Wichita State University Institutional Review Board (IRB)
Exempt Application

Section A: Administrative Information

Principal Investigator Information

(For a student project, Principal Investigator must be a WSU faculty member, student is listed as Co-Investigator)

Name (Last, First, MI):		
Title:	College/Department Affiliation:	
Campus Phone Number:	E-mail Address:	*MyWSU* ID Number:
Has CITI or NIH Human Subjects Research Training been completed: ☐ Yes ☐ No		
Responsibilities for this study (Choose letters from list below):		

Study Responsibilities. Choose all that apply and/or write in others.

a. Conduct informed consent interview
b. Perform tests, procedures, interventions, questionnaires
c. Obtain medical/surgical history
d. Manage study database
e. Take vital signs, height, weight
f. Draw/collect laboratory specimens
g. Assess unanticipated problems
h. Data analysis
i. Report generation
j. Faculty advisor

Co-Investigator Information or ☐ N/A

(If there are more than 2 Co-Investigators please provide their information on a separate Word document)

1. Name (Last, First, MI):		
Department Name:		
E-mail Address:		*MyWSU* ID Number:
☐ Faculty Member ☐ Graduate Student ☐ Undergraduate Student ☐ Other, please specify:		
Has CITI or NIH Human Subjects Research Training been completed: ☐ Yes ☐ No		
Responsibilities for this study (Choose letters from list above):		

2. Name (Last, First, MI):		
Department Name:		
E-mail Address:		*MyWSU* ID Number:
☐ Faculty Member ☐ Graduate Student ☐ Undergraduate Student ☐ Other, please specify:		
Has CITI or NIH Human Subjects Research Training been completed: ☐ Yes ☐ No		
Responsibilities for this study (Choose letters from list above):		

Project Information

Please answer ALL questions

1. Title of Project:

2. Expected Completion Date:

3. Is the research funded? ☐Yes ☐No ☐Plan to submit for funding ☐Have requested funding, awaiting award decision

Sponsor:

Grant or Proposal number: *Please submit a copy of the Grant

4. Have all faculty and unclassified staff listed as personnel completed a disclosure of conflict of interest and time commitment for Wichita State University? ☐ Yes ☐ No If "No" please contact Compliance at compliance@wichita.edu.

5. Do any of the personnel (including students or their immediate family members) on the project have financial arrangements with the sponsoring company or the products or services being evaluated, or consulting agreements, management responsibilities or equity holdings in the sponsoring company? ☐ Yes ☐ No ☐ N/A

If "Yes" please contact Compliance at compliance@wichita.edu.

6. Screening Questions:

a. Will the research expose participants to discomfort or distress beyond that normally encountered in daily life? ☐ Yes ☐ No

b. Could disclosure of participants' responses outside the research reasonably place participants at risk of criminal or civil liability or be damaging to participants' financial standing, employability, or reputation? ☐ Yes ☐ No

c. Does any part of the research require deception or incomplete disclosure of information to participants? ☐ Yes ☐ No

d. Will prisoners (or their data and/or specimens) be participants in the research? ☐ Yes ☐ No

e. For research proposed under category 1, will the research be conducted outside of commonly accepted educational settings or deviate from normal educational practices? ☐ Yes ☐ No or N/A

f. For research proposed under category 2, will the research involve surveys or interview procedures with children? ☐ Yes ☐ No or N/A

g. For research proposed under category 2, will the research involve observations of the public behavior of children, during which an investigator participates in the activities being observed? ☐ Yes ☐ No or N/A

h. For research proposed under category 4, will any of the data, documents, records, or biological specimens be collected or created after the date of this application for exemption? ☐ Yes ☐ No or N/A

i. For research proposed under category 4, will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator in such a manner that participants could be identified directly or through identifiers linked to the participants? ☐ Yes ☐ No or N/A

j. For research proposed under categories 1-5, is the research subject to FDA regulations? ☐ Yes ☐ No or N/A

If you checked YES to ANY of the questions above, your research is NOT EXEMPT. Do not complete this application. Submit A New Study Application.

7. Exempt Category:

Please check the categories of exemption for which you are applying. You may check more than one box. See Category descriptions below: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Category 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
a. research on regular and special education instructional strategies **or**
b. research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

Category 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
a. information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects **and**
b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

Category 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph # 2 (above) if:
a. the human subjects are elected or appointed public officials or candidates for public office, **or**
b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

Category 5. Research and demonstration projects which are conducted by or subject to the approval of (federal) department or agency heads 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. Taste and food quality evaluation and consumer acceptance studies, if:
a. 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 or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U. S. Department of Agriculture.

8. Describe how the proposed research meets the criteria for exemption. Reference the exemption category or categories and the category's corresponding requirements.

9. Do you intend to publish or present the study's findings? Yes ☐ No

10. Please summarize the purpose and procedures of the proposed research using non-technical language that can be readily understood by someone outside the discipline. Submit a word document if more space is needed.

Section B: Design, Methods, and Procedures

1. Check all research activities that apply. ***Attach a copy of materials to be used (instruments, data collection forms, etc)***.

☐ Audio, video, digital, or image recordings	☐ Record review (which may include Protected Health Information)
☐ Existing data, not publicly available	☐ Specimen research (must exist at time of application)
☐ Existing data, publicly available	☐ Surveys, questionnaires, or interviews (one-on-one)
☐ Focus groups	☐ Surveys, questionnaires, or interviews (group)
☐ Internet or e-mail data collection	☐ Taste-testing
☐ Observation of participants	☐ Other (specify):
☐ Oral history (does not include medical history)	

2. Are Codes used to link data to the subject? Yes ☐ No

3. Do you anticipate using any data from this study for other studies in the future? Yes No

If "Yes", explain:

4. Describe the steps you will take to ensure the confidentiality of the participants and data.

5. How will you safeguard data that includes identifying or potentially identifying information (e.g. coding)? ☐ N/A

6. When will identifiers be separated or removed from the data? ☐ N/A

7. Where and how will you store the data?

8. How long do you plan to retain the data? *Research Records must be maintained for a minimum of 5 years. This is based on the longest required retention period under the various applicable federal regulations.*

9. Describe how you will dispose of the data:

- ☐ Identifiers will be permanently removed from the data and destroyed (de-identified)
- ☐ Identifiable/coded (linked) data will be retained and stored confidentially
- ☐ Identifiable data were not collected

Section C: Recruitment, Participants and Privacy

1. Subjects to be recruited (check all that apply)

☐ Adults (18+years) ☐ Children and Minors (under 18 years) ☐ Non-English Speaking ☐ Pregnant Women ☐ Elderly/Aged Persons (65 years and older)	☐ Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols) ☐ Other – describe:

2. Number of Subjects or Records to be accessed:

3. Is Compensation Offered? Yes No **If "Yes", describe amount or kind of compensation:**

4. Provide a detailed description of the population characteristics. ***An example for a category 4 study: Patients age 18-55 with X diagnosis admitted to the hospital between 01/01/2005 and 01/01/2014.***

5. Describe the recruitment process, including any advertisements, to be used for this study.

Section D: Consent Process

1. What type of informed consent will be obtained:

- ☐ Written consent with signatures obtained
- ☐ Consent document without a signature obtained (for online surveys, phone interviews, etc)
- ☐ N/A - explain:

2. Describe the informed consent process. How and by whom will initial contact with potential subjects take place? Where and when will the consent interview take place? ☐ N/A

Principal Investigator's Assurance

I certify that the information provided in this application is complete and correct to the best of my ability and knowledge.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB. I accept responsibility to ensure that all study personnel are adequately trained for their role and have read this application.

I agree to comply with all Wichita State University policy and procedures, as well as all applicable federal, state and local laws regarding the protection of human subjects in research including, but not limited to, the following:

- Implementing no changes in the approved protocol or consent form without prior Wichita State University Institutional Review Board (IRB) approval (except in emergency, if necessary to safeguard the well-being of human subjects).
- Obtaining the legally effective informed consent from human subjects or their legally responsible representative, and using only the currently approved consent form with human subjects.
- Promptly reporting significant or untoward adverse effects to the Wichita State University Institutional Review Board (IRB) in writing within 10 working days of occurrence.

If I will be unavailable to direct this research personally, as when on sabbatical or vacation, I will arrange for a co-investigator to assume direct responsibility in my absence. Either this person is named as a co-investigator in this application, or I will advise the Wichita State University Institutional Review Board (IRB) by letter, in advance of such arrangements.

I assure that I will retain research related records for audit including all documents subject to Human Subject welfare pursuant to the requirements of Code of Federal Regulations TITLE 45 PART 46 PROTECTION OF HUMAN SUBJECTS and Wichita State University Policy.

Signature of Principal Investigator: _____ Date: _____

Questions and completed Forms should be emailed to the IRB Administrator at IRB@wichita.edu