**Future Use/Storage of Genetic Material (**R**emove this section if not applicable.)**

**Purpose and Scope:**

In this optional portion of the study, we are asking to conduct genetic testing of your <specify type of tissue> tissue.

Participation in this portion of the study is voluntary. Deciding for or against participating in this portion of the study will not affect the care you receive (or other elements of your participation in the main study).

Researchers can request to use the stored samples for their studies on <specify type of research or indicate it may be on any research topic>. (Include if applicable: The principal investigator and study team will remove all information that could identify you before sharing with researchers.)

Researchers may do laboratory, animal, or other genetic studies with your sample. Genetic studies identify a role genes play in health, disease, traits, behavior, and ancestry.

Researchers may place results from their studies in scientific databases, which combine information from large numbers of people. This allows scientists to see trends and do studies that are more powerful. The results will not include your name or information that could identify you.

**Potential Benefits:**

Participating in this genetic portion of the research is not likely to benefit you personally, medically, or financially. Some volunteers get satisfaction from contributing to research that may help others in the future.

**Potential Risks/Discomforts:**

The main risk of genetic testing is the potential loss of your privacy.

Choose one: However, this test will only involve a segment of your DNA and at this time would not be enough to identify you. OR The test will involve most of your DNA and could therefore be identifiable.

We will make every effort to protect your privacy. However, information important for research or public health may be stored with your tissue or blood sample. Such information may include your name, race/ethnicity, sex, and your medical history. This information may be retrieved by a government in comnection with a criminal case if the government issues a search warrant.

There is a risk that someone could get access to the stored information or specimens. In spite of the security measures and safeguards we will use, we cannot guarantee that your identify will never become known. You can reduce the risk by not sharing information about taking part in this genetic portion of the study.

Even without your name or identifiers, genetic information is unique to you. The results of genetic research apply to both you and your family members. Genetic information used improperly to discriminate or support negative stereotypes could cause you or your family distress. We do not known whether uture technology will make it possible for someone to trace your genetic information back to you.

Other risks are that disease testing in genetic research may produce results about your medical condition. One question for you to consider is whether you should know the results of the testing and research. Knowing the results has risks. The results may cause you anxiety and other psychological distress. Also, if you tell the results to your doctor, the results may become part of your medical record. If released, the information could lead to health or life insurance discrimination, job or social discrimination. Knowing thr esults could also affect your future relationship with family members. There is a risk that other family members may learn private genetic information about you. Not knowing the results also has risks. It could mean that you will not have enough information regarding the need for treatment or the availability of a cure for a particular disease.

**Financial Considerations:**

There will be no additional costs or chargest to you for taking part in this genetic portion of the main study. You will not need to pay for sample collection or blood tests done just for the genetic testing.

Choose one: You will receive \_\_\_\_\_\_\_ for donating your sample for genetic testing. OR You will not be paid for donating your sample for genetic testing.

The sample that you provide will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value or be used for commercial profit. There are no plans to provide financial payment to you or your relatives if this occurs.

**Genetic Sources:**

The following is a non-exhaustive list of material that can yield genetic material. If you are involved in the study, some or all of the following disclosures must be included:

* Saliva
* Hair follicles
* Skin
* Fecal matter
* Sweat
* Tissue
* Mucus
* Blood
* Urine
* Semen
* Teeth
* Plaque
* Gingival crevicular fluid
* Other tissue and fluids not yet identified as possible DNA sources

**Alternatives:**

If you do not want to participate in the genetic testing portion of this research study, there are no choices except not to take part. Your decision will not affect your current or future medical care.

**Genetic Testing Consent Questions:**

Please place a check in each box to give consent to each item. Understand that failing to consent to all or some of these terms may result in refusal to be allowed to continue to participate in the genetic testing portion of the research. Unless stated otherwise, leaving a box blank is seen as **NOT** giving consent.

**Consent to access health records** (If applicable)**:**

YES  NO I consent to the researchers accessing and using my protected health

information as outlined in the Request for HIPPA Authorization section.

YES  NO (Include/remove as applicable.) I consent to some health information being

included in my genetic sample. This will make your sample more useful for

research in the future.

YES  NO (Include/remove as applicable.) I consent to future access to my health

records to update my genetic sample.

**Financial consent:**

YES  NO I wish to donate my tissue to WVU. This tissue may be used in future

studies.

Below is a list of things that may happen as a result of your donation. Please check each box to indicate being notified about them:

YES  NO I realize and accept my genetic data may be sold to other companies

involved in the research.

YES  NO I realize and accept my genetic data may be sold to data brokers. They may

then go on to sell my data to other companies or even state or federal

governments for use in law enforcement or insurance purposes.

YES  NO I realize and accept my genetic data may be patented only after having been

altered in accordance with the law.

YES  NO I realize and accept my genetic data may be licensed by the investigators and

West Virginia University for use in other research or the development of new

products.

YES  NO I realize and accept that by donating my genetic material I will not retain any

property rights, nor will I share in any money or commercial profit that the

investigators, West Virginia University, or their agents may realize.

YES  NO I accept and realize that If I request research to be stopped on my genetic

material, then WVU will do what it can to stop research being done

underseen by its researchers. However, if the genetic data has been sold on

WVU cannot guarantee that it will be able to stop further research.

Moreover, WVU will retain ownership of all research and patents realized.

**Consent to Future Contact:**

Future research may be conducted for which you are eligible. If you are interested in being contacted for future research, please indicate so by checking this box.

YES  NO I want to be contacted if future research studies, for which I am qualified,

become available.

**Consent to Banking**

(whichever is applicable)

YES  NO I consent to use knowing this tissue will be deidentified. insert time frame for tissue and/or data storage (this could be indefinitely) at insert location of repository and who will be running it.

YES  NO (or) I consent knowing this tissue will retain some identifying markers. insert time frame for tissue and/or data storage (this could be indefinitely) at insert location of repository and who will be running it.

**Remove if not applicable:**

Researchers may also want to relink your tissue and/or data to your personal information which would allow you to be identified. If you will allow this for future research studies, or for information relating to your health, please indicate so by completing this section.

YES  NO I want my tissue and/or data to be relinked with my personal

information for any reason.

YES  NO I want my tissue and/or data to be relinked with my personal

information for future research only.

YES  NO I want my tissue and/or data to be relinked with my personal

information for information relating to my health only.

**Genetic Information Nondiscrimination Act (GINA) (**R**emove this section if not applicable.)**

For research involving biospecimens, include whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequencing of that specimen).

The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request the genetic information provided for this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use the genetic information provided for this research when making decisions to hire, promote, or fire you or for setting the terms of your employment.

GINA does not protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

West Virginia's genetic discrimination laws protect patients from discrimination by health insurers or employers. As a result, health plans or insurance companies cannot raise your rates based on genetic information about you or commit any other form of illegal discrimination. Additionally, employers in West Virginia cannot use your genetic information to make informed decisions related to your employment.