Date Received in Office: _____ HPRC #: _____

Tuskegee University
Institutional Review Board (IRB)

APPLICATION FOR EXEMPTION

Exemption applies only to research with minimal risk. It does not apply to research involving prisoners, children or other vulnerable categories of subjects. **Final determination as to whether a research project is exempt from further review rests with the Institutional Review Board (IRB)**. If the project is determined to be exempt by the IRB, the principal investigator is still required to submit any project modifications to the IRB. The exempt status does not necessarily mean that the investigator is exempt from informed consent requirements.

The Human Participants Review (IRB) Committee regular scheduled meeting date is the last **Wednesday** of each month except December. All applications must be submitted a minimum of 10 working days before the committee's regular scheduled meeting. Any application submitted after that deadline is generally reviewed in next month's meeting.

Date_____

Investigator(s)_____

Address: _____

If Student, Advisor(s)
Name(s)_____Phone_____

T.U. Address (of Advisor if a student)

Department_____College_____

Project Title: _____

Anticipated dates of project: Beginning: _____ Ending: _____

FUNDING: Anticipated source of funds, if any, including T.U. Research Funds. (If this project will be funded under a grant to another investigator, please give the title of the grant, name of agency or institution, and the investigators name.)

RESEARCH CATEGORIES OF EXEMPTION FROM FURTHER HPRC REVIEW
Research activities in which the only involvement of human subjects will be in one or more of the following categories are usually exempt from further IRB review. **Check all that apply to your research study**.

☐ **(A)** Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **(B)** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) **if at least one of the following criteria is met:**

- ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ☐ Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

☐ **(C)** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and **at least one of the following criteria is met**:

- ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ☐ Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- ☐ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

☐ **(D)** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, **if at least one of the following criteria is met:**

☐ The identifiable private information or identifiable biospecimens are publicly available;

☐ Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

☐ The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

☐ The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E- Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

☐ **(E)** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine:

☐ (1) public benefit or service programs
☐ (2) procedures for obtaining benefits or services under those programs,
☐ (3) possible changes in or alternatives to those programs or procedures
☐ (4) possible changes in methods or levels of payment for benefits or services under those programs.

☐ **(F)** Taste and food quality evaluation and consumer acceptance studies, **if**:

___ (1) wholesome foods without additives are consumed, or
___ (2) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ **(G)** Storage or maintenance for secondary research for which broad consent is required:

☐ (1) storage or maintenance of identifiable private information
☐ (2) identifiable biospecimens for potential secondary research use if an IRB

conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

☐ **(H)** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- ☐ (1) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
- ☐ (2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;
- ☐ (3) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
- ☐ (4) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

(Approved by the Office of Management and Budget under Control Number 0990-0260); Accessed Date: December 12, 2022

RESEARCH PROJECT DESCRIPTION

Use lay terms and/or provide definitions of technical terminology. Use extra pages if necessary.

1. Briefly describe the background or justification for your research.

2. Describe your research focus (the purpose or questions to be answered).

3. Describe the research design including the use of a control group and any intervention or treatment to be administered to the subjects whether performed by the researchers or others.

4. Describe your data collection procedures in detail.
   What will the participants (and controls) be doing to create the data (e.g., filling out a survey, performing a task, etc.)? If the participant will need training, explain in detail. (Attach copies of any instruments, tests, surveys, interview guides, etc. and descriptions of any research data collection equipment.)

COMPLETE THE FOLLOWING <u>PARTICIPANT INFORMATION</u> AND SUBMIT WITH REQUEST FOR EXEMPTION. Use Not Applicable (N/A) rather than leaving a blank space.

Age/Age range: _____(For any underage participant, an INFORMED ASSENT PROCESS IS REQUIRED for agreements from parents and child)

Source of participants or existing data:

What is required of a participant?

Will you engage participant in an Informed Consent procedure? ☐ NO ☐ YES (attach copy of Informed Consent Form) ☐ Not Applicable

Will you retain any Identifiers? ☐ NO ☐ YES

Will you retain any Demographic data? ☐ NO ☐ YES (If yes, list)

How will confidentiality/privacy be maintained if identifiers are contained in the data?

What will be the location of research? (If not at T.U., obtain documented permission from the site and attach copy)

An informed consent **COVER LETTER** (or telephone introduction script) addressed to the participants must accompany any survey or questionnaire. The cover letter or telephone script must include the following. I**f certain elements are left out, justify why this is necessary. An** Informed Consent Cover Letter must contain the following: **(SEE TEMPLATE BELOW)**

a. A statement that the project is research being conducted for… (a paper or presentation or in partial fulfillment of the requirements for a course, thesis, independent study, etc.).
b. A comprehensive though succinct description of the study in narrative form.
c. A statement that participants' response will/will not be kept anonymous or confidential (explain extent of confidentiality if participants' names are requested).
d. If audio taping, a statement that the participant is being audio taped (explain how tapes will be stored or disposed of during and after the study).
e. A statement that participants do not have to answer every question.
f. If applicable, a statement that the participant's class standing, grades, or job status (or status on an athletic team) will not be affected by refusal to participate or by withdrawal from the study.
g. A statement that participation is voluntary.
h. A question directly asking the participant if he/she agrees to participate in the study

Attachments (Check all that apply):

☐ Questionnaire/survey, script, etc. to be used with participants
☐ Consent agreement, cover letter/telephone introductory script or justification for waiver
☐ Permission to use existing data and/or permission from external institution (if applicable)

INVESTIGATOR AGREEMENT

I verify that risks to subjects are minimal. I agree to ensure that the rights and welfare of human subjects in my research are properly protected.

I understand that additions or changes in the procedures involving human subjects or any problems with the rights or welfare of the human subjects must be promptly reported to the HPRC administrator.

I further understand that **subjects' data and research records must be maintained in a secure and safe location for a period of at least three (3) years** after the research is completed. The original data will be provided to the HPRC if so requested.

_____ _____
Signature of Investigator Date

_____ _____
Signature of Investigator Date

_____ _____
Signature of Advisor (if student research) Date

AFTER COMPLETING THESE FORMS, SEND AN ELECTRONIC SIGNED COPY OR RETURN THE **ORIGINAL AND ONE (1) COPY** OF THESE MATERIALS AND ALL ATTACHED DOCUMENTS TO:

Office of Grantsmanship and Compliance
Kenney Hall room 44-328
Tuskegee University
Tuskegee, AL 36088
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

INFORMED CONSENT AGREEMENT TEMPLATE
OR
INFORMED CONSENT COVER LETTER TEMPLATE

(No signature required of participant, usually used with anonymous surveys.)

Note: One of the most common reasons for delay of Human Participant Review Committee (HPRC) approval is an inadequate informed consent agreement. It is recommended that you follow this template, write in the 2nd person, use #12 font size and target a sixth to eighth grade reading level. Statements in **bold** type should be included verbatim; however they do not need to be in bold type in your consent agreement.

Tuskegee University
Informed Consent Agreement or Informed Consent Cover Letter TEMPLATE
(Research study title)

[If including the exact title might bias the results, use a general title instead.]

You are being asked to participate in a research study. Before you give your consent to volunteer, it is important that you read the following information to be sure you understand what you will be asked to do.

Investigators

Provide the names and degrees of all investigators involved in the research study. Indicate the department and institution with which the investigator(s) is affiliated. If you are a student, include the name of your faculty advisor. Also provide the TU addresses and phone numbers.

Purpose of the Research

This research study is designed to… (State what the study is designed to assess or study).
The data from this research will be used to… (Explain how data will be used).
If you are a student, indicate how the results will contribute to your course of study.

Procedures

If you volunteer to participate in this study, you will be asked to… [Describe what subject will do using lay language].
[If controls are used, also explain what will be expected of the controls.]
(If the description is complicated, bulleting or listing works well.)
Your participation will take approximately… [Estimate the amount of times, frequency etc.].
If any procedures are experimental, identify them here.

Potential Risks or Discomforts

DO NOT state that there are no risks or discomforts. You may say there are no foreseeable risks associated with the study.

Describe any reasonable foreseeable risks, discomforts, inconveniences, or costs associated with this research that the participants may encounter. These could be physical, psychological, emotional, social or economic. Inform the participant of any provisions for managing these and of the subjects' right to discontinue participation, either temporarily or permanently.

Potential Benefits of the Research
Describe any benefits the participants can expect as a result of participating in the study. If there are no benefits to the participants, state this. Describe any potential benefits to science and/or society that may result from this research.

Confidentiality and Data Storage
Describe the precautions that will be taken to preserve the confidentiality/privacy of subjects (e.g., anonymous survey).
Include the procedures for using and storing data (e.g., in Dr. X's office) and include who will have access to the data (e.g., the investigator and advisor). (It must be stored at TU for at least 3 years after completion of the study.)
If video or audio tapes will be used to record information, describe exactly how the recordings will be used, who will have access, how long the recordings will be stored and when they will be destroyed.

Participation and Withdrawal
Your participation in this research study is voluntary. You may refuse to participate or stop at anytime without penalty. To stop…(Tell how, e.g., simply stop answering the questions).

Questions about the Research
If you have any questions about the research, you may contact… [Name (of advisor, if a student), TU phone].

This project has been reviewed by the Human Participant Review Committee for Tuskegee University. If you believe there is any infringement upon your rights as a research participant, you may contact the IRB Chair, Dr. Stephen O. Sodeke at (334) 727-8210.

xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
I have read the information provided above. I understand that …[by returning a completed questionnaire/survey or by agreeing to be interviewed, etc.] **I am agreeing to participate in this research study.**

Signature of Research Participant (Optional in some cases): _____Date

Signature of Person Obtaining Consent: _____Date

PLEASE KEEP THIS INFORMED CONSENT COVER LETTER FOR YOUR RECORDS.

_____ _____

NOTE ADDITIONAL ELEMENTS ONLY WHEN APPROPRIATE
Incentives to Participate

If an incentive is offered, describe what is being offered and what is required to obtain the incentive.

Reasons for Exclusion from this Study
State in basic lay language reasons why a subject should be excluded from participating (e.g., being a smoker, pregnant, under the age of 18, a medical condition). Include only those reasons which could not be pre-determined by the investigator.

In Case of Injury [Include this section if your study involves *more than minimal risk.*]
It is unlikely that participation in this project will result in harm to participants. If an injury to a participant does occur, he or she may be seen at a local or regional medical facility. All expenses associated with care will be the responsibility of the participant and his/her insurance. (*If the research is not conducted at T.U., leave out the option of using local or regional medical facility.*)