INSTITUTIONAL REVIEW BOARD

GUIDELINES FOR SUBMITTING A PROPOSAL
for
Research Projects Involving Human Participants

Revised 1/15

Mercy College IRB:

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Mercy College Institutional Review Board
Guidelines for Conducting Human Participants Research

Included in this packet are guidelines to assist you in determining what information must be submitted to the Institutional Review Board.

Conditions requiring submission of a Mercy College IRB Application

You are the principle investigator of a research project that involves research with human participants. As principle investigator you may be a(n):
(1) faculty member at Mercy College
(2) student at Mercy College
(3) outside investigator requesting access to Mercy College students, personnel or records.

Collaborative Research Conditions permitting Expedited Review by the Mercy College IRB:

You are a principal investigator in a research project involving human participants where the Mercy college faculty member and/or students are participating in the research at your institution or facility. Your institution has the primary responsibility for protecting the human participants but the Mercy College faculty member and/or student must submit to the Mercy College IRB documentation of:
(1) a letter from the external IRB granting approval for the research
(2) a copy of the informed consent forms that were approved by the external IRB
(3) A copy of the form entitled "**Report of Approval by External IRB** (MCIRB2)" clarifying the roles of the faculty member/student in the research project.
(4) A copy of the research protocol (if permitted) or a project summary that indicates how human participants are involved in the research.

This is a complete set of guidelines for all types of research. Only certain components of the guidelines will apply to your project. After you read the guidelines if you need assistance in determining which components apply to your project please contact the Mercy College Chairperson of the Institutional Review Board at 914-674-7655 or mcirb@mercy.edu.

MERCY COLLEGE
INSTITUTIONAL REVIEW BOARD

PRINCIPAL INVESTIGATOR RESPONSIBILITIES

1. In designing the study, the investigators should take into consideration the three underlying ethical principals for conducting research with human participants: respect for persons, beneficence, and justice.

2. Research investigators should acknowledge and accept their responsibility for protecting the rights and welfare of human research participants and for complying with all applicable provisions of the College policies dealing with protection of human participants.

3. Investigators are responsible for ensuring that all research involving human participants is submitted to and approved by the appropriate Institutional Review Board (IRB) prior to initiation of the research.

4. Research investigators who intend to involve human research participants will not make the final determination of exemption from applicable Federal regulations or provisions. The investigators must submit a request for exemption that will be reviewed by designated representatives of the IRB.

5. Investigators are responsible for complying with all IRB policies, decisions, conditions, and requirements. Investigators are responsible for insuring that the research is implemented as specified in the approved IRB protocol.

6. Unless otherwise authorized by the IRB, investigators are responsible for obtaining and documenting informed consent in accord with federal regulations.

7. Research investigators are responsible for providing a copy of the IRB stamped/approved informed consent document to each participant, unless the IRB has specifically waived this requirement.

8. Unless otherwise authorized by the IRB, investigators are responsible for insuring that assent from research participants who are minors is obtained and documented in accord with IRB policies and requirements.

9. As often as required, and in the manner prescribed by the approving IRB, research investigators are responsible for reporting the status of approved research projects to the IRB. Frequency of documenting project status is based on potential risks to participants, but is required of all projects on an annual basis.

10. Investigators are responsible for promptly submitting to the IRB modifications to a previously approved protocol when:
    a. The modification is proposed to involve human participants, and previous research plan had indefinite plans for involvement of human participants;

    b. The modification proposes to change previously approved human participant research activities. The changes cannot be initiated without IRB review and

approval, except when the plan is changed to eliminate apparent immediate hazards to the participants.

11. Research investigators must promptly report to the IRB any injuries, adverse effects or other unanticipated problems involving risks to human participants and others, in accord with IRB policies and requirements.

12. Research investigators are responsible for retention of signed consent documents for at least three years beyond completion of the research activity.

Adapted from the University of Kentucky.

Training and Education Requirement

In response to federal mandates, Mercy College, along with many institutions, requires that key study personnel conducting research involving human participants demonstrate their knowledge of federal regulations and the ethical principles related to research by completing training on the protection of human research participants.

Key personnel include all Faculty, Researchers, Students & Staff who work with human research participants or the participants' identifiable data.

The College accepts the online computer training offered by the National Institutes of Health [NIH] to meet the basic requirements for training and competency testing. All students and faculty submitting applications to engage human participants in research must submit a copy of the NIH certificate of completion along with the application. The NIH computer based training program on the protection of human participants may be accessed at the website:
http://phrp.nihtraining.com

The NIH training program takes approximately 1 - 1 1/2 hours to complete and ***ALL research proposals submitted to the Mercy College IRB must contain a certificate of successful completion of the NIH training program or a similar program provided by another educational or research institution for all key personnel.***

Mercy College implemented this requirement campus-wide to ensure that everyone engaging in human participants research has the best possible information on how to protect those who make our research possible. As the College highly values research participants' rights and welfare, there will be-no exceptions to this policy.

Mercy College Institutional Review Board
Application Guidelines for Conducting Human Participant Research
as a Principal Investigator

All research involving human participants must be reviewed and approved prior to initiating the research. The method of review (exempt [administrative review], expedited, or full review) depends on the category of research appropriate for the project (as defined by the Federal Guidelines for the Protection of Human Participants). The three project categories, along with examples of the type of projects included in each category are listed below. Although, the investigator makes the initial determination of the project's category, it is the Institutional Review Board for Research that ultimately decides under which category a project will be reviewed. If you have any questions regarding the appropriate category for your project contact the current Chairperson of the Mercy College IRB at 718-678-8812 or mcirb@mercy.edu.

Instructions:

1. Determine the appropriate category for your research project.
2. Complete the application for using human participants in research.
3. Complete the appropriate coversheet including the required signature(s).
4. Submit to the Chairperson of the Mercy College IRB one (1) copy for Category I (Administrative Review), three (3) copies for Category II (Expedited) reviews, and six (6) copies for Category III (Full Review).

Applications should be submitted by the first of each month during the academic year. The information must be typed and free of grammatical and spelling errors. The IRB meets monthly during the fall and spring semesters. Researchers are typically informed of the IRB's decision by the end of the month in which it was reviewed.

PROJECT CATEGORY I - Administrative Review

Application Guidelines:
Complete and submit responses to all questions of the **Application Guidelines for Conducting Human Participant Research as a Principal Investigator**. The proposal should include the **Initial Review** coversheet (MCIRB1). Judgment of whether a given research project is exempt from further review remains a responsibility of the Mercy College IRB. Applications may be submitted at any time to the IRB email account mcirb@mercy.edu. Faculty sponsors of student research may electronically sign off on the application when sending by email by stating that in the email text. Responses are provided within a few weeks.

Sample descriptions of research in this category:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods requires only IRB administrative review.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public

behavior when the participants cannot be identified requires only IRB administrative review. This exemption of full review does not apply to research with children except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior **requires more than IRB administrative review** when:

   - information obtained is recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants;
   - any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation;
   - the human participants are elected or appointed public officials or candidates for public office;
   - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens requires only IRB administrative review, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

5. Research and demonstration projects which are conducted by or participant to the approval of Federal department or agency heads requires only IRB administrative review when they are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) possible changes in or alternative to those programs or procedures; or (iii) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies require only IRB administrative review, (i) if wholesome foods without additives are consumed; or (ii) if a food is consumed that contains a food ingredient found to be safe at or below a particular level, or an agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

PROJECT CATEGORY II (Expedited Review)

Application Guidelines:

Complete and submit responses to all questions of the **Application Guidelines for Conducting Human Participant Research as a Principal Investigator**. The proposal should include the **Initial Review** coversheet (MCIRB1). Applications may be submitted at any time to the IRB email account at mcrib@mercy.edu . Responses are provided within a few weeks.

Expedited reviews may be granted for certain kinds of research involving adult human participants at no more than minimal risk.

Minimal risk is defined by the Federal Guidelines as: *"The risk of harm anticipated in the proposed research is not greater, considering probability and magnitude, than those risks normally encountered in daily life or during the performance of routine physical or psychological examinations or tests."* Please note that all research involving a signed consent document presents a risk of breach of confidentiality that must be stated in the consent form.

Expedited reviews may also be used for minor changes in approved research during the period for which project approval is authorized.

Sample descriptions of research in this category:

1. Interview and interactive surveys where the participant may be identified (e.g. survey is completed face to face with the researcher or demographic data may inadvertently identify the participant). If the research project involves topics identified by the Federal Guidelines as "sensitive" (e.g., illegal conduct, drug use, sexual behavior, or use of alcohol) a full review will be required.
2. Study of existing data sets, documents, or medical records, used in confidential, individually non-identifiable form (additional federal regulations and HIPAA privacy laws may apply).
3. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate participants' behaviors and the research will not involve stress to participants.
4. Voice/ video recordings made for purposes such as investigation of speech defects or recordings of qualitative interviews for the purposes of transcription.
5. Moderate exercise by healthy volunteers.
6. Collection of data through non-invasive, standard clinical procedures already being performed on the participants for diagnostic or treatment purposes. This research may also require the investigator to obtain IRB approval from the clinical site where the data has been collected.

A Note on Documentation of Informed Consent

The IRB may waive the requirement for the investigator to obtain signed consent for some or all subjects if the research presents no more than minimal risk of harm to subjects, and if the only record linking the subject and the research would be the consent document (making the principal risk one of breach of confidentiality). In this case subjects should be provided with a

written statement regarding the research and their rights as participants.

PROJECT CATEGORY III (Full Review)

Application Guidelines:

Complete and submit responses to all the questions on the **Application Guidelines for Conducting Human Participant Research as a Principal Investigator**. The proposal should include the **Initial Review** (MCIRB1) coversheet. Full reviews require that a quorum of members of the Mercy College IRB review and approve the research proposal at a convened meeting. Applications must be submitted at the beginning of the month for review during the convened IRB meeting scheduled on the 3rd Thursday each month (see IRB WebPages for specific application deadlines and meeting dates). Responses are provided to the researcher by the end of the month in which it was submitted.

Sample descriptions of research in this category:

1. Research that might put participants at greater than minimal risk as defined by the Federal Guidelines.
2. Research involving psychological or physiological intervention/treatment.
3. Research involving participants classified as "medically unstable" by a licensed physician.
4. Interviews or surveys on sensitive topics as defined in the Federal Register (i.e., illegal conduct, drug use, sexual behavior, or use of alcohol).
5. Research involving deception.
6. Research on special populations [e.g., children/minors, fetuses, prisoners, and the mentally incompetent (incapable of giving informed consent)].
7. Research projects that involve children (i.e., under the legal age of 18 years) must obtain "assent" from the child to participate in the research and "permission" from the parent(s) or guardian for their child or ward to participate in research.

CATEGORIES OF APPROVAL

The IRB operates under the authority of the Mercy College as a College Committee through the Vice President for Academic Affairs. The IRB functions independently of any other Mercy College Committee, Department, or Research Investigators and is supported in its decisions by the administration. The IRB has the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human participant research.

The Mercy College IRB will provide the principal investigator with documentation of the anonymous reviewers' decisions. Reviewers will grant the proposal one of the following three decisions:

- **approved** - this enables the investigator to begin soliciting participants for participation;
- **conditional approval -** participant solicitation and data collection may not begin until the requested information/changes are provided and approved by the IRB; or
- **denied** - research that is denied must address the concerns and be resubmitted for review. Participant solicitation and data collection may not begin until the research is approved.

APPEAL OF THE IRB DECISION

When a research proposal is disapproved, or changes are required, the investigator may request a re-examination of the protocol by the IRB. The IRB will allow the investigator to present his/her case, in writing and/or person, at a regularly convened IRB meeting. The IRB will comply with subsequent requests for re-review if the investigator has made significant changes to the study or has significant new information to present.

ONGOING REVIEW OF RESEARCH

The Mercy College IRB will conduct ongoing reviews of research at intervals appropriate to the degree of risk to human participants, but not less than once per year. The IRB also has authority to observe or have a third party observe the consent process and the research. Approximately 10 months after the initial approval the Principal Investigator will be mailed a follow up report. It is the responsibility of the Principal Investigator to complete and return this form to the IRB Chairperson on or before the date required. Failure to return the ongoing review documents results in your withdrawal of your IRB approval and closure of your research project.

CHANGES IN PROTOCOL OR CONSENT FORM

Note that all changes to an approved protocol must be submitted to the IRB prior to the implementation of the changes in data collection. The investigator must determine whether the proposed change is a major or minor one. In making this determination, the investigator should consider whether the change will affect the participant population, the degree of risk to the participants, or the general direction of the research.

Minor Changes

If the investigator believes that the change is a minor one {i.e., that it does not change any of the elements listed above} he/she may submit a letter to the IRB requesting approval for the proposed change.

The IRB will perform expedited reviews of this material. If the IRB agrees that it is a minor revision and agrees with the modification(s), the investigator will receive a letter stating the revision has been approved through expedited review. If the IRB feels that the revision would have a major impact on one of the elements listed above, the investigator will be required to follow the procedures described in the following section before initiating the revision. Therefore, if the investigator has any doubts as to the nature of the modification, he/she is encouraged to discuss the revision with the IRB chairperson for a prior opinion of the major or minor status of the proposed change before submitting any request for approval.

Major Changes

The introduction of a new group of participants or adding new procedures all qualify as potential major revisions in a protocol. A major revision must be reviewed in the same manner as a new application for IRB approval. It must undergo exactly the same review procedures as the original protocol. In order to facilitate and thus speed the review process, it is asked that the investigator discuss the anticipated impact of the change and its difference from the originally approved protocol. This can be done in the form of a letter or a brief statement attached to the front of the revised protocol and consent form as they are submitted to the IRB.

INTEGRITY IN RESEARCH *Adapted from the University of California, Irvine, Office of Research and Graduate Studies*

Mercy College defines research misconduct as:

- failure to obtain Institutional Review Board approval prior to initiating research with human participants;
- failure to follow informed consent and approved research protocol;
- fabrication, falsification, plagiarism of research;
- or other practices that seriously deviate from those that are commonly accepted within the academic community for proposing, conducting or reporting research.

Any student, staff, faculty, individual outside of the college community, or a College committee such as the Institutional Review Board, may report incidents of alleged research misconduct. All individuals engaged in research at Mercy College are responsible for fostering an environment that encourages absolute intellectual integrity with open communication and trust -- the cornerstones of the academic enterprise. Incidents of research misconduct violate this trust and harm the research community itself.

Allegations should be addressed to Chairperson of the IRB or the Provost and Vice President for Academic Affairs, who counsels the individual coming forward with an allegation of misconduct. If the initial report of misconduct is oral, it must be put in writing before a preliminary inquiry can proceed.

In accordance with the College policy [Research Misconduct Policy], the proceedings of an inquiry into research misconduct are confidential to protect the members of the inquiry panel, the individual filing the allegation, the person accused, and the witnesses, to the maximum extent possible. All individuals are asked to refrain from discussing the matter with anyone, including faculty members, students, family members, and the media. A Preliminary Inquiry is the first part of a two-step process. Its only purpose is to determine whether there is sufficient credible evidence of academic misconduct to warrant a full-scale, or formal, investigation. A Formal Investigation is the examination and evaluation of all relevant facts to determine if an instance of misconduct has taken place, to evaluate its seriousness and, if possible, to determine responsibility.

Any student, staff, faculty member, or individual outside of the College community may be a participant of a research misconduct inquiry. If an investigative committee determines that research misconduct has occurred, the disciplinary action will depend on the employment or enrollment status of the participant and the recommendations of the Research Misconduct Panel Hearing.

SUSPENSION OR TERMINATION OF IRB APPROVAL OF RESEARCH

The Mercy College IRB has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants.

GUIDELINES FOR THE DEVELOPMENT OF AN INFORMED CONSENT FORM

The consent form should be in language the participant can understand. Please be critical of the person/tense used in the wording of the consent form. Statements involving, *"I"*, *"You"*, and *"We"* cannot be used interchangeably in the statement of the project. The document should be written in the 3rd person (i.e., refer to the potential participant as 'you'). Please review the sample documents on the Mercy College IRB WebPages at http://www.mercy.edu/staffFaculty/IRB/sampleconsent.htm.

An effort should be made to be precise using simple language written at the 6 – 8th grade reading level. Researchers are encouraged to use the Flesch-Kincaid Grade Level readability statistics under the Spelling & Grammar Option under Tools.

The basic elements of the information necessary for the "informed consent" include:

1. The title of the study should be listed on the top of each page and each page of the consent should be numbered (i.e., page # of # total – page 1 of 4)

2. A brief statement of the purpose of the research (e.g., *this research is being done to see if men and women have different opinions on parental involvement in their children's education*).

3. Identification of who will be conducted the research including credentials and affiliation. *(e.g., Mary Smith, a graduate student in the Mercy College Department of Psychology.)*

4. A description of the procedure(s) - How long the procedure(s) will take, frequency, where they will be conducted, estimated total time and or costs required.

5. A description of how you will maintain the participant's anonymity and/or confidentiality, and dispose of his/her research records. A description of your intentions with regard to anonymity and confidentiality in reporting findings.

   If data are in the form of tape recording, photographs, movies or videotapes, the research should describe the period of time this data will be retained before destruction. Showing or playing of such data within a public forum (e.g., classroom or conference) must be disclosed. Participants have a right to review transcripts of video or audio recordings and ask that portions not be used, and this should be stated in the consent document.

6. A description of the risks and benefits that might be expected. If benefits are mentioned add: *"It cannot be guaranteed or promised that you will receive any benefits from this study"*. If there are no direct benefits to the participants this should be stated.

7. A description of appropriate alternative procedures that might be advantageous to the participant, if any. Any standard treatment that is being withheld must be disclosed.

8. A statement describing if the participant will receive any compensation. Describe the amount or nature of the compensation. If there is a possibility of additional costs to the participant because of participation, describe them. (SAMPLE WORDING: "*For your participation in the study, you will be paid $_____ for each study visit up to a total amount of $_____ for completing the study. If you do not complete the study, you will be paid $_____ for each completed study visit.*")

9. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled.

10. The following guidelines relate to studies involving participation of children:

    A statement that adequate provisions are made for soliciting the assent and/or consent of the children and the permission of their parent(s) or guardian. Assent is obtained from children from the ages of 6 years to 14 years of age. Consent is obtained from children from the ages of 14 to the age of adulthood as defined by the state.

    a. "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

    b. "Assent" means a child's affirmative agreement to participate in research. Failure of the child to object to the research tasks should not be construed as assent.

    c. "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

    d. "Parent" means a child's biological or adoptive parent.

    e. "Guardian" means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

    In all cases the consent of at least one parent (custodial parent) is required. The permission must be documented.

    Children who are wards of the state or any other agency, institution, or entity can be included in research according to the regulations spelled out in the Protection of Human Subjects Code of Federal Regulations 45LFR46, provided an appropriate mechanism for protecting the children who will participate as participants in the research is substituted, and provided further that the waiver is not inconsistent with federal, state or local law. Permission must be gained from individual's legal guardian.

11. A statement that the investigator has answered to the best of his/her ability all questions posed by the participant and that he/she will answer to the best of his/her ability any questions the participant may have in the future. This should include a phone number where the participant may reach the principal investigator or the faculty mentor.

12. A statement that the appropriate IRB(s) has/have approved the study. This statement should appear before the signature and include the telephone number of the IRB for participants to call if they have questions regarding the approval of the study or their rights.

13. Conclude with a statement of acceptance to participate in the research study including the signature of the participant or responsible agent.

14. Each participant must receive a copy of the signed consent form. The original form must be kept on file for three (3) years.

15. The following are additional elements of informed consent that may be required depending on the nature of the research:
    - A statement that the particular treatment or procedure may involve risks to the participant that are unforeseeable.
    - Anticipated circumstances under which a participant's participation may be terminated by the investigator without regard to the participant's consent.
    - Any additional costs to the participant that may result from participation in the research.
    - The consequences of a participant's decision to withdraw from the research (e.g., forfeit of the compensation), and procedures for orderly termination of participation by the participant.
    - A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant.
    - The approximate number of participants involved in the study.

Advertising for Participant Recruitment

The Mercy College IRB must approve all materials used to recruit study participants including newspaper ads, emails, radio, television and computer "Internet" postings. Advertising information should coincide with the information in the Informed Consent. The following guidelines are required to be followed advertising:

- Advertisement for recruitment into new treatment approaches, biologic or device studies should not use terms such as "new treatment" without explaining that the test article is investigational.
- A phrase such as "receive new treatments" implies that all study participants will be receiving newly marketed products of proven worth.
- Advertisements may state that participants will be paid, but should not emphasize the payment or amount to be paid. You may simply state that participants will be paid for their time and travel or that participants will be compensated.
- Compensation to participants should not be coercive. It is sufficient to say "up to". Excessive use of dollar signs or larger dollar signs is not allowed. Statement of payment should be the last information given and should not be enlarged or bolded.
- Advertisements should not promise "free medical treatment", when the intent is only to say participants will not be charged for taking part in the investigation. If participants are receive free treatment as part of the study this should be stated but not emphasized (bolded or increased font size).
- You do not advertise for "patients"; you advertise for "study participants" or "participants".
- The name and address of the clinical investigator and/or research facility as well as the person or office to contact for further information should be included.
- Keep in mind that advertising for participants in a particular study is a reflection of the informed consent and information not contained in the informed consent should not be included in the advertising.
- When advertisements are to be taped for broadcast, the IRB should review the final audio/video tape. The IRB may review and approve the wording of the advertisement prior

to taping to preclude re-taping because of inappropriate content. Video and audio submissions will be returned after the IRB has reviewed and confirmed receipt.

- Your advertisement should be included in your submission to the IRB.
- All advertising the researcher wishes to post on campus must be reviewed and approved by the Campus Manager in addition to the IRB.

MERCY COLLEGE

APPLICATION FORM - INITIAL REVIEW

INSTITUTIONAL REVIEW BOARD

555 Broadway Dobbs Ferry NY 10522
Phone: 914-674-7655 / 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.