

**NIH CLINICAL TRIAL QUESTIONNAIRE**

If the answers to all four questions below are yes, this study meets the NIH definition of Clinical Trial, AND a funding opportunity allowing Clinical Trials must be utilized.

1. Does the study involve human participants?     [ ] Yes  [ ]  No
2. Are the participants prospectively assigned to an intervention?     [ ]  Yes  [ ] No
3. Is the study designed to evaluate the effect of the intervention on the participants?
[ ]  Yes  [ ]  No
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?
[ ]  Yes  [ ]  No

**Resources**

* [Parent Announcements (For Unsolicited or Investigator-Initiated Applications)](https://grants.nih.gov/grants/guide/parent_announcements.htm)
* [NIH Grants Policy Statement (Revised October 2017)](https://grants.nih.gov/policy/nihgps/index.htm)
* [How to Apply Application Guide: SF424 Guide](https://grants.nih.gov/grants/how-to-apply-application-guide.html)
* Learn about the changes regarding human subjects and clinical trials on the NIH webpage:  [New Human Subjects & Clinical Trials Information Form](https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm)
* See reference sheet: [InfoEd Instructions: PHS Human Subjects & Clinical Trials Info Form](https://my.ora.miami.edu/_assets/pdf/infoed/PHS%20Human%20Subjects%20and%20CT%20Information%20Form%20InfoEd%20Instructions_DEC2017.pdf)
* View 15-minute video from NIH entitled, “[Overview of NIH Policies on Human Subjects Research and Clinical Trials](https://grants.nih.gov/policy/clinical-trials/tutorial/story_html5.html?utm_source=nexus&utm_medium=email&utm_content=nihupdate&utm_campaign=sep17&lms=1)