PROPOSAL FOR RESEARCH INVOLVING HUMAN SUBJECTS

Date submitted: _____

Title of Proposed Research Project: _____

Proposed starting date of project: _____
Date the collection of data is to end (anticipated): _____
(Approvals are granted for no more than 1 year from the date of review)

Principal Investigator's name: _____
As the signature below testifies, the principal investigator is pledged to conform to the following: As one engaged in investigation utilizing human subjects, I acknowledge the rights and welfare of the participants involved. I acknowledge my responsibility as an investigator to secure the informed consent of the participants by explaining the procedures, in so far as possible, and by describing the risks as weighed against the potential benefits of the investigation. I assure the Committee that all procedures performed under the project will be conducted in accordance with those Federal regulations and College policies that govern research involving human subjects. **Any deviation from the project (e.g., change in principal investigator, research methodology, subject recruitment procedures, etc.) will be submitted to the Committee using a change of protocol form, for its approval prior to implementation. The P.I. agrees to report all protocol deviations or adverse events immediately to the IRB.**

Principal Investigator :_____
(signature) (date)

For Student Researchers

Faculty Advisor name: _____

The Faculty Advisor's signature on the Research Proposal confirms that they have supervised the composition of the proposal and they approve of the research proposal as submitted.

Faculty Advisor: _____
(signature) (date)

For Visiting Principal Investigator(s)

College liaison: _____

Signature of liaison: _____
(signature) (date)

Has this proposal been subject to review by another IRB? Yes No

If "Yes", please attach copies of all documentation submitted for that review, along with the written response (approval, approval with modification, disapproval) from the other IRB.

Purpose of the Study, Background, and Literature Review

Summary: Provide a brief summary of the research in non-technical language.

Purpose of the Study: What are the specific objectives (aims) of the research? Please state your research question(s) and related hypotheses.

Background: State the background of the study. Include a summary of existing knowledge on the topic, and specifically identify gaps that the project is intended to fill. Describe previous work that provides a basis for the proposed research, and that supports the expectation of obtaining useful results without undue risk to human subjects. *Please include appropriate citations to the scientific literature or attach a copy of literature review.*

Participants

a) What is the anticipated number of participants to be included in the project?

b) List specific eligibility requirements for participants, including those criteria that would exclude otherwise acceptable participants. For example, if your study uses only male or female participants, explain why.

c) How will participants be recruited? (Attach any flyers, letters, announcements, etc. that will be used to recruit participants.)

d) Is there any formal relationship between researcher and participant? (e.g. teacher/student, employer/employee, etc.) that might lead to the perception of coercion? If so, please describe how you will address this.

e) Does your research focus **specifically** on any of the following vulnerable populations? If so, please indicate below:

__ Minors (under age 18 – specify the age range; Participants under age 18 require the participant's assent *and* written consent from a parent or legal guardian.)
__ Prisoners
__ Pregnant Women & fetuses
__ Decisionally impaired individuals
__ Marlboro College students or employees as research subjects
__ Institutionalized individuals
__ Economically or educationally disadvantaged persons
__ HIV-positive individuals
__ Non or limited English speaking persons

__ People living outside the U.S.
__ Other, please specify: _____

Please refer to Marlboro College's IRB website (include link once it's up*) for descriptions of each of these categories if you are unsure if your research involves vulnerable populations. (Note: This is just a partial list, there may be other populations not listed here that require a full board review).
If any of the above are to be the primary participants in this research project, please state the justification for their inclusion.

f) Does your research ask about sensitive topics? If so, please indicate below.

__ Sexual orientation, incest, rape, sexual molestation, deviant sexual behavior, or attitudes regarding sexual conduct (pedophilia, bestiality, etc), practices of contraception, abortion, and/or pregnancy
__ Substance use and/or abuse (including but not limited to: alcohol, marijuana, steroids, amphetamines, narcotics, and any prescription medication legally or illegally obtained)
__ Illegal or taboo behavior
__ Questions about mental health (e.g. suicide, depression, obsessive compulsive behaviors like smoking, gambling, etc.)
__ Traumatic experiences of an individual, including war or combat experiences of veterans.

Methods and Procedures

1. Describe the research procedures to be used (what participants will be asked to do, or what treatments will be applied to each subject) in detail. If you will be conducting surveys or interviews, please attach a copy of the survey or interview schedule.

2. Risk to participants: Given the fact that in any study it is possible for participants to experience some degree of discomfort, anxiety, concern about failure, etc., what will you do to minimize the possibility that this will occur, and how will you address or reduce it if it does occur?

4. How will you obtain informed consent? (How and where will the consent process take place? How will it be structured to enhance independent and thoughtful decision-making? What steps will be taken to avoid coercion or undue influence?)

5. Will any information about the research purpose and design be withheld from potential or participating subjects? If so, please justify this, and describe plans for post-study debriefing.

Note: Any non-disclosure must be approved by the IRB and may not exclude information that a reasonable person would want to know in deciding whether to participate in the research. In addition, the alteration in the consent procedure must be approvable under 45 CFR 46.116(d): (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation

6. How will confidentiality or anonymity (whichever is appropriate) be guaranteed? Include a description of how data will be handled to insure confidentiality or anonymity.

7. How will participants' right to terminate or refuse participation be guaranteed?

8. For students and other researchers without previous experience conducting research with human subjects please explain how you have received instruction in the ethical conduct of research conduct (include names of relevant courses):

9. Please print out and attach the certificate indicating that you have gone through the online IRB training module.