

**RESEARCH SUBJECT INFORMATION AND CONSENT FORM ADDENDUM
Use of DNA**

TITLE:

PROTOCOL NO.:

WIRB[®] Pr. #

SPONSOR:

INVESTIGATOR: Name
Address
Telephone No.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Background Information:

You have been asked to participate in research that involves the study of your DNA. Your DNA will be studied from a sample taken from blood or other tissue from your body. DNA is the substance contained in your genes. Genes are received from our parents and can reveal who are our blood relatives. The genes of each person are unique. Differences in genes are probably responsible for many of the differences that may be seen in different people.

If you decide to participate in this study, you will be asked to choose whether your DNA sample will be used only for this study or if you will allow it to be used in other future research studies as well.

Risks:

Your DNA may contain information about whether you or your children MIGHT develop a disease like cancer or diabetes. Usually, your DNA could tell us whether your risk of developing a disease is somewhat higher or lower and NOT whether you will get a disease for certain.

Your DNA might contain information that you or your children would rather NOT know or would only like to know privately. Your DNA might contain information that could be upsetting to you.

Your DNA may contain information that could affect your ability to get a job, life insurance, or health insurance. For these reasons, most laboratories carefully guard the identities of the people who give DNA samples. However, DNA testing is complicated, and even the best laboratories

VCU Template for DNA use.

can make mistakes. Therefore, the results of the DNA testing may not be accurate or there may be a breach in confidentiality.

Study Specific:

In this research study, "NAME OF STUDY", scientists will study your DNA in order to learn something about it that has been described in another consent form. Scientists can also store DNA for long periods of time. DNA stored today might be studied in the future in ways that have not yet even been imagined. Because the technology for this storage is still new, despite continual improvements, the study doctors can't guarantee how long DNA can be stored. The DNA may have to be discarded at some future time because of equipment failure or lack of space.

Voluntary Participation/Withdrawal:

Your participation in this study is voluntary. You may decide not to participate or you may withdraw from the study at any time. Your decision will involve no penalty or loss of benefits to which you are otherwise entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent.

Confidentiality:

Information from this study will be submitted to the sponsor. Medical records which identify you and the consent form signed by you, will be inspected and/or copied by:

- the sponsor;

and may be inspected and/or copied by:

- Department of Health and Human Services (DHHS) agencies;
- Virginia Commonwealth University; and
- the Western Institutional Review Board[®] (WIRB[®]).

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

If you agree, samples of your DNA will be stored along with information about you obtained in the course of this research study (age, gender, etc.). The information stored will not identify you by name. Thus, future investigators will be able to use your DNA, but they will not be able to obtain further information about you personally that could be reported to you or others.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

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Consent:

I have read the information in this consent form. All my questions about this study and my participation in it have been answered to my satisfaction.

I authorize the release of my medical records to the sponsor, DHHS agencies, Virginia Commonwealth University, and WIRB®.

By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

Please initial one of the following options:

—— I would like scientists to study my DNA only to complete the study “NAME OF STUDY” and then to discard my DNA so that other studies cannot be done.

OR

—— I would like scientists to study my DNA to complete the study “NAME OF STUDY”. In addition, I give permission to have my DNA stored for future use.

Subject Signature _____ Date _____

Signature of Person Conducting
Informed Consent Discussion _____ Date _____

Signature of Witness _____ Date _____
(Required)

Signature of Principal Investigator _____ Date _____
(if different from above)

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