APPLICATION FORM - INITIAL REVIEW

MERCY COLLEGE

INSTITUTIONAL REVIEW BOARD
Room 117 Main Building
555 Broadway Dobbs Ferry NY 10522
Phone: 914-674-7814 / Fax: 914-674-7840 / mcirb@mercy.edu

MC IRB Protocol No.: ______________________

Date of IRB Review: ______________________

For office use only

PROJECT TITLE _____		
PRINCIPAL INVESTIGATOR Name (Last, First) _____	Degree(s) _____	Campus Phone Number _____
Department _____	Campus Mailing Address _____	Connect/Mercy E-mail Address _____
FACULTY SPONSOR Name (Last, First) _____	Degree(s) _____	Campus Phone Number _____
Department _____	Campus Mailing Address _____	Mercy E-mail Address _____
List all co-investigators below, including those from other institutions		
STUDENT-INVESTIGATOR Name (Last, First) _____	Phone # _____	Connect E-mail Address _____
Mailing Address _____		
STUDENT-INVESTIGATOR Name (Last, First) _____	Phone # _____	Connect E-mail Address _____
Mailing Address _____		
STUDENT-INVESTIGATOR Name (Last, First) _____	Phone # _____	Connect E-mail Address _____
Mailing Address _____		
STUDENT-INVESTIGATOR Name (Last, First) _____	Phone # _____	Connect E-mail Address _____
Mailing Address _____		

Check the proposed research category:

☐ Category I (Administrative Review) ***Email the application packet to MCIRB@mercy.edu***

☐ Category II (Expedited Review) ***Email the application packet to MCIRB@mercy.edu***

☐ Category III (Full Review) ***Email the application packet to MCIRB@mercy.edu***

FUNDING SOURCES

Check all of the appropriate boxes for funding sources for this research. Include pending funding source(s).

☐ **Federal Grant**

☐ **Faculty Development Grant**

☐ **Personal Funds**

☐ **Department**

☐ **Gift**

☐ **Commercial - company name**: _____

☐ **Other**: _____

If federally funded, provide name and address of individual to whom certification of IRB approval should be sent:

_____
Name

_____
Address line 1

_____
Address line 2

_____
City, State, Zip

Attach the research proposal/protocol that was sent to the agency, committee, or sponsor for peer-review of scientific merit if applicable.

DATA COLLECTION OR COLLABORATING SITES

If the participants are to be recruited from an institution or organization (e.g., hospital, social service agency, prison, school, etc.) or from a privately owned business (private practice, local sports gym, etc.), documentation of permission from the institution must be submitted to the committee before final approval can be given. Letters of permission (on organization's letterhead) from a senior office of the institution, organization, or business should authorize the investigator(s) to contact potential participants, to use the facilities, or access the records of that entity.

If this project is being reviewed by any other human participants research review group (e.g., hospital institutional review board), a copy of the approval of that institutional must be attached or a statement of the status of the review must be noted.

List all collaborating and data collection sites	**Provide certification or letter of IRB approval**	**Provide letters of cooperation or support (as appropriate)**
1.	☐ **Attached** ☐ **Will follow** ☐ **N/A**	☐ **Attached** ☐ **Will follow** ☐ **N/A**
2.	☐ **Attached** ☐ **Will follow** ☐ **N/A**	☐ **Attached** ☐ **Will follow** ☐ **N/A**

1. **Briefly state the problem, the present knowledge relevant to it, and the aims and significance of the proposed research. Cite appropriate literature.**

2. **Describe the tasks/tests or procedures participants will be asked to complete.**
(Suggestions: explain step by step what the participants will be asked to do and distinguish those which are experimental from those which comprise routine clinical care/services.) Attach copies of all questionnaires, testing instruments or interview protocols; include any cover letters or instructions to participants. Provide references on reliability and validity of published tools and written permission to use copyrighted tests if you have not purchased the test.

3. **If participants will come in contact with any mechanical, electrical or other equipment, the form entitled Utilizing Research Equipment with Human Participants must be completed by the investigator and a verified safety check.**

A. Description of the Human Participants and the Recruitment Procedures

1. Participant Population

a. Anticipated number: Male _____ Female _____ Total _____

(This number should be the number of participants you will enroll in order to get the adequate data sets you will need. If multiple sites are to be used, provide an estimate of the number in each category to be recruited from each site. In addition, if you plan to study only one sex, provide scientific rationale in the inclusion/exclusion section of the application.)

b. Age Range (check all that apply):

- ☐ 0 - 7 yrs. (submit parental permission form)
- ☐ 8 - 17 yrs. (submit child's assent form, parental permission form)
- ☐ 18 - 64 yrs. (submit consent form)
- ☐ 65+ yrs. (submit consent form)

c. Source/type of participants: (check all that apply)

- ☐ Mercy College employees
- ☐ Mercy College students
- ☐ inpatients or outpatients
- ☐ Community volunteers
- ☐ other: specify _____

State any relationship (past or present) the researcher may have with the potential participants:

d. Location of participants during research data collection (check all that apply):

- ☐ Participant's home
- ☐ Mercy College locations: specify _____
- ☐ Local hospitals: specify _____
- ☐ community settings: specify _____
- ☐ other institutions: specify _____
- ☐ elementary schools: specify _____
- ☐ secondary schools: specify _____
- ☐ other: specify _____

e. Describe populations to be excluded from the research. Please describe procedures to assure equitable selection of participants. Researchers should not select participants on the basis of discriminatory criteria. Selection criteria that exclude one sex, racial, or ethnic group require a clear scientific rationale for the exclusion.

f. Special populations to be included in the research (check all that apply):

- ☐ minors under age 18
- ☐ pregnant women
- ☐ fetus/fetal tissue
- ☐ prisoners
- ☐ economically disadvantaged
- ☐ other: specify _____

g. Provide rationale for using special populations.

The groups listed in (**f**) above are considered "vulnerable" or require special consideration by the federal regulatory agencies and by the IRB.

2. Recruitment Procedures

a. Describe how participants will be identified and recruited. Attach all recruitment information, e.g., advertisements, bulletin board notices, and recruitment letters for all types of media (printed, radio, email, electronic, TV, or Internet).

b. Initial Contact. Describe who will make initial contact. How? If participants are chosen from records, indicate who gave approval for the use of the records. If records are "private" medical or student records, provide the protocol, consent forms, letters, etc., for securing consent of the participants for the records. Written documentation for cooperation/permission from the holder or custodian of the records should be attached. (Initial contact of participants identified through a records search must be made by the official holder of the record, i.e. primary physician, therapist, public school official.)

c. List criteria for inclusion and exclusion of participants in this study.

1) Inclusion:

2) Exclusion:

3) **How will the inclusion/exclusion criteria be assessed and by whom?**

d. **Will participants receive incentives before or rewards after the study (e.g., academic credit, money)? If yes, explain.** (Note: this information must be outlined in the consent document.)
☐ **Yes** ☐ **No**

e. **Will the participants be charged for research-related procedures? For example, will participants be charged for extra tests/services related to the research?** If yes, explain charges, including estimated amounts. **Will there be financial coverage for the extra costs?** If yes, explain. (Note: this information must be included in the consent document.) ☐ **Yes** ☐ **No**

B. Risks and Benefits of the Research

1. **Identify the risks (current and potential) and describe the expected frequency, degree of severity, and potential reversibility.** Include any potential late effects. (Note: risks can be psychological, physical, social, economic, or legal.)

2. **Does the research involve** (check all that apply):

- ☐ administration of drugs, and chemical or biological agents
- ☐ administration of physical stimuli
- ☐ changes in diet or exercise
- ☐ use of private records (medical or educational records)
- ☐ possible invasion of privacy of participant or family
- ☐ deprivation of physiological requirements such as nutrition or sleep
- ☐ manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stresses
- ☐ the collection of personal or sensitive information in surveys or interviews
- ☐ use of a deceptive technique (If use of deception is part of the experimental protocol, the protocol must include a "debriefing procedure" [provide this procedure for IRB review] which will be followed upon completion of the study, or withdrawal of the participants.)
- ☐ presentation of materials that participants might consider offensive, threatening, or degrading
- ☐ other risks: specify _____

3. **Describe the precautions taken to minimize risk:**

   a. **Care of participants in case of an accident: Describe the provisions that have been made for the care of the participant in the event of an accident or complication related to the research procedures.** (Note: This section may not apply to Category I or II research. Also, unless specific sponsored contracts exist to cover research-related injuries, the standard treatment compensation language must be included in the consent form [see sample].)

4. **Why are the risks and inconveniences mentioned above reasonable? What is the expected scientific yield from the project?** Please justify the risks in relation to the anticipated benefits to the participants and in relation to the importance of the knowledge that may reasonably be expected to result from the research.

5. **Benefits of participation:** List any anticipated ***direct*** benefits of participation in this research project. If none, state that fact here and in the consent form. The knowledge gained from the study could produce a benefit to society. Payment is not considered to be a benefit of participation. Any benefits of treatment should be listed as potential benefits.

C. Confidentiality of Data

1. **Describe provisions made to maintain confidentiality of data.** How will the data be coded? Who will have access to raw data? Will raw data be made available to anyone other than the Principal Investigator and immediate study personnel (e.g., school officials, medical personnel)? If yes, who, how, and why? Describe the procedure for sharing data. Describe how the participant will be informed that the data may be shared.

2. **Where will the data be kept and for how long? How will audio and video tapes be disposed of?** (Disposition of audio and video tapes should be included in consent form.)

3. **Will the research data and information be part of the medical chart, academic record, or other permanent record?** (Explain here and in the consent form.) ☐ **Yes** ☐ **No**

D. Informed Consent Process

Simply giving a consent form to a participant does not constitute informed consent. The following questions pertain to the process. Researchers are cautioned that consent forms should be written in simple declarative sentences. The forms should be jargon-free. Foreign language versions should be prepared for any applicable research.

1. Capacity to consent. Will all adult participants have the capacity to give informed consent? ☐ **Yes** ☐ **No**

If not, describe the likely range of impairment and explain how, and by whom, their capacity to consent will be determined. Note: In research involving more than minimal risk, capacity to consent should be determined by a psychiatrist, clinical psychologist, or other qualified professional not otherwise involved in the research. Individuals who lack the capacity to consent may participate in research only if a legally authorized representative gives consent on their behalf.

a. Is the informed consent document attached? ☐ **Yes** ☐ **No** See MC IRB website for informed consent information: http://www.mercy.edu/stafffaculty/irb/sampleconsent.htm If you are using telephone surveys, telephone scripts are required.

2. **How will participants' understanding be assessed? What questions will be asked to assess the participants' understanding; will there be written responses; will understanding be assessed at other points in time?** (Note: the purpose of this question is to ask you to describe how you will assess participants' understanding of the consent process. Questions requiring "yes/no" answers do not do that very well. Please ask participants to explain the purpose of the study to you along with the risks and benefits to themselves as participants. Their answers to these questions should allow you to determine if they understand the study and their part in it. If they do not understand, informed consent has not been achieved even if the participant signed the consent document.)

3. **In relation to the actual data gathering, when and where will consent be discussed and documentation obtained, for example, immediately prior to the data collection or several days before?** Be specific.

4. **Will the investigator(s) be securing all of the informed consents?** ☐ **Yes** ☐ **No**
   If no, name the specific individuals who will obtain informed consent and include their job title and a brief description of your plans to train these individuals to obtain consent and answer participants' questions.

5. **Are you requesting Waiver or Alteration of Informed Consent?** ☐ **Yes** ☐ **No**

   An IRB may approve a consent which does not include, or alters, some or all of the elements of informed consent (e.g., oral consent). Provide justifications for the following questions for requesting a waiver of written informed consent – ***answer a – d only if you are requesting a waiver***.

   a. **Why does the proposed research present no more than minimal risk to the participants?**

   b. **Why will a waiver of informed consent not adversely affect the rights and welfare of participants?**

c. Why is it impracticable to carry out the research without a waiver or alteration of informed consent?

d. How will pertinent information be provided to the participants, if appropriate, at a later date?

Even if waiver of written informed consent is granted, you may be required to obtain verbal permission which reflects elements of the written consent (if appropriate). **Please specify below the information to be read/given to the research participants.**

E. Investigator Training

1. Describe the investigator(s) training and experience to conduct the research (e.g., training and experience). Include a copy of certificate demonstrating completion of the NIH Computer Based Training Program (required for all key personnel in the research project).

INVESTIGATOR'S ASSURANCE

I certify that the information provided in this application is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human participants, conduct of the study and the ethical performance of the project.

I agree to comply with all Mercy College policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human participants in research, including, but not limited to, the following:

- The project will be performed by qualified personnel according to the MC IRB certified protocol,
- No changes will be made in the protocol or consent form until approved by the MC IRB,
- Legally effective informed consent will be obtained from human participants if applicable, and
- Adverse events will be reported to the MC IRB in a timely manner.

I have completed the required educational program on ethical principles and regulatory requirements.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

_____ _____

Principal Investigator Date

FACULTY SPONSOR'S ASSURANCE

By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular study in accord with the approved protocol.

In addition,

- I agree to meet with the investigator on a regular basis to monitor study progress,
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them,
- I insure that the investigator will promptly report significant or untoward adverse effects to the MC IRB in a timely manner,
- If I will be unavailable, as when on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence and I will advise the MC IRB by letter of such arrangements, and
- I have insured that the investigator completed the required educational program on ethical principles and regulatory requirements.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

_____ _____

Faculty Sponsor* (if PI is a student or a fellow) Date

*The faculty sponsor must be a member of the MC faculty. The faculty member is considered the responsible party for legal and ethical performance of the project.