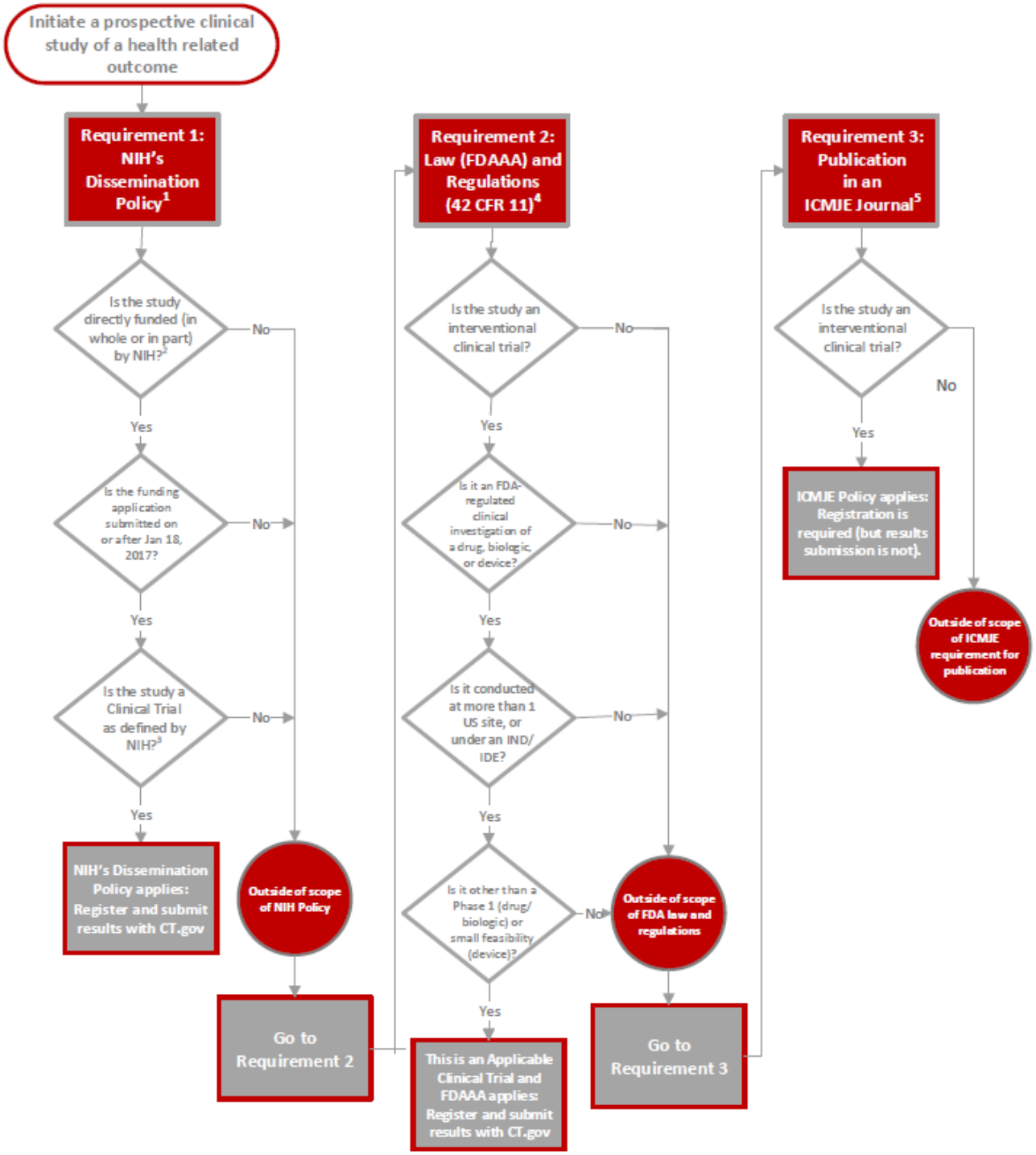
How do I determine if I need to register a study and report results with ClinicalTrials.gov?



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).