

Study Design Section

- Getting Started ✓
- Project Personnel
- Basic Information
- Study Design
- Study Selection
- Study Procedures
- International Research

Study Design

* Summary

Provide a brief summary of the scope of work of this project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.

B I U

- Getting Started ✓
- Project Personnel
- Basic Information
- Study Design

* Hypothesis

Describe the purpose for the proposed project as well as the hypothesis/research questions to be examined.

B I U

- Project Personnel
- Basic Information
- Study Design
- Study Selection

* Objectives

What do the investigators hope to learn from this project?

B I U

- Sections <
- Getting Started ✓
- Project Personnel
- Basic Information

* Study Design

- Discuss the present knowledge, appropriate literature and rationale for conducting the research. Include the rationale for the selected subject population.
- Describe the statistical methods of the research and plans for analysis of the data (i.e. planned statistics, justification of sample size, etc.).

B I U

- Getting Started
- Project Personnel
- Basic Information
- Study Design

* Outcome Measures

Provide the main study outcome measures.

B I U

- Project Personnel
- Basic Information
- Study Design
- Study Selection
- Study Procedures
- International Research
- Participant Protection
- Attachments ✓

* Has a Protocol document been issued by the Lead Site or Sponsor?

For example, industry sponsored clinical trials often issue the same official protocol document to every site.

Yes

Protocol Documents

Please upload any officially issue Protocol documentation.

ATTACH

For any subsequent text field questions about protocol related information, you can answer them directly or state what pages/sections to reference in the Protocol document.

No

- Getting Started ✓
- Project Personnel
- Basic Information
- Study Design
- Study Selection

* Inclusion Criteria

List and describe the inclusion criteria.

B I U

- Project Personnel
- Basic Information
- Study Design
- Study Selection
- Study Procedures

* Exclusion Criteria

List and describe the exclusion criteria.

B I U