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.

- **YES**
  - NIH 2016?

(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.**

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

(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.)