



Office of Research and Sponsored Programs

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NIH Statistical Design and Power Guidance

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The "Statistical Design and Power Guidance" attachment is required if you answered "Yes" to all the questions in the "[Clinical Trial Questionnaire](#)." This document is not allowed for all other human subjects research.

Format:

Attach this information as a PDF file.

Content:

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 4.3 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.