



## Does Your Human Subjects Study Meet the New NIH Definition of a Clinical Trial?

In an effort for the NIH to improve clinical trial data collection and establish a process for using this data effectively, clinical trial policy changes have been implemented to ensure rigor, transparency and effectiveness of the US federally-funded clinical trial enterprise.

One of the steps in this effort included the refinement of the definition of a clinical trial.

### NIH definition of a Clinical Trial:

"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 those interventions on health-related biomedical or behavioral outcomes."

To help researchers determine whether or not their human subjects research study meets the definition, the NIH website provides helpful tools, including an [interactive decision tool](#) that links to case studies and FAQs, and a [decision tree](#) to guide researchers through the questions that will determine if the study is a clinical trial.

The NIH has developed a new application form to consolidate all Human Subjects and Clinical Trial related information into one place, which will be included in the new FORMS-E Application packages. This new application form will be required for all applications with due dates on or after **January 25, 2018**.

For more information, including tutorials on how to navigate through the new form, visit the [NIH New Human Subjects and Clinical Trial Information Form](#) webpage.

