WINSTON-SALEM STATE UNIVERSITY
INFORMED CONSENT FORM

Title of Study--required

Headings with (*) are required for all studies

IMPORTANT: BEFORE FINALIZING & PRINTING THIS DOCUMENT REMOVE THIS TEXT & ALL RED AND BLUE INSTRUCTIONAL TEXT (this document is ONLY a recommended template).

Preamble: include the following information.

- Statement that study involves research, .116(b)(1)
- Explanation of the purposes of the research and the expected duration of the subjects' participation, .116(b)(1)
- A description of the procedures to be followed, .116(b)(1) and
- Identification of any procedures that are experimental .116(b)(1) Description of any reasonably foreseeable risks or discomforts to the subject 116(b)(2)
- Description of any benefits to the subject or to others that may reasonably be expected from the research .116(b)(3)
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject .116(b)(4) *If clinical research only*

Example: You are being asked to participate in a research study. Participation in this study is completely voluntary. The purpose of the study is ------. The duration of the study is -----. The procedures to be followed-------. The procedures that are experimental are none or there are no experimental procedures. The benefits to the subject that may be expected are-----.Please read the information below and ask questions about anything that you do not understand before deciding if you want to participate. A researcher listed below will be available to answer your questions.

RESEARCH TEAM*
Principal Investigator:
Name and Title
Department
Telephone Number

Faculty Sponsor:
Name and Title
Department

Other Co- Investigators or Researchers:
(List only those researchers qualified to be involved in the informed consent process)

Study Location(s):

Study Sponsor(s):

PURPOSE OF STUDY*
The purpose of this research study is to… *(Complete this sentence) Examples include "to explore attitudes of first-generation Americans regarding education; to understand how social support influences mental health."*

SUBJECTS*
Inclusion Requirements
You are eligible to participate in this study if you… *(Complete this sentence or use a bulleted list of inclusion criteria) Examples include, "are at least 18 years of age or older," "are right-handed," "live in Forsyth County"*

Exclusion Requirements *(Optional)*
You are not eligible to participate in this study if you... *(Complete this sentence or use a bulleted list of exclusion criteria) Examples include, "do not have corrected 20/20 vision," "are taking high blood pressure medications," "are not enrolled in at least 8 units at the institution."*

Number of Participants and Time Commitment*

This study will include approximately subjects and will involve approximately of your time.

PROCEDURES*
The following procedures will occur: *(Explain the research procedures in detail and in chronological order; include the expected duration of each procedure or each visit and the procedures to be completed at the visit.) Example:*
"You will complete a survey about your eating habits, then you will have your blood drawn (indicate amount) and your blood pressure taken".

RISKS AND DISCOMFORTS* *(Describe the risks and discomforts associated with the research study)*
[For minimal risk studies] This study involves no more than minimal risk. There are no known harms or discomforts associated with this study beyond those encountered in normal daily life.

OR

[For greater than minimal risk studies] The possible risks and/or discomforts associated with the procedures described in this study include: *(Complete this sentence. Categorize the risks by severity and include the likelihood of the risk/discomfort occurring. Make sure to consider all types of risks – psychological, social, economic, legal and physical.)*
Examples of risks/discomforts include: dizziness, nausea, embarrassment, social stigma (shame or disgrace), psychological distress, loss of employment, invasion of privacy and breach of confidentiality)

UNKNOWN RISKS *(Optional)*
There may be risks to being in this study that we don't know about now. You will be informed of any changes in the way the study will be done and any additional identified risks to which you may be exposed. *[This section is required if the research involves clinical procedures or risk profile of research intervention is not well known.]*

BENEFITS*

Subject Benefits

The possible benefits you may experience from the procedures described in this study include… *(Complete this sentence – the description of subject benefits should be clear and not overstated) Examples: increase reading comprehension, improved writing skills, learning about ways to improve my memory.*

OR

[If no direct benefit to the subject is anticipated, delete the above statement and insert – You will not directly benefit from participation in this study.]

Benefits to Others or Society*

[*Insert a statement about possible benefits to science or society here. Example: a decrease in the number of children injured in car accidents, greater understanding of how stress influences memory.*]

ALTERNATIVES TO PARTICIPATION* *(Describe the alternatives)*

[If no alternatives] The only alternative to participation in this study is not to participate.

[If subjects will be compensated with extra course credit] The course instructor offering extra course credit for participation in research must provide alternatives to earn extra course credit. The alternative assignment must require equal or less time and effort for the same amount of earned extra credit.

Students Participation *(if subjects are students of Principal Investigator)*

(Complete this section if applicable; please delete this section if this does not apply) Please be informed that you do not have to consent to be in a research project. You may also initially consent and then decide to withdraw. The faculty member will not use your refusal to participate in any way to affect your grade or the way you are treated in your courses, the department, or the university.

Furthermore, research data should not be collected during class time except when those data would have been collected as part of the regular teaching and assessment of your learning. If data are collected on all students as part of the regular class, then you have the right to refuse to have your data included in subsequent research from those data.

Should you feel that you have been coerced or forced into participating in this research or that data are being collected during class time solely for the purpose of research, please contact the Institutional Review Board through the Compliance Officer at 336-750-2982.

COMPENSATION, COSTS AND REIMBURSEMENT*

Compensation for Participation*

[CHOOSE ONE OPTION]

You will be paid $ [*enter type of payment and amount of compensation*]

OR

You will be paid $ [*enter type of payment and amount of compensation*] after each study visit. There are [*enter # of study visits if applicable*] visits. Total payment for participation in this study is $[*enter total compensation for completion of the study*]. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits that you have completed.

OR
[If subjects will not be compensated, please insert - You will not be paid for your participation in this research study.*]*

Costs *(Optional)*
There is no cost to you for participation in this study.
OR
You will be responsible for the following costs… (*Complete this sentence).*

Reimbursement *(Optional)*
You will be refunded for the following expenses that you incur… *(Complete this sentence)*
Examples: parking fees, transportation fees

If no reimbursement will be provided, delete the above statement and insert – You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

Compensation for Injury *– [Required if research involves greater than minimal risk]*
If you are injured as a direct result of your participation in this study, you will be referred to the necessary medical agency to treat the illness or the emergency 911 will be called. **Winston-Salem State University does not routinely provide any form of compensation or medical care for injury, other than a referral.** It is important that you report any suspected study-related illness or injury to the research team listed at the top of this form immediately.

WITHDRAWAL OR TERMINATION FROM THE STUDY AND CONSEQUENCES *(Optional)*
[Required if subjects may be terminated by researcher and/or if there are adverse consequences (physical, social, psychological, economic, or legal) of the subject's withdrawal from the study]

You are free to withdraw from this study at any time. **If you decide to withdraw from this study you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety and welfare are at risk.

CONFIDENTIALITY*
Subject Identifiable Data* *(Explain whether subject identifiers will be linked to the research data.)* Examples include:

- All identifiable information that will be collected about you will be removed at the end of data collection.
- All identifiable information that will be collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.
- All identifiable information that will be collected about you will be kept with the research data.

Data Storage* *(Describe how the data will be maintained)*
Examples include:

- All research data will be maintained in a secure location at WSSU. Only authorized individuals will have access to it.
- All research data will be stored on a laptop computer that [is password protected or has encryption software.]

- All research data will be stored electronically on a secure [computer or network] with [encryption or password] protection.
  Other privacy options:
- The [audio/video recordings] will also be stored in a secure location; then transcribed and erased as soon as possible.
- The [audio/video recordings] will also be stored in a secure location; then transcribed and erased at the end of the study.
- The [audio/video recordings] will also be stored in a secure location and transcribed. The recordings will be retained with the other research data.

Data Access* *(Explain who will have access to the research data)*
The research team, authorized WSSU personnel, the study sponsor (if applicable), and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Research records provided to authorized, non-WSSU entities will not contain identifiable information about you. Publications and/or presentations that result from this study will not include identifiable information about you.

Data Retention* *(Explain how long the research data will be maintained)*
- The researchers intend to keep the research data until analysis of the information is completed.
- The researchers intend to keep the research data until the research is published and/or presented.
- The researchers intend to keep the research data for approximately __ years.
- The researchers intend to keep the research data indefinitely.
- The researchers intend to keep the research data in a repository indefinitely. Other researchers will have access to the data for future research.

OTHER CONSIDERATIONS *(Optional)*
Use of Specimens
[If the study involves collection of specimens, one of the following statements is required]

Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the Winston-Salem State University. Once you provide the specimens you will not have access to them. The specimen(s) will be discarded or destroyed once they have been used for the purposes described in the protocol.

OR

Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the Winston-Salem State University. Once you provide the specimens you will not have access to them. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

Investigator Financial Conflict of Interest
[If there could be the appearance of a conflict of interest, the following statement is required]
No one on the study team has a significant financial interest related to this research project.

NEW FINDINGS *(Optional)*

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the researcher team listed at the top of the form.

IF YOU HAVE QUESTIONS*
If you have any comments, concerns, or questions regarding the conduct of this research please contact the research team listed at the top of this form.

If you are unable to reach a member of the research team listed at the top of the form and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact Winston-Salem State University Institutional Review Board (IRB) via the Compliance Officer in the Office of Sponsored Programs at khaniu@wssu.edu or in person at C125, Anderson Center, 601 Martin Luther King Jr. Drive, Winston-Salem, North Carolina 27710.

CONSENT STATEMENT*

You should not sign this form unless you have read and understand the attached Informed Consent Form. Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with Winston-Salem State University. Your signature below indicates that you have read the information in this consent form and have had a chance to ask any questions that you have about the study.

I agree to participate in the study.

_____ _____
Subject Signature* **Date**

_____
Printed Name of Subject *

_____ _____
Legally Authorized Representative/Guardian Signature ***Date***

_____
Printed Name of Legally Authorized Representative/Guardian's

_____ _____
Legally Authorized Representative/Guardian Signature ***Date***

_____
Printed Name of Legally Authorized Representative/Guardian's

_____ _____
Researcher Signature* **Date**

_____
Printed Name of Researcher*