CASE WESTERN RESERVE UNIVERSITY

CWRU ClinicalTrials.gov Registration Requirements

University policy requires ClinicalTrials.gov registration for studies that meet the definitions or parameters outlined in **at least one of the numbered items below**. If you are unsure of your study's alignment with any of the listed items, please contact irbqip@case.edu for consultation.

If ***any*** of the following numbered items are TRUE, you must register your study with ClinicalTrials.gov

1. The study is an Applicable Clinical Trial (ACT), meaning all of the following are true:
    - Is interventional
    - At least one of the following applies:
        - At least one study site is in the US or US Territory
        - Study is conducted under an IND or IDE
        - The product being studied is manufactured in and exported from the US or US Territory
    - Evaluates at least one drug, biological, or device
    - Is NOT a Phase 1* or Early Feasibility study**

2. The study is an NIH-Defined Clinical Trial where all of the following are true:
    - One or more human subjects are prospectively assigned to one or more interventions, including placebo or control groups/arms, to evaluate the effects of those interventions on health-related **biomedical or behavioral** outcomes
    - Grants submitted on or after 1/18/2017 and/or grant renewals of a clinical trial initiated on or after 1/18/2017
    - Trials funded **in whole or in part** by HHS and Common Rule Signatories:
        - Agency for International Development
        - Central Intelligence Agency
        - Consumer Product Safety Commission
        - Department of Agriculture
        - Department of Commerce
        - Department of Defense
        - Department of Education
        - Department of Energy
        - Department of Health and Human Services – **Includes FDA and NIH including all 27 NIH Institutes and Centers**
        - Department of Homeland Security
        - Department of Housing and Urban Development
        - Department of Justice***
        - Department of Labor
        - Department of Transportation
        - Department of Veterans Affairs
        - Environmental Protection Agency
        - National Aeronautics and Space Administration (NASA)
        - National Science Foundation
        - Office of the Director of National Intelligence

- Social Security Administration

3. The study is a WHO-Defined Clinical Trial:
   "Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials."

4. The study is testing a drug, biologic, or device.

5. The study bills insurance, including Medicare, Medicaid, and private insurance.

6. Registration is required by the terms of the grant or funding source (will be listed in the funding/award agreement).

7. Plan to publish in an ICMJE-affiliated journal or journals stating that they follow the ICMJE recommendations. (ICMJE | About ICMJE)

**Done to find the highest dose that can be given safely without causing severe side effects*

***Usually enrolls 10 or fewer people to test the safety/efficacy of the device; very specific criteria must be met: Early Feasibility Studies (EFS) Program | FDA*

****Currently only the Bureau of Prisons, Federal Bureau of Investigation, and Office of Justice Programs but entirety of DOJ will be adopting the Common Rule in the near future*