FOR OFFICE USE ONLY:	IRB Protocol #	Application Received:	Routed:	Training Complete:

KANSAS STATE UNIVERSITY
University Research Compliance Office

Committee for Research Involving Human Subjects (IRB)
Application for Approval Form

Please send your completed application to comply@k-state.edu

Last Revised: 1/18/2019

ADMINISTRATIVE INFORMATION:

Title of Project/Course: Tip: Decide what you want to call your research study.

Type of Application: (check one box)
☐ New / Renewal ☐ Revision (to a pending new application)
☐ Modification to an existing approved application #: on approval letter

Principal Investigator Details: (must be a KSU faculty member):

Name: Degree/Title:

Department: Campus Phone:

Campus Address:

E-mail: Fax #:

Responsible Graduate Student: (Person to contact for questions/problems with the form):

Name: Campus Phone:

E-mail:

Does this project involve any collaborators not part of the faculty/staff at KSU? (projects with non-KSU collaborators may require additional coordination and approvals):

☐ No ☐ Yes

Project Classification (Is this project part of one of the following?):

☐ Thesis ☐ Dissertation ☐ Faculty Research
☐ Other:

Note: Class Projects should use the short form application for class projects.

Copy of the Consent Form: ☐ Copy will be submitted to comply@ksu.edu with this application ☐ Consent form not used

Funding Source: ☐ Federal ☐ State ☐ Internal ☐ Other

Funding Agency: Please give name of Funding Agency. (You will also need to provide a copy of the sponsor's grant application or contract as submitted to the funding agency. Submit documents to comply@ksu.edu with your application.)

Based upon criteria found in 45 CFR 46 – and the overview of projects that may qualify for exemption explained at http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html, I believe that my project using human subjects should be determined by the IRB to be exempt from IRB review:

☐ No ☐ Yes (If yes, please provide the category of "Exemption" in the space below)

Exempt Projects: 45 CFR 46 identifies six categories of research involving human subjects that may be exempt from IRB review. The categories for exemption are listed here: **http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c2** If you believe that your project qualifies for exemption, please indicate which exemption category applies (1-6). Please remember that only the IRB can make the final determination whether a project is exempt from IRB review, or not.

Exemption Category:

MODIFICATION:

Is this a modification of an approved protocol? ☐ **No** ☐ **Yes** **If yes, please comply with the following:**

If you are requesting a modification or a change to an IRB approved protocol, please provide a concise description of all of the changes that you are proposing in the following block. Additionally, please highlight or bold the proposed changes in the body of the protocol where appropriate, so that it is clearly discernible to the IRB reviewers what and where the proposed changes are. This will greatly help the committee and facilitate the review.

Tip: If you've previously submitted and received approval of an IRB application for your study, and you want to make some modifications (e.g., use a new data collection method, collect data from a new audience), you should submit a modification rather than a new application. Start with your original application content. [Note. Make sure you are using the most current version of the IRB application form; if your original application used an older form, you will need to transfer the content over to the new form.] Mark the application as a modification at the top of this page and immediately above. Describe the changes/additions to your study here. Then, throughout the application make updates to sections as needed to reflect the changes to your study. Be sure to highlight additions so reviewers can easily see what is new. For example, you can **bold**, underline, and/or *italicize* the new/changed text by holding down the Control button and the B, U, or I keys, respectively.

I. NON-TECHNICAL SYNOPSIS (Please provide a brief narrative description of proposal. This should typically be less than 75 words and be easily understood by nonscientists):

Tip: Describe your study as you would to a family member, friend, or neighbor. Keep it simple and brief. This is the one response box in the application that specifies a word limit, so try to limit your response to 75 words, as instructed. To check the word count, you can paste the text into a Microsoft Word document and use the Word Count function on the Review tab.

II. BACKGROUND (concise narrative review of the literature and basis for the study):

Tip: Make a case for your study as you would in the literature review section of a grant proposal, thesis, dissertation, or journal article. If you've already developed a literature review related to your study, you won't need to start from scratch (e.g., paste information from your grant or thesis proposal). The instructions request you keep it concise, so only include as much information as you think is necessary to explain the need for your study. This is not expected to be long (it might be half a page or so).

III. PROJECT/STUDY DESCRIPTION

(Please provide a concise narrative description of the proposed activity in terms that will allow the IRB or other interested parties to clearly understand what it is that you propose to do that involves human subjects. This description must be in enough detail so that IRB members can make an informed decision about the proposal).

Tip: Provide basic details on your study (e.g., who, what, where, when, and how). From whom will you collect data (specify the target audience(s) - e.g., university students, K-12 teachers/administrators)? How will you collect the data (specify the method(s) - e.g., web-based survey, face-to-face interviews)? What will be the focus/topic of the data collection (e.g., gaining feedback on a specific event, curriculum, program)? When will you collect the data (e.g., how many times - once, before and after an intervention)? Where will you collect data (e.g., virtually, or onsite at specific locations). Keep it concise; you will provide additional details further into the application.

IV. OBJECTIVE

(Briefly state the objective of the research – what you hope to learn from the study).

Tip: List the research questions/hypotheses your study is seeking to answer/test.

V. DESIGN AND PROCEDURES (succinctly outline formal plan for study)

A. List all sites where this research will be conducted:

Tip: List specific locations where your data will be collected (e.g., names of universities, cities, schools). If data collections will be virtual (e.g., web-based surveys, telephone/Zoom interviews), indicate that as well.

B. Variables to be studied:

Tip: Describe the types of information you will be asking from participants. For example, will you be asking participants' feedback related to specific programs or curriculum (strengths, areas for improvement, impacts)? Will you be collecting their responses related to specific research

constructs? Make sure the instruments (e.g., surveys, interview questions) submitted with your application focus on the variables listed here.

C. Data collection methods: (surveys, instruments, etc **- copies must submitted to comply@k-state.edu**).

Tip: Describe the methods you will use to collect data from your participants. For example, will you collect data through surveys (hard copy, web-based), interviews (face-to-face, telephone, video), focus groups (face-to-face, video), observation, or others? Specify if you will use different methods with different audiences (e.g., interviews with school administrators, web-based surveys with teachers).

D. List any factors that might lead to a subject dropping out or withdrawing from a study. These might include, but are not limited to emotional or physical stress, pain, inconvenience, etc.

Tip: It is okay to say "None". At OEIE, we typically say "Participants may not participate or may withdraw from data collections if they are too busy."

E. List all biological samples taken: (if any)

Tip: If you are not taking biological samples, say "Not Applicable."

Describe storage and disposition of biological samples: (How long will samples be kept, will samples be used for other purposes, how will samples be destroyed)

Tip: If you are not taking biological samples, say "Not Applicable."

Will whole genome sequencing be used:

☐ **No**

☐ **Yes**

F. Debriefing procedures for participants:

Tip: Describe what you plan to say to participants at the conclusion of the data collection (e.g., in a closing message on a survey, or verbally as you end an interview). Explain next steps for the study (what you will be doing with the data) and the extent to which their data will be kept confidential. Also provide contact information for the study researcher and the K-State Research Compliance Office, in case participants have follow-up questions.

VI. RESEARCH SUBJECTS:

A. Source:

Tip: List all of your target audience(s). From whom will you be collecting data (e.g., K-12 teachers, K-12 students, university students, university faculty/staff)?

B. Number: (provide a brief rationale for your sample size)

Tip: It is okay to provide an estimate or approximate number. If you have multiple target audiences listed as Sources in the box above (e.g., K-12 teachers and K-12 students), provide an estimate for each audience. For example, "Approximately 10 K-12 teachers and 200 K-12 students."

C. Inclusion criteria: (List any unique qualifiers desirable for research subject participation)

Tip: Explain how you will select your sample of participants. Will you target individuals attending an event or participating in a specific program/course?

D. Exclusion criteria: (list any unique disqualifiers for research subject participation)

Tip: Explain how you will limit your sample of participants. For example, it may be the opposite of your inclusion criteria (e.g., anyone who does not attend the event, or participate in the program/course, will not be asked to participate).

E. Recruitment procedures:
How will subjects be identified?

Tip: Describe how you will determine your list of participants. For example, will a course instructor provide a list of students in the course, or will an event organizer provide a list of people who attended the event? Will a sign-up sheet be posted where individuals can sign up to participate (participants identify themselves)?

How will subjects be recruited (advertisement, associates, etc.) ?

Tip: Describe how potential participants will become aware of the opportunity to participate in the study. For example, will you post a flyer or sign-up sheet? Will the course instructor inform their students of the study? Will you contact the participants directly by email? Or a combination of methods?

How will subjects be enrolled?

Tip: Describe how individuals become participants in your study. For example, do they respond to your email with interest in participating? Do they enter their name on a sign-up sheet? Do they show up at the identified data collection time/ location? Do they respond to a survey?

Describe any follow-up recruitment procedures: (reminder emails, mailings, etc.)

Tip: Describe what you will do following the initial recruitment efforts you described above. For example, will you send email reminders periodically to individuals who have not yet responded to your initial email invitation? Will you ask a course instructor or other contact to reach out to potential participants to remind them of the study and encourage their participation? Will you attempt to contact individuals by telephone?

VII. RISK - PROTECTION - BENEFITS: The answers for the three questions below are central to human subjects research. You must demonstrate a reasonable balance between anticipated risks to research participants, protection strategies, and anticipated benefits to participants or others.

A. Risk for Subjects: (check all that apply)

- ☐ Exposure to infectious diseases
- ☐ Use of confidential records
- ☐ Exposure to radiation
- ☐ Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stressors
- ☐ Examining for personal or sensitive information in surveys or interviews
- ☐ Presentation of materials which subjects might consider sensitive, offensive, threatening, or degrading
- ☐ Invasion of privacy of subject or family
- ☐ Social or economic risk
- ☐ Risk associated with exercise or physical exertion
- ☐ Legal risk
- ☐ Review of medical records
- ☐ Review of criminal records
- ☐ HIV/AIDS or other STD's
- ☐ Employment/occupational risk
- ☐ Others – Please explain below (Indirect risks, risk to individuals who are not the primary subjects):

B. Minimizing Risk: (Describe specific measures used to minimize or protect subjects from anticipated risks.)

Tip: Considering risks you identified above, describe how you will attempt to protect participants from those risks. Describe how participants' data will be kept confidential. For example, will results be reported in aggregate, with no participants identified in reports or presentations of findings? Will you not report back to course instructors or program coordinators who has vs. has not participated?

C. Benefits: (Describe any reasonably expected benefits for research participants, a class of participants, or to society as a whole.)

Tip: Describe what are you hoping to learn, and whom that knowledge will benefit. For example, will your study result in improved curriculum or instruction for the preparation of future teachers, and improved learning outcomes for students? Will results of your study possibly help to secure future funding?

D. More than Minimal Risk? In your opinion, does the research involve more than minimal risk to subjects? ("Minimal risk" means that "the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.")

☐ Yes ☐ No

VIII. CONFIDENTIALITY:

Confidentiality is the formal treatment of information that an individual has disclosed to you in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure. Consequently, it is your responsibility to protect information that you gather from human research subjects in a way that is consistent with your agreement with the volunteer and with their expectations.

A) Explain the type of data that will be collected (electronic, hard copy, video, specimens, etc.):

Tip: Describe all forms of data you will record. For example, will you use web-based or hard-copy surveys? Will you record audio or video files or take hard-copy notes of interviews, focus groups, or observations? Will you take pictures?

B) Explain where the data will be stores:

Tip: Describe how all types of data will be stored. For example, will you store hard-copy data (surveys, notes) in a locked office or locked filing cabinet? Will you store electronic data (audio files, video files, pictures, web-based survey data files) on a password-protected computer? If you collect data through web-based surveys, will data be saved within the online survey system?

C) Explain the time frame of the data storage, to include how data will be distroyed:

Tip: Describe what data will be stored during the course of the study as well as after the study concludes. For example, will you keep all hard-copy data (surveys, notes) throughout the course of the study, or will you shred the data once you've saved it into an electronic format (e.g., scanned it, entered it into a spreadsheet)? Once the study concludes, will you archive the data for additional analysis or documentation purposes, or destroy it?

D) Explain who will have access to the data, and privacy/security provisions (password protection, encryption, etc.):

Tip: Individuals who will have access to the raw data (during data collection or afterward) should be listed as Project Collaborators (KSU or non-KSU) further into the application (Section XIV). You should indicate that only people listed as collaborators on the application will have access to the data. Further, describe how these individuals will access the data. For example, will there be a password-protected shared network drive/folder that only the collaborators will have the password/access to? If you plan to use an external transcription service for audio files, you will need to describe that exception where a non-collaborator will have access to the data here; also specify the transcription service you plan to use and how you will maintain privacy (e.g., audio files will not be tied to participant names).

IX. INFORMED CONSENT:

Informed consent is a critical component of human subjects research - it is your responsibility to make sure that any potential subject knows exactly what the project that you are planning is about, and what his/her potential role is. (There may be projects where some forms of "deception" of the subject is necessary for the execution of the study, but it must be carefully justified to and approved by the IRB). A schematic for determining when a waiver or alteration of informed consent may be considered by the IRB is found at **http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c10**

Even if your proposed activity does qualify for a waiver of informed consent, you must still provide potential participants with basic information that informs them of their rights as subjects, i.e. explanation that the project is research and the purpose of the research, length of study, study procedures, debriefing issues to include anticipated benefits, study and administrative contact information, confidentiality strategy, and the fact that participation is entirely voluntary and can be terminated at any time without penalty, etc. Even if your potential subjects are completely anonymous, you are obliged to provide them (and the IRB) with basic information about your project. See informed consent example on the URCO website. It is a federal requirement to maintain informed consent forms for 3 years after the study completion.

Answer the following questions about the informed consent procedures.

☐ Yes ☐ No **A.** Are you using a written informed consent form? If "yes," include a copy with this application. If "no" see B.

☐ Yes ☐ No **B.** In accordance with guidance in 45 CFR 46, I am requesting a waiver or alteration of informed consent elements (see section VIII above). If "yes," provide a basis and/or justification for your request.

Tip: There is an option to not use a written consent form requiring a participant's signature prior to participation in your study. The sample informed consent form available on K-State's Research Compliance Office website outlines cases where a waiver or alteration to using a written consent form may be approved. If you request a waiver or alteration to using a written consent form, you will need to explain here why you are making this request and will have to provide a copy of your plan to provide consent elements in a different format.

☐ Yes ☐ No **C.** Are you using the online Consent Form Template provided by the URCO? If "no," does your Informed Consent document have all the minimum required elements of informed consent found in the Consent Form Template? (Please explain)

Tip: The sample informed consent form available on K-State's Research Compliance Office website can be modified to fit your study. If you do not plan to use this consent form template, you must describe the consent elements you will be providing to participants and how.

☐ Yes ☐ No **D.** Are your research subjects anonymous? If they are anonymous, you will not have access to any information that will allow you to determine the identity of the research subjects in your study, or to link research data to a specific individual in any way. Anonymity is a powerful protection for potential research subjects. (An anonymous subject is one whose identity is unknown even to the researcher, or the data or information collected cannot be linked in any way to a specific person).

Tip: If participants are not anonymous (names are tied to data), you should check no. This is typically the case for OEIE's data collections, and we say "Data will be confidential and will only pertain to gathering project stakeholders' input/feedback about the program."

☐ Yes ☐ No **E.** Are subjects debriefed about the purposes, consequences, and benefits of the research? Debriefing refers to a mechanism for informing the research subjects of the results or conclusions, after the data is collected and analyzed, and the study is over. (If "no" explain why.) **Copy of debriefing statement to be utilized should be submitted to comply@k-state.edu with your application.**

Tip: You should check yes and include a sample debriefing statement. For example, OEIE has used "Thank you for your participation in this evaluation activity. Your responses will be compiled with other individuals' responses to identify ways to improve the program. Your name will not be used in any report. If you have any questions, please contact [insert evaluation team contact information and program leadership contact information]. You may also contact the Compliance Office at Kansas State University with questions about the evaluation (comply@ksu.edu)." Like with your consent elements, your debriefing statements should be included with instrumentation submitted with your application.

F. Describe the Informed Consent Process:

Who is obtaining the consent? (i.e. Principle Investigator, Graduate Student, etc.)

Tip: Indicate who will be providing the consent form/elements and gaining participants' consent prior to their participation in the data collection. For example, who will be gaining signatures on consent forms? Who will be administering the survey or conducting the interviews/focus groups? Will another entity be assisting with gaining consent prior to the data collection (e.g., a school)?

When and where will consent be obtained?

Tip: Frequently participants are provided with informed consent elements immediately before participating in a data collection activity and are required to indicate consent (e.g., sign a consent form) before participating. It is possible in some situations that consent elements/forms are provided further in advance of the data collection.

If assent (for minors) is required, please describe who will obtain the assent? (Assent means a child's affirmative agreement to participate in research)

Tip: If your research does not involve minors, enter "Not Applicable."

If assent (for minors) is required, when and where will assent be obtained?

Tip: If your research does not involve minors, enter "Not Applicable."

How will consent be obtained from non-English speaking participants? (a translated written form, orally, identify the name and qualifications of the individual providing the translation)

Tip: If your research does not involve non-English speaking participants, enter "Not Applicable."

Informed Consent Checklist

Items	YES	NO	N/A
Does the title appear at the top of the consent/assent form?	☐	☐	☐
Is the consent/assent form written toward the subject?	☐	☐	☐
Is there a statement that explains that the study is *research*?	☐	☐	☐
Is there a statement that explains the *purpose* of the research?	☐	☐	☐
Are the procedures to be followed explained clearly and adequately?	☐	☐	☐
Does the consent document describe *risks or discomforts* to subjects as a result of participating in the research?	☐	☐	☐
Is the consent/assent form written in the *native language* of the potential subject?	☐	☐	☐
Are participants compensated?	☐	☐	☐
If the subjects' identity is known to the PI, does the form detail how confidentiality of records will be maintained?	☐	☐	☐
Is contact information for both the PI and the URCO/IRB office included?	☐	☐	☐
Does the consent document indicate to the participant that he/she can withdraw at any time from the project without penalty or loss of benefit?	☐	☐	☐
Are there probable circumstances which would require the PI to terminate a subject's participation regardless of his or her consent?	☐	☐	☐
A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent	☐	☐	☐
A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.	☐	☐	☐
A statement that biospecimens (even after identifiers are removed) may (or may not) be used for commercial profit.and whether subjects will or will not share in the profit.	☐	☐	☐
A statement that clinically relevant research results will or will not be provided to subjects. .	☐	☐	☐
A statement indicating whether or not the research project will or will not include whole genome sequencing. .	☐	☐	☐
Is the consent document written in lay language (Recommended 8th grade level)?	☐	☐	☐

X. PROJECT INFORMATION: (If you answer Yes to any of the questions below, you should explain them in one of the paragraphs above)

☐ Yes ☐ No A. Deception of subjects? If "YES" explain why this is necessary.

☐ Yes	☐ No	B.	Shock or other forms of punishment
☐ Yes	☐ No	C.	Sexually explicit materials or sexual experience
☐ Yes	☐ No	D.	Sexual orientation
☐ Yes	☐ No	E.	Sexual abuse
☐ Yes	☐ No	F.	Handling of money or other valuable commodities
☐ Yes	☐ No	G.	Extraction or use of blood, other bodily fluids, or tissues (if "yes', you must comply with facility and handling protections detailed in the 5th Edition of the Biosafety in Biomedical Laboratories (BMBL))
☐ Yes	☐ No	H.	Questions about any kind of illegal or illicit activity
☐ Yes	☐ No	I.	Questions about protected health information as defined by HIPAA
☐ Yes	☐ No	J.	Purposeful creation of anxiety
☐ Yes	☐ No	K.	Any procedure that might be viewed as invasion of privacy
☐ Yes	☐ No	L.	Physical exercise or stress
☐ Yes	☐ No	M.	Administration of substances (food, drugs, etc.) to subjects
☐ Yes	☐ No	N.	Any procedure that might place subjects at risk
☐ Yes	☐ No	O.	Will there be any use of Radioactive materials and/or use of Radioactive producing machines
☐ Yes	☐ No	P.	Any form of potential abuse; i.e., psychological, physical, sexual
☐ Yes	☐ No	Q.	Is there potential for the data from this project to be published in a journal, presented at a conference, etc?
☐ Yes	☐ No	R.	Use of surveys or questionnaires for data collection. **Copies should be submitted to comply@k-state.edu with your application.**
☐ Yes	☐ No	S.	Is this a Clinical Trial? (one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.)

XI. SUBJECT INFORMATION: (If you answer yes to any of the questions below, you should explain them in one of the paragraphs above)

☐ Yes	☐ No	a.	Under 18 years of age (these subjects require parental or guardian consent)
☐ Yes	☐ No	b.	Over 65 years of age
☐ Yes	☐ No	c.	Minorities as target population
☐ Yes	☐ No	d.	Physically or mentally disabled
☐ Yes	☐ No	e.	Economically or educationally disadvantaged
☐ Yes	☐ No	f.	Unable to provide their own legal informed consent
☐ Yes	☐ No	g.	Pregnant females as target population
☐ Yes	☐ No	h.	Victims
☐ Yes	☐ No	i.	Subjects in institutions (e.g., prisons, nursing homes, halfway houses)
☐ Yes	☐ No	j.	Are subjects likely to be vulnerable to coercion or undue influence
☐ Yes	☐ No	k.	Is this international research? If yes, provide details as to if OHRP regulations apply in or near the area you intend to conduct research or if you have contacted individuals for applicable regulations to human subject research.
☐ Yes	☐ No	l.	Are research subjects in this activity students recruited from university classes or volunteer pools? If so, do you have a reasonable alternative(s) to participation as a research subject in your project, i.e., another activity such as writing or reading that would serve to protect students from unfair pressure or coercion to participate in this project? If you answered this question "Yes," explain any alternatives options for class credit for potential human subject volunteers in your study. (It is also important to remember that: Students must be free to choose not to participate in research that they have signed up for at any time without penalty. Communication of their decision can be conveyed in any manner, to include simply not showing up for the research.)

☐ Yes ☐ No m. Is audio from the subjects recorded? If yes, how do you plan to protect the recorded information and mitigate any additional risks?

Tip: OEIE records audio, so we typically say "To accurately document participants' responses in focus groups and interviews, they will be audio taped with the permission of the participants. OEIE will store audio data on a computer network drive. The computer will remain password protected and only those involved in the evaluation project (listed as collaborators) will have access to the data." If you plan to use an external transcription service for audio files, you will need to describe that exception where a non-collaborator will have access to the data here; also specify the transcription service you plan to use and how you will maintain privacy (e.g., audio files will not be tied to participant names).

☐ Yes ☐ No n. Are research subjects' images being recorded (video taped, digitally recorded, photographed)? If yes, how do you plan to protect the recorded information and mitigate any additional risks?

XII. FDA ACTIVITIES:

Answer the following questions about potential FDA regulated activities:

☐ Yes ☐ No a. Is this a Clinical Trial?

☐ Yes ☐ No b. Are you using an FDA approved drug/device/diagnostic test?

☐ Yes ☐ No c. Does this activity involve the use of FDA-Regulated products? (biological products, color additives, food additives, human drugs, etc.)

☐ Yes ☐ No d. Has the protocol been submitted to the FDA, or are there plans to submit it to the FDA?

☐ Yes ☐ No e. Have you submitted an FDA form 3454 or 3455 (conflict of interest)?

XIII. CONFLICT OF INTEREST:

Concerns have been growing that financial interests in research may threaten the safety and rights of human research subjects. Financial interests are not in them selves prohibited and may well be appropriate and legitimate. Not all financial interests cause Conflict of Interest (COI) or harm to human subjects. However, to the extent that financial interests may affect the welfare of human subjects in research, IRB's, institutions, and investigators must consider what actions regarding financial interests may be necessary to protect human subjects. Please answer the following questions:

☐ Yes ☐ No a. Do you or the institution have any proprietary interest in a potential product of this research, including patents, trademarks, copyrights, or licensing agreements?

☐ Yes ☐ No b. Do you have an equity interest in the research sponsor (publicly held or a non-publicly held company)?

☐ Yes ☐ No c. Do you receive significant payments of other sorts, eg., grants, equipment, retainers for consultation and/or honoraria from the sponsor of this research?

☐ Yes ☐ No d. Do you receive payment per participant or incentive payments?

e. If you answered **yes** to any of the above questions, please provide adequate explanatory information so the IRB can assess any potential COI indicated above.

XIV. PROJECT COLLABORATORS:

A. KSU Collaborators: List anyone affiliated with KSU who is collecting or analyzing data: (list all collaborators on the project, including co-principal investigators, undergraduate and graduate students).

Enter all KSU individuals who will have access to the raw data (collection and analysis). Each person has

Name:	Department:	Campus Phone:	Campus E-mail:
to complete IRB training prior to approval of the application.			

Add Row | Delete Row

B. **Non-KSU Collaborators**: List all collaborators on your human subjects research project not affiliated with KSU in the spaces below. KSU has negotiated an Assurance with the Office for Human Research Protections (OHRP), the federal office responsible for oversight of research involving human subjects.

Name:	Organization:	Phone:	Institutional E-mail:
Enter all non-KSU individuals who will have access to the raw data (collection and analysis). Each person has to complete IRB training prior to approval of the application.			

Add Row | Delete Row

C. **Does your non-KSU collaborator's organization have an Assurance with OHRP?** (for Federalwide Assurance listings of other institutions, please reference the OHRP website under Assurance Information at: **http://ohrp.cit.nih.gov/search**).

☐ Yes ☐ No If yes, Collaborator's FWA #

Is your non-KSU collaborator's IRB reviewing this proposal?

☐ Yes ☐ No If yes, IRB approval #

Describe the non-KSU collaborator's role in the research activity.

Tip: Describe how the non-KSU collaborator will be involved. For example, will they assist in collecting the data and/or analyzing the data?

XV. IRB Training:

A. **The URCO must have a copy of the Unaffiliated Investigator Agreement on file for each non-KSU collaborator who is not covered by their own IRB and assurance with OHRP.** When research involving human subjects includes collaborators who are not employees or agents of KSU the activities of those unaffiliated individuals may be covered under the KSU Assurance only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. The Unaffiliated Investigators Agreement can be found and downloaded at **http://www.k-state.edu/research/comply/irb/forms**

Online Training

TRAINING REQUIREMENTS HAVE RECENTLY CHANGED

The IRB has mandatory training requirements prior to protocol approval. Training is now offered through the Collaborative Institutional Training Initiative (CITI) Program. Instructions for registration and access to training are on the URCO website http://www.k-state.edu/research/comply/.

Use the check boxes below to select the training courses that apply to this application. If you have any questions about training, contact URCO at comply@ksu.edu, or (785) 532-3224.

Mandatory Training

Required for all Principal Investigators, research staff and students

☒ Responsible Conduct of Research

☒ IRB core modules (IRB Researchers and personnel on IRB protocols)

Required (Provost-mandated) for all full-time K-State employees

☐ Export Compliance

Required procedure-specific training (check all that apply to this protocol):

☐ International Research ☐ Research in Public Elementary and Secondary Schools ☐ Research with Children

☐ Research with Prisoners ☐ Internet Research ☐ Vulnerable Subjects - Research Involving Workers/Employees

☐ Research with Subjects with Physical Disabilities and Impairments ☐ Illegal Activities or Undocument Status in Human Research

☐ Gender and Sexuality Diversity in Human Research ☐ Research with human blood, body fluids, or tissues

☐ Research with Older Adults

All new personnel or personnel with expired training are required to register for CITI and take the new training requirements. If you previously completed online IRB modules, your training status will remain current until it expires. URCO will verify training from the previous system as well as the new system prior to approval of any protocol.

INVESTIGATOR ASSURANCE FOR RESEARCH INVOLVING HUMAN SUBJECTS

(Print this page separately because it requires a signature by the PI.)

P.I. Name:

Title of Project:

XVI. ASSURANCES: As the Principal Investigator on this protocol, I provide assurances for the following:

A. Research Involving Human Subjects: This project will be performed in the manner described in this proposal, and in accordance with the Federalwide Assurance FWA00000865 approved for Kansas State University available at http://www.hhs.gov/ohrp/assurances/forms/filasurt.html, applicable laws, regulations, and guidelines. Any proposed deviation or modification from the procedures detailed herein must be submitted to the IRB, and be approved by the Committee for Research Involving Human Subjects (IRB) prior to implementation.

B. Training: I assure that all personnel working with human subjects described in this protocol are technically competent for the role described for them, and have completed the required IRB training accessed via the URCO website at: http://www.k-state.edu/research/comply/irb/training. I understand that no proposals will receive final IRB approval until the URCO has documentation of completion of training by all appropriate personnel.

C. Extramural Funding: If funded by an extramural source, I assure that this application accurately reflects all procedures involving human subjects as described in the grant/contract proposal to the funding agency. I also assure that I will notify the IRB/URCO, the KSU PreAward Services, and the funding/contract entity if there are modifications or changes made to the protocol after the initial submission to the funding agency.

D. Study Duration: I understand that it is the responsibility of the Committee for Research Involving Human Subjects (IRB) to perform continuing reviews of human subjects research as necessary. I also understand that as continuing reviews are conducted, it is my responsibility to provide timely and accurate review or update information when requested, to include notification of the IRB/URCO when my study is changed or completed.

E. Conflict of Interest: I assure that I have accurately described (in this application) any potential Conflict of Interest that my collaborators, the University, or I may have in association with this proposed research activity.

F. Adverse Event Reporting: I assure that I will promptly report to the IRB / URCO any unanticipated problems involving risks to subjects or others that involve the protocol as approved. Unanticipated or Adverse Event Form is located on the URCO website at: http://www.k-state.edu/research/comply/irb/forms. In the case of a serious event, the Unanticipated or Adverse Events Form may follow a phone call or email contact with the URCO.

G. Accuracy: I assure that the information herein provided to the Committee for Human Subjects Research is to the best of my knowledge complete and accurate.

You may sign this form using a digital signature. DO NOT sign the form until it has been completed.

You cannot edit the form entries once the form has been digitally signed. If you are making revisions to a previously signed form, right-click the digital signature and select Clear to remove the signature (this can only be done by the person who originally digitally signed the form). Forms that have not been signed will not be accepted.

P.I. Signature: Date: