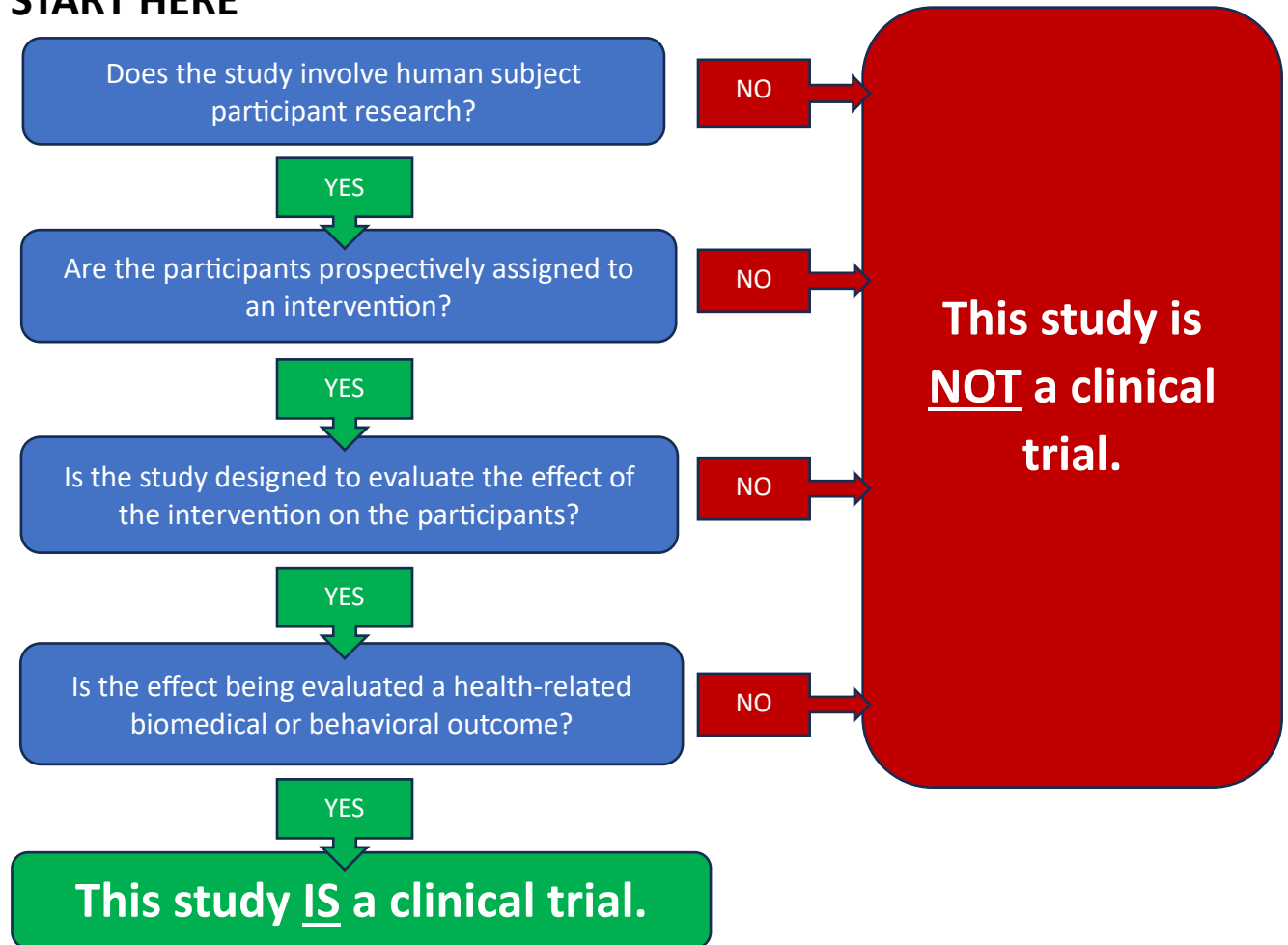


VA OFFICE OF RESEARCH AND DEVELOPMENT (ORD) CLINICAL TRIAL DECISION TOOL

Clinical trial proposals submitted to ORD require submission of a Pre-Application for review. ORD defines a clinical trial as 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 the interventions on biomedical or behavioral health-related outcomes. This flow chart will help applicants determine whether their proposals are appropriate for the clinical trial RFAs.

Please note: Career Development applications must be approved via a Pre-application. CADE applicants can use this tool to determine if their Pre-application requires the clinical trial supplemental information.

START HERE



A clinical trial may involve one or more trial designs (e.g., pilot, mechanistic, interventional, behavioral). If the answers to the above 4 questions are yes, your study meets the ORD definition of a clinical trial, even if...

- The study involves only healthy participants.
- The study is single arm or does not have a comparison group (e.g., placebo or control).
- The study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug.
- The study is utilizing a behavioral intervention or measuring intent to change behavior.
- Only one study aim, or sub-aim, meets the clinical trial definition.
- The study is expected to be no more than minimal risk.

After reviewing this checklist if you are still unsure if your proposed study is a clinical trial, please reach out to us at clin-review@va.gov.