ClinicalTrials.gov Registration Requirements Flowchart

1. NIH Requirements
   - Is the study funded in whole or in part by the NIH?
     - Yes
     - Is the study an interventional clinical trial (behavioral interventions included)?
       - Yes
       - Was the study initiated on or after January 18, 2017?
         - Yes
         - Register!
       - No
       - No
     - No
   - No

2. FDA Requirements
   - Is the study an interventional clinical trial?
     - Yes
     - Is the study conducted under an IND/IDE, OR at ≥1 US site?
       - Yes
       - Does the study evaluate an FDA-regulated drug, biologic, or device product?
         - Yes
         - Is the study not a Phase 1 (drug/biologic) or device feasibility study?
           - Yes
           - Register!
         - No
       - No
       - No
     - No
   - No
   - Not required under NIH policy

3. ICMJE Publication Requirements
   - Is the study an interventional clinical trial?
     - Yes
     - Register!
     - No
     - Not required for ICMJE publication
   - Not required under federal regulations

REFERENCES
NIH Policy on Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149)
FDAAA 801
Final Rule 42 CFR Part 11
Checklist and Elaboration for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial
ICMJE Clinical Trial Registration Policy