**KENTUCKY STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD**

**APPLICATION FOR FULL REVIEW**

This application is to be used to request full review of a study involving human research subjects when the study is not eligible for exempt or expedited review. The investigator must receive approval prior to engaging in research activities involving human subjects. This review level is required for studies representing greater than minimal risk to its subjects, studies with activities that fall outside the categories of exemption and expedited review, and studies that involve prisoners as subjects.

**INSTRUCTIONS FOR APPLYING FOR FULL REVIEW**

1. All applications for IRB review must be submitted by the Principal Investigator.
2. Upon receipt of a new online application, the IRB administrator will review the submission for completeness and return incomplete applications for updates prior to processing.
3. If the IRB reviewers have questions or request updates to the application materials, the principal investigator will be notified by email and asked to resubmit application materials by email.
4. Once the IRB has approved the application, the principal investigator will be notified by email.

**APPLICATION CHECKLIST**

**In order for the IRB to consider an application for full review, the following items are required:**

[ ]  Full Review Application (this application)

[ ]  CITI Training Completion Reports for all investigators, key personnel, and faculty research advisors

*Note that the Basic Course for Social Behavioral or Biomedical Researchers is required. The Refresher Course cannot be accepted unless the investigator has previously completed the Basic Course and is using the Refresher Course to renew training credentials.*

[ ]  Informed Consent Documents (check all that apply):

 [ ]  Informed Consent Form

 [ ]  Parent/Guardian Permission Form (for parents/guardians of subjects who are children)

 [ ]  Child Assent Form(s) (for subjects who are children)

 [ ]  Request for Waiver of Informed Consent Documentation (allowable only in specific situations)

**As applicable:**

 [ ]  Recruitment materials (i.e., advertisements, verbal scripts, cover letters, etc.)

 [ ]  Instrument(s) to be used for data collection (i.e., surveys, questionnaires, interview questions, assessments, etc.)

 [ ]  Letter(s) granting permission to use off-campus facility for research

*All documents that will be provided to subjects must include the title of the study.*

*This includes recruitment, consent, and data collection documents.*

**APPLICATION FOR FULL REVIEW**

**SECTION 1: GENERAL INFORMATION**

1. **Title of Study:**

Click and type.

1. **Principal Investigator:**

Principal Investigator Name: Click and type.

Department: Click and type.

Position: Click and type.

1. **Degree Program, Faculty Advisor, and Committee Members:**

(Skip to Item 4 if principal investigator is not an KSU student)

Degree Program: Click and type.

Faculty Research Advisor: Click and type.

Committee Members (required for theses, dissertations, scholarly projects, field experience, or other studies guided by an academic committee):

Click and type.

1. **Other Investigators:** Identify all other investigators assisting in the study. If additional lines are needed, please attach a Continuation Page for Other Investigators.

Name: Click and type. Authorized to obtain consent? [ ] Yes [ ] No

Responsibility in Project: Click and type.

Name: Click and type. Authorized to obtain consent? [ ] Yes [ ] No

Responsibility in Project: Click and type.

Name: Click and type. Authorized to obtain consent? [ ] Yes [ ] No

Responsibility in Project: Click and type.

Name: Click and type. Authorized to obtain consent? [ ] Yes [ ] No

Responsibility in Project: Click and type.

Name: Click and type. Authorized to obtain consent? [ ] Yes [ ] No

Responsibility in Project: Click and type.

Please check if a Continuation Page for Other Investigators is attached. [ ]

1. **Estimated Duration of Research Project:** upon IRB approval through Click and select a study end date.

*Note that research may not begin until IRB approval has been granted. Projects may be approved for a period of up to three years, after which time, a new application is required.*

1. **Funding Support:** Is the research study funded by an internal grant or an external grant or contract? [ ] Yes [ ] No

Funding Agency: Click and type.

1. **Is the proposed study a clinical trial?** [ ] Yes [ ] No

Please respond to the following questions to determine whether a study meets the clinical trial definition:

* Does the study involve human participants?  [ ] Yes [ ] No
* Are the participants prospectively assigned to an intervention?  [ ] Yes [ ] No
* Is the study designed to evaluate the effect of the intervention on the participants? [ ] Yes [ ] No
* Is the effect being evaluated a health-related biomedical or behavioral outcome? [ ] Yes [ ] No

If the answers are all “yes,” the study is a clinical trial. If any answers are “no,” the study is not a clinical trial

1. **Risk Category:**

[ ]  Not greater than minimal risk

 [ ]  Greater than minimal risk, but of direct benefit to individual participants

 [ ]  Greater than minimal risk and no direct benefit to individual participants, but likely to yield generalizable knowledge about the subject’s disorder or condition

**APPLICATION FOR FULL REVIEW**

**SECTION 2: RESEARCH DESCRIPTION**

1. **Background:**
2. **Provide an introduction and background information for the study and provide a discussion of past research findings leading to this study. Cite literature that forms the scientific basis for the study**.

Click and type.

1. **Research Objectives:**
2. **List the research objectives.**

Click and type.

1. **Project Location:**
2. **Where will the study take place?**

Click and type.

1. **If the study will take place at a location other than KSU, attach a letter from an authorized representative of the organization granting permission to use facility for research purposes.**

[ ] KSU only [ ] Letter(s) attached

1. **Will any data be collected through organizations other than KSU?**

 [ ] No [ ] Yes, complete the following:

* + Will personnel of the organization be involved in the data collection process or have access to data after collection? [ ] No [ ]  Yes - If yes, list personnel in Section 1, include CITI training documentation, and define role here: Click and type.
1. **Subject Population:**
2. **What criteria will be used to determine the *inclusion* of participants in the study?**

Click and type.

1. **What criteria will be used to determine the *exclusion* of participants in the study**?

Click and type.

1. **Anticipated Number of Participants** *(maximum):* Click and type.
2. **Age Range of Participants:** Click and type.
3. **Gender of Participants:** [ ] Male [ ] Female or [ ] Gender not considered in subject selection
4. **Ethnicity of Participants:** Click and type. or [ ] Ethnicity not considered in subject selection
5. **Health Status of Participants:** Click and type. or [ ] Health status not considered in subject selection
6. **Which of the following categories of subjects will be included in the study? Please check all that apply.**

[ ]  Adults

[ ]  College Students age 18 and older

[ ]  Children (under age 18) – complete Section 4

[ ]  Subjects who do not speak and/or read English – *see Translation Certification form and guidance*

[ ]  Pregnant Women (other than by chance)

[ ]  Fetuses/Neonates

[ ]  Hospital Patients

[ ]  Patients at Inpatient Mental Health Facilities

[ ]  Individuals with Impaired Decision-Making Capacity – *complete Section 5*

[ ]  Institutionalized Individuals with Impaired Decision-Making Capacity – *complete Section 5*

[ ]  Prisoners (other than incidentally without the investigator’s knowledge)

[ ]  Other – Please Describe: Click and type.

1. **Recruitment of Participants:**
2. **How will prospective participants be identified for recruitment into the study?**

Click and type.

1. **Describe the recruitment procedures to be used with potential participants identified for the study.**

Click and type.

1. **Recruitment materials to be used:** Check all that will be used and attach copies. The study’s title must be included on all documents.

[ ] None [ ] Advertisement [ ] Flyer [ ] Verbal Recruitment Script [ ] Cover Letter

[ ] Other: Click and type.

1. **Ensuring Voluntary Participation**
2. **Who will be responsible for seeking the informed consent of participants?**

Click and type.

1. **What procedures will be followed to ensure that potential participants are informed about the study and made aware that their decision to participate is voluntary?**

Click and type.

1. **How will consent be documented?**  If you are requesting a waiver of documentation, please explain here and attach a completed waiver request form.

Click and type.

1. **What consent documents will be used in the study?** Attach copies of all.

[ ] Informed Consent Form [ ] Parent/Guardian Permission Form [ ] Child/Minor Assent Form [ ] Oral Script

[ ] Other: Click and type.

1. **Research Procedures**
2. **Describe in detail the research procedures to be followed that pertain to the human participants.** Be specific about what you will do and how you will do it. If applicable, differentiate between standard/routine procedures not conducted for research purposes and those that will be performed specifically for this study.

Click and type.

1. **Potential Risks**
2. **Describe any potential risks, including physical, psychological, social, legal, or other risks.** Note that if identifiable data is used, there are risks to the participants’ confidentiality.

Click and type.

1. **What procedures will be followed to protect against or minimize any potential risks?**

Click and type.

1. **How are the risks reasonable in relation to the anticipated benefit to participants and in relation to the importance of the knowledge that may reasonably be expected to result from the study?**

Click and type.

1. **Will alternative choices be made available to participants who choose not to participate?**

[ ] No [ ] Yes, Describe: Click and type.

1. **Incentives and Research Related Costs**
2. **Will incentives be offered to participants?** [ ] No [ ] Yes, complete the following items:
	1. What incentives will be offered? Click and type.
	2. If monetary compensation will be offered, indicate how much the participants will be paid and describe the terms of payment. If gift cards will be used as incentives, please see Guidance for Projects Using Gift Cards as Subject Payments. Click and type.
	3. Describe the method of ensuring that the incentives will not compel individuals to agree to participate in the study. Click and type.
	4. Describe how the incentives will be funded. Click and type.
3. **Will there be any costs to the subjects for participating?** [ ]  No [ ]  Yes, complete the following item:

1) Describe any costs that will be the responsibility of the subjects as a consequence of their participation in the research. Click and type.

1. **Research Materials, Records, and Confidentiality**
2. **What materials will be used for the research process?** Include a description of both data collected through the study as well as other data accessed for the study. Copies of all data collection instruments must be attached and must include the title of the study.

Click and type.

1. **Who will have access to the data?** If anyone outside the research team will have access to the data, provide a justification and include a disclaimer in consent documents.

Click and type.

1. **Describe how and where research records will be stored.** Note that all research-related records must be securely maintained for a period of three years from the study’s completion and are subject to audit. Following the completion of the study and throughout the records retention period, student research records must be maintained by the faculty advisor identified in Section 1, Item 3 of this application or provided to the IRB for records maintenance.

Click and type.

1. **How will data be destroyed at the end of the records retention period** (i.e., shredding paper documents, deleting electronic files, physically destroying audio/video recordings)?

Click and type.

1. **Describe procedures for maintaining the confidentiality of human subjects data**.

Click and type.

**APPLICATION FOR FULL REVIEW**

**SECTION 3: RESEARCH INVOLVING CHILDREN AS SUBJECTS**

In Kentucky, a child is an individual who is less than 18 years of age unless the individual has been legally emancipated. Some Federal agencies and other states define children differently. If the study is to be funded by a Federal agency, that agency’s definition applies; if a study is to be conducted outside Kentucky, that state’s definition applies.

**1. Will this study involve children as subjects?**

[ ]  No (skip remainder of **section 3**)

[ ]  Yes (complete all items in this section)

**2.** **Suitability of Subjects:** Explain why children are suitable subjects for this research.

Click and type.

**3.** **Previous Research on Adults:** Has this research previously been conducted with adults as subjects?

[ ]  No [ ]  Yes (respond to 3.a. below)

**a.** Explain indications that the proposed research will benefit or at least not be harmful to the children.

Click and type.

**4.** **Number of Children Subjects:** Provide a justification for the number of children proposed for enrollment in the project.

Click and type.

**5.** **Parent/Guardian Permission Process:** Describe procedures for soliciting the permission of at least one parent/guardian. If the study involves greater than minimal risk, the permission of both parents/guardians is required unless only one has legal responsibility for the child.

Click and type.

**6.** **Assent Process:** Describe procedures for soliciting the assent of the children, following permission from the parents/guardians.

Click and type.

**7.** **Understandable Language:** Describe what efforts have been made to present information about the study in a language that is understandable to the children who will be recruited (i.e, informational documents, recruitment flyers, assent forms, data collection instruments).

Click and type.

**8. Wards as Subjects:** Will the study involve wards as subjects?

[ ]  No [ ]  Yes (respond to 8.A. and 8.B. below)

**A. Research Classification:** The use of wards as subjects in research is permissible in only the following two situations. Indicate which classification below applies to the proposed research.

[ ]  The proposed research is related to the subjects’ status as wards of the state.

[ ]  The proposed research is to be conducted in schools, hospitals, or similar settings in which the majority of children involved in the study are not wards.

**B. Ward Advocate:** A ward advocate must be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate(s) must have the background and experience to act in, and agree to act in, the best interests of the child for the duration of the child's participation in the research and may not be associated in any way with the research, the investigator(s), or the guardian organization. Please explain how these ward advocate requirements will be met.

Click and type.

**APPLICATION FOR FULL REVIEW**

**SECTION 4: RESEARCH WITH SUBJECTS WHO HAVE IMPAIRED**

**DECISION-MAKING CAPACITY**

When a prospective research participant lacks the ability necessary to understand and use information relevant to an informed consent process, additional precautions and protections are required.

**1. Will the study involve subjects who have impaired decision-making capacity?**

[ ]  No (skip remainder of **section 4**)

[ ]  Yes (respond to all items in this section)

**2.** **Suitability of Subjects:** Individuals with impaired decision-making capacity should be used as research subjects only in situations where they are the only population who can provide the data needed for the study and only when the potential risks are balanced with expected benefits. Explain why individuals with impaired decision-making capacity are suitable subjects for this research.

Click and type.

**3. Subject Advocate:** What procedures are in place to allow a subject advocate to assist subjects in navigating the research process?

Click and type.

**4.** **Competency to Consent:** Describe who will determine individuals’ competency to consent and the criteria to be used in determining competency (i.e., use of standardized measurements, consultation with qualified professionals, etc.)

Click and type.

**5.** **Consent for Individuals Incapable of Consenting on Their Own Behalf:** Explain how you will identify who is authorized to give legally valid consent on behalf of any individual(s) determined to be incapable of consenting on their own behalf.

Click and type.

**6. Expectations, Obligations, and Authority of Legally Authorized Representatives:** Explain the expectations, obligations, and authority of the legally authorized representative for each subject and describe how this information will be conveyed to the representative (i.e., through a written information sheet).

Click and type.

**7.** **Assent**: Explain the criteria you will use to determine when assent is required for subjects who are not competent and describe the assent process to be used with these subjects.

Click and type.

**8.** **Evaluating Dissent**: Explain the methods to be used for evaluating dissent (i.e., description of behaviors that would indicate that an individual does not want to participate, such as moving away or displaying certain facial expressions or head movements).

Click and type.

**9. Re-Consent/Re-Assent:** Explain procedures to be followed for periodic re-consent and/or re-assent and define the documentation interval.

Click and type.

**10. Monitoring Capacity to Consent:** Describe the process for monitoring capacity to consent and describe procedures for protecting the subjects’ rights in the event they lose their capacity to consent or their capacity to withdraw during the course of the research (i.e., use of legally authorized representative).

Click and type.

**11.** **Use of Institutionalized Individuals:** Does the proposed research involve individuals who are institutionalized?

[ ]  No

[ ]  Yes (Respond to item below and attach approval from an authorized representative at the institution)

* + Provide a justification for the use of institutionalized individuals and explain why individuals who are not institutionalized cannot be substituted.

Click and type.

**APPLICATION FOR FULL REVIEW**

**SECTION 5: RESEARCH WITH PRISONERS AS SUBJECTS**

**1. Will the project involve prisoners?**

[ ]  No (skip remainder of **section 5**)

[ ]  Possibly incidentally without researcher’s knowledge (skip remainder of this section)

 The requirements in this section do not apply to research aimed at involving a broader subject population that only incidentally includes prisoners (i.e., a web-based survey that an inmate may be able to access from a prison computer without the researcher being aware of the prisoner status).

[ ]  Yes (respond to all items in this section)

**2. Category of Research:** Prisoners may be subjects in research only in the specific situations defined below. Please indicate which of the following categories apply to this study:

[ ]  **A.** Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects

[ ]  **B.** Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects

[ ]  **C.** Research on conditions particularly affecting prisoners as a class (i.e., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research

[ ]  **D.** Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research.

**3.** **Advantages and Choice:** Any possible advantages accruing to the prisoners through their participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, must not be of such magnitude that the ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired. Provide a description of the possible advantages that prisoners can expect from their participation and the impact of these advantages on their choices regarding voluntary participation.

Click and type.

**4.** **Appropriate Risks:** The risks involved in the research must be commensurate with risks that would be accepted by non-prisoner volunteers. Provide a description of possible risks to the participants and justify how those risks are the same as they would be for non-prisoners.

Click and type.

**5.** **Fair Selection:** The procedures for the selection of subjects within the prison must be fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the investigator provides justification for following other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for a particular research project. Describe how prisoners will be selected and what measures will be taken to prevent intervention by prison authorities or prisoners in the selection process.

Click and type.

**6.** **Understandable Language:** All information regarding the study must be presented in language that is understandable to the subject population. Describe what efforts have been made to present information about the study in a language that is understandable to the prisoner population being recruited (i.e, informational documents, recruitment flyers, informed consent forms, data collection instruments, etc.).

Click and type.

**7.** **Parole Board Consideration:** Adequate assurance that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole is required, and each prisoner must be clearly informed in advance that participation in the research will have no effect on his or her parole. Describe measures in place to ensure that parole boards are not influenced by prisoners’ participation in the research and how prisoners will be informed that their participation (or refusal or withdrawal from) will not impact their parole status. Parole board considerations must also be addressed in both the informed consent form and the letter of support for off-campus research provided by the correctional institution.

Click and type.