|  |
| --- |
| **Human Subjects Research Determination** Institutional Review Board (IRB) - Human Subjects  |
| SECTION A: General Information |
| Activity Title | Click or tap here to enter text. |
| Principal Investigator (PI): | Click or tap here to enter text. |
| Classification: | Choose an item. |
| Department: | Click or tap here to enter text. |
| UCM 700-Number: | Click or tap here to enter text. |
| University Email: | Click or tap here to enter text. |
| Phone Number: | Click or tap here to enter text. |
| CITI Training Completed: | [ ]  Yes [ ] No |
| Co-Investigator(s): | Click or tap here to enter text. |
| - If you are member the UCM faculty, you may skip to the next section –  |
| Faculty Advisor’s Name: | Click or tap here to enter text. |
| Faculty Advisor’s Email: | Click or tap here to enter text. |

[ ]  By checking this box, the Principal Investigator (PI) certifies that s/he has not begun recruiting or testing research participants and will not do so until a formal notification of approval has been received from this IRB.

|  |
| --- |
| [ ]  Determined Human Subjects:  |
| If the activity is identified to be “research” and involves “human subjects” please submit an application for review to the IRB. |

|  |
| --- |
| SECTION B: Determination of Research (45 CFR 46.102(d)) |
| OVERVIEW |
| 1. Describe the purpose of your project (500 words or less).

Include goals, rationale, and relevant background information. Please use language that may be understood by persons unfamiliar with this area of study |
| 1. Why are you seeking this determination?
 |
| Click or tap here to enter text. |
| 1. How generalizable will the results be? To whom?
 |
| Click or tap here to enter text. |
| 1. What is the importance?
 |
| Click or tap here to enter text. |
| 1. How will it contribute to the body of knowledge?
 |
| Click or tap here to enter text. |
| 1. Indicate by checking the box if the activity meets the following criteria:
 |
| [ ]  The activity is a systematic investigation: an activity that involves a prospective research plan which incorporates data collection, both qualitative and quantitative, and data analysis to answer a research question[ ] The activity is designed to develop or contribute to generalizable knowledge: designed to draw general conclusions, inform policy or generalize findings. Intent to publish or present is one of the indicators that data may be generalizable. Activities such as oral histories, quality assurance, and investigative journalism are generally not research as used here. Evaluation studies may be quality assurance or may be research depending, in part, on the funding agency. |
| *If you checked both boxes, the activity is research.* |

|  |
| --- |
| SECTION C: Determination of the Involvement of Human Subjects (45 CFR 46.102(f)) |
| Subjects |
| 1. What is the source of the participants?
 |
|  |
| 1. What identifying information is available about the participants?
 |
|  |
| 1. What is to be done to or with the participants for the purpose of your study or evaluation?
 |
|  |
| 1. What data is to be obtained and how will it be stored?
 |
|  |
| 1. How identifiable is the data when you get it?
 |
|  |
| 1. Will identifiers be stripped?
 |
|  |
| 1. Indicate by checking the box if the activity meets the following criteria:
 |
| [ ]  The research involves living individuals[ ]  The researcher will obtain data information about those individuals[ ]  The investigator will obtain either of the following: 1. Collect data through investigation or interaction with an individual, including interviews, surveys, physical procedures, manipulations of the subject’s environment, and any other direct contact or communication with the subject (regardless of whether the resulting data is identifiable or not). 2. Obtain, view, or otherwise handle any private information which identifies individual subject(s) through the use of either direct identifiers (name, address, etc.) or indirect identifiers in the form of a code that links back to the identity of the subjects through an existing key. |
| *If you checked all three boxes, the activity involves human subjects.* |
| Applicants Request |
| I assert the proposed activities: |
| [ ]  are research, as determined by 45 CFR 46.102(d)[ ]  are NOT research as determined by 45 CFR 46.102(d)[ ]  involve human subjects[ ]  do NOT involve human subjects |
| \*If the activity is identified to be “research” and involves “human subjects” please submit an application for review to the IRB. |

|  |
| --- |
| Section D: Principal Investigator and Faculty Advisor Agreement |
| *I certify that the information provided in this application is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations designated by the Institutional Review Board (IRB). I accept and will conform to all federal, state, and institutional provisions concerning the protection of human participants in research. I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project.* *I agree to conduct the research involving human participants as presented in this application as approved by the University of Central Missouri’s Institutional Review Board (IRB), and am qualified to perform the procedures described herein. I will submit any proposed changes/modifications for review and approval before they are implemented. I agree to notify the IRB and the Office of Sponsored Programs and Research Integrity of any adverse events that may occur during the study. I also assure that I will follow through with the storage and destruction of data as outlined in the protocol. I understand that the University of Central Missouri owns the research data. If I choose to transfer to another institution, I will need departmental approval to take the data with me.**If a student researcher, I additionally certify that my faculty advisor has an electronic copy of this application as submitted. My advisor has agreed to:** *Oversee this research by communicating regularly with me;*
* *Assist with the resolution of any problems or concerns encountered during the research;*
* *Assure my research complies with Human Subjects Regulations in the Code of Federal Regulations (CFR)*
* *Assure that the UCM IRB is notified in the event of an adverse event or protocol deviation.*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Students please note:**Failure to work with your advisor as described above will be considered a breach of professional ethics which falls under the academic honesty policy. The consequences of violating standards of academic honesty are extremely serious, costly and may result in the loss of academic and career opportunities.*  |
| [ ]  By checking this box, I certify that I have read and agree to the agreement above |
| Principal Investigator (Print Name): Click or tap here to enter text. Date: Click or tap to enter a date. |

**If an unanticipated problem or adverse event should occur, you must immediately notify the IRB by email at researchreview@ucmo.edu and call (660) 543-8562.**