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**Mercy College**

**Research Application for Exemption**

**PART 1: Name(s) and Contact Information.**

**Protocol Title:** Click or tap here to enter text.

**Principal Investigator:** Click or tap here to enter text.

**Department/Program:** Click or tap here to enter text.

**Phone number:** Click or tap here to enter text.

**Mercy Email address:** Click or tap here to enter text.

**Is this a student project?\*** [ ]  **Yes** [ ]  **No**

**If student PI, please provide the following:**

**Faculty Advisor:** Click or tap here to enter text.

**Department/Program:** Click or tap here to enter text.

**Phone number:** Click or tap here to enter text.

**Mercy Email address:** Click or tap here to enter text.

**PART 2: Education Affirmation.**

**Human Subjects CITI training is complete:** [ ]  **Yes** [ ]  **No *Upload certificate below***

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**PART 3: Collaboration Information.**

**Are there multiple sites involved with this study?** [ ]  **Yes** [ ]  **No**

**If yes, list the site(s) involved:** Click or tap here to enter text.

**PART 4: Funding Information.**

**Funding Source(s):**

* If funded, provide the following:
**Sponsor**: Click or tap here to enter text.
**Project title**: Click or tap here to enter text.
**Grant / Contract #**: Click or tap here to enter text.

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| **PART I. EXEMPT ELIGIBILITY SCREENING** |

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| **Exempt studies must meet the federal definition of Human Subjects Research. Answer the following questions to determine if your proposed study meets the federal definitions of both “Research” and “Human subjects.”** |
|  [ ]  Yes [ ]  No | Is this study a [systematic investigation](https://www.mercy.edu/media/mcirb-research-terms-glossary)? |
|  [ ]  Yes [ ]  No | Is this study *designed* to contribute to [generalizable knowledge](https://www.mercy.edu/media/mcirb-research-terms-glossary)? |
|  [ ]  Yes [ ]  No | Is the information being obtained *about* living individuals? |
|  [ ]  Yes [ ]  No | Will you collect information through some type of intervention or interaction? **OR**Will you have access to [individually identifiable information](https://www.mercy.edu/media/mcirb-research-terms-glossary)? **OR**Will you have access to [private information](https://www.mercy.edu/media/mcirb-research-terms-glossary)? |
|  | **If you answered “no” to any of the above questions, your study does not meet the definition of Human Subjects Research. You are not required to submit an Application for Exemption to the Mercy IRB.** |

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| **Complete the below section to identify study characteristics that DO NOT qualify for exemption.Below are the specific characteristics that disqualify a study for exemption. Answer the following:** |
| [ ]  Yes [ ]  No | (e) Does this research propose to study [prisoners](https://www.mercy.edu/media/mcirb-research-terms-glossary) as a targeted population? |
| **In some circumstances, studies that would otherwise qualify for exemption must undergo expedited or full board review by the IRB. These circumstances are study-specific. Please answer the following questions to determine if your study is ineligible for exemption:** |
| [ ]  Yes [ ]  No | (a) Is there a state, federal or other applicable law (e.g., tribal or international law) that prohibits an exemption determination for this research? [If “yes,” please identify the relevant law when submitting your Expedited / Full Board Application.] |
| [ ]  Yes [ ]  No | (b) Does the agency funding your research, or an agency with whom you are working, prohibit an exemption determination and require that you have IRB approval? [If “yes,” please provide written documentation of this prohibition when submitting your Expedited / Full Board Application.] |
| [ ]  Yes [ ]  No | (c) Are there any other study-specific requirements of which you have been informed that prohibit an exemption determination? [If “yes,” please provide written documentation of this requirement when submitting your Expedited / Full Board Application.] |
|  | **If you answered “YES” to any of the above eligibility screening questions, your study does not qualify for an Exempt review. Please complete the** [**Application for Expedited / Full Board Review**](https://www.mercy.edu/media/mcirb-application-expedited-and-full-board-review)**. Otherwise, proceed to** [**PART II**](#PartII)**.** |

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| **PART II. EXEMPTION CATEGORIES & WORKSHEETS** |

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| **1. Below are the Exemption Categories. Select one or more of the categories that are applicable to your proposed research. Fill out the Exempt Category Worksheet(s) that correspond with your selection(s) and submit the applicable Worksheet(s) as part of your Application for Exemption.** |
| [ ]  [Exemption 1](#Exempt1) | Research conducted in an established or commonly accepted educational setting that specifically involves normal educational practices. [Complete Exempt Cat. 1 Worksheet](#Exempt1) |
| [ ]  [Exemption 2](#Exempt2) | Research that ONLY includes interactions involving:1. Educational tests (cognitive, diagnostic, aptitude, achievement); OR
2. Survey procedures; OR
3. Interview procedures; OR
4. Observation of public behavior; OR
5. Focus Groups

[Complete Exempt Cat. 2 Worksheet](#Exempt2) |
| [ ]  [Exemption 3](#Exempt3) | Research involving ONLY benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording. [Complete Exempt Cat. 3 Worksheet](#Exempt3). |
| [ ]  [Exemption 4](#Exempt4) | Secondary research using [identifiable private information](https://www.mercy.edu/media/mcirb-research-terms-glossary) or identifiable biospecimens, collected for a purpose other than this study. [Complete Exempt Cat. 4 Worksheet](#Exempt4). |
| [ ]  [Exemption 5](#Exempt5) | Research and demonstration projects conducted or supported by a Federal department or agency that is designed to study, evaluate, improve, or otherwise examine public benefit or service programs. [Complete Exempt Cat. 5 Worksheet](#Exempt5). |
| [ ]  Exemption 6 | Taste and food quality evaluation and consumer acceptance studies. **Mercy College does not typically review these types of studies. Please contact the** **Mercy’s IRB** **to discuss *before completing this application*.** |
| [ ]  Exemption 7 | Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use for which [broad consent](https://www.mercy.edu/media/mcirb-research-terms-glossary) is required.**Mercy’s IRB does not plan to implement this Exemption at this time. Limited exceptions may be considered. Please contact the** **Mercy’s IRB****.** |
| [ ]  Exemption 8 | Secondary research involving the use of identifiable private information or identifiable biospecimens for potential secondary research use for which [broad consent](https://www.mercy.edu/media/mcirb-research-terms-glossary) is required.**Mercy’s IRB does not plan to implement this Exemption at this time. Limited exceptions may be considered. Please contact the** **Mercy’s IRB****.** |
|  | **If you were unable to identify an applicable exemption category and/or the Worksheet(s) result in a determination that the study does not quality for exemption, please complete the** [**Application for Expedited / Full Board IRB Review**](https://www.mercy.edu/media/mcirb-application-expedited-and-full-board-review)**.** |

**Exempt Category 1 Worksheet**

*Research Conducted in Established or Commonly Accepted Educational Settings*

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| **1. Is the research being conducted in an** [**established or commonly accepted educational setting**](#educationalsetting)**?** |
| [ ]  Yes | Describe the [educational setting](#educationalsetting): Click or tap here to enter text. |
| [ ]  No | This research does not quality for exemption under this category. |
| **2. Does this research involve** [**normal educational practices**](#normaledupractices)**?** |
| [ ]  Yes | Describe the [educational practices](#normaledupractices): Click or tap here to enter text. |
| [ ]  No | This research does not quality for exemption under this category. |
| **3. Is the research on these educational practices NOT likely to** [**adversely impact students’ opportunity to learn**](#advimpactstudents) **required educational content?** |
| [ ]  Yes | Please explain: Click or tap here to enter text. |
| [ ]  No | This research does not quality for exemption under this category. |
| **4. Is the research on these educational practices NOT likely to** [**adversely impact the assessment of educators**](#advimpactedu) **who provide instruction?** |
| [ ]  Yes | Please explain: Click or tap here to enter text. |
| [ ]  No | This research does not quality for exemption under this category. |
| **If you answered “yes” to all of the above questions, please provide the requested descriptions/explanations. These will become part of your Exemption Application. Proceed to** [**PART III**](#PartIII)**. If you answered “no” to any of the questions above, the research is not exempt under this category.** |

**Educational setting**: The consistent interpretation of this term is that commonly accepted educational settings can be almost anywhere, as long as the setting is one where specific educational offerings normally take place or a setting where one would go in order to have an educational experience. Examples include: K-12 schools and college classrooms, after-school programs, preschools, vocational schools, an alternative education programs; professional development seminar for school district personnel; soccer practice field; Boy/Girl Scouts meeting; Medical school; Religious education settings; Training simulators (e.g., medical simulators, flight simulators, etc.).

**Normal educational practices**: Normal educational practices are those activities that are routinely used in similar educational settings and/or are considered proven educational practices with the population under study.

**Adversely impact students’ opportunity to learn**: Consider whether the proposed activity requires students to deviate from a curriculum that is aligned with any national or state-level indicators of student achievement (e.g., state end of grade testing) or if the activity will take instructional time away from students.

**Adversely impact assessment of educators**: Will participation, or the refusal to participate, in the research be a factor in the assessment of educators? Will the outcomes of the research be a factor in the assessment of participating instructors?

**Exempt Category 2 Worksheet**

*Educational Tests, Surveys, Interviews, Observations of Public Behavior*

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| **1. Is the research limited to interactions involving the following:*** **Educational tests (cognitive, diagnostic, aptitude, achievement); OR**
* **Survey procedures; OR**
* **Interview procedures; OR**
* **Observation of public behavior (including visual or auditory recording); OR**
* **Focus Groups**
 |
| [ ]  Yes | Please describe: Click or tap here to enter text. |
| [ ]  No | This research does not quality for exemption under this category. |
| **2. If the research involves children as participants, are the research activities limited to educational tests (defined above) or** [**observation of public behavior**](#observepub) **where the investigator(s) will NOT participate in the activities being observed?** |
| [ ]  Yes | Please describe: Click or tap here to enter text. |
| [ ]  No | This research does not quality for exemption under this category. |
| [ ]  N/A | Children are not involved as participants in this study. |
| **3. Select the following conditions that apply to this research:** |
|  [ ]   | A. The information obtained is recorded in such a manner that the identity of the participants cannot readily be ascertained either directly or through identifiers linked to the participants.  |
|  [ ]   | B. Any disclosure of participants’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, [educational advancement](#eduadvancement), or reputation. |
|  [ ]   | C. Information obtained is recorded in such a manner that the identity of the participants **can be** readily ascertained, directly or through identifiers linked to the subjects, but adequate provisions have been made to ensure that the data collected are appropriate monitored and secured to ensure confidentiality. |
|   | Describe provisions to **protect the privacy of participants**:Click or tap here to enter text. |
|  | Describe provisions to **maintain confidentiality of participant data**:Click or tap here to enter text. |
| **If you answered “yes” to questions 1 & 2 (or N/A to question 2) and were able to select an applicable condition(s) in Section 3, please provide the requested descriptions/explanations. These will become part of your Exemption Application. Proceed to** [**PART III**](#PartIII)**.****If you checked 3C. (including if you are collecting audio/visual recordings) your application must also undergo a Data Security Assessment (“Limited IRB Review”). Please complete** [**PART VI**](#PartVI)**.****If you answered “no” to any of the questions above, the research is not exempt under this category.** |

**Q: When is observation of public behavior without intervention or interaction human subjects research?**

Observation of public behavior without intervention or interaction can be human subjects research when it satisfies the definitions of human subject and research. Within the framework of this exemption, it is possible that an investigator may be observing individuals in a setting where, while public, there is an expectation of privacy (e.g., classrooms, online group, or other venues where you would need permission to be there).  It is also possible under this exemption for an investigator to engage in public observation through which the investigator could capture information that would allow for the identification of observed individuals. In such circumstances, the IRB must conduct Limited IRB Review.

**Q: How should one interpret “educational advancement” as something that potentially could be damaged?**

Examples would be information learned in the study that would disqualify an individual from advancement.  For example, in a survey that collects data about academic integrity where respondents indicate whether they have engaged in misconduct (e.g., cheating on exams, plagiarism, etc.), the disclosure of the subjects’ responses outside the research could be damaging to the subjects’ educational advancement.

**Exempt Category 3 Worksheet**

*Benign Behavioral Intervention*

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| **1. Does the proposed research involve ONLY the participation of adults with adequate decision-making ability to agree to participate in the research?** |
| [ ]  Yes | Please continue to question 2.  |
| [ ]  No | This research does not qualify for exemption under this category. |
| **2. Does this research involve the use of** [**benign behavioral interventions**](#benign)**?** |
| [ ]  Yes [ ]  No | If “no,” this research does not qualify for this exemption. |
| **3. Is the intervention brief in duration?** |
| [ ]  Yes [ ]  No | If “no,” does not qualify for this exemption.If “yes,” please explain: Click or tap here to enter text. |
| **4. Is/are the intervention(s) harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on participants, and neither offensive nor embarrassing?** |
| [ ]  Yes [ ]  No | If “no,” does not qualify for this exemption.If “yes,” please explain: Click or tap here to enter text. |
| **5. Does the benign behavioral intervention include** [**collection of information**](#collectionofinfo) **only through verbal or written responses (including data entry) or audiovisual recording?** |
| [ ]  Yes | Please continue. |
| [ ]  No | This research does not qualify for exemption under this category. |
| **6. Will participants *prospectively* agree to the intervention and information collection?** |
| [ ]  Yes | Please explain:Click or tap here to enter text. |
| [ ]  No | This research does not qualify for exemption under this category. |
| **7. Select the following conditions that apply to this research:** |
|  [ ]   | A. The information obtained is recorded in such a manner that the identity of the participants cannot readily be ascertained either directly or through identifiers linked to the participants.  |
|  [ ]   | B. Any disclosure of participants’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation. |
|  [ ]   | C. Information obtained is recorded in such a manner that the identity of the participants **can readily be** ascertained, directly or through identifiers linked to the subjects, but adequate provisions have been made to ensure that the data collected are appropriate monitored and secured to ensure confidentiality. Audio and visual recordings are considered identifiable. |
|   | Describe provisions to **protect the privacy of participants**:Click or tap here to enter text. |
|  | Describe provisions to **maintain confidentiality of participant data**:Click or tap here to enter text. |
| **8. Does this research involve deception or misleading participants about the nature or purpose of the research?** |
|  [ ]  Yes [ ]  N/A | Please explain, including when/how participants will be informed of the deception.*Note that to qualify for this exemption, there* ***must be*** *prospective agreement by the participant in which the participant is informed that he/she/they will be unaware of or misled regarding the nature or purpose of the research*. *Describe the process for documenting that participants have been informed.*Click or tap here to enter text. |
| **If you answered “yes” to all the above questions and were able to select an applicable condition(s) in Section 7, please provide the requested descriptions/explanations. These will become part of your Exemption Application. Proceed to** [**PART III**](#PartIII)**.****If you answered “no” to any of the questions above, the research is not exempt under this category.** |

**Benign behavioral interventions**: Interventions that are harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on participants and are neither offensive nor embarrassing (considering the participant population and research context). Ordinary, mild, transient forms of discomfort, such as the stress associated with completing a timed cognitive task, anxiety about performance, and boredom, are consistent with the intent of this exemption. Medical interventions, including medical tests, procedures and devices, may not be used under this exemption.

**Accepted methods of data collection**: Only certain data collection methods can be used under this exemption category. Even very low risk physical procedures (e.g., blood pressure monitoring, EEG, wearable activity trackers), minimally invasive procedures (e.g., blood draws), and the collection of bodily fluids via introduction of a tool or sensor into the body (e.g., buccal swab), are not allowed. Data entry via a device (e.g., a Fitbit) would not meet the requirements of this exemption.

**Exempt Category 4 Worksheet**

*Secondary Research Use*

*(Identifiable Private Information/Biospecimens)*

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| **1. Does the proposed research involve** [**secondary research use**](#secondaryuse) **of identifiable private information or identifiable biospecimens?** |
| [ ]  Yes | Please continue to question 2. |
| [ ]  No | This research does not qualify for exemption under this category. |
| **2. Select any of the following provisions applicable to this research:** |
|  [ ]   | **A.** The identifiable private information or identifiable biospecimens are [publicly available](#publiclyavailable). Please explain where this information is publicly available: Click or tap here to enter text. |
|  [ ]   | **B.** The information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained directly or through identifiers linked to the subjects; **the investigator does not contact the subjects; the investigator will not re-identify subjects.**Please explain how the data are recorded: Click or tap here to enter text. |
|  [ ]   | **C.** The research involves **only** information collection and analysis involving the investigator’s use of identifiable health information, when that use is regulated under HIPAA for the purposes of ‘‘health care operations’’ or ‘‘research’’ as those terms are defined at [45 CFR 164.501](https://www.govinfo.gov/content/pkg/CFR-2011-title45-vol1/pdf/CFR-2011-title45-vol1-sec164-501.pdf), or for ‘‘public health activities and purposes’’ as described under [45 CFR 164.512(b)](https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-public-health-activities/index.html). Note that HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information *obtained from* biospecimens).***\*\*Provision C cannot be selected in combination with any other provision (A, B or D)\*\**** |
|  [ ]   | **D.** The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. |
|  [ ]   | None of the above categories applies. |
| **If you answered “yes” and were able to select an applicable condition in Section 2, please provide the requested descriptions/ explanations. These will become part of your Exemption Application. Proceed to** [**PART III**](#PartIII)**. If you checked 2B. or 2C. you must also complete a USE OF SECONDARY DATA (**[**PART V**](#PartV)**)****If you selected “None of the above…” the research is not exempt under this category.**  |

**Secondary research use**: Private information and biospecimens no longer have to be in existence prior to the start of the research. Under the revised Common Rule, for example, a research study that proposes to analyze samples or information that will be collected for clinical purposes in the future, could qualify for this exemption if it meets at least one of the applicability provisions in Section 2.

**Publicly available**: Refers to data and/or specimens that are accessible to anyone in the general public, without the need for special permissions, payment or privileges.  In these cases, the participants do not have a reasonable expectation of privacy of their data/specimens. Examples include data/specimens searchable online, available at a library, or otherwise available to the public when an agreement is entered into with the data provider.

**Exempt Category 5 Worksheet**

*Research and Demonstration Projects on Public Benefit or Service Programs*

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| **1. Is the research or demonstration project conducted or supported by a federal department or agency designed to study, evaluate, improve, or otherwise examine public benefit or service programs?** |
| [ ]  Yes | Please continue to question 2. |
| [ ]  No | This research does not quality for exemption under this category. |
| **2. Does the federal department or agency conducting or supporting the research have a publicly accessible website or other manner for publishing a list of the research and demonstration projects that are conducted or supported under this provision?** |
| [ ]  Yes | Your research may be exempt under this category. To be exempt, the research or demonstration project must be published on this list prior to commencing research with human subjects.Identify the federal department/agency and where the research/demonstration project is published: Click or tap here to enter text. |
| [ ]  No | This research is not exempt under this category. |
| **If you answered “yes” to both questions, please provide the requested information in Section 2. This will become part of your Exemption Application. Proceed to** [**PART III**](#PartIII)**.** |

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| **PART III. RESEARCH DESIGN & METHODS** |

**THE BLUE TEXT IN THE FOLLOWING SECTIONS IS A GUIDE TO ENSURE ALL RELEVANT INFORMATION IS INCLUDED IN YOUR APPLICATION. YOU MAY DELETE THE BLUE TEXT BEFORE SUBMISSION**

1. **Introduction and Background.** *In reviewing the protocol, the IRB must consider the rationale for the study and the importance of the knowledge that may reasonably be expected to result.*
* Briefly summarize the nature, scientific or scholarly rationale and significance of the proposed study and any relevant background information on the topic in lay language.
	+ Explain the relevance of the study to previous and/or continuing work in the field.
	+ Discuss why novel inquiry is necessary.
		- If there is a gap in knowledge, explain how it is anticipated that this research will address the gap.
		- If this research is intended to replicate previous research, provide rationale.
1. **Specific Aims and Study Objectives.** *The IRB must evaluate the objectives of the research to determine whether the risks to participants are reasonable in relation to the importance of the knowledge that may be gained.*
* Clearly outline the specific research question(s).
	+ Include the study objective(s) and/or hypothesis.

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|  | **If your study ONLY involves the use of identifiable secondary data / biospecimens, including coded data from which you may be able to ascertain participant identity, skip to** [**PART V**](#PartV)**. Otherwise, please continue.** |

1. **Materials, Methods and Analysis.** *The study design, methods and procedures must be adequately described for the IRB to understand all activities in which human subjects will participate. The IRB must also be able to differentiate those procedures that are performed for research purposes from those that are performed for routine care or evaluation.*
* Clearly describe the methods and procedures being used
	+ List assessments and instruments
	+ Provide rationale for inclusion of measures
	+ Detail the analysis process
	+ NOTE: The focus of this section is on methods and procedures. Risks will be described later.
1. **Participant Population.** *To approve research, the IRB must determine that the selection of participants is equitable and reasonably related to the purpose and aims of the research. The IRB must also consider whether adequate safeguards are in place to minimize any risks that are unique to vulnerable populations. To make this determination, the IRB must review all methods and materials used to contact and recruit potential participants, including letters, flyers, emails, etc.*
* Describe the participant population:
	+ Provide the rationale for including the participant population. When including any vulnerable populations in the study, explain why inclusion of this population is necessary to accomplish the research aims.
	+ List the inclusion criteria such as age range, race or ethnicity, gender, language and literacy, etc.
	+ List the exclusion criteria and rationale.
	+ Address whether participants must be fluent in English and/or if any of the study activities (i.e., recruitment, consent, assessments, etc.) will be carried out in a language other than English.
* Discuss the number of participants needed for the research including the following:
	+ Provide the targeted number of individuals to be included in the research.
		- * If more than one group, provide numbers needed for each group and total number for the entire study. This number should account for any attrition from participants who may withdraw from the study without completing the procedures.
	+ Provide rationale for targeted numbers.
1. **Recruitment Methods**
* Describe the process and/or method by which participants will be identified, approached, and recruited for the research, including the following:
	+ When and how will each step of recruitment occur (i.e., initial contact, introductions, follow-ups, etc.)?
	+ Describe how the participant population is accessed. Discuss relevant permissions needed to reach the population (e.g., access to listservs, online databases, etc.).
	+ List any recruitment materials that will be used, such as advertisements, flyers, or verbal scripts. If no written recruitment materials will be used, explain.
	+ Explain which research roles (e.g., PI, Research Assistant, etc.) will recruit participants and how they will be trained.
	+ Describe any screening tests and/or procedures that will be used to ensure that potential participants are eligible to participate.
		- State if this information will be destroyed once eligibility is determined.
		- If you intend to keep this information for research purposes, ensure that a screening consent process is described in Part V.
	+ If any part of the recruitment procedures involves a language other than English describe any differences in the recruitment procedures for non-English speaking participants.
		- Describe how the research team member(s) are fluent in the language of the participants or if a translator will be used.
		- Describe how materials will be presented in the language understandable to participants (e.g., will translated materials be used?). If the participant’s language is only verbal and not written, state this and explain translation.
* For research involving a benign behavioral intervention (Exempt Category #3):
	+ Describe how the intervention will be distinguished from typical activities.
	+ Indicate if any deception will be involved in this intervention, and if so, how any risks will be mitigated.
1. **Compensation / Reimbursement**
* If participants are to receive compensation for their time, please describe the following or simply state “no compensation will be offered”:
	+ The amount and nature of the compensation (e.g., cash, gift card, course credit, etc.).
	+ Explain how and when compensation will be provided, including payment schedules, whether compensation will be reduced if the participant does not complete all activities in the study, and how any proration will occur.
	+ Explain how the method and amount of compensation is appropriate for the participant population and study activities (e.g., based on time commitment, number of study visits, travel expenses, age of participant population, etc.).
	+ Explain if participants will receive any reimbursement for travel costs or childcare. Describe the amount and nature of the reimbursement, and when it will be provided.
1. **Potential Research Risks / Discomforts to Participants.** To approve the research, the IRB must consider the risks posed to participants by the research and any efforts to mitigate those risks. The IRB needs to determine that the risks have been both minimized and are reasonable in relation to the anticipated benefits to participants, as well as to the importance of the knowledge that may be gained. The IRB will also consider whether the informed consent process provides potential participants with an accurate and fair description of the risks or discomforts.
* Describe any reasonably foreseeable risks of harm or discomforts for individuals and / or groups that may result from participation in the research. While risks associated with participation may be minimal, all research carries some risk. Consider the following:
	+ Information risks (e.g., loss of privacy and / or breach of confidentiality).
	+ Psychological or emotional risks (e.g., fear, stress, confusion, guilt, loss of self-esteem, depression, triggering of past emotional experiences).
	+ Social risks (e.g., social stigma, chance of being ostracized or shunned), economic risks (e.g., change in employment or insurability).
	+ Physical risks or harms (e.g., fatigue, pain or discomfort, potential for injury, illness or disease, or death, side effects and contraindications of drugs or substances used in the research).
	+ Legal risks (e.g., risk of prosecution, mandatory reporting).
		- Genetic privacy risk (e.g., stigmatization, self-stigmatization, limits to insurance coverage or employability, misattributed paternity, etc.).
	+ For each identified risk, explain all the following:
		- Likelihood of the risk occurring.
		- Magnitude of the effects the risk would have should they occur.
		- How the risk will be minimized.
	+ When appropriate, describe any provisions for data and safety monitoring for the progress of the research and the safety of the participants.
		- If there is a separate Data and Safety Monitoring Plan (DSMP), state this and attach.
		- If there is an established Data and Safety Monitoring Board / Committee (DSMB/C) to monitor the progress of the research and the safety of participants, clearly indicate this. The frequency and operations of the DSMB/C should be covered in the DSMP.
1. **Potential Benefits of the Research.** **NOTE: Compensation for participation is not a benefit and should not be included in this section.** *To approve this research, the IRB must determine that the potential benefits to research participants are reasonable in relation to the potential risks. Very often, research at Mercy College does not include potential direct benefits to participants but may only benefit society as a whole by helping researchers.*
* Describe any potential benefits that may result from the research. Consider the following:
	+ Direct benefits that may result from participation (e.g., weight loss, supporting their own community, etc.). If there are no direct benefits to participants, clearly state this.
	+ Benefits to the general participant population.

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| **PART IV. INFORMED CONSENT** |

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| Informed consent is a *process*, not just a form. The IRB must ensure the informed consent process clearly discloses and facilitates the understanding of all information needed to make an informed decision to participate while promoting the voluntariness of participation.Please use the Mercy College consent / assent templates and related guidance on the IRB Forms & Templates page to develop your consent forms. |

1. **Describe the informed consent process, including:**

* How the required elements of informed consent will be conveyed to participants (i.e., informed consent document, verbal script, online consent, etc.). *In certain circumstances, the IRB may approve a consent process which does not include, or which alters, some or all the elements of informed consent or waive the requirements to obtain informed consent.*
* Where and when the informed consent process will take place (i.e., in-person in a private room, by phone, online etc.).
* Any cultural considerations (e.g., tribal or group permission requirements, age of majority, technological limitations, etc.).
* Steps that will be taken to ensure voluntary participation and to minimize the possibility of coercion or undue influence.
* Which research roles (e.g., PI, Research Assistant, etc.) will conduct the consent process and how that person will be trained (e.g., previous experience or related training, one-on-one training with PI, etc.).
* If multiple participant groups or consent procedures are to be included, these need to be clearly delineated (e.g., consent process for eligibility screening, consent process for in-person main study, etc.).

 2. **Facilitate Understanding**

* Describe how you will ensure that the participants understand all aspects of their involvement in the research (i.e., will participants be asked questions about the procedures, or encouraged to ask questions?)
* Describe any special provisions for individuals who might have trouble comprehending the consent information.
* If any participants do not speak English, describe:
	+ Whether or not the researcher is fluent in the language.
	+ Whether or not and how a translator will be used.
	+ Whether or not translated consent materials will be used.
	+ Whether or not there are any differences in the consent process for different populations based on the language they speak.
* Describe the process by which you will ensure ongoing consent.

3. **Documentation**

* Describe how the researcher plans to document that each participant has provided informed consent and / or assent.

4. **Additional Considerations**

     If the research involves:

* To request a waiver of documentation of consent, so that participants are not asked to sign a consent document:
	+ Detail how the consent document will be the only record linking the participant to the research, explain how the principal risk of the research will be a potential harm from a breach of confidentiality, and confirm that each participant will be asked if they would like documentation linking them to the research. Their wishes will govern their consent process; OR
	+ Detail how the research involves no more than minimal to the participants and involves no procedures for which written consent is normally required outside of the research context; OR
	+ If the participants are members of a distinct cultural group or community in which signing forms is not the norm, detail how the research involves no more than minimal risk to the participants and describe the appropriate alternative mechanisms for documenting that informed consent will be obtained.
* To request a waiver or alteration of consent, so that participants are not asked to go through a full consent process:
	+ Detail how the research involves no more than minimal risk to the participants; AND
	+ Explain how the waiver will not adversely affect the rights and welfare of the participants; AND
	+ Describe how the research could not practicably be carried out without the waiver; AND
	+ If the research involves using identifiable private information or identifiable biospecimens, explain how the research could not practicably be carried out without using such information or biospecimens in an identifiable format; AND
	+ Whenever appropriate, confirm that the participants will be provided with additional pertinent information after participation.
* Minors (those under the age of majority) or individuals of diminished capacity:
	+ Describe the capacity of the participant and their ability to assent.
	+ Describe how assent to participate will be obtained and documented.
		- If a waiver of assent or waiver of assent documentation is being requested, provide justification.
	+ Explain how the permission of the parent(s) or guardian(s) will be obtained and documented.
		- If a waiver of permission or waiver of permission documentation is being requested, provide justification.
* Deception:
	+ Explain how participants will be deceived and why it is necessary for the study.
	+ Deception is an alteration of informed consent; provide justification for how the use of deception meets the criteria for alteration of informed consent.
	+ Describe the debriefing process and provide a script.

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| **PART V. USE OF SECONDARY DATA**  |

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| **For research that involves the use of identifiable secondary data, including coded data from which you may be able to ascertain participant identity.** **If your research does not involve identifiable secondary data, proceed to** [**PART VI. DATA SECURITY ASSESSMENT**](#PartVI) |

1. From what source(s) will you acquire or access the data / biospecimens?

Click or tap here to enter text.

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2. Describe the type(s) of data and date range(s) of the data you will use and the characteristics of the study research population (e.g., age range, sex, and any other pertinent demographic information.)

3. HIPAA and Protected Health Information (PHI). Complete [Appendix D. Use of Protected Health Information for Research](https://www.mercy.edu/media/mcirb-appendix-d-use-phi-research) and include with this application. Describe how authorization from participants to access and use their information is obtained.

Click or tap here to enter text.

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| **PART VI. DATA SECURITY ASSESSMENT (“LIMITED IRB REVIEW”)** |

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| **1. Do the study data include identifiers? Video and audio recordings are considered identifiable.** |
| [ ]  No | Proceed to Question [#3](#PartVI3). |
| [ ]  Yes  | If “yes,” answer the following questions.A. Describe the identifiers associated with the data. Click or tap here to enter text.B. Justify why identifiers are required to conduct the research.Click or tap here to enter text.C. Described the proposed research use of the identifiable data.Click or tap here to enter text.D. Self-classify the Risk Level of these data.Click or tap here to enter text. |
| **2. How will study data be collected?** |
|  [ ]  Mercy College desktop/Laptop [ ]  Personal computer/tablet [ ]  [Departmental server](#PartVI3) [ ]  [College managed server](#PartVI3) [ ]  [REDCap](#PartVI3); Please describe what instance of REDCap is being used: Click or tap here to enter text. [ ]  [Ohmage](http://ohmage.org/index.html): an online open-source data college platform. [ ]  [Amazon Mechanical Turk](https://www.mturk.com/) (MTurk) [ ]  Text messaging 🡪 You must complete the [Text messaging](#textmessaging) section. [ ]  Mobile App (on tablet, iPad, Phone) 🡪 You must complete the [Mobile App](#mobileapp) section. [ ]  [Zoom](https://www.mercy.edu/media/guidelines-and-best-practices-virtual-platforms-classroom) or other video conference platform [ ]  Digital records (audio / videoconferencing tools, digital photographs); please describe the tool: Click or tap here to enter text. [ ]  Paper records (including physical photographs). Please describe, including how you will securely store the paper records: Click or tap here to enter text.  [ ]  Web-based site / survey / other tool not listed above 🡪 You must complete the [Web-based Other](#Webbasedother) section. [ ]  Other; please describe: Click or tap here to enter text. |
| **3. Who will have access to the study data?** |
|  [ ]  A. Mercy College PI only. How will unauthorized access by others be prevented?Click or tap here to enter text. [ ]  B. Mercy College PI and other Mercy College research team members. How will unauthorized access by others be prevented?Click or tap here to enter text. [ ]  C. Data will be shared with research collaborators external to Mercy College. This data sharing intent **must** be described as part of your consent process / form. Please describe how you will securely share / transfer the data outside of Mercy College and contact the Mercy College IRB: Click or tap here to enter text. |
| **4. Where will the study data be stored?** |
|  Click or tap here to enter text. |
| **5. If traveling with your data, describe how your data will be secured.** |
| Click or tap here to enter text. |
| **6. For how long will you retain identifiable data? How will you destroy identifiers when no longer required?** |
| Click or tap here to enter text. |
| **7. Text Messaging (only complete if instructed above.)** |
| A. Are you using the current text messaging service available on the device? |
| [ ]  Yes [ ]  No | If “no,” you must also complete the [Mobile App](#mobileapp) section. |
| B. Whose device will be used? [ ]  Participant’s personal phone [ ]  Mercy College-issued phone [ ]  Researcher’s personal phone |
| C. Content of messaging: (If brief, insert here; otherwise, please provide as an attachment) Click or tap here to enter text. |
| D. Is the communication one-way or two-way? [ ]  One-way [ ]  Two-way |
| **8. Mobile App (only complete if instructed above.)** |
| A. Name of the mobile app: Click or tap here to enter text. |
| B. Provide information on the security and encryption of dataClick or tap here to enter text.  |
| C. Whose device will be used? [ ]  Participant’s personal phone [ ]  Mercy College-issued phone [ ]  Researcher’s personal phoneIf Participant’s personal phone:a. How is the app downloaded to the device? Click or tap here to enter text.b. Is a password or PIN required for the app? [ ]  Yes [ ]  No |
| D. Will data be stored on the device for any period of time? |
| [ ]  Yes [ ]  No | a. If “yes,” please describe (i.e., queue on phone and then transmitted to server): Click or tap here to enter text.b. Is the app data encrypted on the device? [ ]  Yes [ ]  No |
| E. Device features mobile app can access [ ]  N/A [ ]  Device ID and call information [ ]  Identity [ ]  Contacts  [ ]  Camera [ ]  SMS or chat [ ]  Storage [ ]  Device and application history [ ]  Phone [ ]  Photo / media / files [ ]  Microphone [ ]  Location [ ]  Other; please describe: Click or tap here to enter text. |
| F. Will a third-party have access to research data through this app? [ ]  Yes [ ]  No |
| G. Is data transmitted by the device?  |
| [ ]  Yes [ ]  No | If “yes,” how is it encrypted in transit? Click or tap here to enter text. |
| H. Are phone numbers or mobile identification numbers stored with the data? [ ]  Yes [ ]  No |
| **9. Web-based Other (only complete if instructed above.)** |
| A. Name of the site / tool: Click or tap here to enter text. |
| B. Provide information on the security and encryption of dataClick or tap here to enter text.  |
| C. Is informed consent being obtained via this site / tool?  |
| [ ]  Yes [ ]  No | If “yes,” how is re-identification prevented? Click or tap here to enter text. |
| D. Does the technology allow for the explicit exclusion of the collection of IP address of the participant’s connection?  |
| [ ]  Yes [ ]  No | If “yes,” will you use this option to exclude the collection of IP address?[ ]  Yes [ ]  No |

**REDCap**: Mercy College has its own [REDCap access](https://www.mercy.edu/academics/academic-centers-libraries/redcap).

**Data collection**: The expectation is that data collection *devices* will only store data during active data collection. Data must then be transitioned to more secure long-term storage solutions.

**Departmental/College managed servers**: If data are collected/entered directly onto a Departmental or College managed server, **you must ensure** that the server meets the security standards described in the [College Computing Policies](https://www.mercy.edu/information-technology/it-policy).

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| **PART VII. APPENDICES**  |

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| **Please complete & attach the following Appendices to this Application, as applicable.** **Incl. N/A**  |
|[ ] [ ]  [Appendix A. Children as Subjects](https://www.mercy.edu/media/mcirb-appendix-children-subjects)*To be attached when minors are included as participants [please be aware of the age of majority for your specific research site(s)]* |
|[ ] [ ]  [Appendix C. Mental Health Safety Plan](https://www.mercy.edu/media/mcirb-appendix-c-mental-health-safety-plan)*To be attached when participants may experience significant emotional distress or be at risk of themselves or others.* |
|[ ] [ ]  [Appendix D. Use of Protected Health Information (PHI) for Research](https://www.mercy.edu/media/mcirb-appendix-d-use-phi-research)*To be attached when study procedures include a plan to access, use or disclose Protected Health Information (PHI) of participants.*  |
|[ ] [ ]  [Appendix E. International Research](https://www.mercy.edu/media/mcirb-appendix-e-international-research) *To be attached when study involves human subjects research outside the United States.*  |

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| **PART VIII. ATTACHMENTS** |

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| **Please attach the following materials to this Application for Exemption, as applicable.****Incl. N/A**  |
| [ ]  | [ ]  | Additional Investigator CITI Training  |
| [ ]  | [ ]  | Data collection materials (questionnaires, surveys, interview scripts, etc.) |
|[ ] [ ]  HIPAA Authorization |
|[ ] [ ]  Informed consent documents / scripts:  |
|[ ] [ ]  Permissions, approval documents, and/or support letters |
|[ ] [ ]  Recruitment materials (emails, flyers, letters, scripts, posters, brochures, etc.) |
| [ ]  | [ ]  | Request for Approval to Serve as Principal Investigator on a Human Subjects Research Application |
|[ ] [ ]  Other: Click or tap here to enter text. |

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| **PART IX. PRINCIPAL INVESTIGATOR AGREEMENTS & RESPONSIBILITIES**  |

 **A. Conduct of the Research**

1. I accept responsibility for the ethical conduct of this research and protection of participants as set forth in the [Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html), [Common Rule](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML), and Mercy College policies.
2. I accept responsibility for ensuring this research is conducted in accordance with:
3. Sound research design and methods;
4. The parameters of the research plan and activities described in this Application;
5. The applicable terms of the grant, contract, or other signed funding agreements;
6. Applicable laws and regulations, including those protecting the rights, safety and welfare of human subjects.
7. I certify that I am sufficiently qualified by education, training and experience to assume responsibility for the proper conduct of this research. I accept responsibility for ensuring that all members of the research team have or will complete human subjects [CITI training](https://www.mercy.edu/media/2020-citi-program-training-guide) before any work with participants or identifiable data / biospecimens begins.
8. I accept responsibility to personally conduct this research. I certify that I have sufficient time and resources to properly conduct this research.

**B. Ensuring and Maintaining Compliance**

1. I will comply with relevant regulatory and institutional reporting requirements, including Mercy College’s [*Reportable Events Policy*](https://www.mercy.edu/media/mcirb-reportable-events-policy).
2. I understand that it is my responsibility to ensure that any research personnel, including myself, responsible for the design, conduct or reporting of the research declares any conflicts of interest related to this research.
3. I will ensure that informed consent is obtained and a copy is provided to participants, when appropriate.
4. If there are changes to the research described in this Application for Exemption that may impact the study’s classification as exempt research, I will promptly notify the Mercy College’s IRB of such changes.
5. I will notify the Mercy College IRB when I have completed all activities involving human subjects or identifiable participant data.
6. I will maintain approval, as applicable, with collaborative parties, including approvals from other countries or jurisdictions.
7. I will cooperate with any post-approval monitoring or auditing of study activities and/or study records as requested and/or required by the Mercy College’s IRB, funding entities, sponsors, and/or any federal or state regulatory agencies.

**C. Study records, Reports and Documentation**

1. I will maintain all research protocol materials and consent materials for the duration of this study.
2. I will maintain research records for at least three years following the end of this research, or for a longer length of time if specified in applicable regulations or sponsor requirements. I will take measures to prevent accidental or premature destruction of these records.
3. I will ensure that the data security measures for acquisition, collection, transfer and use of study data described in PART VI. of this Application are adhered to by all members of the research team.

**By my signature below, I certify that I have read and agree to uphold all the Agreements and Responsibilities in PART IX.**

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



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***For IRB Use Only***

**Signature of the IRB:**

**Date of IRB determination / Limited IRB Review approval:** Click here to enter a date.