

Download and complete form electronically. Once complete, save the form as a Word document and send as an email attachment to IRB committee at jcastro@mariacollege.edu. Also include any supporting documentation as attachments to the email (see bottom of p. 7) Please use **Maria College** **webmail**. **All paperwork is filed electronically.**



MARIA COLLEGE

For IRB Use Only
Protocol Number:

Amendment & Modification Request Form

Current Study Information

IRB#

Current Proposal Title

Current Primary Investigator

Amendments & Modifications

Change in Protocol Title

New Protocol Title

Change in principal investigator (PI) and/or addition of a co-investigator (Co-PI)

Name	Address <i>(campus or business)</i>	Email Address	Phone Number(s)
Affiliation with Maria College (e.g, professor, administrator)			
Program Affiliation (e.g. nursing, psychology)			
Role / Responsibilities			

<input type="checkbox"/> Change in Secondary or Student Investigator			
Name	Address <i>(campus or business)</i>	Email Address	Phone Number(s)
Affiliation with Maria College (e.g, professor, administrator)			
Program Affiliation (e.g. nursing, psychology)			
Role / Responsibilities			

<input type="checkbox"/> Removal of Research Staff	
<i>Name(s) of Staff to be Removed</i>	

<input type="checkbox"/> Consent Form Changes
<ul style="list-style-type: none"> Submit one hard copy of the revised document with changes highlighted AND one clean (unhighlighted) copy

<input type="checkbox"/> Change in total number of subjects			
<i>Current authorized total</i>		<i>New Anticipated Total</i>	

<input type="checkbox"/> Change in Methods

<input type="checkbox"/> Change in and/or additional research instruments / tools / questionnaires	
<i>List the new research instruments</i>	

- Submit one hard copies of the appropriate documents

<input type="checkbox"/> Change in recruitment materials / methods	
<i>Are the Revisions intended to replace current materials?</i>	
<i>Are the Revisions intended to be used in addition to current materials?</i>	

- Submit one hard copies of the appropriate documents

<input type="checkbox"/>	Changes in funding
Name of New Funding Source	
Contact Information	

- Submit one hard copies of the new grant or funding documentation

<input type="checkbox"/>	Additional involvement of sites or organizations other than Maria College
Site / Organization	
Addresses / contact Information	

- Submit one hard copies signed approval letters for each new site or organization

Rationale for Changes

How does this change your currently approve study?	
Provide a summary of the changes	

What is your justification for the change(s)?

Does the change(s) affect the risks or benefits of the participants	<input type="checkbox"/> No	<input type="checkbox"/> Yes
If YES , provide your rationale		

Could the requested amendment alter a participant's willingness to continue to take part in this research?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
If YES , provide your rationale		

Should currently enrolled participants be notified of the changes described by this amendment?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
If YES , provide your rationale		

Signature

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Print P.I. Name

P.I. Signature

Date