University of Wisconsin-Oshkosh
Institutional Review Board (IRB)

STANDARD OPERATING PROCEDURES (SOP)	
SOP Number: 19 Effective Date: 11/07/2022 Last Reviewed: 11/07/2022 Prepared By: K. Schill	**Title:** **IRB Oversight for Clinical Trials**

I. Definitions

A **clinical trial** is defined by NIH as 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.

The term **"prospectively assigned"** refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

An **"intervention"** is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.

- Examples: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

A **"health-related biomedical or behavioral outcome"** is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life.

- Examples: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and positive or negative changes to quality of life.

II. Determining if a Study is a Clinical Trial

A. Answer the following four questions to determine if the study is a clinical trial:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?

4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the answer is yes to all four questions, the study meets the definition of a clinical trial.

B. A study is considered to meet the NIH definition of a clinical trial even if:

- The study uses healthy participants, or does not include a comparison group (e.g., placebo or control)
- The study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- The study utilizes a behavioral intervention
- The study uses an intervention for the purposes of understanding fundamental aspects of a phenomenon (See more information about Basic Experimental Studies with Humans).

C. A study is NOT considered to meet the NIH definition of a clinical trial if:

- The study is intended solely to refine measures.
- The study involves secondary research with biological specimens or health information.

D. NIH Online Decision Tool:

The following decision tool may be accessed on NIH's website to assist researchers and the IRB: Decision Tool: Does your Human Subjects Research Meet the NIH Definition of a Clinical Trial?

III. Regulatory Oversight and Considerations for Clinical Trials

A. Which regulations apply to clinical trials?

If a clinical investigation is conducted or supported by HHS and involves an FDA-regulated product, then the study is subject to both Common Rule 45 CFR part 46 and FDA 21 CFR parts 50 and 56. As part of the 21st Century Cures Act, FDA and HHS are working to harmonize human subjects protections regulations to the extent possible. FDA guidance states that where the regulations differ, the regulations that offer the greater protection to human subjects should be followed.

B. What are the requirements for an IRB to oversee a clinical trial?

- The IRB providing review and oversight must be registered in the online system hosted by OHRP: Electronic Submission System (nih.gov)
  - IRBs reviewing research conducted or supported by HHS must have a Federalwide Assurance and be designated as an OHRP IRB.
  - IRBs reviewing FDA-regulated research must be reviewed by an FDA IRB designated to review and monitor biomedical research (21 CFR 56.106)
  - IRB type must be indicated in IRB Registration: OHRP only, FDA only, or OHRP and FDA
    - IRB membership requirements for OHRP IRB: 45 CFR § 46.107
    - IRB membership requirements for FDA IRB: 21 CFR § 56.107

- Note: UW Oshkosh currently is registered as an OHRP only IRB

C. Considerations for FDA-regulated research:

- The institution where the study is to be conducted (research site) should be contacted to determine if they have their own IRB. If the study is conducted at a site that does not have its own FDA IRB, non-local IRB review may be considered.
- The investigators should be queried to see if they are affiliated with an institution with an IRB that would be willing to act as the IRB for that site in the study.
- There are also independent/commercial IRBs that can be contracted to act as the IRB for a site (i.e., Advarra IRB, WIRB).
- A reliance agreement should be established if local review is not conducted.
- An IRB must comply with all applicable requirements of the IRB regulation (Part 56) and the IDE regulations (Part 812) in reviewing and approving device investigations involving human testing.
- FDA does periodic inspections of the IRB's records and procedures to determine compliance with the regulations.

D. What is the requirement for posting consent forms for clinical trials?

The revised Common Rule requires that for any clinical trial conducted or supported by a Common Rule department or agency to post the consent form on a publicly available federal website within a specific time frame. The consent form must have been used to enroll subjects in order to satisfy this new provision. At this time, two publicly available federal websites have been identified that satisfy the revised Common Rule's consent form posting requirement: ClinicalTrials.gov and a specified docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

Resources:

NIH Grants and Funding: NIH Central Resource for Grants and Funding Information:
Does Your Human Subjects Research Study Meet the NIH Definition of a Clinical Trial? | grants.nih.gov

Institutional Review Boards Frequently Asked Questions: Guidance for IRBs and Clinical Investigators:
Institutional Review Boards Frequently Asked Questions | FDA

FDA Clinical Trials Guidance Documents:
Clinical Trials Guidance Documents | FDA