KANSAS WESLEYAN UNIVERSITY

Committee for the Ethical Treatment of Human Subjects

HUMAN SUBJECTS RESEARCH PROPOSAL

INVESTIGATOR INFORMATION

PRINCIPAL INVESTIGATOR

Name (First, MI, Last): _____ MyKWU ID Number: _____

Degree: _____ Department: _____

Campus Mailbox: _____ Phone Number or Ext: _____

Email Address: _____

Has completed training modules and is aware of all KWU policies regarding the ethical treatment of human subjects in research in the last 3 years: ☐ Yes *(Please submit all required attachments to IRB administrator by email)* ☐ No

FACULTY SUPERVISOR (if researcher is a student):

Name: (First, MI, Last) _____

Title/Rank: _____ Department: _____

Campus Mailbox: _____ Phone Number or Ext: _____

Email Address: _____

Has completed training modules and is aware of all KWU policies regarding the ethical treatment of human subjects in research in the last 3 years: ☐ Yes *(Please submit all required attachments to IRB administrator by email)* ☐ No

CO-INVESTIGATOR INFORMATION OR ☐ N/A

(If more than one co-investigator, please provide their information on a separate Word document)

Name (First, MI, Last): _____ MyKWU ID Number: _____

Degree: _____ Department: _____

Phone Number or Ext: _____

Email Address: _____

☐ Faculty Member ☐ Undergraduate Student ☐ Graduate Student ☐ Other: _____

Has completed training modules and is aware of all KWU policies regarding the ethical treatment of human subjects in research in the last 3 years: ☐ Yes *(Please submit all required attachments to IRB administrator by email)* ☐ No

PROJECT INFORMATION

1. Descriptive Title of your Proposed Project: _____

_____

2. Level of Project:

☐ Faculty Research ☐ Student Research: ☐ Thesis ☐ Honors Project ☐ Class Project ☐ Other (specify) _____

3. Expected Completion Date: _____

4. Type of Review Requested (Required)

☐ New: ☐ Exempt ☐ Expedited ☐ Regular (Full committee)

☐ Previously approved: IRB Number: _____

☐ Change in Title or Funding Agency ☐ Modification/Addendum ☐ Annual Review

If you believe your project using human subjects should be determined to be exempt by the IRB based upon criteria found in **45 CFR 46.104 Exempt Research, please check the categories of exemption for which you are applying**.
Exemptions explained at: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c2

_____ 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. 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.

_____ 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.
NOTE: When subjects are children, this may only apply to research involving educational tests or observation of public behavior when the investigators do not participate in the activity being observed. [45 CFR 46.104(b)(3)]

_____ 3. 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;
(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.

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.

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. **NOTE: Research activities involving children do not qualify under this exemption.**

_____ 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 under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); 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 laws.

_____ 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 (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements,

cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. **NOTE: The Federal department or agency must publish a list of projects prior to the start of research.**

_____ 6. Taste and food quality evaluation and consumer acceptance studies

_____ 7. Storage or maintenance for secondary research for which broad consent is required: 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 determinations

_____ 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:

(a) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
(b) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
(c) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
(d) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

5. Research Design: ☐ Experimental ☐ Quasi-Experimental ☐ Non-Experimental *(e.g. descriptive, correlation)*

☐ Other (specify): _____

6. Is the research Funded? ☐ Yes ☐ No ☐ Plan to submit for funding ☐ Have requested funding, awarding decision

☐ Funding Agency or Source (if applicable): _____ *(Please submit all required attachments to IRB administrator by email)*

7. List all locations, including off campus locations, where the study activities will take place:

8. Will multiple institutions (other Universities, etc.) participate in the study? ☐ Yes (complete # 8.1a-8.1c) ☐ No (proceed to #9)

8.1a. Please list all participating institutions:

8.1b. Has the IRB at the institution(s) listed above approved the study? ☐ Yes *(submit copy of approval letter)*

☐ No, explain: _____

8.1c. Will the PI oversee or coordinate the research being conducted at the non-KWU site(s)? ☐ Yes ☐ No
If yes, describe the PI's oversight plans (e.g. including how PI will ensure adherence to study protocol, obtain informed consent, monitor unanticipated problems, and secure and maintain IRB approval at other sites).

9. Non-Technical Synopsis: Please summarize the purpose of the proposed research activity using non-technical language that can readily be understood by somone outside of the discipline. Please avoid jargon and overly technical descriptions. Explain what is intended to be discovered; include goals, aims, objectives, address gaps in current knowledge, and or/ state the hypothesis to be tested. (the description must be detailed enough so that the IRB members can make an informed decision about the proposal):

10. Procedures: Describe the setting and tasks subjects will be asked to perform. Describe the frequency and duration of procedures, tests, and experiments. Note if you are using standardized tests, questionnaires, interviews, internet or other. Note how this is being recorded (e.g. written notes, audiotape, videotape, webcam). Note administration process, (e.g. In person-group, In person-individual, telephone, mail, e-mail, other). A timeline or step by step listing is helpful.

11. Findings will be used for: ☐ Publication ☐ Thesis ☐ Needs assessment ☐ Evaluation ☐ Other (specify): _____

RECRUITMENT & SUBJECTS

Describe the recruitment process for the study. Explain how you will gain access to and recruite the subjects for participation. Identify all applicable recruitement methods (e.g. flyers, poster, personal/professional contacts, internet listserves, email, social media, other)

Are you recruiting students from a class you teach or for which you have responsibility? ☐ Yes ☐ No

Are you recruiting employees who directly or indirectly report to you? ☐ Yes ☐ No

If you answered Yes, to the above, please explain why this population is necessary and describe what precautions have been taken to minimize potential undue influence or coercion.

Number of Subjects or Records to Be Accessed: _____

Provide the number of subjects you expect to use and a brief rationale for your sample size. (minimum of 25 participants per study variable to generate reliable averages)

Ethical Issues Information

Does your research involve any of the following:

Yes	No	Question
		Deception (misleading information or false feedback)
		Shock or other forms of punishment
		Sexually explicit materials (e.g. exposure to pornographic materials-readings, videos)
		Sexual experience/practice/attitudes (e.g. discussion of behaviors, fetishes)
		Sexual orientation
		Sexual abuse
		Handling of money
		Extraction of blood
		Extraction of other bodily fluids (if yes, please specify) Text box entry
		Information pertaining to substance use
		Information pertainint to illegal activity
		Purposeful creation of anxiety
		Use of private information without consent
		Physical and/or Mental stress
		Administration of substances (food, drugs, etc.—please specify) Text box entry
		Mechanical or electrical device applied to subjects (e.g. TENS units, biofeedback)
		Information that if released could damage an individual's financial standing, employability, reputation, or cause social stigmatization or discrimination
		Any other procedure that might place participants at risk (specify): Text box entry

If you answered "Yes" to any of these, please provide an explanation, ethical justification, and discuss the special protections being implemented to minimize risk and how you would adequately protect participants. If using deception, include a justification for the deception.

SPECIAL POPULATIONS

Does your research recruit from any of the following vulnerable populations (check all that apply):

Yes	No	Question
		Under 18 (minors)
		Over 65
		Non-English speakers
		Physically disabled
		Mentally or developmentally disabled persons?
		Economically disadvantaged
		Educationally disadvantaged
		Individuals with diminished capacity to provide informed legal consent
		Pregnant female as target population
		Subject in an institution (prison, hospital, halfway home—please specify)
		Victims (e.g. crime, abuse, catasrophic events/war)

If you answered "Yes" to any of these, please provide an explanation and discuss the special protections being implemented to minimize risk of coercion or undue influence.

RISK/BENEFIT INFORMATION:

Yes	No	Question
		In your opinion, does the research involve more than minimal risk to participants?

If you answered "Yes," provide an explanation of the benefits of the research to the participants and to the discipline or profession.

When risks are greater than minimal, list the steps that will be taken to minimize the risks or harm to protect the subject's welfare?

Should unforseen or unintended problems arise from the research (such as dealing with upset or emotionally distraught subjects; emergencies or adverse reactions (physical, psychological, social, legal, etc.) What is your plan for responding to any of these? Include specific sources.

(Do not say N/A-it cannot be assumed that there are no risks)

Yes	No	Question
		Do subjects leave the study or experiment in approximately the same emotional state as they began? If no, then explain how distress will be handled (usually this involves a more detailed informed consent and debriefing).
		Do you preserve the anonymity of participants? If no, explain why and describe how you will protect the identity of participants.

If you answered "No" to any of these, please provide an explanation.

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

Note: Your potential/actual risks/benefits should be included in the informed consent.

Is compensation offered? ☐ Yes ☐ No

If yes, describe amount, type (gift card,etc) and when:

CONFIDENTIALITY

How will you safeguard data that includes identifiable or potentially identifiable information (e.g. coding, pseudonyms)

When will identifiers be separated or removed from the data?

How and where will data be stored? *Based on the longest required retention period under various federal regulations, research records must be maintained for a minimum of 5 years after completion.*

How will you dispose of data (e.g. shredding data, erasing tapes)?

INFORMED CONSENT

The basic elements of informed consent are noted by the Office of Human Research Protections:

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html#nodequeue_14-page_4-30

NOTE: It is a federal requirement to maintain informed consent forms for 3 years after the study completion date.

Informed consent is an critical component of human subjects research and it is your responsibility to make sure that potential subjects are well informed of what the project that you are planning is about. Please review this information and KWU's sample copy of informed consent. Informed Consents are to be written in language that the person can understand, therefore it is necessary to adapt the presentation of information to the subject's capacities (e.g. avoid jargon, child vs. adult) and MUST include: 1) A statement about the purposes of the research, 2) a description of the procedures to be followed, 3) the expected duration of the subject's participation, 4) a description of any reasonably foreseeable risks or discomforts, 4) a description of any reasonably expected benefits to the participant and/or others, 5) a statement describing the extent to which confidentiality of records will be maintained, 5) a description of any compensation to the participant if applicable, 6) contact information for researcher, supervisor, and IRB in case of questions, and 7) a statement that participation is voluntary, that participants may choose to not participate or discontinue their participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. If participants are unable to provide their own consent, please provide copies of the assent form (in simplified language) and the consent form to be signed by a parent/guardian. A written consent is not required for "exempt" level submissions unless participants will be audio- or video-taped or unless participants are minors, but is required for all "expedited" and "regular" level submissions. Please copy and paste your informed consent or attach it to this application ***(Required)***

Specify the type of informed consent you will use in this research project:

Type of Consent:

☒ Adult

☐ Parent/Gaurdian (for minors)

☐ Assent (for minors with script and procedures)

☐ Foreign language version

☐ Other: _____

Are you requesting a waiver of consent or assent? ☐ Yes ☑ No

If yes, please select how the research meets the federal criteria (45 CFR 46.116). In order for an IRB to waive consent, the IRB must find and document that:

☐ The research involves no more than minimal risk to the subjects;

☐ The research could not practicably be carried out without the requested waiver or alteration;

☐ 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;

☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

☐ Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Include your research instructions and debriefing that will be given to the participants (orally or written). If participants are not debriefed, explain why. Debriefing generally involves an educational process whereby the participant learns about the hypotheses and theories involved (including disclosure of any deception) and is given the opportunity to provide feedback about the research process. Every attempt should be made to undo any ill effects so that participants leave in as good as, if not better, a state than they were when they began.

Please attach a copy of any questionnaires, tests, or stimulus materials that will be given or presented to the participants.

FOR ALL RESEARCHERS:

I certify that the information provided in this application is complete and correct to the best of my knowledge and ability. I hereby certify that I have completed training on and am aware of all KWU policies regarding the ethical treatment of human subjects in research. I have attached evidence of my training quiz scores to this application or have previously submitted evidence of training (if completed within the last 3 years). I understand that I have the ultimate responsibility for the conduct of the study, ethical performance of the project and the protection of the rights and welfare of human subjects. I agree to adhere to the stipulations imposed by the IRB of Kansas Wesleyan University.

Signature: _____ Date: _____

Signature: _____ Date: _____

Signature: _____ Date: _____

FACULTY ASSURANCE (When serving as supervisor)**:**

I hereby certify that I have reviewed this project and application with the student and have approved their submission to the IRB Council. I accept responsibility to ensure that all study personnel are adequatley trained for their role and assue that I will retain research related records for audit including all documents subject to requirements of Code of Federal Regulations Title 45 Part 46 Protection of Human Subjects and Kansas Wesleyan University Policy.

Faculty Signature: _____ Date: _____

Save this document and send it to the IRB Council Chair with the following format:
Lastname_firstname_Semester_Year_IRB_Submission