

Study Selection Section

Depending on your responses, additional questions may appear.

Project Personnel	<h3>Study Selection</h3> <h4>Subject Enrollment</h4> <p>Enter the number of subjects that will be enrolled in this study.</p> <p>* Enrollment at this Institution Please enter the number of subjects that will be enrolled at this Institution.</p> <input type="text"/> <p>* Total Study Enrollment Please enter the total number of subjects to be enrolled at all study sites.</p> <input type="text"/>
Basic Information	
Study Design	
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Study Procedures	
International Research	
Participant Protection	
Attachments ✓	

Sections	<p>* Ages</p> <p>Indicate the age range of subjects included in the study. You may indicate ranges for distinct populations (e.g., if fetuses are included, less than 1 month age, or ranges like 12-17 and 30-89).</p> <input type="text"/>
Getting Started ✓	
Project Personnel	

Sections	<h3>Vulnerable Populations</h3> <p>Knowing including a vulnerable population means:</p> <ol style="list-style-type: none">Subjects will belong to the vulnerable population at any time during the intervention, interaction, or collection of identifiable private information for the study; ANDYou will obtain knowledge that identifies a subject as a certain member of the vulnerable population. <p>While you generally aren't required to determine a subject's status as a member of a vulnerable population (unless determining status is necessary to minimize risks or ensure an appropriate informed consent process), you still need to consider the involvement of vulnerable populations even if you are not specifically targeting a vulnerable population for enrollment.</p> <p>* Included Vulnerable Populations Please indicate any population(s) that will knowingly be enrolled. Check all that apply.</p> <ul style="list-style-type: none"><input checked="" type="checkbox"/> Fetuses<input checked="" type="checkbox"/> Pregnant Women<input checked="" type="checkbox"/> Neonates (birth to less than 1 month)<ul style="list-style-type: none"><input checked="" type="checkbox"/> Nonviable Neonates<input checked="" type="checkbox"/> Neonates of Uncertain Viability<input checked="" type="checkbox"/> Children (including infants from birth to less than 1 month determined to be viable)<input checked="" type="checkbox"/> Prisoners<input checked="" type="checkbox"/> Cognitively Impaired Adult Subjects<input checked="" type="checkbox"/> Other<ul style="list-style-type: none">* Please describe.<input type="text"/><input checked="" type="checkbox"/> None of the Above <p>All boxes were checked to demonstrate additional applicable sections below.</p>
Getting Started ✓	
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Basic Information	<h3>Justification of Vulnerable Populations</h3> <p>* Necessity of Inclusion</p> <p>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:</p> <ul style="list-style-type: none">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. <p><input type="text"/></p>
Study Design	
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Basic Information	<p>* Special Arrangements</p> <p>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.</p> <p><input type="text"/></p>
Study Design	
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Study Selection	<p>* Excluded Vulnerable Populations</p> <p>Will any Vulnerable Populations be deliberately excluded from participation?</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>* Exclusion Justification</p> <p>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.</p> <p><input type="text"/></p>
Study Procedures	
International Research	
Participant Protection	
Attachments ✓	