KANSAS STATE UNIVERSITY

# Print xForm - IRB Application for Approval

IRB Application for Approval

## Data Entry

### Amendment Header

**Form Creator**

Dehart, MaKenna

**Email:** makenna@k-state.edu

**Principle Investigator Output**

N/A

**Department Output**

**College Output**

**Protocol Number Output**

**Please provide a concise description of all of the changes that you are proposing and the justification for the changes.** *(Required)*

*You will need to update the body of the protocol to reflect the modification request indicated above. All changes will automatically be highlighted.*

**Are you changing/amending personnel identified on the protocol?**
*(Required)*

○ Yes

○ No

**Personnal Change Types** *(Required)*

☐ Change in PI

☐ Removal of Personnel

☐ Additional of Personnel

**Enter in the new Principle Investigator**
*(Required)*

**Enter the names of personnel**
*(Required)*

*Repeat as necessary. Do not include the principle investigator.*

*No answer provided.*

**Addition of personnel:**
*(Required)*

*List each KSU person being added to this protocol. Please remember to click "Save" after each entry.*

### Administrative Information

**Instructions**

*The KSU IRB is required by law to ensure that all research involving human subjects is adequately reviewed for specific information and is approved prior to inception of any proposed activity. Consequently,*

*it is important that you answer all questions accurately. If you need help or have questions about how to complete this application, please call the Research Compliance Office at 532-3224, or e-mail us at comply@ksu.edu.*

**Form Creator**

Dehart, MaKenna

**Email:** makenna@k-state.edu

**Title of Project/Course** *(Required)*

**Principal Investigator** *(Required)*

*Principal investigator must be a K-State faculty member.*

**Degree/Title** *(Required)*

**Department** *(Required)*

**Campus/Cell Phone Number** *(Required)*

**Select/Provide College** *(Required)*

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

**Contact Phone**

**Project Classification** *(Required)*

- ☐ Thesis
- ☐ Dissertation
- ☐ Faculty research
- ☐ Other

**Other Explanation** *(Required)*

**Short form criteria** *(Required)*

*(**By clicking None of the Above, you will proceed to the full application.** If you are doing data analysis plus another form of data collection, do not select "existing data analysis only".)*

- ☐ Class Project
- ☐ Oral History
- ☐ Existing Data Analysis Only
- ☐ None of the Above

**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):** *(Required)*

○ Yes

○ No

**Funding Source** *(Required)*

☐ Federal

☐ State

☐ Internal

☐ Other

☐ N/A

**Please give the name of the Funding Agency:** *(Required)*

**Please provide a copy of the sponsor's grant application or contract as submitted to the funding agency, if applicable.**

**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:** *(Required)*

○ Yes

○ No

**Requested Exempt Category** *(Required)*

☐ 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.

☐ 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).

☐ 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.

☐ 4 Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens.

☐ 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.

☐ 6 Taste and food quality evaluation and consumer acceptance studies:

## Study Information

**Non-Technical Synopsis** *(Required)*

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

(Limited to 300 words.)

**Background** *(Required)*

*(concise narrative review of the literature and basis for the study):*

**Project/Study Description** *(Required)*

*(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).*

**Objective** *(Required)*

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

## Class Project Form

**Non-Research Class Project**

*This form is designed to document class projects that do not constitute research involving human subjects. The IRB is required by federal law (45 CFR 46) to review activities that involve human subjects in research. The regulations define research as: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purpose of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes". The key phrase is "to develop or contribute to generalizable knowledge."*

*If your class project does not constitute research in accordance with the federal definition above, you may use this simplified form - appropriate for non-research class projects only - to document your activity. To qualify as non-research under the federal definition, the data collected cannot be "generalized" (publications, presentations or disseminated outside the classroom in any fashion, including seminars, conferences, weblogs, social networks, etc). If you need clarification or have questions about how to complete this application, please call the Research Compliance Office at 532-3224, or e-mail us at comply@ksu.edu.*

**I have reviewed and understand the federal definition for research involving human subjects provided in the above paragraph:**

**(http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)**
*(Required)*

- ○ Yes
- ○ No

**I conclude that the class project described does not constitute research under the federal definition.**
*(Required)*

- ○ Yes
- ○ No

**I agree that the information or data gathered in this activity will not be "generalized or disseminated" in any way outside of the classroom.**
*(Required)*

- ○ Yes
- ○ No

**I understand that if activities in my class do constitute research under the federal definition above, the Application for Approval Form must be submitted to the IRB and approved prior to initiation of the activity involving research with human subjects.**
*(Required)*

- ○ Yes
- ○ No

**As you indicated no to the above following, please contact the IRB office for further discussion.**

**The items listed below are categories/topics that may be considered high risk. If selected as project topics you should proceed with caution. If these topics are involved, a full application to the IRB should be considered. Problematic activities might include but are not limited to:**

- *more than minimal risk encountered by subjects on a daily basis*
- *persons under 18 years of age (these subjects require parental or guardian consent)*
- *use of video taping or auto recording*
- *persons who are physically or mentally disabled*
- *subjects in institutions (e.g., prisons, nursing homes, halfway houses)*
- *pregnant females as target population*
- *persons 65 years and older as a target population*
- *ethnic or racial populations as a target population*
- *victims*
- *questions about any kind of illegal or illicit activity*
- *sexually explicit materials or questions about sexual orientation, sexual experience or sexual abuse*
- *any procedure that might be viewed as invasion of privacy*
- *deception of subjects*
- *any form of potential abuse; i.e., psychological, physical, sexual*
- *administration of substances (food, drugs, etc.) to subjects*
- *handling of money or other valuable commodities*
- *extraction or use of blood, other bodily fluids, or tissues*

**Class Number** *(Required)*

**Class Title** *(Required)*

**Project Description** *(Required)*

*Please provide a concise narrative description of the proposed activity in terms that will allow the URCO or other interested parties to clearly understand what it is that you propose to do that might involve project participants.*

**Procedure** *(Required)*

*Briefly state how the data for this project is to be collected.*

**Class Roster and Email Address Table**

*Please provide the class roster by either completing this table or attaching a copy of your class roster below.* ***It is not required to do both****.*

**Class Roster Attachment**

*Please attach a copy of the class roster if you did not complete the table above.*

## Oral History Form

**Non-Research Oral History Project Instructions**

*Complete this form if you believe that your oral history project in not research involving human subjects. The IRB is required by federal law (45 CFR 46) to review activities that do involve human subjects in research. The regulations define research as: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purpose of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes".*

*According to an Office for Human Research Protections policy statement, in general, oral history projects do not constitute research involving human subjects. It is primarily on the grounds that, oral history interviews are not designed to contribute to "generalizable knowledge". Rather, they are most often used to give a unique perspective on a particular topic, that they are not subject to the requirements of the HHS regulations at 45 CFR 46. Therefore, oral history projects can often be excluded from IRB review.*

*If you need clarification or have questions about how to complete this application, please call the Research Compliance Office at 532-3224, or e-mail us at comply@ksu.edu.*

**Based on the information above I conclude that my oral history project described below does not constitute research under the federal definition, and does not need to be reviewed by the IRB.** *(Required)*

- ○ Yes
- ○ No

**I understand that if my project does constitute human subjects research under the federal definition above, I must apply to the IRB for approval to do the project.** *(Required)*

- ○ Yes
- ○ No

**Is there potential for the information from this project to be published in a journal or presented at a conference?** *(Required)*

- ○ Yes
- ○ No

**Indicate possible publication/presentation options.** *(Required)*

**Class Number** *(Required)*

**Class Title** *(Required)*

**Project Description** *(Required)*

*Please provide a concise narrative description of the proposed activity in terms that will allow the URCO or other interested parties to clearly understand what it is that you propose to do that might involve project participants.*

(Limited to 300 words.)

**Procedure** *(Required)*

*Briefly state how the information for this project is to be collected, i.e. audio taping, etc.*

## Design and Procedures

**List all sites where this research will be conducted:** *(Required)*

**List all Variables to be Studied:** *(Required)*

**Data Collection Methods** *(Required)*

**Supporting Documents for Data Collection**
*(surveys, instruments, etc.)*

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

**Will Biological Samples be Collected/Taken?**
*(Required)*

- ○ Yes
- ○ No

**List all biological samples taken/collected** *(Required)*

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

**Will whole genome sequencing be used:** *(Required)*

- ○ Yes
- ○ No

**Debriefing procedures for participants:** *(Required)*

## Research Subjects

**Provide the source of Subject Population used in the research activity:**
*(Required)*

**Number of Subjects** *(Required)*

*(provide the number of subjects to be used and a brief rationale for your sample size)*

**Inclusion Criteria** *(Required)*

*(List any unique qualifiers desirable for research subject participation)*

**Exclusion Criteria** *(Required)*

*(list any unique disqualifiers for research subject participation)*

**How will subjects be identified?** *(Required)*

*(Members of a professional organization, Screening tools, etc..)*

**How will subjects be recruited?** *(Required)*

*(advertisement, associates, etc.)*

**How will subjects be enrolled in the study?** *(Required)*

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

## Design Procedures/Research Subjects Existing Data Analysis

### Design and Procedures

**List all sites where this research was originally conducted.** *(Required)*

**Variables to be Studied** *(Required)*

**List the original data collection methods** *(Required)*
*i.e. surveys, instruments, etc.*

### Research Subjects

**Source of the secondary data** *(Required)*
*i.e. public, restricted use, private, etc.*

**Original sample inclusion and exclusion criteria** *(Required)*

*List any criteria used to select the population recruited for participation in the original study.*

**Recruitment procedures used in original study** *(Required)*

**Sample size of the full originally collected dataset:** *(Required)*

**Secondary sample inclusion and exclusion criteria:** *(Required)*

*List any inclusion and exclusion criteria you will be using to narrow down your sample from the larger dataset.*

**Secondary Data Sample Size** *(Required)*

*Provide an estimate of the sample size you will have access to - full sample or a subsample of the number listed in VI.C.*

## Project/Subject Information Existing Data Analysis

**Does the original data set include, or were original subjects exposed to, any of the following activities?** *(Required)*

**Does the original data set include any of the following?** *(Required)*

- ☐ Under 18 years of age
- ☐ Over 65 years of age
- ☐ Minorities as target population
- ☐ Physically or mentally disabled
- ☐ Economically or educationally disadvantaged
- ☐ Unable to provide their own legal informed consent
- ☐ Pregnant females as target population
- ☐ Victims
- ☐ Subjects in institutions
- ☐ Subjects vulnerable to coercion or undue influence

☐International research

☐Data contains audio files

☐Data contains any video/digital images or recordings

☐None of the above

## Risk-Protection-Benefits

**Risk-Protection-Benefit:**

*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.*

**Risk for Subjects (check all that apply)**
*(Required)*

*(If this is records based research, indicate the risk for subjects during the original study.)*

☐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

☐Other

☐N/A

**Please explain risks not mentioned above (Indirect risks, risk to individuals who are not the primary subjects):** *(Required)*

**In your opinion, does the research involve more than minimal risk to subjects?** *(Required)*

*("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

**Minimizing Risk:** *(Required)*

*(Describe specific measures used to minimize or protect subjects from anticipated risks.)*

**Minimizing Risk/Confidentiality Existing Data**

**How will data be securely received?** *(Required)*
*(Thumb drive, DVD, online download, etc.)*

**How will data be securely stored?** *(Required)*
*(Thumb drive, DVD, encryption use, password protected, etc.)*

**How will participant identities be protected?** *(Required)*
*(Are subjects anonymous or when and how will data be deidentified, etc.?)*

**How and/or will data be securely destroyed at the completion of the study?** *(Required)*
*(Describe how files will be destroyed or erased.)*

**Provide Study Benefits:** *(Required)*

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

**Benefits of secondary analysis of this data.** *(Required)*

*(Describe any benefit for society as a whole.)*

## Confidentiality

**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.*

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

**Explain where, and how, the data will be stored:** *(Required)*

**Explain the time frame of the data storage, to include how data will be destroyed:** *(Required)*

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

## Informed Consent

**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 their 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.*

**Are you using a written informed consent form?** *(Required)*

○ Yes

○ No

**Attach a copy of the informed consent form here.**
*(Required)*

**In accordance with guidance in 45 CFR 46, I am requesting a waiver or alteration of informed consent elements (see section VIII above).** *(Required)*

○ Yes

○ No

**Provide a basis and/or justification for your request.** *(Required)*

**Are you using the Consent Form template provided by the URCO?** *(Required)*

○ Yes

○ No

○ N/A

**Does your Informed Consent document have all the minimum required elements of informed consent found in the Consent Form Template? (Please explain)** *(Required)*

**Are your research subjects anonymous?** *(Required)*

*(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, and the data or information collected cannot be linked in any way to a specific person.))*

○ Yes

○ No

**Please explain why subjects will be identifiable.**
*(Required)*

**Are subjects debriefed about the purposes, consequences, and benefits of the research?** *(Required)*

*(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.)*

○ Yes

○ No

**Please attach a copy of the Debriefing Statement**

**Please provide an explanation for not Debriefing the participants/subjects.** *(Required)*

**Describe the Informed Consent Process:**

**Who is Obtaining the Consent?** *(Required)*

*(i.e. Principle Investigator, Graduate Student, etc.)*

**When and where will consent be obtained?** *(Required)*

**If assent (for minors) is required, please describe who will obtain the assent?** *(Required)*

*(Assent means a child's affirmative agreement to participate in research)*

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

**How will consent be obtained from non-English speaking participants?** *(Required)*

*(a translated written form, orally, identify the name and qualifications of the individual providing the translation)*

## Informed Consent Checklist

**Informed Consent Checklist**
*(Required)*

## Project Information

**Project Information:**

*(If you answer "yes" to any of the questions below, you should explain them in the appropriate section on a previous page)*

**Will deception of Subjects be used in the research?** *(Required)*

- ○ Yes
- ○ No

**Provide the explanation/justification for the deception.** *(Required)*

**Will shock or other forms of punishment be used in the research?**
*(Required)*

- ○ Yes
- ○ No

**Will sexually explicit materials or sexual experience be used or collected as part of the research?**
*(Required)*

- ○ Yes
- ○ No

**Will information about sexual orientation be part of the research?**
*(Required)*

- ○ Yes
- ○ No

**Will information about sexual abuse be part of the research?**
*(Required)*

- ○ Yes
- ○ No

**Will there be handling of money or other valuable commodities as part of this research?** *(Required)*

*This does not include incentives for participation.*

- ○ Yes

○ No

**Will there be extraction or use of blood, other bodily fluids, or tissues in this research?** *(Required)*

*(if "yes', you must comply with facility and handling protections detailed in the 5th Edition of the Biosafety in Biomedical Laboratories (BMBL))*

○ Yes

○ No

**Will questions about any kind of illegal or illicit activity be a part of the research?**
*(Required)*

○ Yes

○ No

**Will questions about protected health information as defined by HIPAA be part of the research?**
*(Required)*

○ Yes

○ No

**Will there be purposeful creation of anxiety as part of the research?**
*(Required)*

○ Yes

○ No

**Will any procedure that might be viewed as invasion of privacy be used in the research?**
*(Required)*

○ Yes

○ No

**Will physical exercise or stress be part of the research?**
*(Required)*

○ Yes

○ No

**Will there be administration of substances (food, drugs, etc.) to subjects as part of the research?**
*(Required)*

○ Yes

○ No

**Will any procedure that might place subjects at risk be part of the research?**
*(Required)*

○ Yes

○ No

**Will there be any use of Radioactive materials and/or use of Radioactive producing machines as part of the research?**
*(Required)*

○ Yes

○ No

**Will any form of potential abuse; (i.e., psychological, physical, sexual) be used in the research?** *(Required)*

- ○ Yes
- ○ No

**Is there potential for the data from this project to be published in a journal, presented at a conference, etc?** *(Required)*

- ○ Yes
- ○ No

**Will data be collected using surveys, questionnaires, or interviews?** *(Required)*

- ○ Yes
- ○ No

**Attach the Data Collection Instrument** *(Required)*

**Is this a Clinical Trial?** *(Required)*

*(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.)*

- ○ Yes
- ○ No

## Subject Information

**Subject Information:**

*The below questions refer to intentional targeting of these groups as a study population, not an incidental chance that a member of one of the below populations may take part in your study.*

*If you answer yes to any of the questions below, you should explain in the appropriate section on a previous page of the application).*

**Will individuals under 18 years of age be part of the research?** *(Required)*

*(these subjects require parental or guardian consent)*

- ○ Yes
- ○ No

**Will individuals over 65 years of age be part of the research?** *(Required)*

- ○ Yes
- ○ No

**Will minorities be the target population used in the research?** *(Required)*

- ○ Yes
- ○ No

**Will physically or mentally disabled individuals be part of the research?**
*(Required)*

○ Yes
○ No

**Will economically or educationally disadvantaged individuals be part of the research?**
*(Required)*

○ Yes
○ No

**Will any individual be unable to provide their own legal informed consent?** *(Required)*

○ Yes
○ No

**Will pregnant females be the target population?** *(Required)*

○ Yes
○ No

**Will the target population be victims?**
*(Required)*

○ Yes
○ No

**Are subjects in institutions?** *(Required)*

*(e.g., prisons, nursing homes, halfway houses)*

○ Yes
○ No

**Are subjects likely to be vulnerable to coercion or undue influence?** *(Required)*

○ Yes
○ No

**Is this international research?** *(Required)*

○ Yes
○ No

**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.** *(Required)*

**Are research subjects in this activity students recruited from university classes or volunteer pools?** *(Required)*

○ Yes

○ No

**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)? Explain any alternatives options for class credit for potential human subject volunteers in your study.**
*(Required)*

*(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.)*

**Is audio from the subjects recorded?** *(Required)*

○ Yes

○ No

**How do you plan to protect the recorded information and mitigate any additional risks?** *(Required)*

**Are research subjects' images being recorded (video taped, digitally recorded, photographed)?** *(Required)*

○ Yes

○ No

**How do you plan to protect the recorded information and mitigate any additional risks?** *(Required)*

## FDA Activities and Conflict of Interest

**FDA Activities:**

*Answer the following questions about potential FDA regulated activities*

**Is this a Clinical Trial?** *(Required)*
○ Yes
○ No

**Are you using an FDA approved drug/device/diagnostic test?** *(Required)*
○ Yes
○ No

**Does this activity involve the use of FDA-Regulated products?** *(Required)*

*(biological products, color additives, food additives, human drugs, etc.)*

○ Yes
○ No

**Has the protocol been submitted to the FDA, or are there plans to submit it to the FDA?** *(Required)*
○ Yes
○ No

**Have you submitted an FDA form 3454 or 3455 (conflict of interest)?** *(Required)*
○ Yes
○ No

**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 themselves 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, IRBs, institutions, and investigators must consider what actions regarding financial interests may be necessary to protect human subjects. Please answer the following questions:*

**Do you or the institution have any proprietary interest in a potential product of this research, including patents, trademarks, copyrights, or licensing agreements?** *(Required)*
○ Yes
○ No

**Do you have an equity interest in the research sponsor?** *(Required)*
*(publicly held or a non-publicly held company)*
○ Yes
○ No

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

**Do you receive payment per participant or incentive payments?** *(Required)*
○ Yes
○ No

**Please provide adequate explanatory information so the IRB can assess any potential COI indicated above.** *(Required)*

## Project Collaborators

**KSU Collaborator**

*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).*

**Non-KSU Collaborator**

*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.*

***Note**: If you answered "yes" on Page 1 (administrative information) to the inclusion of non-KSU collaborators, this section will appear. If this was in error, please go to back to administrative information and change your answer to "no".*

**Does your Non-KSU collaborator's organization have an Assurance with OHRP?** *(Required)*

*(for Federalwide Assurance listings of other institutions, please reference the OHRP website under Assurance Information at: http://ohrp.cit.nih.gov/search).*

○ Yes
○ No
○ Both

**Provide your Collaborator's FWA Number:** *(Required)*

**Is your Non-KSU collaborator's IRB reviewing this proposal?** *(Required)*
○ Yes
○ No

**Provide your Non-KSU Collaborator's IRB Approval Number.** *(Required)*

**Describe the Non-KSU collaborator's role in the research activity.** *(Required)*

**Attach Your Unaffiliated Investigator Agreement Attachment Here**
*(Required)*
*An unaffiliated investigator agreement form is required for individuals who are at institutions that do not have their own FWA number with OHRP.*

## Additional Attachments

**Additional Attachments:**

*Please attach any supporting document not requested at earlier points within the application. Examples; letters of support, recruitment emails or fliers, charts/diagrams, photos of devices to be used.*

## Online Training

**Online Training**

*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)*

*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** *(Required)*

☐ Export Compliance

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

*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.*

☐ 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
- ☐N/A

## INVESTIGATOR ASSURANCE

**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.*

**Class Project Assurance**

- *I assure that this project will not result in data that will be "generalized" in accordance with the federal definition of research in 45 CFR 46.*
- *I assure the protection of participants involved in the class project in accordance with 45 CFR 46 and Kansas State University Policy.*
- *The URCO strongly recommends all personnel involved complete the online training (http://www.k-state.edu/comply/irb/training/). I assure that students will complete training as deemed necessary.*
- *I assure that the information herein provided to the URCO is to the best of my knowledge complete and accurate. I also assure that no modifications or changes will be made to the activity that would change the project's Non-Research status, without notification to the URCO.*
- *I assure that I will promptly report to the URCO any unanticipated problems involving participants in the activity as described.*

**Oral History Assurances**

- *The URCO strongly recommends all personnel involved complete the online human subjects training (http://www.k-state.edu/comply/irb/training/). I assure that students will complete training as deemed necessary.*
- *I assure that the information provided to the URCO is to the best of my knowledge complete and accurate. I also assure that no modifications or changes will be made to the activity that would change the project's Non-Research status, without notification to the URCO.*

**PI Signature** *(Required)*

**Please click next and submit, in order to send to PI for signature.**