

MARIST COLLEGE
INSTITUTIONAL REVIEW BOARD
HUMAN SUBJECTS RESEARCH REVIEW FORM

INSTRUCTIONS

- All research involving human subjects must be reviewed and approved prior to initiating the research.
- For questions regarding human subject research please refer to the guidebook entitled: [POLICY AND PROCEDURES FOR RESEARCH INVOLVING HUMAN SUBJECTS](#).
- The Principal Investigator and, if appropriate, his/her Faculty Supervisor must sign the form on page 4.
- The appropriate number of copies (see below) should be submitted to the address below.

PROJECT CATEGORIES

- The method of review (expedited or full review) depends on the category of research appropriate for the project.
- Although the investigator makes the initial determination of the project's category, it is the IRB which ultimately decides under which category a project will be reviewed.
- If you have any questions regarding the appropriate category for your project, refer to the [guidebook](#).

EXPEDITED REVIEW

(SUBMIT 1 COPY ONLY)

- Anonymous, mail or telephone surveys on innocuous topics
- Anonymous, non-interactive, non-participating observation of public behavior
- Secondary analysis of existing data
- Educational research involving no interaction with students; e.g., observation of intact classes without modifying or disrupting regular classroom activity
- Research involving the use of educational records if information taken from these sources is provided to the researcher in such a manner that subjects cannot be identified
- Research on individual or group behavior of normal adults where there is no psychological intervention, physiological intervention or deception
- Interviews and interactive surveys on non-sensitive topics

FULL REVIEW

(SUBMIT 5 COPIES PLUS THE ORIGINAL)

- Research which might put subjects at risk
- Research involving psychological or physiological intervention
- Noncurricular, interactive research in schools
- Research involving deception
- Interviews or survey on sensitive topics
- Research on special populations (e.g., minors, prisoners, and the mentally incompetent)
- Research conducted outside the United States, regardless of the procedures involved

Submit completed forms and address any questions to:

Elizabeth Quinn
Dyson 337
Marist College
Poughkeepsie, NY 12601
Telephone: (845) 575-3000 ext.2458

PLEASE DETACH THIS SHEET BEFORE SUBMITTING THE REVIEW FORM

Marist College
3399 North Road
Poughkeepsie, New York 12601

Human Subjects Research Review Form

Review Requested (check one): FULL (Original + 5 copies of application form* and all attachments)
 EXPEDITED (Original + 1 copy of application form* and all attachments)

Primary Investigator Name:

Research Proposal Type:

Collaborative Research (Specify if your research will be a collaborative effort with another institution.)

No
 Yes; Please specify the institution _____

Check all of the following that apply to your research proposal:

- | | |
|---|---|
| <input type="checkbox"/> Research Involving LESS than Minimal Risk | <input type="checkbox"/> Research Involving MORE than Minimal Risk |
| <input type="checkbox"/> Prisoners | <input type="checkbox"/> Oral History Project |
| <input type="checkbox"/> Children | <input type="checkbox"/> Intervention (Physiological, psychological, etc.) |
| <input type="checkbox"/> Elected or Appointed Officials | <input type="checkbox"/> Biological Specimens (e.g. noninvasive saliva, urine collection) |
| <input type="checkbox"/> Class Research Assignment | <input type="checkbox"/> Deception |
| <input type="checkbox"/> Secondary Data Analysis | <input type="checkbox"/> Biomedical Research (e.g. invasive procedures, venipuncture) |
| <input type="checkbox"/> Human Tissue Research | <input type="checkbox"/> International Research (any phase of research occurs outside US) |

General Funding Information	
Are you seeking funding or sponsorship for this project?	<input type="checkbox"/> Yes: If Yes, is the funding: <input type="checkbox"/> Pending <input type="checkbox"/> Approved <input type="checkbox"/> No: If No, skip to Page 2 Grant #:
Funding/Sponsorship Source(s) Specify all possible sources of funding including federal, state, university, foundation, etc. <i>Please be as specific as possible.</i>	
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 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.

Institutional Research Board
New Research Protocol Submission Form

GENERAL PROTOCOL INFORMATION

Research Proposal Title				
Primary Investigator Name/Contact Information (Provide contact information where we can reach you regarding this project.)	PI Name	Address (campus or business)	Email Address	Phone Numbers
	PI Affiliation with Marist College (e.g. professor)			
PI Department Affiliation (e.g. Psychology Department)				
Faculty Advisor Name/Contact (Required when PI is a student)	Name	Department/Campus Address	Email Address	Phone Numbers
	Marist College Primary Investigator Role/Responsibility in Research (Please be as specific as possible)			
Anticipated Start Date for Research				
Expected Duration of Research (From initial recruitment through data analysis)				
Dissemination Forum(s) (e.g. journals, poster sessions, presentations, etc.)				

PLEASE COMPLETE ALL QUESTIONS IN LAYPERSON'S TERMS

1. Describe the proposed research in lay person's terms:

9. Will you obtain anonymous data (no personal identifiers recorded anywhere, including the informed consent document or your personal records)?

- If **Yes**, you can request a **waiver from the requirement of signed consent** if you meet one of the following criteria:

- a) The consent form is the only record linking the participant and the research and the principal risk would be potential harm resulting from breach of confidentiality; and/or
- b) The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

- **If you meet the criteria and would like a waiver of signed consent, please request waiver here. Your request must include a rationale for the waiver, and you must specify which criteria (a or b) your project meets.**

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

Yes **No**

- 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	

11. Describe where the 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.

12. Are you requesting any sensitive information about the participants or any other individual known to the participant:

Yes **No**

- 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 subject's financial standing or employability? If **Yes**, please explain.

- **If you checked any of the above, specify any additional confidentiality measures you will take.**

- **Describe any additional services you will offer to the participants.**

13. How will information be obtained from your participants? Check all that apply.

- | | |
|--|--|
| <input type="checkbox"/> Questionnaire/Survey | <input type="checkbox"/> Test/Task |
| <input type="checkbox"/> Interview | <input type="checkbox"/> Video Recording/Photograph |
| <input type="checkbox"/> Observation | <input type="checkbox"/> Audio Recording |
| <input type="checkbox"/> Focus Group | <input type="checkbox"/> Internet/Email |
| <input type="checkbox"/> Other – Please Explain Below | <input type="checkbox"/> Review of Personal Files (e.g. school, medical records, etc.) |

14. Do you plan on using deception in your research?

Yes **No**

- If **Yes**, justify the need for use of deception and explain how participants will be debriefed about the true intent of the research.

15. Do you plan on offering compensation to the participants?

Yes **No**

- If **Yes**, explain the type, amount and schedule by which it will be distributed (you must include provisions for payment withdrawn prior to completion.)

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

- | | |
|---|--|
| <input type="checkbox"/> Children | <input type="checkbox"/> Pregnant Women |
| <input type="checkbox"/> Prisoners | <input type="checkbox"/> Mentally Disabled Persons |
| <input type="checkbox"/> Economically Disadvantaged – If Yes , please explain | |
| <input type="checkbox"/> Educationally Disadvantaged – 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 this research project involve organizations other than Marist College?** (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.)

Yes **No**

- If **Yes**, identify the organization(s)/institution(s) in the following table, specify the role(s) of the organization in the research project and provide a signed letter of approval/permission from each organization, school or institution. **Attach additional pages if necessary.**

Organization Name	Role in Research Proposal*	Site Address/Contact Person	<u>Signed Approval Letter Attached</u>	Approval Letter Requested

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

18. All personnel associated with this project are required to complete CITI Protection of Human Subjects training and submit the Certification of Completion with this proposal . Refer to the IRB Policies and Procedures for current training requirements available on the Marist College website <http://www.marist.edu/academics/irb/>.

Study personnel include the **faculty advisor, principal investigator and all other 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 Marist College. In addition, all co-investigators listed on a funding application or grant must be included as study personnel and complete required training.**

Attach additional pages if necessary.

Identify all study personnel who are affiliated with Marist College.

Study Personnel Names	Individual Responsibility/Role in Study	CITI Training Completion Date	Training Certificate Attached*

***Provide the Office of Research Compliance 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.**

Identify all study personnel who are not affiliated with Marist College.

(Unaffiliated Investigator Agreement(s) may be required)

Study Personnel Names	Individual Responsibility/Role in Study	CITI Training Completion Date	Training Certificate Attached*

***Provide the Office of Research Compliance 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.**

PRINCIPAL INVESTIGATOR ASSURANCE: By signing this you are acknowledging the following:

- You have completed the Marist College required CITI training as specified in the IRB Policies and Procedures.
- You must conduct the research in compliance with Marist College Policies, federal, state and local laws, Declaration of Helsinki and the Belmont Report and will promptly report any deviations to the IRB.
- You will not begin this research project until you have received final written approval from the Marist College IRB.
- You must report all intended changes in previously approved research prior to implementation.
- You will report all adverse events within **10 calendar days** to the IRB.
- 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 with **30 calendar days** to the Office of Research Compliance.
- 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 his research proposal from your faculty advisor.

Print Principal Investigator Name	Principal Investigator Signature	Date

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

- You have completed the Marist College required training as specified in the current Investigator Handbook (CITI training).
- You have reviewed and approved this research proposal and certify that the student principal investigator is under your supervision.
- You will oversee the conduct of the research for compliance with Marist College Policies, federal, state and local laws, and will promptly report any deviations to the Office of Research Compliance.

Print Faculty Advisor Name	Faculty Advisor Signature	Date

PLEASE INDICATE THE ITEMS INCLUDED WITH THIS FORM

- | | | |
|--|--|---|
| <input type="checkbox"/> Informed Consent(s) | <input type="checkbox"/> Script(s) | <input type="checkbox"/> Existing Data Set Approval(s) |
| <input type="checkbox"/> Institution Permission/Approval Letter(s) | <input type="checkbox"/> Interview Questions | <input type="checkbox"/> Internet/Email text |
| <input type="checkbox"/> Request for Alteration or Required Elements of Informed Consent | <input type="checkbox"/> Test(s) | <input type="checkbox"/> Recruiting Materials (fliers, scripts, etc.) |
| <input type="checkbox"/> Questionnaires/Surveys | <input type="checkbox"/> Debriefing Information | <input type="checkbox"/> Child Assent(s) |
| <input type="checkbox"/> Request for Waiver of Signed Consent | <input type="checkbox"/> Secondary Participant Consent | <input type="checkbox"/> Training Certificate(s) |
| | <input type="checkbox"/> Unaffiliated Investigator | |

__ Funding/Grant Proposals

__ Participant Referral Information

Agreement(s)

__ Local Contact/Expert for
International Studies

__ IRB Approval from
Collaborating Institution(s)