

Comparison of Notices of Funding Opportunity NOFO Types by Clinical Trial Allowability

Clinical Trial Not Allowed NOFO	Clinical Trial Required NOFO	Basic Experimental Studies with Humans Required NOFO
<ul style="list-style-type: none"> • Studies not involving humans as research participants • Studies of biospecimens obtained from humans in which any experimental manipulation is performed on the biospecimens, not on the humans • Human observational studies in which no experimental manipulations of independent variables and no prospective assignment of interventions are performed • Studies in which experimental manipulations or prospective assignment of interventions are performed by someone other than the investigator (e.g., health service delivery studies in which the assignment is performed by the healthcare system, natural experiments in which a natural or policy event occurs outside the investigator's control) • Studies of tests (e.g., laboratory, biomarkers, patient-report, performance, observational) in which the purpose of the study is to assess the various properties of the test (reliability, validity, sensitivity/specificity, etc.), not to assess biomedical or behavioral outcomes or processes 	<ul style="list-style-type: none"> • Studies of the safety, efficacy, or effectiveness of an intervention on biomedical or behavioral outcomes or processes • Studies that prospectively assign interventions intended or anticipated to change the health status of human participants even if not for the purpose of assessing the safety, efficacy or effectiveness of the intervention (e.g., to study the mechanisms or pathways by which the treatment produces its effect) • Studies that prospectively assign interventions or experimentally manipulate independent variables to understand the fundamental aspects of phenomena with a specific application in mind (e.g., FDA Phase 0 or 1 trials, translational/applied studies in which fundamental processes are applied to a particular problem or health condition) 	<ul style="list-style-type: none"> • Studies that prospectively assign interventions or experimentally manipulate independent variables with human participants and assess biomedical or behavioral outcomes for the purpose of understanding the fundamental aspects of phenomena without specific application towards processes or products in mind • Studies that use an experimental manipulation or intervention probe in order to understand normal functioning or the pathophysiology of a disorder <p><i>Note: Many ICs will continue to accept basic experimental studies with humans through existing NOFOs that accept clinical trials (Clinical Trial Required or Clinical Trial Optional) However, these BESH studies will not have registration and results reporting flexibilities temporarily afforded to those responsive to designated BESH NOFOs.</i></p>

Note: Participation in Notices of Funding Opportunities will vary by NIH Institutes and Centers (ICs)