Clinical Trial Decision Tree

START

Does the study involve one or more human subjects? Yes → Are participants prospectively assigned to an intervention? Yes → Is the study designed to evaluate the effect of the intervention on the participants? Yes → Is the effect evaluated a health-related biomedical or behavioral outcome? Yes → This is a Clinical Trial

No → Not Sure?

Is the study a mechanistic clinical trial? Yes → This study is a Clinical Trial

No → Is the study supported in whole or in part by NIH funding? Yes → This study is an NIH mechanistic clinical trial and must fulfill all additional clinical trial requirements for NIH and VCU.

No → Do you intend to publish in an ICMJE member journal? Yes → This study may be considered a clinical trial by ICMJE. VCU recommends registering your study on ClinicalTrials.gov to protect your ability to publish your findings.

No → Is the study not a clinical trial.

* Mechanistic studies are designed to explore or understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention. If the study is mechanistic and the answer to all four clinical trial questions is “yes,” the study is a mechanistic clinical trial.