SOP#: RPS-25	**Registering Research Studies on ClinicalTrials.gov**
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NCI Clinical Director Signature/ Effective Date:	James Gulley Digitally signed by James Gulley Date: 2022.09.20 07:20:58 -04'00'

POLICY

The Center for Cancer Research (CCR) registers all research studies on ClinicalTrials.gov per the Food and Drug Administration Amendments Act of 2007 (FDAAA) and NIH policy. NIH policy for registering studies applies to all NIH-funded research studies regardless of study phase, type of intervention, or whether they are subject to the FDAAA regulation, including observational and natural history studies. This registration should occur prior to the study opening for recruitment and is required to be completed within 21 calendar days after enrolling the first subject per FDAAA and NIH Policy Manual 3007.

The ClinicalTrials.gov Protocol Registration and Results System (PRS) is used to register a clinical study and/or submit results information for a registered study. The NIH Clinical Center is the "Responsible Party" of the ClinicalTrials.gov record and the NIH Office of Protocol Services (OPS) is the administrator for the PRS. OPS is responsible for registering research studies on ClinicalTrials.gov and updating ClinicalTrials.gov following protocol amendments and continuing reviews. For industry-sponsored protocols or other multi-site protocol in which the NIH is not the lead site/coordinating center, OPS will not be registering the protocol.

The study Principal Investigator (PI) is responsible for routinely reviewing the information about the study on ClinicalTrials.gov to ensure it is accurate and contacting OPS (CC_Protocol_Services@cc.nih.gov) if corrections are needed.

Principal Investigators must be in compliance with NIH Policy Manual 3007 and be familiar with consequences of not following the policy.

Note: There is not a requirement to register secondary use studies or exempt studies that do not recruit patients.

DEFINITION

- *Responsible Party:* the sponsor of the clinical trial (as defined in 21 CFR 50.3) or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information.

PURPOSE

To identify the process for registering research studies on ClinicalTrials.gov and the study PI's responsibilities.

RESOURCES

- NIH Policies
  - NIH Policy and Regulation on ClinicalTrials.gov Registration and Reporting
  - NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
  - NIH Policy Manual 3007 – Clinical Trial Registration and Results Information Reporting
- ClinicalTrials.gov
  - Food and Drug Administration Amendments Act of 2007 801 Requirements and Final Rule
  - FAQs on the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11)
  - 2020: Federal Court Decision in Seife et al. v. HHS et al
- FDA
  - Food and Drug Administration Amendments Act (FDAAA) of 2007
  - Public Law 110-85 September 27, 2007

PROCEDURES

Registration of Research Study

- Office of Protocol Services (OPS) will initiate research study registration with information contained in IRB Management System and the protocol and will create a lay summary.
  - The lay summary will inform clinicians and the public about the clinical research study.
- The lay summary is routed through the Protocol Support Office (PSO) Director to the PI and PSO Manager for input/edits. The PSO office will return the edited version of the lay summary to OPS.
- The OPS will register the protocol on ClinicalTrials.gov.
- Once the study is registered on ClinicalTrials.gov, the study PI is responsible for reviewing the record for accuracy. If any changes are needed, the PI will contact OPS via CC_Protocol_Services@cc.nih.gov.
- OPS will automatically update the ClinicalTrials.gov record following protocol amendments and at time of Continuing Review (CR).