RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**TEMPLATE OUTLINE FOR: VCU**

**TITLE:**

**PROTOCOL NO:**

WIRB®

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*

**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. The Western Institutional Review Board® (WIRB®)

**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 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.

The sponsor will reimburse you or the VCU Health System 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*

*plus autotext “witness” to meet VA state law:*

Signature of Witness Date