

Study Selection

Study Enrollment

Enter the approximate number of subjects that will be enrolled in this study **or** the approximate number of individuals whose data will be analyzed.

If you are working with data only, the latter half of this question applies.

Text Box to enter response

Getting Started ✓	Study Selection * Study Enrollment Enter the approximate number of subjects that will be enrolled in this study or the approximate number of individuals whose data will be analyzed.
Project Personnel ✓	
Basic Information ✓	
Study Selection	
Study Design	
Study Procedures	

Ages

Indicate the age range of subjects included in the study. (e.g., 12-17 or 30-89).

Text Box to enter response

Basic Information ✓	* Ages Indicate the age range of subjects included in the study. (e.g., 12-17 or 30-89).
Study Selection	
Study Design	
Study Procedures	

Vulnerable Populations

Knowingly intend to include a vulnerable population means:

1. Participants will belong to the vulnerable population at any time during the intervention, interaction, or collection of identifiable private information for the study; AND
2. You will obtain knowledge that identifies a participant as a certain member of the vulnerable population.

Included Vulnerable Populations

As a population is check marked, sub options may appear. Such as “Other”, a text box will appear asking to please describe.

Sections	<
Getting Started	✓
Project Personnel	✓
Basic Information	✓
Study Selection	
Study Design	
Study Procedures	
Participant Protection	
Attachments	

Vulnerable Populations

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2. You will obtain knowledge that identifies a participant as a certain member of the vulnerable population.

*** Included Vulnerable Populations**

Please indicate any population(s) that will knowingly be included. Check all that apply.

- ☐ Fetuses
- ☐ Pregnant Women
- ☐ Neonates (birth to less than 1 month)
- ☐ Children (including infants from birth to less than 1 month determined to be viable)
- ☐ Students - any grade (including pre-school to post-graduate)
- ☐ Prisoners
- ☐ Cognitively Impaired Adult Subjects
- ☐ Other
- ☐ None of the Above

*** Excluded Vulnerable Populations**

Will any Vulnerable Populations be deliberately excluded from participation?

☐ Yes

☐ No

Justification of Vulnerable Populations

Necessity of Inclusion

For each vulnerable population that will knowingly be included in the study, explain why their inclusion is appropriate and does not pose unreasonable additional risks. Consider:

- If the risk to the population is minimal or greater than minimal.
- The prospect of direct benefit.
- If generalizable knowledge about the subject's disorder or condition may be gained.

Text Box to enter response

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

☐ None of the Above

Justification of Vulnerable Populations

*** Necessity of Inclusion**

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Special Arrangements

For each vulnerable population that will knowingly be included in the study, describe any additional measures to ensure protection of the rights and welfare of these populations.

Text Box to enter response

Basic Information ✓	
Study Selection	
Study Design	
Study Procedures	
Participant Protection	

*** Special Arrangements**

For each vulnerable population that will knowingly be included in the study, describe any additional measures to ensure protection of the rights and welfare of these populations.

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Excluded Vulnerable Populations

Will any Vulnerable Populations be deliberately excluded from participation?

If yes

Exclusion Justification

List the Vulnerable Populations to be excluded and how you will identify these individuals as members of the vulnerable population. Justify how excluding that population is consistent with principles of equitable recruitment.

Text Box to enter response

Basic Information ✓	
Study Selection	
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*** Excluded Vulnerable Populations**

Will any Vulnerable Populations be deliberately excluded from participation?

☒ Yes
☐ No

*** Exclusion Justification**

List the Vulnerable Populations to be excluded and how you will identify these individuals as members of the vulnerable population. Justify how excluding that population is consistent with principles of equitable recruitment.

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End of Section