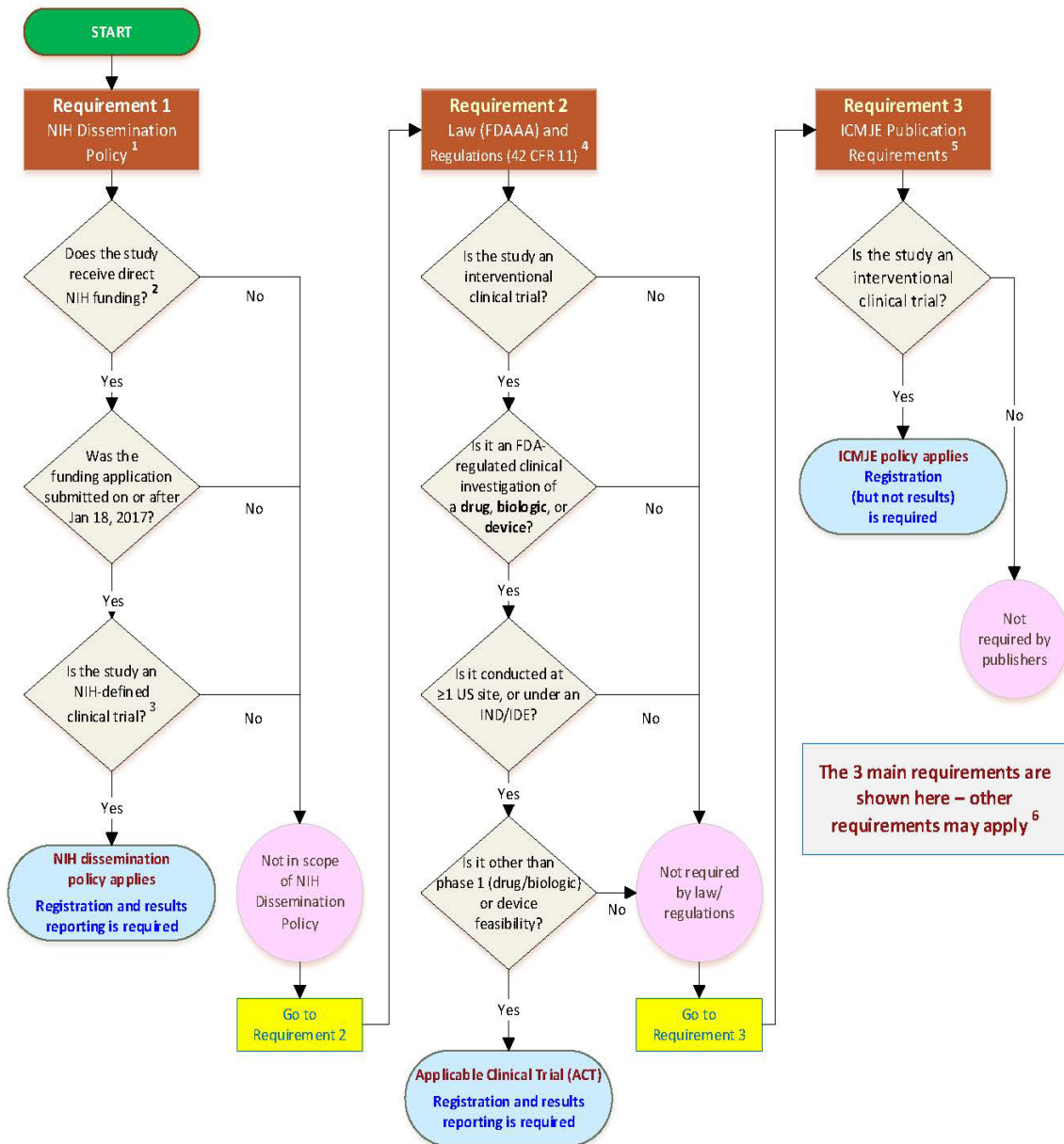


CLINICALTRIALS.GOV STUDY REGISTRATION AND RESULTS REQUIREMENTS DECISION TREE

ClinicalTrials.gov Study Registration and Results Requirements (Decision Tree)

More than one requirement may apply — Evaluate all requirements



1. NIH Policy on the Dissemination of Clinical Trial Information ([NOT-OD-16-149](#)).
2. Studies using NIH-funded infrastructure but not directly funded by NIH are not in the scope of the NIH policy.
3. Visit the NIH website [Clinical Trial Requirements for Grants and Contracts](#) which contains the NIH [clinical trial definition](#), definition [case studies](#), and [FAQs](#).
NOTE: The clinical trial definitions used by NIH and ClinicalTrials.gov are synonymous (see NOT OD 16 149), and are aligned with the definition used by publishers (International Committee of Medical Journal Editors [ICMJE]).
4. For complete definitions of Applicable Drug and Applicable Device Clinical Trials, see the [ACT checklist](#) and [FAQs](#).
5. Publishers require registration of all clinical trials as a condition of publication. For more information, see the ICMJE [Clinical Trial Registration Policy](#).
6. 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](#).