**Navajo Technical University**

**Application for Review of Human Subjects Research**

**INSTRUCTIONS TO APPLICANT:**

1. Use the form below. Keep your document in Microsoft Word format. Single click on the shaded boxes. You can tab from box to box. Box size will expand as you type. DO NOT CONVERT YOUR APPLICATION INTO PDF FORMAT.
2. You must have your faculty sponsor 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.
3. Return the completed application as a MS Word document to Committee on Institutional Research (CIR) Chairperson or member.

Thank you!

|  |  |
| --- | --- |
| **INVESTIGATOR: *(****name, campus address****)*** | **FACULTY SPONSOR** *(contact Information)* |
| **NAME:**      |       |
| **TELEPHONE:**       |       |
| **NTU E-MAIL:**       |       |
| *(required)* |  |
| **OTHER E-MAIL:**       |       |
|  |  |

**PRIMARY DEPARTMENT OR CONCENTRATION:**

**INVESTIGATOR STATUS (***Indicate one—Graduate student, Post-doc, Undergraduate, Fellow, Other (specify))***:**

**FACULTY SPONSOR'S TITLE (***Indicate one—Assistant, Associate, Fellow, Other (specify))***:**

**PROJECT TITLE:**

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

**NTU internal funding**:       **External funding**:       **None**:

**DURATION OF ENTIRE PROJECT:**

**From**       **to**      **.**

**APPROVAL REQUESTED FOR** *(maximum one year; must be renewed annually)***:**

**From**       **to**      **.**

**1. 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). You may 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) Characteristics of participants--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? 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 is an online component to your project, such as web-based surveys? *(****Append copies of instructions, tests, questionnaires, or interview guides 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 is obtained from cooperating institution(s)--school, hospital, corporation, prison, or other relevant organization.** *(Append letters.)* **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 training.**

|  |  |  |
| --- | --- | --- |
| **Names of people working on this project** | **Role** | **Human Subjects Training** |
| **Investigator** |
|  |  |  |
| **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 Appendix A, or Samples)*

**(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., 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, e.g.***), and by whom (anyone other than investigator?) is consent obtained?**

**(c) Are subjects children, 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, e.g., to legal status, economic status, illiteracy, or other circumstance, 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 and a completed Translation Attestation Form***.*

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

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

**(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 monitoring data to ensure 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., emergency care training for lab staff if physical harm is a risk; 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. SurveyMonkey, iCommons, 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 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* [*Policies*](http://.edu/conflict) *and Procedures for what may constitute a conflict of interest that must be disclosed.)*

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

**If yes, a CIR committee 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 certify that the study has been adequately designed to protect human subjects.**

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

**DATE:**

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

**DATE:**

**ATTACHMENTS:**

[ ]  Recruitment letter, poster, ad

[ ]  Written consent form, information sheet, or script

[ ]  Subject instructions

[ ]  Tests or questionnaires

[ ]  Interview guides

[ ]  Debriefing materials

[ ]  Translation Attestation Form

[ ]  Other institutional approval