Wichita State University Institutional Review Board (IRB)
New Study Application

Investigator Information

Principal Investigator must be a WSU faculty member. Students and anyone outside of WSU are listed as Co-Investigators.

Name (First, MI, Last):		
Title:	College/Department Affiliation:	
Campus Phone Number:	E-mail Address:	*MyWSU* ID Number:
Has CITI or NIH Human Subjects Research Training been completed in the last 3 years: ☐ Yes ☐ No		
Responsibilities for this study (Choose letters from list below and/or write in any others):		

Study Responsibilities. Choose all that apply.

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 3 Co-Investigators please provide their information on a separate Word document)

Name (First, MI, Last):	
Department Name:	
E-mail Address:	*MyWSU* ID Number:
☐ Faculty Member ☐ Graduate Student ☐ Undergraduate Student Other:	
Has CITI or NIH Human Subjects Research Training been completed in the last 3 years: ☐ Yes ☐ No	
Responsibilities for this study (Choose letters from list above and/or write in any others):	

Name (First, MI, Last):	
Department Name:	
E-mail Address:	*MyWSU* ID Number:
☐ Faculty Member ☐ Graduate Student ☐ Undergraduate Student Other:	
Has CITI or NIH Human Subjects Research Training been completed in the last 3 years: ☐ Yes ☐ No	
Responsibilities for this study (Choose letters from list above and/or write in any others):	

Name (First, MI, Last):	
Department Name:	
E-mail Address:	*MyWSU* ID Number
☐ Faculty Member ☐ Graduate Student ☐ Undergraduate Student Other:	
Has CITI or NIH Human Subjects Research Training been completed in the last 3 years: ☐ Yes ☐ No	
Responsibilities for this study (Choose letters from list above and/or write in any others):	

Conflict of Interest

1. Have all WSU employees, except student employees and graduate students, listed as personnel completed a disclosure of conflict of interest and time commitment for Wichita State University within the last 12 months? ☐ Yes ☐ No - submit a form via myWSU. For log on instructions: Annual Conflict of Interest Reporting form

2. 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 which may include consulting agreements, management responsibilities or equity holdings in the sponsoring company? ☐ Yes ☐ No ☐ N/A

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

Project Information

1. Project Title:

2. Expected Completion Date:

3. Type of Project: ☐ Class Project ☐ Capstone Project ☐ Research

4. Type of Review Requested: ☐ Exempt
☐ Expedited
☐ Full Committee

5. Research Design: ☐ Experimental ☐ Quasi-Experimental ☐ Non-Experimental (e.g. descriptive, correlation)
☐ Qualitative ☐ Secondary Data/Collection/Analysis ☐ Program Evaluation or QI (STOP here, submit determination form)

6. Is the research funded? ☐ Yes ☐ No ☐ Plan to Submit for funding ☐ Have requested funding, awaiting award decision
Sponsor:
RTT Grant or Proposal # (if unsure ask your RTT contact):

Please submit a copy of the grant or statement of work from the contract.

6.1 If you have requested funding but do not receive it, will you still conduct the study? ☐ Yes ☐ No ☐ N/A
6.2 If the funding is from an industry contract, is there an agreement in place? ☐ Yes (*fill in sponsor name above*) ☐ No
☐ In process, name of your RTT contact: ☐ N/A

7. List all locations where study activities will take place:

7.1. Will multiple institutions (other Universities, Hospitals, etc) participate in the study? ☐ Yes (*complete #7.1a - 7.1c)*
☐ No (*proceed to #8*)

7.1a. Please list all participating institutions:

7.1b. Has the IRB at the institution(s) listed above approved the study? ☐ Yes (*please submit copy of approval letter)*
☐ No, explain:

7.1c. Will the WSU PI oversee or coordinate the research being conducted at non-WSU sites? ☐ Yes ☐ No
If yes, Describe the PI's oversight plans, including how the PI will ensure adherence to the study protocol, obtain informed consent, secure and maintain IRB approval at the other sites, monitor adverse events or other unanticipated problems, and ensure general coordination of study conduct.

8. Please summarize the purpose of the proposed research using non-technical language that can be readily understood by someone outside the discipline:

9. Describe each procedure step-by-step, including the frequency, duration, and location of each procedure. A numbered or bulleted list of steps is helpful. *Submit a separate Word document if additional space is needed.*

10. Instruments:	11. Recorded by:	12. Administered:	13. Findings used for….
☐ Standardized Tests ☐ Questionnaire ☐ Interview ☐ Internet ☐ Other (specify):	☐ Written Notes ☐ Audiotape ☐ Videotape ☐ Photograph/film ☐ Standard mail ☐ Webcam/digital camera	☐ In person (group) ☐ In person (individual) ☐ Telephone ☐ Mail ☐ E-Mail ☐ Other (specify):	☐ Publication ☐ Dissertation, Thesis ☐ Needs assessment ☐ Evaluation ☐ Results to be released to:

14. Data will include: (Check all variables, if no personal identifiers will be accessed please mark this box ☐)

☐ Names of People	☐ Finger or voice print
☐ Mailing or Email Addresses	☐ Photographic image
☐ Phone or Fax Numbers	☐ Web URL
☐ Age	☐ Biometric Identifiers
☐ Gender	☐ Income
☐ Ethnicity	☐ Student ID#
☐ Marital Status	☐ Job Title
☐ IP Address	☐ Names of employers
☐ Date of Birth	☐ Types of employers
☐ License, Certificate or Vehicle ID	☐ Other Information:
☐ Social Security Numbers	
☐ Medical Record Number	
☐ Admission/Discharge Date	
☐ Account Numbers	

15. Will this study involve the use of existing data, documents, records, and pathological specimen? ☐ Yes ☐ No
If "Yes", include a letter of authorization to access data if not publicly available.

16. Do you anticipate using any data from this study for other studies in the future? ☐ Yes ☐ No
If "Yes", explain:

17. Is this study similar or build upon a previous study approved by WSU IRB? ☐ Yes - IRB# ☐ No

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

Subject Selection

1. Number of Subjects or Records to be accessed:

2. Age of Subjects:

3. Will all participants be fluent in English? ☐ Yes ☐ No

4. Vulnerable populations to be recruited (check all that apply):

☐ Children	☐ N/A
☐ Cognitively Impaired Persons	☐ Other –describe:
☐ Prisoners	
☐ Minorities	
☐ Educationally or Economically disadvantaged	

5. If vulnerable populations are targeted for the study, discuss the special protections being implemented to minimize risk of coercion or undue influence or ☐ N/A.

6.1 What are the primary inclusion criteria?

6.2 What are the primary exclusion criteria?

7. Is Compensation Offered? ☐ Yes ☐ No **If "Yes", describe amount, type (gift card, greenphire, etc) and when:**

8. Describe the recruitment process, including any advertisements (flyers, emails, phone scripts, Strategic Communications Ads, etc.) to be used for this study. Include the flyer and text of the ads, emails, scripts as applicable in a separate document.

Risks/Benefit Information

1. Potential Risk Exposure: ☐ Physical (cognitive or motor) ☐ Psychological ☐ Economical ☐ Legal ☐ Social

2. Describe the nature and degree of the risks. (Do not say N/A - It cannot be assumed that there are no risks). Be sure all items listed are described in the informed consent document.

3. Describe how risks and discomforts (physical, psychological, or social) will be minimized:

4. Please describe the benefits of the research to human subjects, if any, and of the benefits to human or scientific knowledge:

Confidentiality

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

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

3. Where and how will you store the data?

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

5. Describe how you will dispose of the data (e.g. erasing tapes, shredding data)?

Informed Consent

1. What type of informed consent will be obtained (may select more than one):
   - ☐ Written consent with signatures obtained
   - ☐ Consent document given but no signature obtained
   - ☐ N/A - explain:

2. Specify the consent forms included with this submission: ☐ Adult ☐ Parent ☐ Child Assent ☐ Foreign Language
   Other:

3. Are you requesting a waiver of consent or assent? ☐ Yes ☐ No ***If yes, explain how the research meets the federal criteria (45 CFR 46.116(d)) for waiving the informed consent requirement:***

a) The research involves no more than minimal risk to subjects. ☐ Yes ☐ No

b) The research could not practicably be carried out without the requested waiver or alteration. ☐ Yes ☐ No

c) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format ☐ Yes ☐ No

d) The waiver will not adversely affect the rights and welfare of the subjects. ☐ Yes ☐ No

e) Whenever appropriate the subjects or legally authorized representatives will be provided with additional pertinent information after participation. ☐ Yes ☐ No

4. 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? Or mark ☐ N/A

If you are requesting an **Exempt** review please check the categories of exemption for which you are applying. You may check more than one box. See Category descriptions below. Note – these descriptions are truncated. The full text can be found under 45 CFR 46.104
☐ **N/A if not Exempt**

☐ Category 1. Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, involving normal educational practices. This includes most research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

☐ Category 2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
b. Any disclosure of the human subjects' 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; **or**
c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination.
PLEASE NOTE: the only research activities involving children that may fall under this exemption are those involving educational tests or observation of public behavior where the investigators do not participate in the activity being observed.

☐ Category 3(i). Research involving benign behavioral interventions in conjunction with the collection of information from an **adult** subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; **or**
b. Any disclosure of the human subjects' 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; **or**
c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination.
(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a **prospective agreement** to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
Please Note: research activities involving children do not qualify under this exemption

☐ Category 4. 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:
a. The identifiable private information or identifiable biospecimens are publicly available; **or**
b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; **or**
c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by HIPAA "health care operations" or "research" or for "public health activities and purposes"; **or**
d. The research is conducted by, or on behalf of, a Federal department or agency using government generated or government-collected information obtained for nonresearch 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 specified federal privacy laws.

☐ Category 5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs. **Note: these must be posted on a Federal Web site.**

☐ Category 6. Taste and food quality evaluation and consumer acceptance studies

Describe how the proposed research meets the criteria for **exemption**. Reference the exemption category or categories (above and on page 7) and the category's corresponding requirements.

If you are requesting an **Expedited** review please check the categories for which you are applying. See category descriptions below. You may check more than one box.

☐ **N/A if not Expedited review**

☐ Category 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ Category 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or b. from other adults and children2, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ Category 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ Category 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ Category 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

☐ Category 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ Category 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Describe how the proposed research meets the criteria for **expedited** review. Reference the category or categories (on page 8) and the category's corresponding requirements.

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's 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 affects to the Wichita State University Institutional Review Board (IRB) in writing within 10 working days of occurrence. See SOP 12.0 Event Reporting and Non-compliance.

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's 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