Grambling State University

Application for Human Subjects Review

IRB Protocol

Approval Date _____IRB #_____

SUBMIT CITI COMPLETION CERTIFICATION WITH FORM

1. Principal Investigator_____
   [Last Name, First Name, Middle Initial]

   Email_____ Phone _____

2. Department _____

3. University Status (Check one)
   a. _____ Faculty
   b. _____Staff
   c. _____Undergraduate Student
   d. _____Graduate Student (Master's Level)
   e. _____Graduate Student (Doctoral Level)

4. Faculty Advisor: (required if PI is a student) _____☐ **NA**

   Email_____ Phone _____

5. Department Head: (required if PI is faculty or staff) _____☐ **NA**

   Email_____ Phone _____

Are you requesting EXEMPTION from IRB Review? ☐ **YES** ☐ **NO** ☐ **Not Sure**

Title of Research Project:

_____

[Insert study title]

Research Team: List all members of the research team. Indicate under the affiliation column whether the investigators or study personnel are faculty or staff of Grambling State University, or faculty or staff from a collaborating institution, or are not formally affiliated with any institution. **ALL members of the research team MUST complete CITI Training for Human Subjects and Responsible Conduct of Research before they may be listed on the protocol. See NOTE below.**

NOTE: The IRB will remove from the protocol any personnel who have not completed required training. A request to change study personnel will need to be submitted when training is completed.

	Name	**Affiliation: Grambling/Other Institution (Identify)**	**G #**
Principal Investigator			
Member/Role:			
Member/Role:			
Member/Role:			

5. Purpose
   [Provide a **brief** overview (1-3 paragraphs) of your study written for a general audience explaining the purpose of the research and theories and/or hypotheses to be tested.]

6. Research Categorization: Do any of the following apply to the current study? (Check all that apply.)

- ☐ Class Project
- ☐ Master's Thesis or Project
- ☐ Doctoral Dissertation Prospectus
- ☐ Grant Proposal
- ☐ Participant Observation
- ☐ Interviews
- ☐ Surveys
- ☐ Focus groups (study is not anonymous)
- ☐ Research in K-12 schools (submit a School Agreement form for the study)
- ☐ Deception (submit a Debriefing sheet)
- ☐ Audiotaping, videotaping or photography of individuals (study is not anonymous)
- ☐ Public viewing of videotapes or photographs
- ☐ International research sites (attach the International Checklist)
- ☐ Online (web-based) activities
- ☐ Social networks
- ☐ Other _____

7. Procedures

Briefly describe your research methodology and study design. Outline step-by-step what will happen to participants in this study. You must include information that allows the IRB to conduct an analysis of the risks and the potential benefits.

a. Location

[Describe where data collection and all other study activities will occur. Indicate the names of all sites or agencies (e.g., school districts, day care centers, etc.) involved in the research.]

For a multi-site study in which the University is the lead or coordinating institution, provide the following:

i. The name(s) of each participating institution that will be engaged in human subject research.
ii. Confirmation that each participating institution has an FWA.
iii. The contact name and information for the PI at each institution.
iv. The contact name and information for the IRB of record at each institution.
v. The method of multilateral communication between institutions/IRBs if any unanticipated problems involving risks to subjects or others and other study related information.

b. Resources
[Describe whether internal/external funds, personal funds, other resources will be used to support this research.]

c. Study Timeline
[Describe how long the project will take from data collection to dissemination of results.]

8. Measures
Describe all study measures. For surveys, focus groups, or interviews – clarify whether question items and measures are standardized, published, or designed specifically for this project. Attach surveys, interview guides, etc.

9. Participants
   a. Target Population
   [Briefly describe the study population (e.g., students, patients, etc.) and your anticipated sample size (N) of participants, and/or societal benefits.]

   b. Inclusion/Exclusion
   [If applicable, list criteria that will be used to include or exclude participants from the study (e.g., age restrictions, health restrictions, etc.).]

   c. Benefits
   [List any potential benefits that participants may expect from the study, such as, health information, and/or other intrinsic value stemming from study participation.]

d. Risks
[Discuss any possible risks that participants may incur by participating in the study. Explain what will be done to minimize those risks (if applicable). Describe procedures regarding notification of the IRB and treatment of participant in the event that a participant is harmed during the study.]

e. Recruitment
Discuss how potential participants will be recruited to participate. Attach all recruitment materials (e.g., flyers, scripts, letters, e-mails, etc.), if applicable.

f. Obtaining Informed Consent
[Explain all informed consent/assent procedures. If applying for a waiver of signed consent, specifically state this and explain why. If the study involves deception, describe the procedures for debriefing the participants. For international research you must include how the informed consent could be affected by local customs, cultural context, laws and regulations. You must also describe how you will address these issues. Attach consent and assent forms. (See Informed Consent Template)]

10. Privacy and Confidentiality

[Describe how you will protect the identity of study participants (privacy).

Confidentiality of the Data or Samples

a. Describe how data or samples will be collected.

b. Describe how the data or samples will be securely stored.

c. How long [length of time] will the data or samples be kept?

d. Describe whether data or samples will be kept confidential (i.e., data can potentially be linked to participants) or anonymous (i.e., impossible to link data and participants). You must indicate whether the data or samples will be shared by other researchers for research purposes not detailed in this study.

e. If the data or samples will be destroyed, describe when and how the destruction will occur.

11. Compensation

    Clarify if participants will be compensated for participation and specify how participants will receive compensation (e.g., required course credit, extra course credit, cash, a gift card, etc.). Compensation should not unduly influence potential participants.

12. International Research (Eliminate this section if it does not pertain to your study.)
    [Participant protections need not to be the same as provided in the US but should be equal in function and effect.]

    a. Provide the name of each country in which the research will be conducted.

    b. Describe how you are aware or will become aware, (i.e., with a local collaborator,) of the local customs, cultural context, laws, and regulations of the site where the research will be conducted.

    c. Clarify if your research requires local ethics committee review and approval and/or permission/certification by a local, provincial or national government entity.

SIGNATURES		
SIGNATURE OF PRINCIPAL INVESTIGATOR		
The undersigned accept(s) responsibility for the study, including adherence to the ethical guidelines set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the ethical principles of your discipline, the Common Rule and Grambling State University policies regarding protections of the rights and welfare of human participants participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.		
Print Name of Principal Investigator	Signature of Principal Investigator	Date
S**IGNATURE OF FACULTY ADVISOR --- REQUIRED FOR STUDENT RESEARCH**		
By signing this form, the faculty research supervisor attests that (s) he has read the attached protocol submitted for IRB review, and agrees to provide appropriate education and supervision of the student investigator, above and share the above Principal Investigator responsibilities.		
Name of Faculty Research Supervisor	Signature of Faculty Research Supervisor	Date
SIGNATURE OF DEPARTMENT CHAIR OR DEAN --- REQUIRED FOR FACULTY RESEARCH		
Your signature below affirms that you have been informed about the research project		
Name of Chair or Dean	**Signature of Chair or Dean**	**Date**

Print

Approval Date _____IRB #_____

IRB Decision*

_____ _____ APPROVE ☐ DISAPPROVE ☐

IRB COMMITTEE SIGNATURE DATE

Subject to the following restrictions:

_____
_____
_____
_____

Period of approval is from_____ through_____

* See notification letter for detailed information regarding IRB decision.