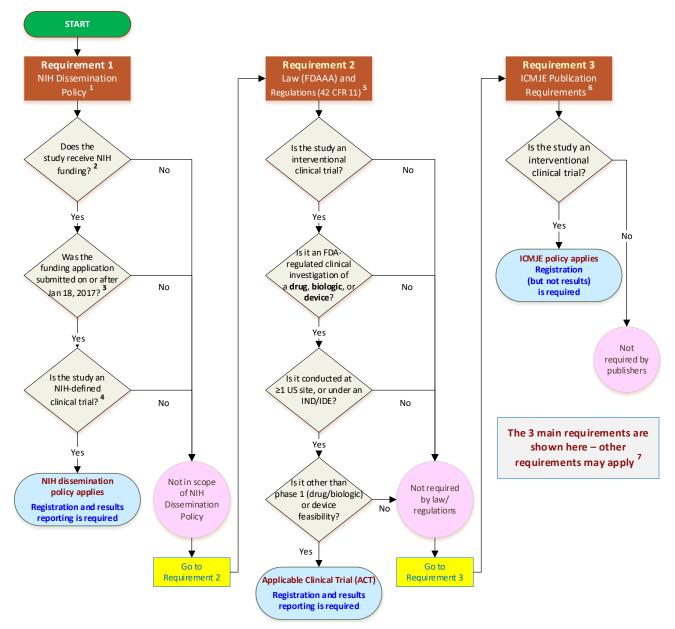


THE UNIVERSITY OF ARIZONA HEALTH SCIENCES

**Research Administration** 

## **ClinicalTrials.gov Registration and Results Requirements Decision Tree**

**Evaluate all requirements (more than one may apply)** 



- <sup>1</sup> NIH Policy on the Dissemination of Clinical Trial Information (<u>NOT-OD-16-149</u>)
- <sup>2</sup> A study that uses NIH-funded infrastructure but that does not receive NIH funds to support its conduct is not in scope.
- <sup>3</sup> Applies to both initial and competing renewal grant applications.
- <sup>4</sup> 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])

- <sup>5</sup> For complete definitions of Applicable Drug and Applicable Device Clinical Trials, see the <u>ACT checklist</u> and <u>FAQs</u>.
- <sup>6</sup> Publishers require public registration of all clinical trials as a condition of publication. For more information, see the ICMJE <u>Clinical Trial</u> <u>Registration Policy</u>, and FAQ <u>"What is the ICMJE definition of a clinical trial?"</u>
- <sup>7</sup> See: ClinicalTrials.gov help on <u>Medicare and Medicaid Services (CMS) billing requirements</u>; National Cancer Institute (<u>NCI) reporting policy</u>; and Patient-Centered Outcomes Research Institute (<u>PCORI) reporting policy</u>.

Questions? Contact regulatory@arizona.edu or visit our website. See also UA IRB guidance on Clinical Trials.

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