The GW Medical Faculty Associates

Office of Clinical Research

POLICY: ClinicalTrials.gov Registration and Results Reporting Policy			
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1. PURPOSE

1.1. To provide an organizational framework to GWU MFA investigators responsible for complying with regulation, grantor requirements and/or publication standards regarding registration and reporting of certain clinical trials on ClinicalTrials.gov.

2. SCOPE

2.1 This policy applies to all faculty and researchers conducting clinical trials requiring registration and results reporting on the George Washington University premises, using the George Washington University property or facilities, and the George Washington University Institutional Review Board (IRB) authorization.

3. RESPONSIBILITY

3.1. This Policy sets forth the requirements for registering a clinical trial in ClinicalTrials.gov and when/how to report results.

4. DEFINITIONS

ClinicalTrials.gov: registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. In accordance with the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11). In addition, trial registration is required for journal publication of any clinical trial results.

Clinical Trial:
Applicable Clinical Trial, or ACT (**FDAAA**): includes interventional studies (with one or more arms) of FDA-regulated drugs, biological products or devices that meet one of the following conditions: (a) the trial has one or more sites in the U.S.; (b) the trial is conducted under an FDA investigational new drug application (IND) or investigational device exemption (IDE); or the trial involves a drug, biologic or device that is manufactured in the U.S. or its territories and is exported for research.

There are two types of FDAAA-defined applicable clinical trials which must be registered and results reported:

- **Applicable Clinical Drug Trial**: A controlled clinical investigation, other than a Phase I clinical investigation, of a drug or biological product subject to FDA regulation; and
- **Applicable Clinical Device Trial**: A controlled trial with health outcomes of devices subject to FDA regulation, other than small feasibility studies or pediatric post-market surveillance required by FDA.

Registration is required for applicable clinical trials (ACT) initiated after September 27, 2007 or ongoing as of December 26, 2007.

Clinical Trial (**NIH**): A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

NOTE: NIH requires registration and results reporting for all NIH-supported clinical trials, regardless of study phase, type of intervention, or whether or not they are subject to FDAAA.

Qualifying Trial (**CMS**): The activity must be a clinical trial that qualifies for coverage (as specified in CMS Section 310.1 of the Medicare National Coverage Determination Manual) and the purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' services, durable medical equipment, diagnostic test, etc.). The trial must have therapeutic intent and must enroll patients with diagnosed disease, not only healthy volunteers.

Clinical Trial (**ICMJE**): A clinical trial is a research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes—includes drugs, biologics, devices, surgical procedures, and behavioral treatments; this definition includes Phase I studies.

Final Rule: Effective on January 18, 2017, the Final Rule for Clinical Trials Registration and Results Information Submission outlines the requirements for submitting registration and summary results information, including adverse event information, for specified clinical trials of drug products (including biological products) and device products and for pediatric post-market surveillances of a device product to ClinicalTrials.gov (42 CRF Part 11).

Grantee: Recipient institution of a grant or cooperative agreement from a federal agency.

Primary Completion Date: The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome. This applies whether the clinical trial concluded according to the pre-specified protocol or was terminated.
Principal Investigator (PI): The individual who is responsible and accountable for conducting the clinical trial.

Responsible Party (FDAAA): The holder of an Investigational New Drug Application (IND) or an Investigational Device Exemption (IDE); or the PI if so designated by the study sponsor or award recipient.

- For most industry-initiated Clinical Trials, the industry sponsor is the Responsible Party. The PI is advised to check with the industry sponsor to verify registration of the Clinical Trial.
- For PI-initiated Clinical Trials, the PI is designated to be the Responsible Party.
- The lead institution or cooperative group will be the Responsible Party for most multi-site and collaborative group Clinical Trials. The PI is advised to check with the study chair or coordinating site to verify registration of the Clinical Trial.

Protocol Registration System (PRS): The PRS is a web-based data entry system used by ClinicalTrials.gov for investigators to register a clinical study or submit results information for a

registered study. Investigators must have a PRS account to register study information on ClinicalTrials.gov.

National Clinical Trial (NCT) Number: The NCT# is a unique identifier assigned by ClinicalTrials.gov to a study that has been successfully registered at its site. The NCT number must be included on claims for items and services provided in clinical trials that are qualified for coverage as specified in the Medicare National Coverage Determination Manual, Section 310.1.

2018 Common Rule: The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies issued final revisions to the Federal Policy for the Protection of Human Subjects, the Common Rule. Effective July 19, 2018.

5. POLICY

5.1 GWU Office of Clinical Research (GW OCR) requires that qualifying studies be entered into ClinicalTrials.gov once the IRB approves the study or NO later than 21 days after the first subject is enrolled. For guidance on agency requirements, registration, updating records, and results reporting, please review the ClinicalTrials.gov guidance document. This policy defines the responsible party (RP) of the clinical trial as the principle investigator. It is the responsibility of the RP to ensure that their qualifying trial is entered and updated in accordance with federal regulations.

The following new or ongoing clinical trials shall be registered at http://www.clinicaltrials.gov by the RP

(A) All Applicable clinical trials defined by Title VIII of the Food and Drug Administration Amendment Act of 2007 (**FDAAA**);

(B) Clinical trials funded, either in whole or in part, by the National Institutes of Health (**NIH**);

(C) Qualifying clinical trials which will render claims for items and services to the Center for Medicare and Medicaid Services (**CMS**)

(D) Clinical trials that meet the clinical trial definition of the International Committee of Medical Journal Editors (**ICMJE**) and, the results of which, the investigator plans to publish in a member journal. **NOTE**: ICMJE accepts registration at registries other than ClinicalTrials.gov to meet their publication requirements.

(E) Clinical Trials where it is written in the contract that the Principal Investigator will register the trial (even in the case that it is considered a Phase I trial)

6. REFERNCES

• FDAAA 801

• Clinical Trials Registration and Results Information Submission (Final Rule): https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission

• Final Rule (42 CFR Part 11) Information