Registration of Clinical Trials in Research Guidelines

Accommodations for individuals with disabilities in accessing these policies are available upon request by emailing accessiblepolicy@wcupa.edu

Purpose and Scope

West Chester University (WCU) is dedicated to the dissemination of the results of research conducted by our faculty, staff, and students. These guidelines describe the WCU requirements for registering clinical trials in accordance with federal regulations and policies and publishing standards.

Policy Statement

The National Institutes of Health (NIH) defines **Clinical Trials** as any research that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. **Health-related** interventions include any intervention used to modify a biomedical or health-related outcome) for example drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care-changes). **Health outcomes** include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Policy Framework

A. Federal Regulations and Policies:

The following new or ongoing types of clinical trials must register on ClinicalTrials.gov (https://clinicaltrials.gov/), a database for disclosing summary protocol information

before and during clinical trials and summary results and adverse events information upon completion of a clinical trial:

1. All clinical trials funded either in whole, or in part by NIH, including Phase 1 studies. ***Registration Period- ClinicalTrials.gov registration must occur within 21 days of enrollment of the first participant. Results Reporting Period- Submission of results to ClincalTrials.gov must occur no later than 1 year after the primary completion date (date of the final data collection for the primary outcomes measure) of the clinical trial.***

2. Applicable Clinical Trials covered by the Food and Drug Administration (FDA) Amendments Act 801 and Federal Regulation 42 CFR Part 11 including:
a. Trials of Drugs/Biologics. Controlled, clinical investigations of a product subject to FDA regulations. This includes preliminary studies or phase I trials to be published in an ICMJE-affiliated journal.
b. Trials of Devices. Controlled trials with health outcomes, other than small feasibility studies, and including pediatric post-market surveillance as described in the Federal Food Drug and Cosmetic Act.
c. Interventional Studies (with one or more arms) of FDA-regulated drugs, biological products, or devices that meet one of the following conditions-

- The trial has one or more sites in the U.S.
- The trial is conducted under an FDA Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) application.
- The trial involves a drug, biologic, or device that is manufactured in the U.S. or its territories and is exported for research.

Registration Period- ClinicalTrials.gov registration must occur within 21 days of enrollment of the first participant. Results Reporting Period- Submission of results to ClincalTrials.gov must occur no later than 1 year after the primary completion date

(date of the final data collection for the primary outcomes measure) of the clinical trial.

3. Qualifying clinical trials which will render claims for items and services to the Center for Medicare and Medicaid Services (CMS). For these trials, the National Clinical Trial 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 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_Part4.pdf. ***Registration Period- ClinicalTrials.gov registration must occur before enrollment of the first participant. Results Reporting Period- Submission of results to ClincalTrials.gov must meet the requirements of the project's funding and regulatory agencies.***

B. Publishing Standards.

New or ongoing types of clinical trials should register on ClinicalTrials.gov (https://clinicaltrials.gov/) if they meet the definition of The International Committee of Medical Journal Editors (ICMJE)- any trials that assign human subjects to intervention and comparison groups to study cause and effect relationships between interventions and health outcomes. A list of journals that follow the ICMJE clinical trials definition can be found at http://www.icmje.org/journals-following-the-icmje-recommendations/.

Participating journals may refuse registration if the trials are not registered. ***Registration Period- ClinicalTrials.gov registration should occur before enrollment of the first participant. Results Reporting Period- Submission of results to ClinicalTrials.gov should meet the requirements of the project's funding and regulatory agencies.***

C. Exclusions.

The following trials are generally excluded ***(unless funded either in whole, or in part by NIH)***:

1. Non-serious/life-threatening, Phase 1 drug trials, including studies in which drugs are used as research tools to explore biological phenomena or disease processes.

2. Small clinical trials to determine the feasibility of a device or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes. Trials that do not include drugs, biologics, or devices (e.g., behavioral interventions).

3. Non-interventional (observational) clinical research, such as cohort or case control studies.

4. Trials that were ongoing* as of September 27, 2007, and reached the Completion Date before December 26,2007. (*An "ongoing" trial has enrolled one or more subjects and the final subject has not been examined or received an intervention for the purpose of collecting data on the primary outcome).

D. Responsibilities of the Principal Investigator (PI).

The PI assumes responsibility for the ethical conduct related to their work including the registration of required clinical trials information on ClinicalTrials.gov. The PI is also responsible for the following:

1. Updating ClinicalTrials.gov records ***no later than 30 calendar days*** after any of these changes occur:

- Study start date
- Intervention name(s)
- Availability of expanded access
- Expanded access status
- Overall recruitment status
- Explanation for change status
- Actual enrollment date
- Individual site status
- IRB status
- Completion date
- Responsible party
- Official title
- Contact information

2. Closing out any studies before departing from WCU or ensuring that continuing studies are properly transferred to another investigator.

3. Submitting results to ClinicalTrials.gov in agreement within the Results Reporting Periods described in Section I.A. Though reporting results on ClinicalTrials.gov. is the responsibility of the PI, this duty may be performed by a member of the research team.

4. Consulting with commercial sponsors to assure that posting of a clinical trial is in accord with terms of the study contract. A Sponsor providing drugs only generally does not accept the registration and results reporting responsibilities.

E. Noncompliance.

Failure to register clinical trials that fall under the federal regulations and policies described in Section I.A. is a violation of federal law which could lead to loss of federal funds, negative federal funding decisions in the future, civil monetary penalties, and public identification of the PI as non-compliant on ClinicalTrials.gov. This may also result in disciplinary action in accordance with the appropriate Collective Bargaining Agreement on personnel policies.

Procedures for Registration

The PI must submit a request for a ClinicalTrials.gov username and password to research@wcupa.edu. A Grants Specialist at the Office of Research and Sponsored Programs (ORSP) will then create an sub-account for the PI in the university's organizational account.

1. The PI must be the only person to register a clinical trial.
    - Under the Organization Name choose ***WestChesterU***.
    - There are two choices in the Sponsor/Collaborator section.
        - Select Sponsor as the responsible party if the PI would like a Grants Specialist in ORSP to be delegated to receive emails from ClinicalTrials.gov to review and release the record once it is complete.
        - Select Principal Investigator as the responsible party if the PI does not want assistance in reviewing and releasing the completed record.
    - Once submission is complete, select Entry Complete at the top of the protocol record. The Office of Research and Sponsored Programs will then receive an email, review the information for errors, and release it.
    - ClinicalTrials.gov will assign an identifier associated with the clinical trial, an NCT number, within 2 to 5 days.

2. Registration of a clinical trial must be concurrent with submission of related protocols to the IRB. The NCT number must be listed on the initial IRB application. If the trial is submitted to the IRB with the NCT number pending, the PI or member of the research team must update the NCT number as soon as the number is assigned by ClinicalTrials.gov. ***IRB approval will not be granted until the NCT number is provided.***

References

1. Washington University in Saint Louis, *Clinical Trials Registration Guidelines*, (https://research.wustl.edu/clinical-trials-registration-guideline/).
2. University of California, San Francisco, *Clinical Trial Registration and Reporting*, (https://policies.ucsf.edu/print/381).
3. University of California, Irvine, *Guidelines for Registering with Clinical Trials.gov*, (https://research.uci.edu/compliance/human-research-protections/researchers/guidelines-for-registering-in-a-clinicaltrialsgov-registry.html).
4. John Hopkins Medicine, *Organization Policy on Registration of Clinical Trials*, (https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/103_25.html).
5. Pennsylvania State System of Higher Education (PASSHE), *PASSHE Procedures and Standards for University Operations, #2012-14-A, Compliance with United States Export Control Laws (*http://www.passhe.edu/inside/policies/Policies_Procedures_Standards/Compliance%20with%20United%20States%20Export%20Control%20Laws%202012-14-A.pdf*)*.

Reviewed by: Office of Research and Sponsored Programs, Academic Deans Council, and Chair and Faculty Members in the Department of Psychology.

Policy Owner: Office of Research and Sponsored Programs

Approved by: 

Jeffery L. Osgood, Jr., Ph.D.
Deputy Provost and Vice President of Academic Operations
3/15/21

Effective Date: 04/16/2019
Next Review Date: 04/16/2023

History
Initial Approval: **Effective Date:** 04/16/2019
Review Date: 03/20/2021