PRAIRIE VIEW A&M UNIVERSITY
A Member of the Texas A&M University System

IRB USE ONLY

Last Name _____
IRB# _____

Prairie View A&M University

IRB Protocol Application

INSTRUCTIONS

1. Complete Training

PI, Co-Investigator and anyone interacting with potential participants must complete necessary training.
Refresher training must be completed every three years. More details can be found at: http://www.pvamu.edu/research/office-of-research-compliance/207-revision-v1/irb-training/

2. Complete Form

Form must be typed and free of typographical/grammatical errors.

3. Attach Documents to Application

- ☐ Recruitment materials as applicable: flyers, letters, scripts, e-mail, etc.
- ☐ Consent documentation as applicable: consent protocol, consent form or assent form
- ☐ Survey and/or Interview Questions
- ☐ Funding Proposals (as applicable)
- ☐ Any other documents referenced in this application as applicable

4. Submit Application

Submit the complete IRB protocol (application and required documentation) to the Office of Research and Compliance, Wilhelmina Delco Building, Room #163 in person or by email at research@pvamu.edu.
Review of proposal will not begin until the **complete protocol** is received.

Warning: The following is considered protocol non-compliance:

a.) personnel beginning research with human subjects before being added to the approved IRB protocol;
b.) proceeding with the protocol before obtaining final IRB approval;
c.) failing to follow the established criteria or procedures that were approved by the IRB;
d.) adding, removing or modifying a research instrument (or adding to an existing instrument) in a survey study without prior IRB approval unless the changes are within a range of anticipated potential changes specified as acceptable within the IRB approval; and
e.) implementing any change in the protocol without IRB approval is considered protocol non-compliance.

Non-compliance may result in a report being made to the funding agency listed on this protocol and/or the Office of Human Research Protections (OHRP). PVAMU's Federalwide Assurance (FWA) with OHRP is restricted to research funded by the Department of Health and Human Services. However, the same process for conducting investigations and taking actions by the IRB will apply to all research regardless of funding source. PVAMU reserves the right to voluntarily report any event that is not associated with federal funding to OHRP.

If you have any questions or need assistance completing this application, please call Crysta Mendes (936) 261-1553, or e-mail research@pvamu.edu

INVESTIGATOR INFORMATION

Principal Investigator Name: _____

☐ Faculty ☐ Staff ☐ Graduate Student* ☐ Undergraduate Student*

Department: _____ College: _____

Mailing Address (if not PVAMU): _____

Phone: _____ Fax: _____ E-mail: _____

Co - Investigator Name: _____

☐ Faculty ☐ Staff ☐ Graduate Student* ☐ Undergraduate Student*

Department: _____ College: _____

Mailing Address (if not PVAMU): _____

Phone: _____ Fax: _____ E-mail: _____

Please list additional investigators (if applicable): _____

_____

***For Students: Answer the following and list your faculty advisor**

Is this study part of your Thesis or Dissertation? ☐ Yes ☐ No

If Yes, do you have approval from your Thesis/Dissertation Committee? ☐ Yes ☐ No

Graduate Committee Chair/Faculty Advisor Name: _____

Department: _____ College: _____

Mailing Address (if not PVAMU): _____

Phone: _____ Fax: _____ E-mail: _____

Project Title:

Anticipated Start and End Dates: _____

Funding Status: ☐ Externally Funded* ☐ Grant Application* ☐ Internally Funded* ☐ Not Funded

☐ Other _____

Funding Agency (if applicable): _____

Must include a draft of the grant application. Once grant is completed/submitted, a final draft must be submitted to the IRB.

Does this protocol require approval from multiple IRBs? ☐ Yes, please state below ☐ No, only from PVAMU IRB

PURPOSE OF STUDY

Provide a **brief** statement, in lay terminology, outlining the purposes of this study. The following issues must be addressed:

a. Why are you doing this research project and what do you propose to learn?
b. What is the justification for doing the study? Include, as appropriate, preliminary data and/or references to previous research, or gaps in our knowledge.

If you need more space, put "see attached" in the box and attach your complete purpose of study statement. Please title the attachment.

RISKS AND BENEFITS

Describe any potential risks or discomforts to the participant (including physical, psychological and/or social):
Risks to subjects are rated as "Low", "Medium", "High". ***Do not say "none".***

Describe any potential benefits to the research participant or society:

Describe alternatives to participation/opportunity to withdraw:

SUBJECT RECRUITMENT

Number of participants (target population): _____ Ages of Participants: _____

Gender of subjects: ☐ Male ☐ Female

Maximum anticipated sample size: ☐

What are the selection criteria for participation (i.e. include target population and maximum anticipated sample size)?
For clarification on target population and maximum anticipated sample size, please refer to FAQ #35 on the PVAMU IRB website.

Do the criteria for selection exclude individuals based on gender, culture, language, economic status or ethnicity?

☐ Yes ☐ No

If yes, please justify exclusion:

Are there any special physical or psychological conditions of subjects? (If so, please describe.)

Source of participants:

☐ PVAMU students (provide explanation below) ☐ Community (provide explanation below)

☐ Schools* (provide explanation below) ☐ Other (provide explanation below)

For studies involving schools:
Does the study involve a school district? ☐ Yes ☐ No

If Yes, which school district(s)?: _____

Note: <u>If the study involves a school district</u>, approval must be obtained from the school district.

Vulnerable Populations:

☐ Not applicable

☐ Children

☐ Pregnant women

☐ Prisoners

☐ Adults who lack ability to consent

☐ Employees

☐ Other, describe: _____

If vulnerable populations will be used, please describe additional safeguards to protect their rights and welfare:

Recruitment Method **(all flyers, advertisements, etc. are subject to IRB review):**

- ☐ Telephone solicitation (attach script)
- ☐ Radio (attach script)
- ☐ Television (attach script)
- ☐ Newspaper advertising (attach ad copy)
- ☐ Posted notices (attach copy)
- ☐ Letter (attach copy)
- ☐ E-mail (attach copy of text to be sent for recruitment)
- ☐ Direct person-to-person contact, describe: _____
- ☐ Other, describe: _____

How will initial contact be made with potential participants? (*be specific*)

Other than as an Investigator, do you have any other relationship with participants? (*i.e. doctor-patient, teacher-student, counselor-student, etc.*) ☐ Yes ☐ No

If Yes, explain the relationship and describe how you will avoid any type of coercion:

CONSENT

LOCATION

Describe the setting where the consent process will take place (*i.e. classroom, office, park, personal computer, etc.*):

PERSONNEL

Name individuals or group of individuals who will be speaking directly to potential participants during the consent process:

CONSENT TOOLS

Please check all that apply and attach to the application:

- ☐ Cover Letter
- ☐ Adult Consent Form
- ☐ Information Sheet
- ☐ Minor Assent Form
- ☐ Telephone Script
- ☐ Parental Consent Form

Location where consent forms will be filed:
(***Consent forms must be kept on file for 3 years after completion of the study and data analysis***)

WAIVER

Request for waiver of informed consent or waiver of documentation of informed consent:

☐ Yes ☐ No

If Yes, explain below:

COMPENSATION / COURSE CREDIT

Will monetary compensation be given to the participant?

☐ Yes ☐ No

If Yes, explain below and attach a detailed compensation of payment including amount and schedule of payments to participant:

Will course credit be given to the participant as compensation?

☐ Yes ☐ No

If Yes, provide details below and alternate assignment to obtain equal credit:

SUBJECT MATTER

Check the appropriate box(es) concerning the subject matter of the research:

- ☐ No sensitive matters
- ☐ Abortion
- ☐ AIDS/HIV
- ☐ Alcohol
- ☐ Body composition
- ☐ Criminal activity
- ☐ Depression
- ☐ Drugs
- ☐ Learning disability
- ☐ Physical disability
- ☐ Psychological inventory
- ☐ Review of criminal records
- ☐ Review of educational records
- ☐ Sexual Activity
- ☐ Suicide
- ☐ Other, specify: _____

DECEPTION OR COERCION

Will deception or coercion be used?

☐ Yes ☐ No

If Yes, **attach debriefing form** and briefly describe deception:

PROCEDURES

What will participants be asked to do? (Describe the study in detail from recruitment to completion)
If you need additional space, put "see attached" in the box below and attach complete description of procedures.

Describe the location where research activities will take place:

How long will the participants be engaged in research? (*length of time, i.e. 15 minutes on day 1, etc.*):

During data collection, describe what steps will be taken to ensure participant privacy:

Is the research anonymous or confidential? **(*Cannot be both*)**

- ☐ **Anonymous**: The identity of the participant cannot be readily determined by the investigator AND the identity of the participant is not connected to information gathered.
- ☐ **Confidential**: Research participants can be identified; however, information gathered will be protected.

Provisions for anonymity/confidentiality:

- ☐ Secure storage (**required**)
- ☐ Replies coded

What specific steps will be followed to ensure anonymity or confidentiality of participants' responses?

DATA COLLECTION

Research Type:

- ☐ Qualitative
- ☐ Quantitative
- ☐ Both

Will any new data or documents be collected? (*i.e. public records, survey instruments, evaluation tools, etc.)*

☐ Yes ☐ No

If Yes, describe what data or documents will be used and how they will be obtained:

Will recordings be made?

☐ Yes ☐ No

If Yes:

- ☐ Video Taping
- ☐ Audio Taping
- ☐ Mandatory Recording
- ☐ Voluntary Recording

Is the use of recordings detailed in the consent form?

☐ Yes ☐ No

Will recordings be retained?

☐ Yes ☐ No

If Yes, how long will records be retained before they are destroyed/erased?

Will any new specimens be collected? (*i.e. blood tissue, etc.)*

☐ Yes ☐ No

If Yes, describe what specimens will be used and how they will be obtained:

Does the experiment involve the use of human fluid, tissue and/or blood?

☐ Yes ☐ No

Will any invasive or sensitive procedures be done?

☐ Yes ☐ No

If Yes, check all that apply:

- ☐ Blood Samples
- ☐ Physical Measurements (electrodes, etc)
- ☐ rDNA
- ☐ Stress Exercise
- ☐ Urine Samples
- ☐ Other, specify:_____

DOCUMENT RETENTION

Federal regulations require that human research documents be retained for a minimum of three years AFTER the completion of the study AND data analysis. Some disciplines or granting agencies require longer retention times.

Length of time retained after completion of study and data analysis:

Person responsible for data retention (*If you are a student, please list faculty mentor) & data storage location:*

OTHER COMPLIANCE ISSUES

If the study involves the use of **animals, infectious biohazards (e.g. blood), and/or recombinant DNA**, it is required that approval be granted for the use of such through the appropriate compliance committee.

SIGNATURE ASSURANCES

PRINCIPAL INVESTIGATOR

I understand Prairie View A&M University's procedures concerning research involving human subjects and **by initialing** below, I certify:

_____I have read The Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" and subscribe to the principles it contains.

_____I accept responsibility for the scientific and ethical conduct of this research study.

_____I will obtain prior approval from the Institutional Review Board (IRB) before amending or altering the research protocol or implementing changes in the approved consent form and/or information sheet.

_____I will immediately report to the IRB any unanticipated effects on subjects which may occur as a result of this study.

_____I will retain the consent forms and other research documents in a locked/secure manner for a minimum of three years. Students must turn over all documents to the primary faculty advisor upon completion of the study in most cases.

_____I will complete, on request by the IRB, the Continuation/Final Review forms.

_____I do not have a personal/financial conflict of interest and I have submitted my Financial Conflict of Interest Disclosure Statement in Maestro (if applicable).
(*If you have a conflict of interest, you must specify - as an attachment - the conflict of interest and describe what safeguards are in place to ensure that the conflict of interest does not affect the experimental results.)*

_____I have reviewed all forms and documents being submitted.

Principal Investigator Signature: _____

Typed Name: _____ Date: _____

FACULTY / RESEARCH ADVISOR

I certify that I have read and agree with this proposal, that the Principal Investigator has received adequate training to perform this research, and will receive adequate supervision while performing this research:

_____By initialing, I certify that I do not have a personal/financial conflict of interest and I have submitted my Financial Conflict of Interest Disclosure Statement in Maestro (if applicable).
(*If you have a conflict of interest, you must specify - as an attachment - the conflict of interest and describe what safeguards are in place to ensure that the conflict of interest does not affect the experimental results.)*

Faculty/Research Advisor Signature: _____

Typed Name: _____ Date: _____

CO-INVESTIGATOR or PERSONNEL

(If needed, print additional copies for studies with more than one Co-Investigator or Personnel)

I understand Prairie View A&M University's procedures concerning research involving human subjects and **by initialing** below, I certify:

_____ I have read The Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" and subscribe to the principles it contains.

_____ I accept responsibility for the scientific and ethical conduct of this research study.

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(If you have a conflict of interest, you must specify - as an attachment - the conflict of interest and describe what safeguards are in place to ensure that the conflict of interest does not affect the experimental results.)

_____ I have reviewed all forms and documents being submitted.

Co-Investigator or Personnel Signature: _____

Typed Name: _____ Date: _____

FACULTY / RESEARCH ADVISOR

I certify that I have read and agree with this proposal, that the Principal Investigator has received adequate training to perform this research, and will receive adequate supervision while performing this research:

_____ By initialing, I certify that I do not have a personal/financial conflict of interest and I have submitted my Financial Conflict of Interest Disclosure Statement in Maestro (if applicable).
(If you have a conflict of interest, you must specify - as an attachment - the conflict of interest and describe what safeguards are in place to ensure that the conflict of interest does not affect the experimental results.)

Faculty/Research Advisor Signature: _____

Typed Name: _____ Date: _____

TRAINING

(for office use only)

PRINCIPAL INVESTIGATOR

IRB Member:	☐ YES	☐ NO	Date:_____
Social/Behavioral Research Course:	☐ YES	☐ NO	Date:
IRB accepts Alternative Training:	YES	NO	Date:
_____	☐ YES	☐ NO	Date:_____

CO-INVESTIGATOR or PERSONNEL *(if more than one Co-Investigator or Personnel, please write training completion dates on a separate page)*

IRB Member:	☐ YES	☐ NO	Date:_____
Social/Behavioral Research Course:	☐ YES	☐ NO	Date:_____
IRB accepts Alternative Training:	☐ YES	☐ NO	Date:_____
_____	☐ YES	☐ NO	Date:_____

Training Reviewer:_____ Date:_____

PROTOCOL APPROVAL

(for office use only)

☐ **EXEMPT**

Declared by:_____ Date:_____

☐ **EXPEDITED**

Approved - Reviewer 1:_____ Date:_____

Approved - Reviewer 2:_____ Date:_____

☐ **FULL REVIEW**

Referred for Full Review:_____ Date:_____

Approved:_____ Date:_____

Date of Full Review (attach minutes): _____