

# Holyoke Community College IRB APPLICATION FOR PROTOCOL MODIFICATION

<b>Name of Principal Investigator:</b> _____	<b>Date:</b> _____
<b>Address</b> _____	<b>Email:</b> _____
<b>Phone:</b> _____	
<b>Full Title of Protocol:</b> _____	

**Please complete only the applicable sections and select the checkbox in the upper left corner of each section that is being changed. Modifications may require that consent forms or other study materials be updated.**

<input type="checkbox"/> <b>Section A. Change in Investigator or Investigator Information</b>	
<b>Changing the Principal Investigator Information (PI)</b>	
<input type="checkbox"/> Changing PI	Name: _____ Department: _____ Title: _____ Phone: _____ Address: _____
<input type="checkbox"/> Editing PI information	E-mail: _____ Online Human Subjects Protection Training Completed: <input type="checkbox"/> Yes <input type="checkbox"/> No*
<b>Adding Co-Investigators or changing existing Co-Investigator information</b>	
<input type="checkbox"/> Adding Co-I	Name: _____ Department: _____ Title: _____ Phone: _____ Address: _____
<input type="checkbox"/> Editing Co-I information	E-mail: _____ Online Human Subjects Protection Training Completed: <input type="checkbox"/> Yes <input type="checkbox"/> No*
<b>Removing Investigators</b> <i>For additional removals from the study personnel, please submit an attached sheet</i>	
Name: _____	Name: _____ Name: _____
<i>*If No, please explain, as all investigators must complete the education requirement prior to submitting the application.</i>	

<input type="checkbox"/> <b>Section B. Change in Title of Protocol</b>
<b>New Protocol Title:</b> _____

<input type="checkbox"/> <b>Section C. Change in Funding Source:</b>	<input type="checkbox"/> Addition	<input type="checkbox"/> Removal
<b>Status:</b>	<input type="checkbox"/> Proposal <input type="checkbox"/> Funding Pending <input type="checkbox"/> Funded <input type="checkbox"/> Not Awarded (applied for funding but was not awarded)	
Title of Grant: _____		
Sponsor: _____		PI on Grant: _____
Sponsor #: _____	Is the funding from a Federal source? <input type="checkbox"/> Yes <input type="checkbox"/> No	
<i>Please describe the changes in the funding:</i>		

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<input type="checkbox"/> <b>Section D. Change in Participant Numbers and/or Site</b>		
<b>Indicate below whether any changes will be made in the following areas:</b>		
1. Change in the number of participants		<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>If yes, please state the number of participants: a) currently approved, b) additional requested and c) new total number of participants.</i>		
Current Site(s):		
Current #	Additional # Requested:	New Total:
2. Addition of new site locations		<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>If yes, please state the number of participants being added to the new site. For additional sites, attach an extra sheet.</i>		
New Site Location(s)	Purpose	Number of Participants

<input type="checkbox"/> <b>Section E. Change in Study Population</b>	
The age range of the sample	<input type="checkbox"/> Yes <input type="checkbox"/> No
The gender representation of the sample	<input type="checkbox"/> Yes <input type="checkbox"/> No
The racial/ethnic makeup of the sample	<input type="checkbox"/> Yes <input type="checkbox"/> No
The inclusion/exclusion of vulnerable populations	<input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> Minors <input type="checkbox"/> Pregnant women <input type="checkbox"/> Prisoners <input type="checkbox"/> Fetuses	
The inclusion/exclusion of the following groups ( <i>check all relevant boxes below</i> )	<input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> Diminished capacity/Impaired decision-making ability <input type="checkbox"/> Elderly <input type="checkbox"/> Economically disadvantaged <input type="checkbox"/> Holyoke Community College faculty or staff <input type="checkbox"/> Persons not fluent in English <input type="checkbox"/> Holyoke Community College students	
<i>If you answered yes to any of the above, please describe the changes and explain the rationale for the changes.</i>	

<input type="checkbox"/> <b>Section F. Change in Recruitment</b>
<i>Please list and explain the rationale for changes to any recruitment techniques for the study, and submit a copy of the modified recruitment techniques (e.g., advertisements, telephone scripts).</i>

<input type="checkbox"/> <b>Section G. Modification or Additions to Instruments, Measures, and/or Type of Data Collected</b>	
Recording of participants via audiotapes, videotapes, photographs, etc.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Use of deception	<input type="checkbox"/> Yes <input type="checkbox"/> No
Data collection methods	<input type="checkbox"/> Yes <input type="checkbox"/> No
Instrumentation (e.g., surveys, questionnaires, interviews, observational scales, etc.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Other ( <i>Explain below</i> ):	<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>If any of the above changes will be made, explain the rationale for the changes.</i>	

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**Section H. Modification of Methodology and/or Procedures**

*Please list and explain the rationale for any alterations to research methods or study procedures (e.g., sampling method, duration of the study, or duration of participants' involvement in the study).*

**Section I. Modification to Consent Form(s) and/or the Process by which Consent is Obtained**

**Is there a change in the type of consent being requested?** (standard written consent, waiver or alteration of consent, third party, non-English speaking, assent)  Yes  No

*If yes, please provide the type of consent you are now requesting as well as the rationale for the change.\**

**Are there changes to the current consent forms?**  Yes  No

*If yes, please provide an explanation of the alterations to the consent forms as well as the rationale for the change.\**

*For all additions or alterations to consent forms, please submit copies of the forms.*

**Do the changes affect currently enrolled subjects?**  Yes  No

*If yes, attach the addendum that will be included to inform enrolled subjects.*

**Are the risks to subjects affected (increased or decreased) by the modification(s)?**  Yes  No

*Rationale for determination:*

**I. Principal Investigator Assurance**

**As Principal Investigator, I certify that:**

- I will protect the rights and welfare of all human participants.
- Upon approval of this protocol, I agree to conduct this research as detailed in the protocol.
- I will request and receive approval from the IRB for any alterations to the current protocol prior to implementing changes.
- I will comply with federal and Holyoke Community College policies for conducting ethical research, and I will be responsible for ensuring that my co-investigator(s)/student researcher(s) comply with this protocol.
- Any unexpected, adverse, or otherwise significant events in the course of this study will be promptly reported to the IRB.

\_\_\_\_\_  
Principal Investigator's Signature

\_\_\_\_\_  
Typed Name

\_\_\_\_\_  
Date

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<b>II. Faculty Advisor Assurance (<i>Necessary if PI is a student</i>)</b>
<p><b>As Faculty Advisor, I have reviewed the application and supporting documents and certify that:</b></p> <ul style="list-style-type: none"><li><input type="checkbox"/> The research design is sound, appropriate to the discipline, and will ensure protection of all human participants.</li><li><input type="checkbox"/> Informed consent contains the required elements.</li><li><input type="checkbox"/> Appropriate protections are in place for ensuring privacy and confidentiality of participants.</li><li><input type="checkbox"/> When applicable, the PI has made appropriate considerations for vulnerable populations.</li></ul>

\_\_\_\_\_  
Faculty Advisor's Signature (*Necessary if PI is a student*)

\_\_\_\_\_  
Typed Name

\_\_\_\_\_  
Date