

Clinical Trials Defined

The revised common rule updates and clarifies the definition for clinical trial. This new definition is as follows.

Clinical trial means 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.

In addition, there is an added requirement for posting clinical trial consent forms on a publicly available Federal website as a repository for consent forms. One consent form for each study must be posted on the Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. The Office of Human Research Protection issued guidance in late summer 2018 that these consent forms must be posted either on clinicaltrials.gov or to a docket folder on regulations.gov.