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| Exempt Review Protocol Institutional Review Board - Human Subjects |
| SECTION A: General Information |
| 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 or staff, 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.**

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| SECTION B: Exempt Research Qualification  |
|  | **YES NO** |
| 1. Does this research involve more than minimal risk? (Will participating in this research expose participants to harm, distress, or discomfort beyond levels encountered in daily life?)
 | [ ]  [ ]  |
| 1. Will the collected data include identifying information AND be potentially damaging to a participant’s financial standing, employability, or reputation OR result in criminal or civil liability or could it damage the subjects “educational advancement”?
 | [ ]  [ ]  |
| 1. Does your research involve minors, prisoners, pregnant women (where the research would put the pregnancy or fetus at risk), (human) fetuses, or in vitro fertilization?
 | [ ]  [ ]  |
| 1. Has this research previously been reviewed by UCM’s IRB?
 | [ ]  [ ]  |
| b. IF YES, please explain: Click or tap here to enter text. |
|  CHECK A CATEGORY BELOW THAT ACCURATELY DESCRIBES YOUR RESEARCH |
| [ ]  CATEGORY 1 | **Research conducted in established or commonly accepted educational settings, involving normal educational practices**, such as 1. research on regular and special education instructional strategies, or
2. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods or
3. research must also not be likely to adversely impact the student’s opportunity to learn required educational content or the assessment of the educators who provide the instruction. [46.104(d)(1)]
 |
| [ ]  CATEGORY 2 | **Research that only includes interactions involving educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures, interview procedures or observation of public behavior that** **DOES NOT:**1. Include identifying information about the participant;
2. Put the participant at risk criminal or civil liability should his or her responses be disclosed; or Be potentially damaging to the participants’ financial standing, employability, or reputation, or that the disclosure of the subjects’ responses outside the research would not reasonably be damaging to the subjects “educational advancement.”
3. And where identifiable information (even if sensitive) is recorded, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections to the study. [46.104(d)(2)]
 |
| [ ]  CATEGORY 3 | **Research involving benign behavioral interventions with data collections from adult subjects through verbal or written response (including data entry) or audiovisual recording it the subject agrees to the intervention and information and if at least one of the following criteria is met:**1. The information recorded cannot be readily linked back to the subjects in such a manner that subjects’ identity can be readily ascertained, directly or through identifiers linked to the subjects; or
2. Any disclosure of this information would not place the subjects at risk of certain harms, or
3. The information is recorded in an identifiable manner, even if sensitive, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study. [46.104(d)(3)]
 |
| [ ]  CATEGORY 4 | **Research involving secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:**1. The identifiable private information or identifiable biospecimens are publicly available;
2. If the investigator records information about individuals in a nonidentifiable manner, the investigator must not attempt to re-identify or contact the research subjects.
3. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated as “healthcare operation,” “research,” or “public health.”
4. When the secondary research is conducted by or on behalf of a federal department or agency, using data collected or generated by the government for non-research purposes, and the information is subject to federal privacy standards and other requirements specified in the exemption. [46.104(d)(4)]
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| [ ]  CATEGORY 5 | **Research conducted/supported by a federal department/agency** and which are **designed to study, evaluate, improve, or otherwise examine:**1. Public benefit or service programs;
2. Procedures for obtaining benefits or services under those programs;
3. Possible changes in or alternatives to those programs or procedures; or
4. Possible changes in methods or levels of payment for benefits or services under those programs.
5. And the federal entity conducting or sponsoring the research to publish a publicly available list of the projects that are covered by this exemption before the research begins. [46.104(d)(5)]
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| [ ]  CATEGORY 6 | **Taste and food quality evaluation and consumer acceptance studies**, 1. If wholesome foods without additives are consumed or
2. 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 (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture. [46.104(d)(6)]
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| [ ]  CATEGORY 7 | **Storage/Maintenance for secondary research (broad consent required)**1. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determination.
2. Can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials. [46.104(d)(7), 46.111(a)(8), 46.116(d)]
 |
| [ ]  CATEGORY 8 | **Secondary research for which broad consent is required. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:**1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens.
2. Documentation of informed consent or waiver of documentation of consent.
3. An IRB conducts a limited IRB review and makes the determination required and make the determination that the research to be conducted is within the scope of the broad consent, investigator does not include returning individual research results to subjects as part of the study plan.
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| Other? | **If your research does not fit into any of the above categories, it does not qualify for EXEMPT status.** Please discontinue this form and complete the EXPEDITED / FULL REVIEW form instead.  |

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| SECTION C: Project Details |
| OVERVIEW |
| 1. Project Title:
 | Click or tap here to enter text. |
| 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. |
| Click or tap here to enter text. |
| 1. What is/are your research question(s)?
 |
| Click or tap here to enter text. |
| 1. What is/are your hypothesis/hypotheses?
 |
| Click or tap here to enter text. |
| 1. What do you plan to do with the results of your study (e.g. publish, present at a conference, etc.)?

If this project is only for an internal evaluation or class assignment, IRB may not be required. Please contact the Human Subjects Committee for more information. |
| Click or tap here to enter text. |
| FUNDING |
| 1. Is this research currently, or do you intend for it to be, funded in whole or part by an external (non-UCM) grant or contract?
 | [ ] YES [ ] NO |
| IF YES:1. Is there a completed FCOI on record with the Office of Sponsored Programs & Research Integrity?
 | [ ] YES [ ] NO |
| 1. Provide the following
* Sponsor Name: Click or tap here to enter text.
* PI on Grant: Click or tap here to enter text.
* Grant Title/Contract: Click or tap here to enter text.
* Estimated Project Period:
	+ From: Click or tap here to enter text.
	+ To:Click or tap here to enter text.
 |
| 1. Copy of Grant Application or Project Summary is Attached
 | [ ] YES [ ] NO |
| PARTICIPANT POPULATION |
| 1. Describe the participant population you will target for this research (e.g., sex, age range, ethnic background, health status, or other targeted demographics).
 |
| Click or tap here to enter text. |
| 1. How many participants will you need to complete your study?
 | Click or tap here to enter text. |

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| RECRUITMENT |
| 1. Describe your recruitment process. Include how, where, when, and who will contact potential research participants.
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| Click or tap here to enter text. |
| 1. Attach all applicable recruitment materials. Check all that apply.
 |
| [ ] Recruitment Scripts [ ] Letter/Cover Letter[ ] Flyers [ ] Advertisements[ ] Recruitment Emails [ ] Other: Click or tap here to enter text. |
| 1. Will you be directly emailing or mailing participants?
 | [ ] NO [ ] YES |
| IF YES, how are you obtaining emails and\or mailing addresses? |
| Click or tap here to enter text. |
| 1. Will participants be compensated for their participation?
 | [ ] NO [ ] YES |
| IF YES, describe how participants will be compensated – include the amounts and method of distribution: |
| Click or tap here to enter text. |
| RISKS & BENEFITS |
| 1. Check the potential risks to the participants involved in this study.
 |
| [ ] Economic [ ] Psychological[ ] Legal [ ] Social[ ] Physical [ ] Other[ ] None |
| 1. Check the potential direct or indirect benefits to the participants involved in this study.
 |
| [ ] Economic [ ] Psychological[ ] Legal [ ] Social[ ] Physical [ ] Other[ ] None |
| 1. Describe the potential risks to your participants.
 |
| Click or tap here to enter text. |
| 1. Describe the potential benefits to your participants and/or society.
 |
| Click or tap here to enter text. |
|  METHOD OF DATA COLLECTION |
| 1. *Attach copies of all data collection tools to be used.*

Check all that apply.  |
| [ ] Questionnaire/Survey [ ] Interviews (attach scripts, questions)[ ] Observations [ ] Existing Data[ ] Other: Click or tap here to enter text. |
| 1. Describe the research methods or procedures you will use to collect your data.

That is, what exactly are your participants going to do? Your response should include a step-by-step description of each procedure, including the frequency and duration of each procedure. If analyzing existing data, describe how you will obtain and analyze these data.  |
| Click or tap here to enter text. |
| 1. Where will the study take place?

That is, where will participants be observed, complete surveys, etc? |
| Click or tap here to enter text. |
| 1. Does your study include plans to recruit participants from or collect data at an external site?

(I.e., off UCM campus – for example, at an elementary school, hospital, etc.) | [ ] NO [ ] YES |
| IF YES, name and describe the external site(s) below. *You must also attach a written acknowledgement indicating that you have permission to use the named facility and/or personnel.* |
| Click or tap here to enter text. |
| INFORMED CONSENT |
| *The consent document(s) must contain all the required elements of consent. We recommend you use the appropriate template(s) available on the* [*OSPRI website*](http://www.ucmo.edu/osp)*.* |
| 1. How will you obtain consent?

Describe your process for obtaining informed consent from your participants – include how, when, and where the consent process will take place, and who will collect it.  |
| Click or tap here to enter text. |
| 1. Which of the following will you use to present the informed consent? *(Attach all.)*
 |
| [ ] Paper Consent Form [ ] Web-based Consent Form[ ] Cover Letter [ ] Verbal Consent Script  | [ ]  Minor’s Assent Form (Must also include Parental Consent)[ ] Parental Consent Form (Must also include Minor’s Assent) [ ] Other: Click or tap here to enter text. |
| 1. Will you inform your participants of the full nature and purpose of your study before (during consent) or after (during debriefing) they complete your study?
 | [ ] Before - During Consent[ ] After - During Debriefing |
| 1. Will non-English-speakers be included in your study?
 | [ ] NO [ ] YES |
| *IF YES, include translated versions of your consent documents.* |

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| PARTICIPANT PRIVACY & CONFIDENTIALITY |
| 1. Describe any procedures you will use to protect the privacy of your participants during data collection.

*(E.g., participants will complete surveys in the privacy of their own homes; interviews will be performed at a location of their choosing, etc.)*  |
| Click or tap here to enter text. |
| 1. During data collection, will you collect or have access to identifiable information about your participants?
 |
| [ ] NO – Data collection will be anonymous (*The investigators will not collect or have access to identifiable information about the study’s participants*) [ ] YES – Data collect will be confidential (*The investigators will collect or have access to identifiable information about the study’s participants*)  |
| 1. How will you handle identifiable information?
 |
| [ ]  Identifiable information will not be collected[ ]  Identifiable information will be coded and investigators will not have access to a code key[ ]  Identifiable information will be coded and investigators will have access to a code key[ ]  Identifiable information will be collected and will be de-identified for analyses[ ]  Identifiable data will be collected and will remain identifiable for analyses |
| 1. How will the collected data be secured?
 |
| [ ] Locked in a cabinet or office[ ] Password protected PC, hard disk drive, or other secure electronic storage[ ] Encrypted online or cloud storage[ ] All data will be destroyed (shredded/deleted/etc.) after use[ ] Other: Click or tap here to enter text. |
| 1. Who will have access to the data?
 |
| Click or tap here to enter text. |

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| 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 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 protocol 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 Research Compliance Officer 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 already reviewed and approved 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*
* *Assure that the UCM IRB is notified in the event of an adverse event or protocol deviation.*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**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. |