**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**FOR AN ADULT**

**GENETIC INFORMED CONSENT – PART I**

*(The Informed Consent process is not complete without participant signatures on both Informed Consent Parts I and II)*

*Text in red is informational only and should be deleted before submitting to IRB.*

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| --- | --- |
| ***Title of Study:*** |  |

1. ***Who is doing the study?***

Investigator Information:

Principal Investigator: Name, Degree

Telephone Number

Medical Investigator: Name, M.D.

Telephone Number

24-hr. Emergency Phone Nos.:

      (Weekdays 7:00 a.m.-4:30 p.m.)

(225) 765-4644 (After 4:30 p.m. and Weekends)

Sub Investigators: Name, Degree

Name, Degree

1. ***What you should know about genetic testing.***

Research to identify genes that cause or contribute to a disease or trait is an increasingly important way to try to understand the role of genes in human disease. You have been given this consent form because the Pennington Biomedical Research Center investigators want to include your (specify: tissue, cell or blood sample) in a research project, or because they want to save such biological samples for future genetic research.

There are several things you should know before allowing your (specify: tissue, cell or blood sample) to be studied or to be stored.

1. You have the right to refuse to allow your (specify: tissue, cell or blood sample) to be studied or saved for future research studies. You may withdraw from this study at any time and remove any samples that contain identifiers from research use after the date of your withdrawal.
2. You will still be able to participate in the main portion of the research study even if you do not consent to participate in the genetic testing portion of the research.
3. Your (specify: tissue, cell or blood sample) will be stored under an identifier, such as a code, which could be linked to you. Sometimes these samples are shared for research purposes with other investigators at other research sites. If this is done, the other investigators would not know your name (known as de-identified samples).
4. In addition to the code, other information about you might be connected to your (specify: tissue, cell or blood sample). For instance, information about race, ethnicity, sex, your medical history, and so forth might be available to investigators studying your (specify: tissue, cell or blood sample).

Such information is important for scientific reasons and sometimes for public health. It is possible that genetic information might come to be associated with your racial or ethnic group.

1. Genetic information about you will often apply (in one degree or another) to family members. Pennington Biomedical Research Center will not provide genetic information about you to your family members without your permission.
2. A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.
3. ***Purpose***

* You have been invited to participate in this research study because you have (fill in the name of the disorder).
* Inform the subject how long samples will be used/stored.

Your (specify: tissue, cell or blood sample) will be stored only for this research, which is expected to last for (duration), and then the (specify: tissue, cell or blood sample) will be destroyed.

Or

Your blood/tissue samples will be stored for (duration; if intent is to store indefinitely, make this clear).

1. ***Procedures***

Investigators would like to take (specify amount of blood/tissue, e.g., 2 tsp. of blood) at (specify time point, e.g., 2nd visit) to be used for genetic analysis.

1. ***Risks and Discomforts***

Although we have made every effort to protect your identity, there is a small risk of loss of confidentiality. If the results of these studies of your genetic makeup were to be accidentally released, it might be possible that the information we will gather about you as part of this study could become available to an insurer, an employer, a relative or someone else outside the study. Even though there are discrimination protections in Louisiana state law, there is still a small chance that you could be harmed if a release occurred.

1. ***Benefits***

As appropriate, include benefits such as advancement of knowledge, clinical relevance to individual family or society, and long-term benefit if investigator intends to re-contact subjects to disclose clinically relevant information in the future.

Unless direct benefits to subject is assured, use the following statement:

You may or may not personally benefit from participating in this study. However, by serving as a subject, you may contribute new information which may benefit patients in the future. The research done with your specimens may help to develop new products in the future, or may be used to establish a test that could be patented or licensed. You will not receive any financial compensation for any patents, inventions or licenses developed from this research.

***7- Confidentiality***

* Explain how information will be kept confidential, both at Pennington Biomedical Research Center and upon transfer to any other laboratory or institution.

Such as:

* We will store your signed consent form in a locked file; only members of the study team at Pennington Biomedical Research Center will have access to this file.

Or

* We will label your sample with a unique series of letters and numbers. Pennington Biomedical will store your (specify: tissue, cell or blood sample) with this unique identifier and the minimum number of personal identifiers to meet laboratory standards.

Or

* We will collect more samples than we will use, so that nobody—not even you or us—will know for sure whether your sample was used or if any of the information in the scientific databases came from your sample. Samples that are not used will be destroyed.
* If information/samples will be transmitted outside Pennington Biomedical Research Center, indicate who the recipient(s) will be.

Suggested wording (use all that apply):

A code number will be assigned to you, your cells and genetic information, as well as to information about you. Only the investigators named on this consent form will be authorized to link the code number to you. Other investigators who may receive samples of your (specify: tissue, cell or blood sample) for research will be given only the code number which will not identify you.

Or

All identifying information about you will be removed from the samples before they are released to any other investigators.

* All other parties including employers, insurance companies, personal physicians, and relatives will be refused access to the information or to the samples, unless you provide written permission, or unless we are required by law to do so.
* Neither your name nor your identity will be used for publication or publicity purposes.

***8- Participation***

* *You must include one of the following statements:*

The (specify: tissue, cell or blood sample) that we will collect from you in this study will be stored with a unique identifier and the minimum number of personal identifiers to meet laboratory standards.

Or

If in the future you decide you no longer want to participate in this research, we will destroy all your (specify: tissue, cell or blood sample). However, if your information has already been included in a research database or registry as described above, Pennington Biomedical Research Center considers itself to have relied on it and therefore information will not be removed from the repository, unless you request for it to be removed. Please see the last page of this consent for contact information of the Principal Investigator.

Or

If in the future you decide you no longer want to participate in this research, we will remove your name and any other identifiers from your (specify: tissue, cell or blood sample), but the material will not be destroyed and we will continue to use if for research.

* The investigator or investigator’s staff has offered to answer any other questions you may have about this study. If you have any questions regarding your rights as a research subject, you may contact the IRB Office at (225) 763-2693.
* You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

***9- Costs***

There are no costs to you for participating in this study. You will not be paid for participating in this study.

***10- If you have any questions or problems, whom can you call?***

If you have any questions about your rights as a research volunteer, you should call the Institutional Review Board Office at 225-763-2693 or the Executive Director of Pennington Biomedical at 225-763-2513. If you have any questions about the research study, contact insert name of PI at PI's phone number. If you think you have a research-related injury or medical illness, you should call insert name of MI at MI's phone number during regular working hours. After working hours and on weekends you should call the answering service at 225-765-4644. The on-call physician will respond to your call.

***11- Will you be compensated for a study-related injury or medical illness?***

(If the study sponsor will compensate volunteers, so state.) No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from the Pennington Biomedical Research Center. In the event of injury or medical illness resulting from the research procedures in which you participate, you will be referred to a treatment facility. Medical treatment may be provided at your expense or at the expense of your health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. The Pennington Biomedical Research Center is a research facility and provides medical treatment only as part of research protocols. Should you require ongoing medical treatments, they must be provided by community physicians and hospitals.

***12- Signatures***

By signing this consent I agree to participate in the optional genetic research portion of this study. My signature below indicates all my questions have been answered.

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Signature of Research Subject Date

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Printed Name of Research Subject

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Signature of Legally Authorized Representative Date

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Relationship of Legally Authorized Representative

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Signature of Person Obtaining Consent Date

If you decide you would like to withdraw your consent to use your samples, you will be able to do so unless the samples have been de-identified. You will not be able to withdraw de-identified samples because investigators will not know which one is yours. You must provide a written request to have your samples destroyed.

For destruction of your samples, you can contact the Principal Investigator at:

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Add Principal Investigator name and address