**UNIVERSITY of NEBRASKA at KEARNEY**

**INSTITUTIONAL REVIEW BOARD**

**Request for Approval of Human Subjects Research**

**DIRECTIONS:**

1. Download this form into Microsoft Word. Single click on the shaded boxes. (If you double click, we can’t use tracked changes to communicate with you, if needed.) You can tab from box to box. Box size will expand as you type. PLEASE DO NOT SEND YOUR APPLICATION IN PDF FORMAT.
2. Check Quick Tips ([www.unk.edu/irb](http://www.unk.edu/irb) under Forms) for problems most commonly found in IRB applications.
3. **FOR STUDENT applicants:**  You must have your faculty sponsor email a note or sign a paper copy of the application that s/he has reviewed the completed application and is satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects.
4. **Return the completed application as an MS Word document to** **unkirb@unk.edu****.**

**Any of the required attachments not available electronically must be sent or delivered to the IRB Office.**

UNK Institutional Review Board

Founders Hall, Suite 1000

Kearney, Nebraska 68849

Telephone: (308) 865-8843; Fax: (308) 865-8837.

Thank you!

**UNIVERSITY of NEBRASKA at KEARNEY**

**INSTITUTIONAL REVIEW BOARD**

**Request for Approval of Human Subjects Research**

|  |  |
| --- | --- |
| **INVESTIGATOR: *(****name, campus address****)*** | **Secondary Investigator(s):** *(if any)* |
|       |       |
| **TELEPHONE:**       |       |
| **UNK E-MAIL:**       |       |
| *(required)* |  |
| **OTHER E-MAIL:**       |       |
| *(optional)* |  |

**PRIMARY DEPARTMENT OR CONCENTRATION:**

**INVESTIGATOR STATUS (***Indicate one—Faculty, Graduate student, Undergraduate, Staff, Visiting Scholar, Other (specify))***:**

**PROJECT TITLE:**

**ANTICIPATED FUNDING SOURCE:** *(add name of grant recipient for externally sponsored funding)***:**

**UNK internal funding**:

**External funding**:

|  |  |
| --- | --- |
| **FACULTY SPONSOR'S NAME AND EMAIL ADDRESS** *(required for non-faculty applicants)*:  | Supervising lecturer, instructor, or graduate student *(if applicable)*: |
|       |       |

**DURATION OF ENTIRE PROJECT:**

**from**       **to**      **.**

**APPROVAL REQUESTED FOR** *(maximum one year; must be renewed annually if not exempt)***:**

**from**       **to**      **.**

**1. Please give a brief summary of the purpose of the research in non-technical language. Be sure to include a statement of the research problem, its importance, and how your project will address it, i.e., briefly explain how your methodology will help to answer the research question(s). Cite two or three references directly relevant to the proposed inquiry.**

**2. Give details of procedures that relate to subjects' participation.**

**(a) Subjects and Recruitment:**

**(i) Salient characteristics of subjects--number who will participate, age range, sex, institutional affiliation, other special inclusion and exclusion criteria** (*if children, prisoners or other vulnerable subjects are recruited, explain why their inclusion is necessary, append screening materials, if applicable*)**:**

**(ii) How are subjects recruited? What inducement is offered? If participants are paid, what amount and when are they paid** *(investigator(s) must comply with University guidelines for compensating research subjects)****?* Is there partial pay for partial completion? (***Append copy of letter, advertisement, poster, or recruitment text for online posting, if any*.**)**

 **(b) Research Procedures:**

**(i) What do subjects do, or what is done to them, or what information is gathered? Is there an online component to your project, such as web-based surveys? *(****Append copies of instructions, tests, questionnaires, interview guides, etc. to be used. If applicable, include a link to the web-based survey.****)***

**(ii) How many times will interviews, observations, tests, etc., be conducted? How long will their participation take? *(****Describe in terms of what the subject will experience.****)***

**(iii) Are subjects to be:**

AUDIO recorded: [ ]  tape [ ]  digital

VIDEO recorded: [ ]  tape [ ]  digital

**3. Describe how permission has been obtained from cooperating institution(s)--school, hospital, company, prison, or other relevant organization(s).** *(Append letters on letterhead or emails.)* **Is the approval of other research compliance committees or another Institutional Review Board required?**

**4. Describe your research experience and your research ethics training.**

**(a) Cite your experience with this kind of research and/or this population.**

**(b) Provide the names of everyone working with human subjects and/or their identifiable data and human subjects (e.g., CITI) training.**

|  |  |  |
| --- | --- | --- |
| **Names of people working on this project** | **Role** | **Human Subjects Training** |
| **Investigator(s)** |
|  |  |  |
|  |  |  |
| **Others** |
|  |  |  |
|  |  |  |
|  |  |  |

**(c) Describe experience and role(s) of others:**

**5. How do you inform subjects about your research and then obtain their consent?** *(For an explanation of the elements of informed consent and documenting it, please see* [*http://www.unk.edu/academics/gradstudies/reviewboard/ConsentAssent/Process\_for\_Obtaining\_Informed\_Consent/*](http://www.unk.edu/academics/gradstudies/reviewboard/ConsentAssent/Process_for_Obtaining_Informed_Consent/)*)*

**(a) Do subjects sign a written consent form and receive a copy for their records? If not, do they receive an information sheet that provides what they need to know before deciding to participate?** (*In addition to answering parts a. – e. of Question 5, append a copy of consent form, information sheet, or script for oral explanation to subject.*)

**(b) Where (***in a lab? online?***) , when (***immediately before participation? at another time?***), and by whom** *(anyone other than investigator?)* **is consent obtained?**

**(c) Are subjects children** *(persons younger than 19 years old)***, mentally infirm, or otherwise not legally competent to consent? If so, how is their assent obtained, and who consents on their behalf?**

**(d) If subjects are vulnerable due to legal status, economic status, illiteracy, or other circumstance** *(such as relationship with the investigator(s))***, describe steps to minimize the risk of coercion or undue influence. Include in your answer how you ensure subjects understand that participation is voluntary.**

**(e) Is there any language barrier that could affect the consent process (***your explanation of the research and the subject’s agreement to participate***)? If so, please provide details, such as plans for use of translators or translating documents.**

**6. Give details of possible risks of harm to participants.**

 **(a) What are the possible risks—physical, psychological, legal, social?**

**(b) If there are any risks, why are they necessary? Is there any other way to conduct the research that would reduce the risk to subjects, and, if so, why have you not chosen that alternative?**

**(c) What steps will be taken to minimize the risk? (***If the research may involve greater than minimal risk to participants, describe provisions for ensuring participant safety.***)**

**(d) Should a subject be injured or otherwise harmed, or experience significant distress, what are your plans for addressing the problem?** *(e.g., referral for evaluation or treatment if there are significant psychological risks)*

**If risks are anticipated to be no more than minimal, please state so here and in the consent form, if used.**

**7. Are subjects deliberately deceived in any way? If so, what is the nature of the deception? Is it likely to be significant to subjects? Is there any other way to conduct the research that would not involve deception, and, if so, why have you not chosen that alternative? What explanation for the deception do you give to subjects following their participation?**

**8. How will participation in this research benefit subjects? If subjects will be "debriefed" or receive information about the research project following its conclusion, how do you ensure the educational value of the process?** *(Append copies of any debriefing or educational materials.)*

**9. How are confidentiality and/or anonymity assured? For online studies, will IP addresses or other potentially identifying information be collected? What host site will be used** *(i.e. Qualtrics, SurveyMonkey, etc.)***? Will identifiers be removed from the data? If so, at what point, and if not, please explain why identifiers must be retained.**

**10. How is the privacy of subjects protected?** (*e.g., are questions tailored to the research question so subjects are not asked to provide unnecessary information?*)

**11. Will research data** (*written or otherwise recorded*) **be destroyed at the end of the study? If not, where and in what format and for how long will they be stored? To what uses--research, demonstration, public performance, archiving--might they be put in future? How will subjects' permission for further use of their data be obtained? If there is a key code connecting subjects' data to their identity, when will the link be destroyed?** *(Include this information in the consent form, information sheet, or consent script.)*

**12. Do you believe this research meets the criteria to be reviewed as Exempt? If so, please state and justify the category under which this proposal is submitted.** *(See* [*http://www.unk.edu/academics/gradstudies/reviewboard/Human/Exempt/*](http://www.unk.edu/academics/gradstudies/reviewboard/Human/Exempt/) *for information on categories of research that qualify for Exempt Status.)*

**13. Do you and/or any other investigators associated with the project described in this application have, or appear to have, any actual or potential conflict of interest with respect to this research?** *(See* [*http://www.unk.edu/uploadedFiles/academics/sponsordeprograms/FCOI policy 120802.pdf*](http://www.unk.edu/uploadedFiles/academics/sponsordeprograms/FCOI%20policy%20120802.pdf) *for what may constitute a conflict of interest that must be disclosed.)*

**[ ]  Yes** **[ ]  No**

**If yes, an IRB staff member will contact you to determine the extent of any conflict and assist in the development of a management plan.**

**By submitting this application, I understand and accept the following obligations to protect the rights and welfare of research subjects in this study:**

I certify that I have carefully reviewed this application and all supporting documents. I have determined that the application is accurate, complete and ready for submission to the IRB.

I certify that all listed research personnel and I have the necessary qualifications, human subjects research training, and expertise to conduct this study in a manner that fully protects the rights and welfare of research subjects.

I certify that all listed research personnel will be given a copy of the final IRB-approved application and any other relevant study related documents in accordance with their defined responsibilities.

I recognize that as the principal investigator it is my responsibility to ensure that this research and the actions of all research personnel involved in conducting the study will comply fully with the IRB-approved protocol, all applicable federal regulations, state laws, and IRB policies.

I recognize that it is my responsibility to ensure that valid informed consent/assent has been obtained, as appropriate, from all research subjects or their legally authorized representative (LARs). I will ensure that all research personnel involved in the process of consent/assent are properly trained and are fully aware of their responsibilities relative to the obtainment of informed consent/assent according to applicable federal regulations, state laws, and IRB policies.

I will promptly inform the IRB of any unanticipated problems involving risk to the subjects or to others, as required within the timeframe defined by IRB policies. I will analyze each reported problem to determine if it impacts the risk-benefit relationship of the study, the safety of the subjects, or informed consent.

I will promptly inform the IRB if I become aware of 1) any complaints from research subjects or others about research participation, 2) violations of federal regulations or state law, or 3) violations of IRB policies.

I will not initiate any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject, in which case the IRB will be notified as soon as possible.

I will promptly inform the IRB of any significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.

I will maintain all required research records on file and I recognize that representatives from the IRB, OHRP, HHS, and other federal departments or agencies may inspect these records in accordance with granted authority.

I understand that failure to comply with the Common Rule, applicable Subparts B, C, and D of HHS regulations at 45 CFR 46, applicable state law, and the provisions of the IRB-approved protocol may result in suspension or termination of IRB approval of my research project and/or other administrative or legal actions.

**APPLICANT'S SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DATE:**

***(For student applicants):***

**I have reviewed this completed application and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects.**

**FACULTY SPONSOR'S SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Peer Review:** The chairperson, authorized delegate, or peer review committee of the principal investigator’s department/division is responsible for peer review of research proposals. Faculty sponsors may not provide peer review of their students’ proposals. By signing below, the peer reviewer certifies the proposal meets disciplinary standards for research and is recommended for submission to the IRB.

**PEER REVIEWER’S SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**ATTACHMENTS:**

|  |  |
| --- | --- |
| [ ]  Recruitment letter, poster, ad [ ]  Written consent form, information sheet, or script[ ]  Subject instructions[ ]  Tests or questionnaires  | [ ]  Interview guides[ ]  Debriefing materials[ ]  Other institutional approval |