

## ADDITIONAL CONSENT LANGUAGE INSTRUCTIONS

There are many additional elements that may or may not apply to your study such as genetic testing, future use of specimens, or certificate of confidentiality. This document provides suggested text for these sections. Required language will be noted as such.

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## **I. IN THE “PROCEDURES” SECTION**

### **Blood Draw**

To obtain the blood sample, we will wipe the skin on your arm with alcohol to clean it. Then, we will insert a small needle into a vein and **[INSERT NUMBER OF TUBES]** tube[s] of blood will be drawn, about **[TRANSLATE INTO TEASPOONS OR TABLESPOONS]**.

### **HIV Testing**

#### **Will there be testing for HIV?**

Yes, HIV testing will be done during this research study. The following is important information about HIV, HIV testing and your test results:

- HIV causes AIDS and can be spread through sexual activity, sharing needles, by pregnant women to their fetuses, and through breastfeeding infants.
- There is treatment for HIV that can help you stay healthy.
- People with HIV or AIDS should adopt practices to protect people in their lives from becoming infected with HIV.
- HIV testing is voluntary and can be done anonymously at a public testing center. However, testing is required if you would like to be in this research study.
- The law protects the confidentiality of HIV related test results.
- The law prohibits discrimination based on your HIV status and services are available to address any discrimination.

### **MRI**

Magnetic resonance imaging (MRI) is a test that uses a magnetic field and pulses of radio waves to make pictures of organs and structures inside the body. For an MRI test, the area of the body being studied is placed inside a special machine that contains a strong magnet. Pictures from an MRI scan are saved and stored on a computer for more study. Although the MRI you will have in this study is being done for research purposes only, it is possible that doctors may notice something that could be important to your health. If so, we will contact you to explain what was observed and tell you whether you should consult your doctor. We will make the MRI report available to your doctor, and if you want, we will talk with your private physician or refer you to someone for follow-up.

### **Audio or video recording**

#### **Will there be audio and/or video recording?**

## **Genetic Testing**

*If NO, use the first section. If YES, use the second section.*

### **Will there be genetic testing?**

This study will not involve genetic research or genetic testing. [However, DNA extracted from **[specify, e.g., blood cells]** will be stored for future research studies.]

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your samples/data or for any tests, treatments, products or other things of value that may result from the research.

### **Will there be genetic testing?**

Genes are made up of DNA, and have the information needed to build and operate the human body. Genetic factors are personal traits or characteristics that are inherited and run in families. Your blood or tissue sample will be tested for genetic changes that may relate to **[an increased or decreased risk of developing a disease, an increased chance of disability, etc.]** in you or your offspring. **[State the specific test(s) to be done, e.g., specify phenotype.]** The information obtained from these tests will include genetic information about you. To protect your identity, we will give your sample(s) a unique code number. Since genetic information is shared by family members, the information from these tests may have implications for your family members, as well.

If there is a positive test result, you may want to have additional independent testing, and consult with a genetic counselor, clinical geneticist and specialist physicians. Genetic consultation and counseling are not provided through the study. You should be aware that insurance companies sometimes use information from genetic testing to deny life insurance or disability coverage to applicants.

The meaning of the results of this genetic research is not known, therefore we will not give you the results of these studies. You should be aware that insurance companies sometimes use information from genetic testing to deny life insurance or disability coverage to applicants. If you decide to participate in this research study, if your insurance company asks, you should state that you have not had a genetic test.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your samples/data or for any tests, treatments, products or other things of value that may result from the research.

**Specimen Banking (Future Use and Storage)**

*If NO, use the first section. If YES and IDENTIFIABLE, use the second section. If YES and completely DE-IDENTIFIED (no identifiers and no linking code), use the third section.*

**Will any of my samples or data be used for future research studies?**

No. We will destroy the data/samples when the study is completed.

**Will any of my samples or data be used for future research studies?**

Yes. We will store your samples/data in a “biobank,” which is a library of data and specimens (tissue and blood) from many studies. These samples/data can be linked to you. In the future, researchers can apply for permission to use the samples/data for new studies to prevent, diagnose or treat disease, including genetic research. If the biobank shares your samples/data with other researchers, it will remove your name. If you agree to the future use, some of your de-identified genetic and health information may be placed into one or more scientific databases. These may include databases maintained by the federal government. Your samples/data may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237. If you do, we will destroy remaining samples/data but if these were already shared with other researchers, we cannot get them back.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your samples/data or for any tests, treatments, products or other things of value that may result from the research.

**INITIAL ONE (1) OF THE FOLLOWING OPTIONS**

- I consent to have my specimens used for future research studies.
- I consent to have my specimens used for future research studies only for the study of \_\_\_\_\_.
- I do NOT consent to have my specimens used for future research studies. The specimens will be destroyed at the end of the study.

**INITIAL YOUR CHOICE BELOW**

- I consent to be contacted in the future to learn about:
- New research protocols that I may wish to join.
  - General information about research findings.
  - Results of tests on my samples that may benefit me or my family members regarding preventive or clinical care.
  - I do not agree to be contacted in the future, even if the results may be important to my health or my family's health.

**Will any of my samples or data be used for future research studies?**

Yes. We will store your samples/data in a “biobank,” which is a library of data and specimens (tissue and blood) from many studies. These samples/data cannot be linked to you. In the future, researchers can apply for permission to use the samples/data for new studies to prevent, diagnose or treat disease, including genetic research. Your samples/data may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified genetic and health information may be placed into one or more scientific databases. These may include databases maintained by the federal government.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your samples/data or for any tests, treatments, products or other things of value that may result from the research.

**INITIAL ONE (1) OF THE FOLLOWING OPTIONS**

\_\_\_\_\_ I consent to have my specimens used for future research studies.

\_\_\_\_\_ I consent to have my specimens used for future research studies only for the study of \_\_\_\_\_.

\_\_\_\_\_ I do NOT consent to have my specimens used for future research studies. The specimens will be destroyed at the end of the study.

## II. IN THE “RISK” SECTION

**If there are conditions in which researchers may violate participant confidentiality**

**Are there any times you would not keep my data confidential?**

If you give us information that suggests that your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.

If you give us information that you may hurt yourself **[insert language describing conditions under which you may break confidentiality]**

If you give us information that you may hurt someone else, we **[insert language describing conditions under which you may break confidentiality and whether you will report this information to the authorities].**

### **Blood Draw**

Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless “black and blue” may develop. Very rarely, fainting may occur.

### **MRI**

There are no known significant risks from an MRI. Some people are bothered by feelings of confinement (claustrophobia), and by the noise made by the machine during the procedure. You will be asked to wear earplugs or earphones while in the machine. You may not participate in this study if you have a pacemaker, an implanted defibrillator or certain other implanted electronic or metallic devices. It is important for you to advise the MRI staff if you have had brain surgery for a cerebral aneurysm, or if you have implanted medical or metallic devices, shrapnel, or other metal, such as metal in your eye.