

**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)