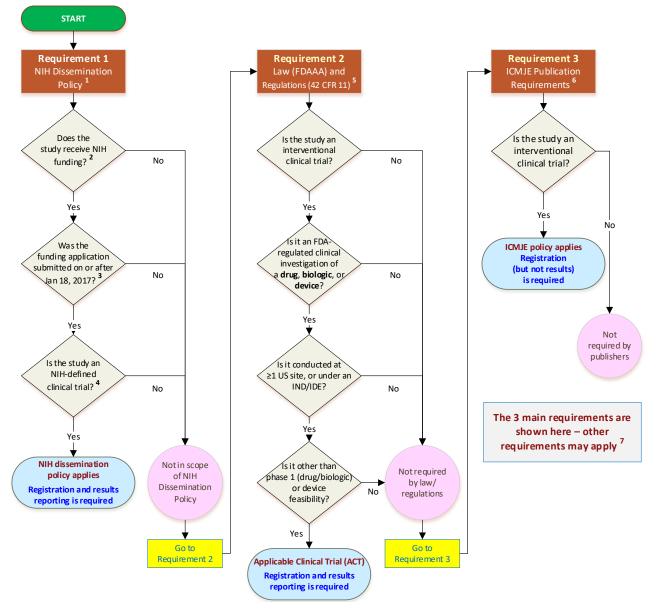
<u>UCD Decision Flow Chart to Determine Applicable Clinical Trials That Must be Registered on</u> <u>ClinicalTrials.gov</u>

Evaluate all requirements (more than one may apply)



- ¹ NIH Policy on the Dissemination of Clinical Trial Information (<u>NOT-OD-16-149</u>)
- ² A study that uses NIH-funded infrastructure but that does not receive NIH funds to support its conduct is not in scope.
- ³ Applies to both initial and competing renewal grant applications.
- ⁴ Visit the NIH website <u>Clinical Trial Requirements for Grants and Contracts</u> which contains the NIH <u>clinical trial definition</u>, definition <u>case studies</u>, and <u>FAQs</u>. *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])
- ⁵ For complete definitions of Applicable Drug and Applicable Device Clinical Trials, see the <u>ACT checklist</u> and <u>FAQs</u>.

- ⁶ Publishers require public registration of all clinical trials as a condition of publication. For more information, see the ICMJE <u>Clinical Trial Registration Policy</u>, and FAQ <u>"What is the ICMJE definition of a clinical trial?"</u>
- ⁷ See: ClinicalTrials.gov help on <u>Medicare and Medicaid Services (CMS) billing requirements</u>; National Cancer Institute (<u>NCI</u>) reporting policy; and Patient-Centered Outcomes Research Institute (<u>PCORI</u>) reporting policy.

Questions?

⇒ Contact the UC Davis CTSC Clinical Trials Office: <u>hs-ctgov@ucdavis.edu</u>