

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](mailto: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.**



**For IRB Use Only**  
Protocol Number:

**Request for Exempt Research**

**GENERAL PROTOCOL INFORMATION**

**Research Proposal Title**

**Primary Investigator\* Contact Information**

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

\* If the research is conducted by a student, please fill in student's faculty advisor's contact here

**Secondary / Student Investigators Contact Information** (Please include the information for all secondary or student researchers)

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

**Is this research in collaboration with another institution?**

No       Yes

If you marked yes, please list each institution and the information of all involved personnel in **Appendix A**

<b>Anticipated Start Date for Research</b>		<b>Expected Duration of Research</b> (From initial recruitment through data analysis)	
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### Qualification for Exempt Status

In order to qualify for exempt status a study must first qualify as research as defined by the Department of Health and Human Services (DHHS) regulations.

**Does this activity meet the following requirements?**

- It is a **systematic** investigation.
- It is **designed** to develop or contribute to **generalizable** knowledge.
- Does it involve a living individual about whom information or biospecimens are obtained through intervention or interaction.
- Is the information or biospecimens used, studied, and/or analyzed?

No  Yes

**If you marked yes then your project is considered research by the DHHS regulations, continue filling out the form**

A) Does this research require that participants be deceived?	<input type="checkbox"/> No <input type="checkbox"/> Yes
B) Will participants in this research be exposed risk, harm, discomfort, pain, or harassment beyond which they may encounter in their everyday lives?	<input type="checkbox"/> No <input type="checkbox"/> Yes
C) Does this research involve any members of a vulnerable population; including children, prisoners, pregnant women, mentally disabled persons, or participants that are economically or educationally disadvantaged?	<input type="checkbox"/> No <input type="checkbox"/> Yes
D) Would the participants' response reasonably place them at risk for criminal or civil liability or be damaging to their financial standing, employability, educational advancement, or reputation <u>AND</u> the information is recorded in such a manner that the identity of the participant can be readily ascertained?	<input type="checkbox"/> No <input type="checkbox"/> Yes
E) Does this research involve human tissue or biological specimens (e.g noninvasive saliva, urine collection)?	<input type="checkbox"/> No <input type="checkbox"/> Yes
F) Does this research involve a behavioral intervention that is likely to have adverse effects the participants, likely to offend or embarrass the participants, and/or will have a long duration?	<input type="checkbox"/> No <input type="checkbox"/> Yes
F) Does this research involve and biomedical research (e.g. invasive procedures)?	<input type="checkbox"/> No <input type="checkbox"/> Yes
G) Will any phase of this research occur internationally?	<input type="checkbox"/> No <input type="checkbox"/> Yes

**If you marked yes to at least one of the above, then your research is not Exempt. Please fill out the form for the Expedited / Full Board review**

## Informed Consent

**Please provide a copy of the written or electronic informed consent document or oral consent script to be used in your study. Your document must include the following and information required by your institution:**

- 1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
- 2) A description of any reasonably foreseeable risks or discomforts to the subject
- 3) A description of any benefits to the subject or to others which may reasonably be expected from the research
- 4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- 5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- 6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
- 7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- 8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

## Signatures

**PRINCIPAL INVESTIGATOR ASSURANCE: By signing this form you are acknowledging that:**

- You must conduct the research in compliance with Maria College Policies, federal, state and local laws, Declaration of Helsinki and the Belmont Report.
- You will not begin this research project until you have received final written approval from the Maria College's Institutional Review Board.
- You must report all intended changes in previously approved research prior to implementation.
- If you have obtained funding for this research, you will submit all changes in research that have been made to the sponsor's funding application within 30 calendar days to the IRB.
- You will report all adverse events within 5 calendar days of the occurrence to the IRB.
- You will provide an annual update if your research extends beyond the final approval period.

If you are a student principal investigator, you are responsible for obtaining review and approval for this research proposal from your faculty advisor.

<b>Print P.I. Name</b>	<b>P.I. Signature</b>	<b>Date</b>

<b>Print S.I. Name</b>	<b>S.I. Signature</b>	<b>Date</b>

# Appendix A

*If there are any personnel or organizations involved in the research that are not listed above. Please enter their information here.*

## Study Personnel and Organizations

**1) Please list any organization other than Maria College involved in the research.** *(Such as organizations or institutions involved in any of the following activities: participant interaction or recruitment, viewing, obtaining or storing identifiable private information, coordinating research centers, study participant providers, data analysis or storage, etc.)*

Organization	Role*	Site Address	Contact (Name / Number)	Signed Approval Letter Attached
				<input type="checkbox"/> Yes  Pending
				<input type="checkbox"/> Yes  Pending
				<input type="checkbox"/> Yes  Pending
				<input type="checkbox"/> Yes  Pending
				<input type="checkbox"/> Yes  Pending

\*e.g. use of organization’s facility or resources, collaborator (actively engaged in research project), data analysis, data storage, etc.

All personnel associated with this project are required to have appropriate human subjects training. Refer to the Maria College Faculty Handbook for current training requirements. Contact the IRB Chair, Dr. Joseph Castro at [Jcastro@mariacollege.edu](mailto:Jcastro@mariacollege.edu) or (518) 861-2591 for more information.

Study personnel include the faculty advisor, principal investigator and all individual(s) who will interact with the study participants, collaborate on study design, analyze or record data or view any personal identifying information about the participants, including those individuals that are not affiliated with Maria College. In addition, all co-investigators listed on a funding application or grant must be included as study personnel and complete required training.

**2) Please list all personnel involved with the research affiliated with Maria college.**

Study Personnel Name	Role / Responsibility in study	Training Completion Date	Training Certificate Attached*
			<input type="checkbox"/> Yes  No

			<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No

\* Provide the IRB with documentation of training when initial training is completed or renewed. Once documentation is on file, it is not necessary to provide additional copies with each new project/protocol submission.

**3) Please list all personnel involved with the research who are not affiliated with Maria college.**

Study Personnel Name	Role / Responsibility in study	Specify Institution / Organization	Training Completion Date	Training Certificate Attached*
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No

\* Provide the IRB with documentation of training when initial training is completed or renewed. Once documentation is on file, it is not necessary to provide additional copies with each new project/protocol submission.

# Appendix B

Please list all attached documentation