Decision Tree for NIH Clinical Trial Definition

Does the study involve human participants research?

- YES
- NO

Are participants prospectively assigned to an intervention?

- YES
- NO

The study is NOT a clinical trial.

Is the study designed to evaluate the effect of the intervention on the participants?

- YES
- NO

Is the effect being evaluated a health-related biomedical or behavioral outcome?

- YES
- NO

This study is a clinical trial.