VIRGINIA STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD
CONSENT TO PARTICIPATE IN RESEARH

You are invited to participate in a research study of **[Insert general statement about study]**. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by **[Indicate the investigators' names and University/Departmental affiliation]**. It is funded by **[Indicate study sponsor, if any, and state if the sponsor is also the manufacturer of the drug/device being studied, if applicable]**.

STUDY PURPOSE

The purpose of this study is to **[Explain why the research is being done using language understandable to the subject, e.g., eighth grade level. Clarify if the study involves the use of an investigational drug or device, including that "investigational" means it is not approved by the Food and Drug Administration (FDA)]**.

PROCEDURES FOR THE STUDY:

If you agree to be in the study, you will do the following things:

[Explain in language understandable to the subject, all procedures/tests, including surveys, focus groups, audio or video taping, assignment to study groups. Clarify where the procedures will be performed, how frequently they will be performed, and the expected amount of time each procedure and/or visit will last. Also clarify the total duration of the study.

RISKS OF TAKING PART IN THE STUDY:

While on the study, the risks [**side effects, and/or discomforts**] are:

[**List in language understandable to the subject, the risks, side effects, and/or discomforts of each of the procedures to be employed in the study, including physical, psychological, social, and legal. Include risks and side effects of all medications to be given to subjects for the purpose of the study. The likelihood of the risks and/or side effects should also be included].**

Examples of possible risk/side effect statements include:
The risks of completing the survey are being uncomfortable answering the questions.
The risks of possible loss of confidentiality
The risks of drawing blood include, pain, bruising, and rarely, infection.)
The side effects associated with taking [Insert study medication] are mild diarrhea, confusion, sleepiness, depression, anxiety, and headaches. In rare instances, hair loss, rash, decrease in the number of red and white blood cells and blood platelets, which could cause fatigue, increase in infection and/or bleeding can occur.

If appropriate, add the following statement: There also may be other side effects that we cannot predict.]

[**Explain measures that will be employed to minimize the risks and side effects listed above.**

Examples include:

While completing the survey, you can tell the researcher that you feel uncomfortable or do not care to answer a particular question.
Explain any psychological, social, or medical services that may be required because of research participation such as counseling, social support services or medical services. (If there are significant psychological risks to participation, the subject should be told under what conditions the researcher will terminate the study).
Blood will be drawn by experienced technicians and whenever possible it will be obtained at a time when blood is being obtained for other tests your doctor has ordered.
While you are receiving [Insert study medication], you will be questioned weekly about possible side effects; you will be monitored by the blood tests we are obtaining.

BENEFITS OF TAKING PART IN THE STUDY:

The benefits to participation that are reasonable to expect are [**describe any direct benefit to the subject or benefit to others, which may reasonably be expected from the research. If there is no direct benefit to the subject, state this. Note: payment to subjects is not considered a benefit of participating in the study and should not be listed in this section. Rather it should be listed under a separate Payment section.**]

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published [**Include the following statement, if applicable, "and databases in which results may be stored." If tape recordings or videotapes are made, explain who will have access, if they will be used for education purposes, and when they will be destroyed.**]

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher [**Insert name of investigator**] at [**Insert telephone number**] during regular business hours (i.e. 8:00 AM – 5:00 PM).

For questions about your rights as a research participant or concerns about a research study, or to obtain information, contact Dr. Justina Osa, IRB Chair at (804) 504-7516 or josa@vsu.edu.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

SUBJECT'S CONSENT

(***This section should be in first person)*** In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name:_____

Subject's Signature:_____ **Date**:_____
(must be dated by the subject)