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:

Request for Expediated / Full Board IRB Review Cover Page

GENERAL PROTOCOL INFORMATION

Research Proposal Title

Primary Investigator* Contact Information

PI Name	Address (*campus or business*)	Email Address	Phone Number(s)

P.I. Affiliation with Maria College (e.g, professor, administrator)	
P.I. Program Affiliation (e.g. nursing, psychology)	
P.I Role / Responsibilities	

*** 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 (*campus or business*)	Email Address	Phone Number(s)

S.I. Affiliation with Maria College (e.g, professor, administrator)	
S.I. Program Affiliation (e.g. nursing, psychology)	
S.I. Role / Responsibilities	

Is this research in collaboration with another institution?	☐ *No* ☐ *Yes*
If you marked yes, please list each institution and contact person's name and email	
Anticipated Start Date for Research	
Expected Duration of Research (From initial recruitment through data analysis)	

General Funding Information		
Are you seeking funding or sponsorship for this project?		
Funding / Sponsorship Source(s) Specify ***all possible*** sources of funding including federal, state, university, foundation etc. *Please be as specific as possible.*		
Title of Funding Application or Grant* ***2 COPIES*** *of the grant or funding documentation must be provided with this form.*		
Primary Investigator/Author on Grant/Funding Application: *(If different than PI)*		
Name of Maria College Grant Administrator		

You are required to identify the RELEVANT SECTION (S) of the application or grant for which this submission corresponds. If the grant or* ***application is written in highly technical terms you are required to provide a summary in layperson's terms.*

Research Proposal Details

1) Please describe the proposed research

2) Please describe the methodology of the proposed research. (Include all physiological, psychological, and medical procedures, tests, interaction, interventions, and questionnaires that will be utilized during the conduct of the study. Copies of materials must be submitted with this form)

3) Does your research involve the use of existing data or data sets? ☐ *No* ☐ *Yes*

(If **YES**, identify the source, specify if the data is publicly available and if it will contain personal information)

4) Describe your intended participant populations, where participants will be recruited, and the selection or recruitment process you will use to obtain the participants.

5) How many participants will you obtain data from?

6) Do you plan on offering compensation to the participants? No Yes

(If **YES**, explain the type, amount and schedule by which it will be distributed, you must include provisions for payment if participant withdraws prior to completion.)

7) Do you plan on deceiving your participants? No Yes

(If **YES**, Explain the necessity of the deception and steps taken to inform the participants as to the actual intent of the study)

8) Will participants in this research be exposed risk, discomfort, or harassment beyond which they may encounter in their everyday lives?

No Yes

(If **YES**, What risks will the participant encounter and what steps are taken to alleviate or minimize this risk)

9) What is the benefit of this study? (

10) Does this research involve human tissue or biological specimens (e.g noninvasive saliva, urine collection)??

No Yes

(If **YES**, Explain the steps taken to minimize exposure and possible contamination of the specimens, including storage procedures)

11) Does this research involve and biomedical research (e.g. invasive procedures)?

No Yes

(If **YES**, Explain the steps taken to minimize exposure and possible contamination of the specimens, including storage procedures and steps taken to minimize the invasiveness of the procedure)

12) Will identifiable, private information be obtained about the participant(s)?

☐ *No* ☐ *Yes*

- If **YES**, complete the following table:

Describe the type of information to be obtained	
Describe how the information will be obtained (electronically, paper, voice recording, etc.)	
Describe the confidentiality procedures to be used	
Identify risks to participants if confidentiality is broken	

13) Describe where study records (research data, signed consent forms, voice recordings, transcripts, etc.) will be stored, specify how long data will be maintained and how it will be destroyed.

14) Are you requesting any sensitive information about the participants or any other individual known to the participant?

☐ *No* ☐ *Yes*

- If **YES**, check all that apply.

☐	**Sexual Behavior**	☐	**Drug Use / Abuse**	☐	**HIV / AIDS Status**
☐	**Illegal Conduct**	☐	**Alcohol Use / Abuse**	☐	
☐	**Any other types of information about the subject that, if it became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects financial standing or employability? If YES, please explain below**				
☐					

• If you checked any of the above, specify any additional confidentiality measures you will take

15) How will information be obtained from your participants? Check all that apply

	Questionnaire / Survey		Test / Task		Observation
	Interview		Audio Recording		Video Recording / Photograph
	Focus Group		Internet / email		Review of Personal Files (e.g. school, medical records, etc.)
	Other – Please Explain:				

16) Do you plan on including any of the following populations as participants? Check all that apply

	Children / Minors (Ages 0-17)		Pregnant Women
	Individuals with diminished mental / physical capacity		Individuals with FERPA Accommodated Learning Needs
	Economically/Educationally Disadvantaged		Individuals who are institutionalized
	Students in your classroom		Prisoners
	Other – If YES please explain		

• If you checked any of the above, explain the safeguards you will use to protect the participant's rights and welfare.

17) Will any phase of this research occur internationally?

No *Yes*

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

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
				☐ *Yes* ☐ *Pending*
				☐ *Yes* ☐ *Pending*
				☐ *Yes* ☐ *Pending*
				☐ *Yes* ☐ *Pending*
				☐ *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 complete 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 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*
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ 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*
				☐ Yes ☐ No
				☐ Yes ☐ No
				☐ Yes ☐ No
				☐ Yes ☐ No
				☐ Yes ☐ 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.**

GENERAL FUNDING INFORMATION	
Are you seeking funding or sponsorship for this project?	☐ **Yes:** If **YES,** is the funding: ☐ **No** (If **NO**, skip to ***page 1***) ☐ Pending ☐ Approved **Grant #:**
Funding / Sponsorship Source(s) Specify ***all possible*** sources of funding including federal, state, university, foundation etc. *Please be as specific as possible.*	
Title of Funding Application or Grant* ***2 COPIES*** *of the grant or funding documentation must be provided with this form.*	
Primary Investigator/Author on Grant/Funding Application: *(If different than PI)*	
Name of Maria College Grant Administrator	

You are required to identify the RELEVANT SECTION (S) of the application or grant for which this submission corresponds. If the grant or **application is written in highly technical terms you are required to provide a summary in layperson's terms.*

Signatures

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

- You have completed the Maria College required training as specified in the Faculty Handbook.
- 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.

Print P.I. Name	**P.I. Signature**	**Date**

Print S.I. Name	**S.I. Signature**	**Date**

SUPERVISOR ASSURANCE: By signing this form you are acknowledging that:

- You have reviewed the research proposal.
- You support implementation of the research proposal.
- The investigator(s) have the appropriate academic and clinical and credentials and experience to conduct this study.

Print Supervisor Name	**Supervisor Signature**	**Date**

FACULTY ADVISOR ASSURANCE (if applicable): By signing this form you are acknowledging that:

- You have completed the Maria College required training as specified in the current Maria College Faculty Handbook.
- You have reviewed and approved this research proposal and certify that the student principal investigator is under your direct supervision.
- You will oversee the conduct of the research for compliance Maria College Policies, federal, state and local laws, Declaration of Helsinki and the Belmont Report and will promptly report any deviations to the IRB.

Faculty Advisor Name	**Faculty Advisor Signature**	**Date**

Please list all attached documentation