# MERCY COLLEGE OF HEALTH SCIENCES

Institutional Review Board (IRB) Application

**SECTION I**

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| Title of Study: | |
| Principal Investigator: | |
| Work Address: | |
| Phone Numbers: (work) | (cell/home) |
| Mercy College Email:[1] | |
| Principal Investigator's Status:<br>☐ Faculty ☐ Staff ☐ Other (please identify): | |
| Co-Investigator: | |
| Work Address: | |
| Phone Numbers: (work) | (cell/home) |
| Mercy College Email:[1] | Student ID: |
| Co-Investigator's Status:<br>☐ Faculty ☐ Staff ☐ Student ☐ Other (please identify): | |

Type of Study (Check all that apply):

☐ **Research**: Systematic investigation, including research development, testing and evaluation, designed to answer a research question and contribute to generalizable knowledge.

☐ **Evidence-Based Practice**: Objective, balanced, responsible use of current research, well designed studies and data to guide policy and practice decisions such that outcomes for consumers are improved.

☐ **Quality Improvement/Assessment**: Studies to assess or improve quality of healthcare or other operations which are generally not considered research, are not going to be published or for public presentation, and will not contribute to generalizable knowledge. May refer to case reports, course related student projects, surveys, questionnaires, interviews, and/or observational studies.

☐ **Other** (please identify):

[1] Investigators outside the College should provide the email address issued by their institution.

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| Present or Proposed Source of Funding (*if applicable)*: |
| Type of Review Requested (*please see review guidelines on p. 2-5)*:<br>☐ Exempt ☐ Expedited ☐ Full Board |
| (Office Use Only)<br>**IRB #:** **Date Received:** |

**REVIEW LEVELS: EXEMPT, EXPEDITED, FULL BOARD.** An *Exempt Review means the study must still be reviewed, but not by the Full Board. After reading the Categories below, check all the Categories that apply. Upon review of the application, the IRB office will determine if the application is eligible for the Exempt Review.*

A study may qualify for an EXEMPT review if it fits into one of the categories outlined below. Check all that apply:

☐ **Category 1: 45 CFR 46.101(b)(1)**

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

(a) research on regular & special education instructional strategies, or

(b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2: 45 CFR 46.101(b)(2)**

**FOR ADULTS:** Research involving the use of educational tests (e.g. cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior UNLESS:

(a) data obtained are recorded in such a way that human subjects can be identified, directly or through identifiers linked to the subjects;

(b) any disclosure of the human subjects' responses would place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; and/or

(c) the research deals with sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

☐ **Category 3: 45 CFR 46.101 (b)(3)**

**FOR SUBJECTS WHO ARE ELECTED OR APPOINTED PUBLIC OFFICIALS OR CANDIDATES FOR PUBLIC OFFICE:** Research involving the use of educational tests (e.g. cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior.

☐ **Category 4: 45 CFR 46.101(b)(4)**

Research involving the collection or study of existing data, documents, records, or specimens if:

(a) the sources are publicly available; or

(b) the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers or codes linked to the subjects.

"Existing" means the data have been collected previously for some other purpose at the time the research is proposed.

"Publicly available" means available to the general public, with or without charge. Under condition (b) above, investigators with legitimate access may view identified information, but may not record identities, identifiers, or codes that link private information to individual subjects. Even a brief recording of identifiers or codes disqualifies the exemption. This category excludes studies of publicly authored documentation such as newspaper articles, novels, works of art, or a literature review.

☐ **Category 5: 45 CFR 46.101(b)(5)**

Research and demonstration projects that are conducted by or subject to the approval of supporting agencies, and which are designed to study, evaluate, or otherwise examine:

(a) public benefit or service programs;

(b) procedures for obtaining benefits or services under those programs;

(c) possible changes in or alternatives to those programs or procedures; or

(d) possible changes in methods or levels of payment for benefits or services under those programs.

☐ **Category 6: 45 CFR 46.101(b)(6)**

Taste and food quality evaluation and consumer acceptance studies,

(a) if wholesome foods without additives are consumed or

(b) if a food is consumed that contains a food ingredient at or below the level, and for a use, found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration and approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ **Category 7: 45 CFR 46.101(b)(7)**

Storage or maintenance of identifiable bio-specimens for secondary research for which a Broad Consent is required.

☐ **Category 8: 45 CFR 46.101(b)(8)**

Secondary research involving use of identifiable private information or identifiable bio-specimens for which a Broad Consent was required.

NOTE: Exempt Categories do not apply to research involving vulnerable populations (see 45 CFR common rule guidelines).

NOTE: Even if your initial determination is Exempt, complete the following checklists for Expedited and Full Reviews. If any of those categories apply, your study is not Exempt.

*An Expedited Review is indicated for research involving no more than minimal risk, no vulnerable populations, or a review of minor changes in previously approved research or research protocols. For the review covered by the Regulations 45 CFR 46.110, the IRB will determine that all of the requirements are satisfied.*

A study may qualify for an Expedited Review if it fits into one of the categories outlined below. Check all that apply:

☐ **Category 1:** Studies involving the recording of information so that participants are identifiable (audio or video recordings) require at least an expedited review.

☐ **Category 2:** Studies using instruments, questionnaires, or surveys that have been generated or modified by the researchers require an informed consent and at least an expedited review.

☐ **Category 3:** Obtaining data from subjects 19 years or older using routine noninvasive procedures.[2]

☐ **Category 4:** Analysis of video or audio recordings.

☐ **Category 5:** Moderate exercise by healthy volunteers.

☐ **Category 6:** Studies involving collection of existing unidentifiable specimens by non-invasive means.

☐ **Category 7:** Studies of individual or group behavior, or characteristics of individuals, without manipulating subjects' behavior and in a manner that does not cause stress to subjects.

NOTE: Even if your initial determination is Expedited Review, complete the checklist for Full Review. If any of those categories apply, your study is not Expedited.

[2] Noninvasive procedures refer to medical procedures that do not involve taking tissue or blood samples.

*A Full-Board Review is indicated under the following conditions:*

A study may qualify for Full-Board Review if it fits into one of the categories outlined below. Check all that apply:

☐ **Category 1:** Surveys or interview questions whose answers, if known outside the research, would create legal liability or adverse financial or employment consequences for the participant.

☐ **Category 2:** Surveys of interviews involving questions dealing with very personal and sensitive behavior, such as sexual behavior, alcohol or drug use, or if subjects may be placed at risk for criminal or civil penalties or would otherwise suffer embarrassment or humiliation if the subjects' responses were to become known outside the research.

☐ **Category 3:** Studies that include members of a protected population in the pool of participants, including but not limited to children under age 19, veterans of military service, persons who are decisionally impaired, fetuses, pregnant women, prisoners, and anyone else who cannot provide informed consent.

☐ **Category 4:** Studies involving deception or if the subjects are not fully informed of the purpose and procedures of the study.

☐ **Category 5:** Studies involving support from non-university sources requiring full IRB approval.

☐ **Category 6:** Likelihood of risk or substantial stress or discomfort to the subject.

☐ **Category 7:** Procedures that may potentially threaten or embarrass subjects.

☐ **Category 8:** Personality tests, inventories or questionnaires of a personal and sensitive nature where subjects' identities will not be anonymous to the researcher.

☐ **Category 9:** Healthcare procedures not conducted for the primary benefit of the subject.

☐ **Category 10:** Diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice.

☐ **Category 11:** Exposure to surgery, drugs, or chemical agents.

☐ **Category 12:** Exposure to electromagnetic radiation (X-rays, microwaves), lasers, high frequency sound waves.

☐ **Category 13**: Collection of blood samples or other body fluids in any amount.

NOTE: Minimal risk as defined by 45CFR 46.102(I) http://www.hhs.gov/ohrp/ 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 or psychological examinations or tests. Studies involving more than minimal risk to participants will not be approved.

| **SECTION III** |
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| Title of Study: |
| Study Site(s) & Address(es) (please include letter(s) of approval for data collection from study site(s) in the Appendices: |
| Co-Investigator's Role at Study Site: |
| Problem Statement, PICO, or PICOT (1-2 focused sentences): |
| Background of and Rationale for the Study: |
| Population and Characteristics: |
| Method of Subject Selection, Inclusion and Exclusion Criteria, and Number Anticipated: |
| Description of Research Design, Methodology, Recruitment Procedure, and Data Collection (enumerated or bulleted): |
| Disposal and Protection of Data Collected: |
| Risk/Benefit Assessment (Describe fully): |
| a. Potential Psychological, Social, Economic, or Legal Risks: |
| b. Risk Classification: |
| c. Protection Against Risks: |

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| Potential Benefits to the Subjects: |
| Potential Benefits to Society: |
| Compensation for Participation: |
| Steps to Protect Confidentiality and Privacy: |
| Information Purposely Withheld: |
| Written or Implied Informed Consent Documentation (Include waivers, consent forms, and cover letters in the Appendices): |
| a. Readability Statistics (e.g., Flesch-Kincaid) of cover letters, fliers, surveys, questionnaires, tests):[3] |
| b. Documentation of Consent: |
| c. Consent: |
| List of Appendices (Include recruitment materials, permission and consent letters and emails, tests, surveys, and data collection tools): |

[3] Regardless of subject pool's educational background, readability of documents should be at or around 8th-grade reading comprehension levels.

**SECTION IV**

CERTIFICATION OF REVIEW

As Principal Investigator, I certify that all sections are completed as directed and in full and agree with the following:

- ☐ Human Subject training certification is attached. Certificates from accepted IRB Human Subjects Training courses include: OHRP, PHRP, or CITI. Please contact IRB@mchs.edu with any questions.
- ☐ The research design conforms to discipline standards.
- ☐ The type of review requested is appropriate.
- ☐ The Application--including the Appendices--is complete, accurate, and coherent.
- ☐ I have thoroughly reviewed this research study, and it has my full support.

As Investigator(s), we assert that this Application is ready for IRB review:

| Printed Name of Principal Investigator | Signature of Principal Investigator | Date |
|---|---|---|
| Printed Name of Co-Investigator | Signature of Co-Investigator | Date |
| Printed Name of Co-Investigator | Signature of Co-Investigator | Date |
| Printed Name of Co-Investigator | Signature of Co-Investigator | Date |
| Printed Name of Co-Investigator | Signature of Co-Investigator | Date |

Submit the Application and Appendices to the IRB at IRB@mchs.edu or mail them to the College.

Mercy College - Institutional Review Board
928 6th Avenue
Des Moines, IA 50309

**SECTION V**

IRB SUBMISSION AND REVIEW CALENDAR

*NOTE: The study must not begin prior to IRB approval.*

The Mercy College IRB meets a minimum of quarterly, and in some cases, monthly (except August).

All applications must be submitted a minimum of 30 days before the next IRB meeting.

Applications that are incomplete, inaccurate, or incoherent will be referred back to the Principal Investigator and may be re-submitted according to the IRB Submission and Review Calendar.

Reference: Clarkson College Institutional Review Board: https://www.clarksoncollege.edu/students/institutional-review-board/ (2019).

Adapted with permission (2019) from Clarkson College's *Institutional Review Board Application*.

Updated 02/15/2021