VIRGINIA STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
CONSENT TO PARTICIPATE IN RESEARH

***My initials certify that I am 18 years or older _____**

(Please provide your answers in the gray boxes and where it states to insert your answer)

You are invited to participate in a research study of **[give a 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, administration of study medications, x-rays, blood draws, study visits, etc., which will be employed in the study. 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. Identify which procedures are experimental and which are standard procedures. If blood is to be drawn, explain how and from where the blood will be drawn, e.g., "from a vein in your arm." Indicate the total number of times blood will be drawn, the amount of blood to be drawn each time, and the total amount of blood to be drawn over the course of the study. Translate the amount to be drawn to common measurement terms, such as teaspoonfuls or cupfuls)].

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.

IN CASE OF INJURY:

[**If a source of funds for payment of treatment costs is NOT available, include the statement below:**]

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

[**If a source of funds for payment of treatment costs IS available, the source and conditions for payment of those costs should be identified**.]

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.**]

COMPENSATION

You (will/will not) receive financial payment for taking part in this study.
[**Describe the details and any conditions of payment. If subjects will not be paid, this should be stated.**]

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher at . You may also contact my advisor, during regular business hours (i.e. 8:00 AM – 5:00 PM).

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact Dr. Larry Keen, IRB Institutional Officer at (804) 524-5523 or irb@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. Your decision whether or not to participate in this study will not affect your current or future relations with [**Insert appropriate entity, e.g University, school**]. [**If withdrawal from the study prior to completion could pose risk to the subject, state what those risks might be and how orderly termination will occur.**]

[**If appropriate, include the following statement:** Your participation may be terminated by the investigator without regard to your consent in the following circumstances: [**state when and why study participation may be terminated and how orderly termination will occur**].

[**If appropriate, include the following statement:** You will be told about new information that may affect your health, welfare, or willingness to stay in the study. This study may be terminated by [**Insert sponsor/investigator, as appropriate**] if [**State reason for possible premature termination**].

USE OF SPECIMENS
(*If applicable - Use the following statement*)

If specimens obtained as part of the study will be used for commercial use, include the following statement: As this is a research institution, specimens obtained in medical situations may later be used for research purposes. The investigator intends to include specimens taken from you along with other specimens that may also be used in an attempt to develop products to be sold, and it is not the intention of the investigator to enter into an agreement with you to become partners in sharing the profits or losses in the sale of those products.

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)

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____

If the study involves children who will be providing their assent on this consent document, rather than on an assent document, use the following signatures:

Printed Name of Parent:_____

Signature of Parent:_____**Date**:_____

If two (2) parents are required to sign the consent document, include this additional signature line:

Printed Name of Parent:_____

Signature of Parent:_____Date:_____

Printed Name of Child:_____

Signature of Child:_____Date:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____