

NIH Human Subjects and Clinical Trials

In an effort to improve data collection and improve transparency on clinical trials, effective January 25, 2018, NIH added a new Human Subjects and Clinical Trials Information form to all applications. The form consolidates human subjects information into one, more detailed form that provides the level of information needed for peer review. It also aligns with ClinicalTrials.gov (where possible) and positions the NIH for future data exchange with ClinicalTrials.gov.

What does this mean for researchers that work with human subjects?

For application due dates on/after January 25, 2018, you will have to apply under separate funding opportunities if your project falls under the definition of a clinical trial.

The NIH definition of a clinical trial is fairly comprehensive. Some investigators conducting human subjects research may not be aware that NIH considers their study to be a clinical trial. Use [this tool](#) to help determine if your research meets the NIH definition of a clinical trial.

Does your human subjects research study meet the NIH Definition of a clinical trial?

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

If the answer is "Yes" to all four of these questions, this study meets the definition of a NIH clinical trial.

Identifying whether your study is a clinical trial will be important for:

- picking the right NIH funding opportunity
- ensuring your application includes all the information required for peer review
- complying with the appropriate policies and regulations

References:

<https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm>

<https://grants.nih.gov/policy/clinical-trials.htm>

<https://grants.nih.gov/ct-decision/index.htm>

<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm>