU MFA ClinicalTrials.gov Policy