

SAINT MARY-OF-THE-WOODS COLLEGE

Institutional Review Board (IRB)
Human Subjects Review Form A



I. Review Status (please check one)

- Exempt (Complete Form B)
 Minor Changes
 Expedited (Complete Form C)
 Limited Board Review
 Full Board Review
 Approved by Other IRB (Attach

It is the policy of Saint Mary-of-the-Woods College that no activity involving human subjects be undertaken until those activities have been reviewed and approved by the Institutional Review Board (IRB).

II. Principal Investigator (PI)

The PI must be a member of the Saint Mary-of-the-Woods College faculty (including adjunct) or staff.

PRINCIPAL INVESTIGATOR				
Name				Date
Address				
Department				
Phone				
Status	<input type="checkbox"/> Faculty	<input type="checkbox"/> Staff	E-mail	
CITI Training	Please attach CITI training completion report(s)			

III. Co-investigator

Please list all co-investigators. If more than three, please add to the end of the section.

CO-INVESTIGATOR				
Name				
Address				
Status	<input type="checkbox"/> Undergraduate Student	<input type="checkbox"/> Graduate Student	<input type="checkbox"/> Faculty	<input type="checkbox"/> Staff
<input type="checkbox"/> Other	Please explain.			
E-mail Address				
Phone				
CITI Training	Please attach CITI training completion report(s)			

CO-INVESTIGATOR			
Name			
Address			
Status	<input type="checkbox"/> Undergraduate Student	<input type="checkbox"/> Graduate Student	<input type="checkbox"/> Faculty <input type="checkbox"/> Staff
<input type="checkbox"/> Other	Please explain.		
E-mail Address			
CITI Training	Please attach CITI training completion report(s)		

CO-INVESTIGATOR			
Name			
Address			
Status	<input type="checkbox"/> Undergraduate Student	<input type="checkbox"/> Graduate Student	<input type="checkbox"/> Faculty <input type="checkbox"/> Staff
<input type="checkbox"/> Other	Please explain.		
E-mail Address			
Phone			
CITI Training	Please attach CITI training completion report(s)		

IV. Investigation Information

INVESTIGATION	
Title	
Research Question(s)	
Background and Purpose	

Continue Background and Purpose					
Significance or Rationale					
Design, Procedures, Materials and Methods					
Start Date			End Date		
Location of Research					
Number of Participants	Age Range of Participants				
<input type="checkbox"/> Students	<input type="checkbox"/> Minors (under 18)*	<input type="checkbox"/> Employees	<input type="checkbox"/> Patients*	<input type="checkbox"/> Prisoners*	
<input type="checkbox"/> Educationally or Economically Disadvantaged*	<input type="checkbox"/> Pregnant Women*	<input type="checkbox"/> Institutionalized*		<input type="checkbox"/> Cognitively Impaired*	
<input type="checkbox"/> People Living outside the USA	<input type="checkbox"/> Non or Limited English Speaking persons			<input type="checkbox"/> Other*	
If Other, Specify					
* State necessity for using this population					
How will subjects be recruited?					

<p>How will subjects be assigned to experimental groups?</p>	
<p>What will the subjects be asked to do? Include a description of the instruments or protocols. (Attach instruments to be used)</p>	
<p>Informed Consent (if an international study, do participants have the informed consent form in their language?)</p> <p>Has the cross-cultural or international study approach considered consent requirements (i.e. do you need the consent of a community leader or spouse)?</p> <p>Please attach the Informed Consent Form</p>	
<p>If international study, were additional CITI modules completed?</p>	
<p>What is the level of risk involved?</p>	<input type="checkbox"/> Low or Minimal <input type="checkbox"/> Moderate <input type="checkbox"/> High
<p>Explain the nature of the risk(s) involved to subjects.</p>	
<p>If more than minimal risk, explain potential benefits to subjects.</p>	
<p>What procedures will be used to obtain informed consent? (Attach a copy of consent form)</p>	
<p>If subjects are under age 18, what procedures will be used to obtain assent? (Attach a copy of assent form)</p>	
<p>What procedures will be used to provide feedback and/or debriefing to subjects following completion of the study?</p>	
<p>Is there any potential conflict of interest?</p> <p>(see website for more information about conflict of interest).</p>	