How do I determine if I need to register a study and report results with ClinicalTrials.gov?

Initiate a prospective clinical study of a health related outcome

**Requirement 1: NIH’s Dissemination Policy**

Is the study directly funded (in whole or in part) by NIH?

- Yes
  - Is the study an interventional clinical trial?
    - Yes
      - Is it conducted at more than 1 US site, or under an IND/IDE?
        - Yes
          - Outside of scope of NIH Policy
        - No
          - Go to Requirement 2
    - No
      - Is it other than a Phase 1 (drug biology), or small feasibility (device)?
        - Yes
          - Go to Requirement 3
        - No
          - Outside of scope of NIH Policy

- No
  - Is the funding application submitted on or after Jan 18, 2017?
    - Yes
      - Outside of scope of NIH Policy
    - No
      - Go to Requirement 2

**Requirement 2: Law (FDAAA) and Regulations (42 CFR 11)**

Is the study an interventional clinical trial?

- Yes
  - NIH’s Dissemination Policy applies: Register and submit results with CT.gov

- No
  - Outside of scope of FDA law and regulations

**Requirement 3: Publication in an ICMJE Journal**

Is the study an interventional clinical trial?

- Yes
  - Out of scope of ICMJE requirements for publication

- No
  - ICMJE Policy applies: Registration is required (but results submission is not)

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Note: If none of the above three major requirements for CT.gov registration applies, registration/submission of results is not required unless there are other requirements that must be considered (e.g., Medicare and Medicaid Services billing requirements; U.S. Department of Veterans Affairs (VA) requirement; National Cancer Institute (NCI) reporting policy; or, Patient-Centered Outcomes Research Institute (PCORI) reporting policy). See: ClinicalTrials.gov help on Medicare and Medicaid Services (CMS) billing requirements; National Cancer Institute (NCI) reporting policy; and Patient-Centered Outcomes Research Institute (PCORI) reporting policy.

1 NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

2 Do not include studies using NIH-funded units (e.g., CTRU) but not directly funded by NIH.

3 Visit the NIH website Clinical Trial Requirements for Grants and Contracts which contains the NIH clinical trial definition, case studies, and FAQs.

4 See the Applicable Clinical Trial (ACT) checklist and FAQs for help with definitions.

5 Publishers require registration as a condition of publication; see the International Committee of Medical Journal Editors (ICMJE) clinical trial registration policy for their clinical trial definition and detailed requirements.

For questions or assistance, please contact Kimberly Schmitz (schmitzk@uga.edu).