Wright State University IRB Guidance Regarding ClinicalTrials.gov Registration

As of April 18, 2017, compliance with the recently revised NIH final rule (42 CFR Part 11) regarding Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) is required. FDAAA is a "mandate for sponsors and others responsible for certain clinical trials of FDA-regulated drug, biologic, and device products to register their studies and report summary results information to ClinicalTrials.gov which is managed by NIH."

This document is to provide additional information and references for WSU investigators to use to evaluate if they are required to take actions with regards to the registration process. Any WSU investigator who determines that he/she is responsible for registering their study, must first consult with the Wright State University Associate Vice President for Research to confirm that the he/she has "Responsible Party" status before initiating the registration process.

Which clinical trials are subject to the requirements (aka Applicable Clinical Trial)?

Both ClinicalTrials.gov registration and results information are required for any trial for which all of the following are true:

- Study type is interventional
- Primary purpose is NOT device feasibility
- Studies an FDA-regulated device product, and
- One or more of the following:
    - At least one U.S. facility location
    - Product manufactured in and exported from the United States
    - Conducted under an FDA IDE

OR

- Study type is interventional
- Primary purpose is NOT phase 1
- Studies an FDA-regulated drug product (including biological product), and
- One or more of the following:
    - At least one U.S. facility location
    - Product manufactured in and exported from the United States
    - Conducted under an FDA IND

References and Guidance

http://www.nejm.org/doi/full/10.1056/NEJMsr1611785 - New England Journal of Medicine Summary

https://prsinfo.clinicaltrials.gov/ - NIH Educational Materials Related to Implementation