RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**TEMPLATE OUTLINE FOR: VCU**

**TITLE:**

**PROTOCOL NO:**

External IRB Protocol #

HMxxxx *(the VCU internal tracking number)*

**SPONSOR:**

**INVESTIGATOR:**

**INTRODUCTION:**

*standard*

**PURPOSE OF THE STUDY:**

*standard*

**DESCRIPTION OF THE STUDY**

*standard*

**PROCEDURES**

*standard*

*If tests are done that require reporting of positive results to the Health Department (eg hepatitis, HIV, STDs), these must be mentioned, along with that information. EX:*

Your blood sample will also be tested for hepatitis and HIV. Virginia state law requires the study staff to report the results of positive tests for hepatitis and HIV to a local health agency.

**RISKS AND DISCOMFORTS**

*standard*

**BENEFITS**

*standard*

**COSTS**

*standard*

**PAYMENT FOR PARTICIPATION**

*standard*

Total payments within one calendar year that exceed $600 will require the University to annually report these payments to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

**ALTERNATIVE TREATMENT**

*standard*

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES *or* CONFIDENTIALITY

*standard, with the addition:*

* The U.S. Food and Drug Administration (FDA)

1. Department of Health and Human Services (DHHS) agencies
2. Governmental agencies in other countries
3. Governmental agencies to whom certain diseases (reportable diseases) must be reported
4. Virginia Commonwealth University
5. Name of the IRB of Record (reviewing IRB)

**CONFIDENTIALITY**

*Standard*

*[If this is a clinical research study that has the potential for clinical billing or is a clinical trial or research information will be placed in the medical record at VCUH]*

It will be noted in your protected electronic medical record at VCUHealth that you are in this clinical trial. Information about the study including any medications you may receive will be noted in the record. This information is protected just as any of your other medical records are protected.

*[If there is the potential for you to discover suspected child abuse, as an employee of an institution of higher education in Virginia, you are obligated to report this. Include a statement indicating the requirement to report. If there is the potential for any participant to disclose that they may cause injury to themselves or others, you should state in this section that you are required by law to report that information to the appropriate authorities.].*  Example language:

We will not tell anyone the answers your child gives us. But, if your child tells us that someone is hurting her or him, or that she might hurt herself or someone else, the law says that we have to let people in authority know so they can protect your child.

*Required*

VCU and VCUHealth have established secure databases to help with monitoring and oversight of clinical research. Your information may be maintained in these databases but is only accessible to individuals working on this study or VCU/VCUHealth officials who have access for specific research related tasks. Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law.

**COMPENSATION FOR INJURY**

[The language replaces sponsor’s language, unless otherwise noted on the submitted consent form. Check the submitted consent form for any alterations.]

***Note: This language should be used when Sponsor agrees to pay***

If you are injured by or become ill from participating in this study, please contact your study doctor immediately. Medical treatment is available at Virginia Commonwealth University Health (VCUHealth). Your study doctor will arrange for short-term emergency care at VCU Health or for a referral if it is needed.

The sponsor will reimburse you or VCUHealth for the costs of reasonable and necessary medical care for diagnosis and treatment of a research injury. A research injury is any injury or illness caused by your participation in the study.

If you are injured by a medical treatment or procedure that you would have received even if you weren’t in the study, that is not a research injury. Fees for medical treatment of injuries or illness which are not research injuries may be billed to you or to an appropriate third party (such as your medical insurance).

Payment for such things as lost wages, expenses other than medical care, or pain and suffering will not be offered. To help avoid injury, it is very important to follow all study directions.

***Note: Alternative language when Sponsor requests and VCU agrees that insurance should be billed first:***

If you are injured by or become ill from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

If you are injured as a result of administration of the research drug (or device) or any medical procedures required by the written study plan, your private health insurance company will be billed. Your private health insurance company may not pay for treatment of research related injuries. The sponsor will reimburse you or the VCU Health System for the costs of reasonable and necessary medical care to treat a research related injury to the extent not paid by your private health insurance.

Payment for such things as lost wages, expenses other than medical care, or pain and suffering will not be offered. To help avoid injury, it is very important to follow all study directions.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

*standard*

**SOURCE OF FUNDING FOR THE STUDY**

*standard*

**QUESTIONS**

*standard*

**CONSENT**

*standard*

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Subject Name

**CONSENT SIGNATURE:**

*standard*