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): Other:		
Study Responsibilities. Choose all that apply. a. hõûl·ly informed consent 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): Other:		
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): Other:		
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): Other:		

Conflict of Interest

1. 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.

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, 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.

Project Information

1. Project Title:

2. Expected Completion Date:

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

4. Type of Review Requested: ☐ Exempt (STOP here and submit an Exempt Application)
☐ Expedited (please also submit the IRB Request for Expedited Review form)
☐ Full Committee

5. Research Design: ☐ Experimental ☐ Quasi-Experimental ☐ Non-Experimental (e.g. descriptive, correlation)
☐ Qualitative ☐ Secondary Data/Collection/Analysis ☐ Program Evaluation

6. 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. *Federal regulations (45 CFR 46.103(f)) require that each grant application or proposal for most federally supported human subjects research be reviewed and approved by an IRB. As part of this review, IRBs are required to ensure that the activities described in the grant are consistent with the proposed or IRB-approved protocol.*
6.1. If you have requested funding but do not receive it, will you still conduct the study? ☐ Yes ☐ No ☐ N/A
6.ʜ. Iŧ ŭḰŜ ŧdzyŘλyƎ λă Ŧℕƨϒ˙ I·y˙λyŘdžăúℕè Ŏƨyűℕ I·ŎŭΣ λă ŭḰŜℕŜ I·y˙ I·ƎℕŜŜϒ˙Ŝyű λy˙ŁJℕƨŎŜăă? ☐ Yes (fill in sponsor name above) ☐ No ☐ 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	☐ Social Security Numbers
☐ Mailing or Email Addresses	☐ Medical Records
☐ Phone or Fax Numbers	☐ Biometric Identifiers
☐ Age	☐ Income
☐ Gender	☐ Student ID#
☐ Ethnicity	☐ Job Title
☐ Marital Status	☐ Names of employers
☐ IP Address	☐ Types of employers
☐ Date of Birth	☐ Other Information:
☐ License, Certificate or Vehicle ID	

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:

2. Age of Subjects:

3. Does this study involve participants who are not fluent in English? ☐ Yes ☐ No

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

☐ Cognitively Impaired Persons	☐ Pregnant Women
☐ Prisoners	☐ Other –describe
☐ Minorities	☐ N/A

5. If vulnerable populations such as children, pregnant women, cognitively impaired, etc., are targeted for the study, discuss the special protections being implemented to minimize risk of coercion or undue influence. ☐ N/A

6. What are the primary inclusion and exclusion criteria?

7. Is Compensation Offered? ☐ Yes ☐ No **If "Yes", describe amount or kind of compensation:**
8. Describe the recruitment process, including any advertisements (flyers, emails, phone scripts, etc) to be used for this study:

Risks/Benefit Information
1. Potential Risk Exposure: ☐ Physical ǒŎƵƎƴ ƛǘƛǾŜ Ƶǋ ϒƵǘƵǋǘ ☐ Psychological ☐ Economical ☐ [Ŝgal ☐ Social
2. Describe the nature and degree of the risks. (It cannot be assumed that there are no risks):
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:
5. What type of monitoring is planned to ensure the safety of subjects ŘdzNJƛƴƎ ŘŀǘŀΡ ǒƵffŜŎǘƛƵƴ? ☐ Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) ☐ Medical Monitor designated by the sponsor (for multi-center trials) ☐ Medical Monitor designated at the local level Name: Affiliation: ☐ Study team members only

Confidentiality
1. Describe the steps you will take to ensure the confidentiality of the participants and data.
2. How will you safeguard data that includes identifying or potentially identifying information (e.g. coding)? ☐ N/A
3. When will identifiers be separated or removed from the data? ☐ N/A
4. Where and how will you store the data?
5. 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.*
6. 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: ☐ Written consent with signatures obtained ☐ Consent document without a signature obtained (for online surveys, phone interviews, etc) ☐ N/A ǿăŜŜ̂ʅʎyƎ Ɩ· ǿ Ɩ·ʎǾŜ̂ǊǗ - explain:
2. Specify the consent forms included with this submission: ☐ !dult ☐ tarent ☐ Child Assent ☐ Foreign Language ☐ bκ! ☐ Other
3. Are you requesting a waiver of consent or assent? ☐ Yes ☐ No ***<u>If yes,</u> please confirm that 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 waiver will not adversely affect the rights and welfare of the subjects. ☐ Yes ☐ No c) The research could not practicably be carried out without the waiver. ☐ Yes ☐ No d) Whenever appropriate the subjects 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?

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 Even 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