

**221 East 71st Street**

**New York, NY 10021**

**MMC INSTITUTIONAL REVIEW BOARD**

**FACULTY/STAFF APPLICATION FOR EXPEDITED OR FULL REVIEW OF**

**RESEARCH WITH HUMAN PARTICIPANTS**

**Instructions: Please complete the application below; obtain the approval and signature of the MMC liaison (if relevant); complete the educational requirement; email the materials to the IRB Chair(s).**

1. **Project Title:**

**PRINCIPAL INVESTIGATOR INFORMATION**

|  |  |
| --- | --- |
| 1. **Principal Investigator:** |  |
| **Department/Affiliation:** |  |
| **Phone:** |  |
| **Email:** |  |

|  |  |
| --- | --- |
| 1. **Co-PI (if any):** |  |
| **Department:** |  |
| **Phone:** |  |
| **Email:** |  |

1. **PI Status (check one):**   Faculty  Staff  Other (please explain)
2. **Co-PI Status (check one):**  Faculty  Staff  Other (please explain)
3. **FOR NON-MMC RESEARCHERS *ONLY***, please also give your postal address here:

|  |  |
| --- | --- |
| **Address:** |  |

1. **MMC LIAISON INFORMATION** (***Required for outside researchers***)

|  |  |
| --- | --- |
| **Marymount Manhattan College Liaison:** |  |
| **Department:** |  |
| **Phone:** |  |
| **Email:** |  |

**PROTOCOL INFORMATION**

|  |  |
| --- | --- |
| 1. Does your study involve the collection of data from a vulnerable population (for example, children under 18 years of age or incarcerated persons)? | Yes  No |
|  |  |
| *If yes, please specify type of population*: |  |
|  |  |
| 1. If the study involves deception, false information, false feedback, or withholding of critical information, will the participant be told why or debriefed? | Yes  No  N/A (*Skip to Q. 14)* |
|  |  |
| ***If the study involves deception (Yes or No to Q. 9):*** |  |
| 1. Are there adequately effective non-deceptive alternatives? | Yes  No |
|  |  |
| 1. Is the deception potentially harmful (even with debriefing)? | Yes  No |
|  |  |
| 1. Does deception threaten the participant’s dignity? | Yes  No |
|  |  |
| 1. If the study involves deception, please use the box below to justify the use of deception, and address any potential harm to participants. |  |
|  |  |
| 1. If the study involves risk to subjects, is the risk greater than that incurred in ordinary life or tasks? | Yes  No |
|  |  |
| 1. Has this study ever been previously approved by this IRB? | Yes  No |
|  |  |
| 1. Is this proposal new or revised in response to previous IRB review? | New  Revised |
|  |  |
| 1. Is funding being sought for this study? If yes, through what sponsoring agency? | Yes  No |
| Agency: |  |

**Please sign below if you answered YES to Question 17:**

**I certify that the research plan and safeguards to human subjects described in this application conform to those which have been/will be submitted to an external funding source.**

Principal Investigator:       Date: Click here to enter a date.

1. Is this study being reviewed by an Institutional Review Board at another institution? If so, please list the institutions below. Documentation of IRB approval of this study from other institutions must be provided. **Research may not begin until IRB review has been concluded at all institutions involved.**

Study is being reviewed by:

**EDUCATIONAL REQUIREMENT**

**Please sign below:**

I certify that the following key personnel involved in this project either have completed an approved training program for the protection of human subjects in research and have certificates on file with the IRB, or they will have completed an approved training program and certificates will be placed on file before the research actually begins. A free online instruction program is available from the National Institutes of Health [here](http://phrp.nihtraining.com/users/login.php).

1. Principal Investigator:

Date: Click here to enter a date.

1. **Please submit certificates for all personnel listed below.**

**Name Role in Project Date Training Completed**

     

1. **The IRB will make the final determination of the type of review.** Please indicate the type of review requested by checking the appropriate box below. Please visit the MMC IRB Levels of Review document [here](http://www.mmm.edu/offices/academic-affairs/institutional-review-board.php) for guidance on selection of the appropriate level of review. If you believe that your proposed project may be exempt from review, please complete the MMC IRB Application for Approval of Research as Exempt from Review [here](http://www.mmm.edu/offices/academic-affairs/institutional-review-board.php).

Expedited

Full IRB Review

1. **Please answer the following questions on a separate sheet.**
2. State the purpose(s) of the research. Include research design and major hypotheses, if any. If the study is part of a larger study, briefly describe that larger study and indicate whether it has received Institutional Review Board (IRB) approval from another institution. Please keep in mind that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts.
3. Describe the source(s) of subjects and the selection criteria. Describe any characteristics common to potential participants that are relevant to being selected as a participant or that are relevant to the research question. *Selection of subjects must be equitable* and, in the case of protected populations such as children, prisoners, the cognitively impaired, etc., the selection process should address their special needs. Include the number of subjects. The text of any advertisement, letter, flier, oral script or brochure used to solicit potential subjects must be attached.
4. Provide a description of the research procedures to be followed once informed consent has been obtained. If available, include copies of questionnaires and/or interview protocol, or a sufficiently detailed description of the measurement instruments to allow the IRB to understand the nature of the subjects’ involvement.
5. Describe any potential harms or benefits to the subjects that may reasonably be expected from the research, with a discussion of the risk/benefit ratio. Also, describe benefits, if any, to others. For any study with more than minimal risk to be approved, the benefits must clearly be shown to outweigh the risk. Describe how the study may expose participants to stress; or to risks to the dignity, reputation, rights of the person; or to physical, psychological or interpersonal hazards, including the possibility of pain, injury, disease, discomfort, embarrassment, worry or anxiety. Describe the measures you will take to protect against or to minimize each risk.
6. Describe the specific methods by which confidentiality and anonymity will be protected, including the use of data coding systems, how and where data will be stored for three years after completion of the research and who will have access to it, and what will happen to the data after the study has been completed.
7. If applicable, provide the following: 1) a description of the nature of any debriefing of subjects after they have completed the procedures; 2) a statement describing the actions you will take if a medical or other potentially troubling condition arises in the process of the research.
8. Describe the oral and written consent processes, and attach all consent documents, including scripts for oral consent and any assent forms for research involving minors ages 12-17. When the consent form to be used will be in a language other than English, an English translation must be provided. Unless one or more of the required elements described below is explicitly waived by the IRB, informed consent documents should contain:
9. A fair 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 that are experimental;
10. A description of any possible discomforts and risks reasonably expected. This includes any potential financial risks that could ensue;
11. A description of any benefits reasonably expected;
12. A disclosure of any appropriate alternative research procedures;
13. A statement that participation is voluntary; that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
14. An offer to answer any inquiries concerning the goals of the research or the research procedures and to provide a summary of results upon request and 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;
15. An instruction that the subject is free to withdraw or discontinue participation at any time without prejudice.
16. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; and
17. Provisions for parent or guardian approval for the participation of minors or for subjects from vulnerable populations when appropriate.

Upon approval of the study, the consent document will be issued an expiration date. **Only this document may be used when enrolling subjects.** **Any changes to the consent form or the research procedure, or extension beyond the expiration date must be approved by the IRB**; submit the MMC IRB Application for Modification of MMC IRB-Approved Projects.

8. Briefly describe the training and experience that qualifies you to carry out the proposed research.

9. Please provide any other information that might be pertinent to the IRB’s decision.

1. **SIGNATURE and CERTIFICATION**

**I (we) agree to use all reasonable procedures to safeguard human research participants in this activity. If significant change in investigative procedure involving human research participants is called for during the activity covered by this application, I (we) shall seek prior approval for such change from the IRB by submitting the MMC IRB Application for Modification of MMC IRB-Approved Projects, and agree to follow the advice of the IRB.**

**Signed:**

**Principal Investigator** **Date** Click here to enter a date.

**Co-PI       Date** Click here to enter a date.

**MMC Liaison       Date** Click here to enter a date.

***(Required for non-MMC affiliated researchers)***

*NOTE: A hand written signature is not needed if this application is submitted electronically with your name and date entered above.*