



## 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 \(For Unsolicited or Investigator-Initiated Applications\)](#)
- [NIH Grants Policy Statement \(Revised October 2017\)](#)
- [How to Apply Application Guide: SF424 Guide](#)
- Learn about the changes regarding human subjects and clinical trials on the NIH webpage: [New Human Subjects & Clinical Trials Information Form](#)
- See reference sheet: [InfoEd Instructions: PHS Human Subjects & Clinical Trials Info Form](#)
- View 15-minute video from NIH entitled, "[Overview of NIH Policies on Human Subjects Research and Clinical Trials](#)"