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.

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, involving normal education instruction practices, such as
____ (1) research on regular and special education instruction strategies, or
____ (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

____ B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless**:
____ (1) information obtained will be recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
____ (2) any disclosure of the human participants responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants financial standing, employability, or reputation.

____ C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph B (2) of this section, if:
____ (1) the human participants are elected or appointed officials or candidates for public office; or
____ (2) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

____ D. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if:
____ (1) the sources are publicly available, or
____ (2) the information will be recorded by the investigator in such a manner that participants ***cannot*** be identified, directly or through identifiers linked to the participants.

____ E. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, 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; or

____ (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.

Note: If you have checked B (1) and B (2) your research is **not** exempt from IRB review. You must apply for full or expedited IRB review.

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
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

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.*)