Marist College Institutional Review Board
3399 North Road, Poughkeepsie, New York 12601
HUMAN SUBJECTS RESEARCH REVIEW FORM

All research involving human subjects must be reviewed and approved prior to initiating the research.

Submit the appropriate number of copies (based on project category, see below) of the entire packet. Included should be:

- **A copy of this form** (Must be signed by the Primary Investigator, and, if appropriate, his/her Faculty Supervisor)
- **Informed consent** and/or debriefing forms/scripts
- **CITI training certificates** for every investigator not on file
- **Additional materials** relevant to your particular study
- **Letters/approvals** for unaffiliated/collaborating institutions/investigators and funding

Submit completed forms to:
IRB Mailbox, 3rd floor Dyson
Marist College
Poughkeepsie, NY 12601

For questions regarding human subject research at Marist College, refer to policy and procedures for research involving human subjects found at: **www.marist.edu/academics/irb/pdfs/policies.pdf**

For further questions, contact the IRB chair: Erik Moody @ ext. 2692

Name of Primary Investigator Submitting Application:

Research Proposal Type (check at least one of the following)
Method of review (expedited or full) 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 that ultimately decides under which category a project will be reviewed.

RESEARCH THAT REQUIRES **EXPEDITED REVIEW**
Submit original packet (application form and all attachments) and 1 copy

- ☐ 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

RESEARCH THAT REQUIRES **FULL REVIEW**
Submit original packet (application form and all attachments) and 8 copies

- ☐ Research which might put subjects at risk
- ☐ Research involving psychological or physiological intervention
- ☐ Non-curricular, interactive research, e.g., in schools, prisons, social service agencies
- ☐ Research involving deception
- ☐ Interviews or surveys 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

GENERAL PROTOCOL INFORMATION

Research Proposal Title:	
Anticipated Start Date for Research:	
Expected Duration of Research (From initial recruitment through data analysis)	
Dissemination Forum(s) (e.g., journal, poster session, presentation, etc.):	

Primary Investigator (PI)	
Name	
Address (campus or business)	
Email Address	
Phone number	
Affiliation with Marist (e.g., professor, student)	
Department Affiliation (e.g., Psychology)	
Role/Responsibility in Research (Please be as specific as possible)	

Faculty Advisor (Required when PI is a student)	
Name	
Department/Campus Address	
Email Address	
Phone number	

Briefly describe the proposed research in lay person's terms:

Describe the methodology/procedure(s) you will use in more detail. Include all physiological, psychological and medical procedures, tests, interaction or interventions that will be used during the conduct of the study. If you need more space, attach a separate document. Make sure to refer to and attach to this application any associated research materials being used (psychological scales, surveys, stimuli, etc.)

SPECIFIC HUMAN SUBJECTS CONSIDERATIONS

RESEARCH PARTICIPANTS

1. **Total number of participants expected:**

2. **Type of participants:**
   - ☐ Marist Students (over 18)
   - ☐ Other Adults (over 18)
   - ☐ One of the special populations below:

   - ☐ Prisoners
   - ☐ Mentally Disabled Persons
   - ☐ Economically Disadvantaged-
     If Yes, please explain:
   - ☐ Children (below 18) Age Range: to
   - ☐ Pregnant Women
   - ☐ Educationally Disadvantaged-
     If Yes, please explain:

   If you are planning to use participants from one of the special populations listed above, explain the safeguards you will use to protect the participant's rights and welfare:

3. **Where and how will participants be recruited/selected?**

Are you planning to use the Marist College Participant Pool to recruit Marist College students as participants for your study? (Only psychology faculty and honors/independent study students can use this pool)

☐ **No** ☐ **Yes**

(If "yes", be sure to review the policies at www.marist.edu/sbs/psych/participant_pool.html and fill out and attach the Sona recruitment document to this submission.)

RISKS AND BENEFITS

4. **Risk level of this study.** "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical/psychological examinations or tests.
   □ Minimal Risk or Less Than Minimal Risk
   □ More than Minimal Risk

5. **Identify all possible risks to participants involved in this study. Check all that apply.**
   □ Physical □ Psychological □ Privacy
   □ Discomfort □ Confidentiality □ Other – Please Explain:
   □ Social □ Economic

6. **Do you plan on offering compensation to the participants?**
   □ **No**
   □ **Yes,** partial fulfillment of research participation requirement (when Participant Pool is being used)
   □ **Yes,** something else. Please explain the type, amount and schedule by which it will be distributed (you must include provisions for payment if participant withdraws)

7. **Identify any additional benefits to participants in this study:**

INFORMED CONSENT (If informed consent is necessary, you must attach to this submission EITHER a form with which you will obtain signed consent, or a script to be read to participants to obtain consent.)

8. **How will you obtain informed consent?** If you are obtaining anonymous data (i.e., no personal identifiers recorded anywhere, including the informed consent document or your personal records), and you meet at least one of the criteria listed below, you may request a waiver of signed consent below to obtain consent orally.
   □ Informed consent not necessary for this research project
   □ Signed informed consent will be obtained
   □ Oral consent will be obtained because data collected will be anonymous and project meets at least 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 (you must do this to obtain consent orally), please request waiver below. Include an explicit request for the waiver of signed consent and provide rationale, specifying which criteria your project meets.

   Request Waiver here:

9. Describe in more detail the process you will use to obtain informed consent from participants:

CONFIDENTIALITY

10. Will identifiable information be obtained about participants?

☐ **Data will be anonymous** (unconnected to any information that would indicate participant's identity)

☐ **Data will not be anonymous but will be kept confidential. If so,** complete the following information:

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. Will any sensitive information about the participants or any other individual known to the participant be collected?

☐ **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 participant at risk of criminal or civil liability or be damaging to the subject's financial standing or employability
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.

12. Does your research involve the use of existing data or datasets?

☐ **No**

☐ **Yes.** If yes,

Source of data:

Are the data is publicly available? ☐ **No** ☐ **Yes**

Will the data contain personal identifiers? ☐ **No** ☐ **Yes**

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

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

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

DECEPTION

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

☐ **No**

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

TRAINING IN ETHICAL TREATMENT OF HUMAN SUBJECTS

All personnel associated with this project are required to complete CITI Protection of Human Subjects training for the following two courses and attach the Certification of Completions with this proposal if current documentation does not exist on file.

- Social/Behavioral Basic Course
- Responsible Conduct of Research (RCR) course for your discipline

16. Have all study personnel completed both required courses in the CITI Protection of Human Subjects training?

☐ **No. If no, STOP!** Complete the required training and re-answer this question

☐ **Yes. If yes,** please be sure to attach certificates to this application

Refer to the IRB Policies and Procedures for current training requirements available on the Marist College website: http://www.marist.edu/academics/irb/.

COLLABORATION AND FUNDING

Will this research project involve organizations other than Marist College?
(This includes 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.)

□ **No**
□ **Yes. 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	Signed Approval Letter Attached	Approval Letter Requested
			□	□
			□	□
			□	□

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

Has funding been sought or attained for this research project?
(Please consider all sources of funding including federal, state, university, foundation, etc.)

□ **No**
□ **Yes. If yes,** complete the following section. **Attach additional pages if necessary.** Also, attach two copies of funding documentation and identify the RELEVANT SECTION(S) for which the submission corresponds. If the document is written in highly technical terms, please provide a summary in layperson's terms.

FUNDING SOURCE 1: **The funding is** □ Pending □ Approved

Name of Funding Agency	
Title of Funding Proposal	
Main Contact on Funding Application (If not PI):	
Funding proposal number (if available):	

FUNDING SOURCE 2: **The funding is** □ Pending □ Approved

Name of Funding Agency	
Title of Funding Proposal	
Main Contact on Funding Application (If not PI):	
Funding proposal number (if available):	

LIST OF ALL STUDY PERSONNEL

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.**

Those affiliated with Marist College:

Study Personnel Name	Individual Responsibility/Role in Study	CITI Training Completion Date(s)	Training Certificates Attached*
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐
			☐

* Provide the Institutional Review Board 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.

Those not affiliated with Marist College (if applicable)
(Unaffiliated Investigator Agreement(s) may be required)

Study Personnel Name	Individual Responsibility/Role in Study	CITI Training Completion Date(s)	Training Certificates Attached*
			☐
			☐
			☐
			☐
			☐

* Provide the Institutional Review Board 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.

PRIMARY 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 Institutional Review Board.
- 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 Primary Investigator Name	**Primary 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 Institutional Review Board.

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

ITEMS INCLUDED WITH THIS FORM

Necessary
- □ Training Certificates
- □ Informed Consent form(s) or Script(s)
- □ All Research Materials Being Used – check all that apply:
  - □ Questionnaire/Survey(s)
  - □ Interview Questions
  - □ Test(s) and/or Task(s)
  - □ Recruiting Materials (fliers, scripts, etc.)
  - □ Debriefing Information

Depending on Nature of Research
- □ Institution Permission/Approval Letter(s)
- □ Secondary Participant Consent
- □ Unaffiliated Investigator Agreement(s)
- □ Existing Data Set Approval(s)
- □ Child Assent(s)
- □ Funding/Grant Proposals
- □ IRB Approval from Collaborating Institution(s)
- □ Local Contact/Expert for International Studies
- □ Sona Recruitment Document