

This template is based on the NIH instructions here <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#4.3>

This attachment is required only if you answered "Yes" to all the questions in the "[Clinical Trial Questionnaire](#)." (i.e. your study is an NIH-defined clinical trial).

When document is complete, delete this box and save as PI Last Name_4.3 Statistical Design and Power_DDMOYEAR (example-01JAN2022)

NIH-recommended fonts: Arial, Georgia, Helvetica, Palatino Linotype, 11 pt or larger, margins .05 or larger
<https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm>

4.3 STATISTICAL DESIGN AND POWER

- Specify the number of subjects you expect to enroll, the expected effect size, the power, and the statistical methods you will use with respect to each outcome measure you listed in [4.2 Outcome Measures](#).
- You will need to show that your methods for sample size and data analysis are appropriate given your plans for assignment of participants and delivery of interventions. For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the [Research Methods Resources](#) webpage.