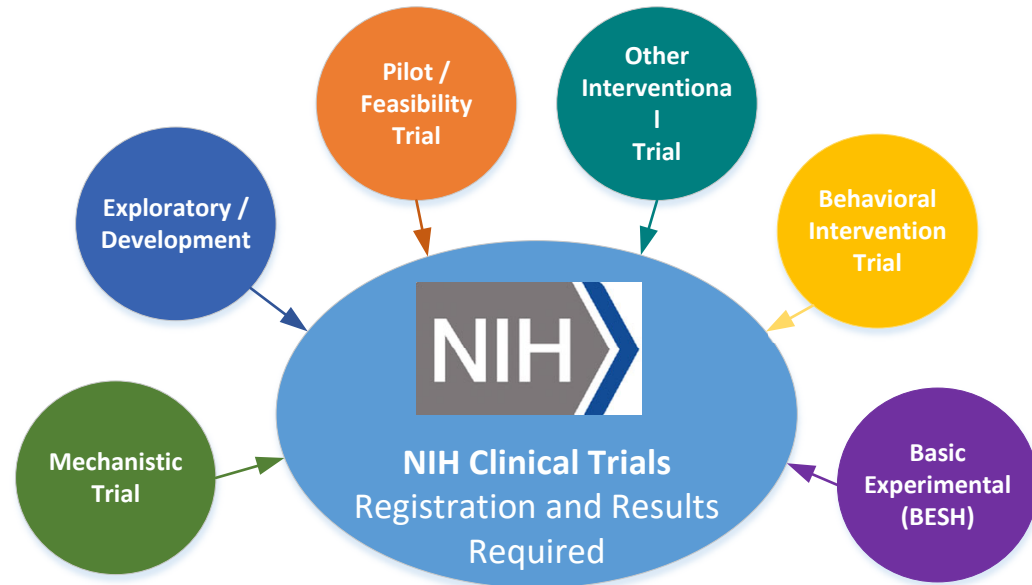
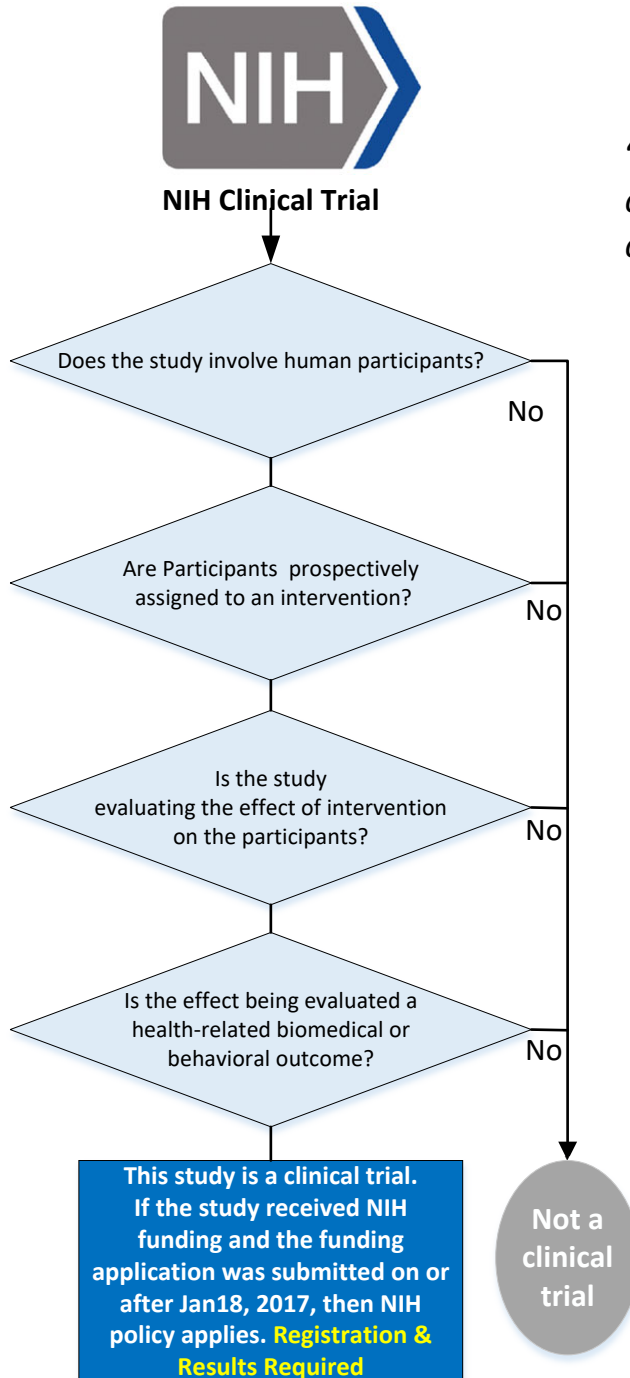


# ClinicalTrials.gov Reporting Decision Tree for NIH Clinical Trial

NIH Dissemination Policy requires NIH funded clinical trial to be registered and results reported in the clinicaltrials.gov (effective on Jan 18, 2017)

How Does NIH Define a Clinical Trial?

“A research study in which one or more **human subjects** are **prospectively assigned** to one or more **interventions** (which may include placebo or other control) to evaluate the effects of those interventions on **health-related biomedical or behavioral outcomes**”



**Prospectively Assigned:** a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo) of a clinical trial

**Interventions:** a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral process and/or endpoints

**Health-related biomedical or behavioral outcomes:** the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life

