

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.

Getting Started ✓	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>I</i> <u>U</u> S
Project Personnel ✓	
Basic Information ✓	
Study Selection	
Study Design	
Study Procedures	
Participant Protection	

Hypothesis

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

Basic Information ✓	* Hypothesis Describe the purpose for the proposed project as well as the hypothesis/research questions to be examined. B <i>I</i> <u>U</u> S
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Objectives

What do the investigators hope to learn from this project?

Basic Information ✓	* Objectives What do the investigators hope to learn from this project? B <i>I</i> <u>U</u> S
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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.).

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Study Selection	
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Attachments	

Outcome Measures

Provide the main study outcome measures.

Project Personnel ✓	* Outcome Measures <i>Provide the main study outcome measures.</i> B I U
Basic Information ✓	
Study Selection	
* Study Design	

Inclusion Criteria

List and describe the inclusion criteria.

Study Selection	* Inclusion Criteria <i>List and describe the inclusion criteria.</i> B I U
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Exclusion Criteria

List and describe the exclusion criteria.

Study Selection	* Exclusion Criteria List and describe the exclusion criteria. B I U     
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