ClinicalTrial.gov Registration and Results Reporting Simplified Decision Tree

Which studies?

(1) Does the study prospectively assign human subjects to an intervention or comparison groups to evaluate the effects on health-related outcomes in humans? (This may include process of care, dietary or behavioral studies.)

→ **NO** → Registration is not required even by ICJME, *unless there are goods or services being billed to Medicare or Medicaid,* though ICMJE says "When in doubt, register." Use "may register" or no Clinicaltrials.gov language.

NIH 2016?

↓ **YES**

(2) Is it a controlled clinical investigation of a FDA regulated drug, biologic, or device, but is not a phase I or device feasibility study or is it a pediatric post-approval surveillance?
Note: Phase I trials may still be required to register under FDAMA if related to a serious or life-threatening disease or condition.

→ **NO** → **Registration required** by ICJME (prior to enrolling the first subject). PI may not be able to publish later! Template informed consent language not required. Use "may register" or no Clinicaltrials.gov language.

↓ **YES**

Registration required by ICJME (prior to enrolling the first subject) **and by FDAAA** (within 21 days of enrollment of the first subject at any site).
FDAAA considers these studies "Applicable Clinical Trials". ==USE REQUIRED INFORMED CONSENT LANGUAGE.==

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Who controls the study? Who can make substantive choices about the protocol, and who will control the data?

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(3) Is the study's responsible party at the UM?

→ **NO** → Confirm that the other institution or industry is responsible for the registration. Multi-site trials only register once.

↓ **YES**

(4) Does the trial test an FDA approved drug, biologic, or device?

→ **NO** → The PI is responsible for the registration and updates. Results reporting is not required.

↓ **YES**

The PI is responsible for the registration and updates annually.

Add NCT number to Update NCT # Activity in eResearch.

Results reporting will be required within 12 months of primary completion date (last patient, collection of data for primary endpoint.)