***This document has more information about DNA research we will perform and the ways we may share the data and the blood, tissue and other samples we collected from you. . All of the information in the document you signed, Permission to Take Part in a Human Research Study, remains the same.***

***Does this Study Involve Genetic or Genomic Research?***

This study also involves genetic/genomic testing (analysis).

Genetic testing refers to the study of single genes. Genomic testing refers to the study of all of a person’s genes (genome). Genes are made up of DNA (deoxyribonucleic acid). You inherit genes from your parents. The genes control how your body grows and changes and how your body reacts to certain things. For example, genes you inherited from your parents determined your eye and hair color.

Scientists can collect genes from blood, saliva, or other tissue samples. We will collect DNA from your (***blood/saliva/cheek, etc***.). This testing and research may help us learn why some people are more likely than others to have ***[describe the disease or condition****]*.

We ***[will/will not****]* tell you what we find out about your genes. For example, we might find out that you have a certain kind of gene. We may know that if people have this gene, they sometimes get a certain disease or do not respond to treatment. You could have a gene that may make it more likely for you to have a health problem, but that does not mean you will get that health problem. You should ask the study team or a genetic counselor if you have any questions about genetic research.

***[Choose this paragraph or the next]*** We will not include your name or other identifying information on the ***[blood/ tissue]*** that came from you. We will apply a random code to this sample. We will link the code to your identity, but we will keep the link in a separate place. We will keep your ***[blood/ tissue]*** until it is all used up. We will also keep the information we learn about your DNA indefinitely. If you want to remove your ***[blood/ tissue]*** from this study, contact the study doctor or study team and let them know. If the link to your identity has not been destroyed, we will find your sample and destroy it. We cannot remove the information we learned about your DNA.

***[Choose this paragraph or the one above]*** No one will know that the ***[blood/ tissue]*** sample came from you. Since we will not link your name or other identifying information to the ***[blood/ tissue]*** sample, you cannot change your mind after you agree. We will not be able to find your sample to remove it. It will be forever separated or “unlinked” from your identifying information to protect your privacy. We will keep your ***[blood/ tissue]*** until it is all used up. We will also keep the information we learn about your DNA indefinitely. We cannot destroy this information.

***[Include if applicable]*** We may share your ***[blood/ tissue]*** the information we learn about your DNA with other researchers so they can use it to learn more about ***[insert condition] [or other conditions.]*** But we will not include any information that directly identifies you.

Even though your name will not be connected with the tissue or blood sample, other information about you might still be connected. Examples of this information may be your race, ethnicity, or parts of your medical history. This information may be important to scientists studying genes. The information they discover may be important for research or for public health.

PARTICIPANT’S STATEMENT/SIGNATURE

You will receive a signed and dated copy of this consent form if you agree to take part in this study and sign the form.

* *I have read this form and a member of the study team explained this part of the research study to me.*
* *I had a chance to ask questions, and a research team member answered my questions.*
* *The research team told me whom to contact if I have more questions.*
* *I agree to allow the study team to collect specimens from my body, conduct DNA analysis on the specimens and to share the de-identified specimens and DNA results with other researchers as described in this document.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent

***Remove “signature of participant” above if the subject is a child or is incapable of consenting.***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent(s)/Legally Authorized Representative Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name(s) of Parent(s)/Legally Authorized Representative

***Remove “Parent(s)” above if the subject is not a child or has an LAR other than the parent***

***If the IRB approved inclusion of cognitively impaired adult participants who cannot personally consent, you must submit a proxy consent document.***

***Assent is usually required for participants who are minors age 7 to 17 years.***

I described this study to the child in a manner suited to the child’s age and ability to comprehend. I answered all of the child’s questions about this study. I asked the child questions to see if the child understood that the procedures are research and that s/he doesn’t have to participate if s/he doesn’t want to.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Assent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Assent

A witness is only required if:

1. The subject, parent or LAR is unable to read the consent document;
2. The subject, parent or LAR is unable to sign the document due to physical limitations; and/or
3. Consent is obtained using the short form process, and this consent document is the summary.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Witness

***Review the appendixes following this section. Include or delete them as applicable. When the document is complete, delete all text after the signature section, i.e. this line onward.***