



POLICY: Protocol Registration and Results System			
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BACKGROUND

The Food and Drug Administration Amendment Act 2007, (FDAAA 801) encompasses sections of the Public Health Service Act (PHS 402(j)) and United States Code 42 (42 U.S.C.282(j)). The legislation is intended to improve public access to information for clinical trials with FDA regulated drugs, biological products. Title 42 Code of Federal Regulations (42 CFR 11) known as the “final rule” clarifies and expands the regulatory requirements for the registration, submission of study information and results reporting for clinical trials.

1. PURPOSE

- 1.1. To provide an organizational framework of standards that complies with regulations, regarding registration and reporting of clinical trials.

2. SCOPE

- 2.1 This policy applies to all clinical researchers conducting clinical trials on the George Washington University (GW) premises, using the GW staff, property or facilities.

3. DEFINITIONS

Clinical Trial: 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.¹

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.²

ClinicalTrials.gov: registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. In addition, trial registration is required for journal publication of any clinical trial results. Registration is required for applicable clinical trials initiated after September 27, 2007 or ongoing as of December 26, 2007.

Responsible Party (RP): 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.

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.

¹ <https://grants.nih.gov/policy/clinical-trials/definition.htm>

² https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf



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Protocol Registration and Reporting System (PRS): The PRS is a web-based data entry system used 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 in the system.

National Clinical Trial Number (NCT #): The NCT# is a unique identifier assigned by the PRS to a study that has been successfully registered at its site.

4. POLICY

The final rule³ details 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 to the Protocol Registration and Reporting System (PRS), the clinical trial registry and results data bank operated by the National Library of Medicine (NLM) of the National Institutes of Health (NIH).⁴ GW requires compliance with federal regulations for the registration and reporting of clinical trials.

GW Office of Clinical Research (GW OCR) requires that qualifying studies be entered into the PRS 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 PRS SOP 17.

The designated RP is to ensure that the qualifying trial is entered and updated in accordance with federal regulations.

The RP should register in PRS, trials that meet the following criteria:

- a) All applicable clinical trials defined by FDAAA 801.
- b) Clinical trials funded, either in whole or in part, by the NIH.
- c) Clinical trials, which will render claims for items and services to the Center for Medicare and Medicaid services.
- d) Clinical trials that the results of which, the investigator plans to publish in a member journal.
- e) Clinical trials where it is written in the contract that the PI will register the trial (even in the case that it is considered a Phase I trial)

5. REFERENCES

[Clinical Trials Registration and Results Information Submission](#)

[Public Health Service, Department of Health and Human Services 42 CFR Part 11](#)

[Food and Drug Administration Amendment Act 2007](#)

[Title 42 Code of Federal Regulations](#)

³ <https://www.ecfr.gov/current/title-42>

⁴ <https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission>