**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**FOR AN ADULT**

**INFORMED CONSENT - PART I**

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

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

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

***What you should know about a research study***

1. We give you this consent form so that you may read about the purpose, risks and benefits of this research study.
2. The main goal of research studies is to gain knowledge that may help people in the future.
3. You have the right to refuse to take part, or agree to take part now and change your mind later on.
4. Please review this consent form carefully and ask any questions before you make a decision.
5. Your participation is voluntary.
6. By signing this consent form, you agree to participate in the study as it is described.

***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

Dr. Principal Investigator's name directs this study, which is under the medical supervision of Dr. Medical Investigator's Name. We expect about enter number people from enter number sites will be enrolled in this study. *If this is a multi-site study, also include the number being enrolled here at PBRC.* The study will take place over a period of days/weeks/months/years. Your expected time in this study will be days/weeks/months/years. *Indicate whether this study is part of a national study or a Pennington Biomedical Research Center study.*

***2- Where is the study being conducted?***

*For example, “This study takes place in 12 parishes across the Louisiana Delta” or “This study takes place in the Metabolic Unit at Pennington Biomedical Research Center”.*

***3- What is the purpose of this study?***

*Describe what the study is designed to discover or establish.*

*If an investigational drug or device is being used, state that the drug, combination of drugs, device, etc. are investigational and include the following:* The use of study drug(s) or device name in this study is investigational. The word “investigational” means that study drug(s) or device name is not approved for marketing by the Food and Drug Administration (FDA). The FDA is allowing the use of study drug(s) or device name in this study.

*If you are using an FDA approved drug or device, but not for an FDA approved purpose, include the following:* Study drug(s) or device name is approved by the Food and Drug Administration (FDA) for the treatment of disease name. It is not approved for use in disease name. The FDA is allowing the use of study drug(s) or device name in this study.

***4- Who is eligible to participate in the study?***

*Provide inclusion criteria. Use bullets for ease of reading and understanding and to reduce the grade level of the consent.*

You may not qualify for this study based on other eligibility criteria not listed. The study coordinator will go over this information in detail.

***5- What will happen to you if you take part in the study?***

*Tell the subject what to expect. Give a time-line description of the procedures that will be performed, any drugs that will be administered.*

The following table shows what will happen at each study visit:

***Insert a table of procedures (train schedule) here.***

*Describe all visits and procedures chronologically in lay language, using simple terms and short sentences/bulleted lists/short paragraphs (*[***refer to Study Procedures with Associated Risks document for approved language for standard procedures***](http://www.pbrc.edu/hrpp/forms/)*).*

*Provide a lay description of the randomization procedure, if applicable, and describe the chances of being assigned to any one group (for two groups use ‘flipping a coin;’ for more than two groups use ‘like drawing numbers from a hat’).*

*If you are drawing blood, you must list the amount (use teaspoons, tablespoons, ounces, etc.) per procedure and the reason for the blood draw (for example, cholesterol or fasting plasma glucose).*

*If the study includes genetic testing, include the following:*

The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or health-related employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

* may not ask for genetic information from this research and
* may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as life, disability or long-term care).

Despite the GINA protections and the best efforts of the research team to protect your information, you may still be at risk if information about you were to become known to people outside of this study.

***6- Biospecimens for Future Research***

*If the study includes collection of biospecimens for future research, include the following (if you are not storing biospecimens for future research, delete this section and renumber the following sections):*

You are being asked to allow some of your list biospecimen(s) being stored to be stored and used for research at a later time. These bodily materials are called biospecimens.

If biospecimens for future research is optional, include the following: The donation of biospecimens in this study is optional. No matter what you decide to do, it will not affect your study participation. You will still be allowed to take part in the study even if you don't want your specimens to be collected and used for future research.

*If biospecimens for future research is not optional, include a criterion in Section 4 above that states subjects must be willing to have their blood/tissue/etc. stored for future research. If storage for future use is required, the consent still must include the information about who to contact to have their samples destroyed if they change their mind. Include the following:* The donation of biospecimens in this study is not optional. If you do not want your biospecimens stored for future research, you may not participate in this study.

Some biospecimen samples will be stored and used for the study and other biospecimen samples will be stored for future studies. The collection of samples may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases. If you agree to have your samples stored, you can change your mind later.

The samples will be stored indefinitely. If you agree to donate your samples, they may be given to other investigators for future research as well. The future research may take place at Pennington Biomedical and may involve Pennington Biomedical Researchers in this study. The future research may not take place at Pennington Biomedical Research Center and may not be reviewed by Pennington Biomedical Research Center’s Institutional Review Board. For privacy and confidentiality, your biospecimens will be labeled with a unique series of letters and numbers. Pennington Biomedical will store your biospecimens with this unique identifier and the minimum number of personal identifiers to meet laboratory standards. The research done with your specimens may help to develop new products in the future, or may be used to establish a cell line or test that could be patented or licensed. You will not receive any financial compensation for any patents, inventions or licenses developed from this research.

*If there is a* ***possibility*** *that future research will involve gene sequencing or creation of cell lines, include the following appropriate statement(s):* The research may involve research tools such as gene sequencing or the creation of cell lines. Gene sequencing of your DNA provides researchers with the code to your genetic material. Cell lines are living tissue samples that can be grown in a laboratory. A cell line can provide an unlimited supply of cells in the future without asking for more samples from you. Each cell contains your complete DNA.

What you should know about the cell lines that will be derived in the course of this study?

* The cell lines created will be genetically similar or identical to you.
* The cell lines may be kept indefinitely.
* There is the possibility that your cells or the created cell lines might be used in research that will involve genetic manipulation of the cells or the mixing of human and non-human cells in animal models.
* The cell lines may be shared with researchers both inside and outside of Pennington Biomedical, including our commercial partners.
* The cell lines may be used to develop treatments for a variety of diseases and conditions.

**Blood**

If you give permission, approximately list amount in teaspoons, tablespoons, or ounces of blood will be collected and stored by this study. Your stored samples may be tested at Pennington Biomedical Research Center or other locations used in future research. Do you give permission for your blood to be collected and used in future research by this study?

Yes, I give permission \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature Date

No, I do not give permission \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature Date

**Tissue**

If you give permission, your left over tissue, tissue not be used for the purposes of the current study will be collected and stored by this study. Your stored samples may be tested at Pennington Biomedical Research Center or other locations used in future research. Do you give permission for your tissue to be collected and used in future research by this study?

Yes, I give permission \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature Date

No, I do not give permission \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature Date

**Urine**

If you give permission, your urine will be collected and stored by this study. Your stored urine may be tested at Pennington Biomedical Research Center or other locations used in future research. Do you give permission for your urine to be collected and used in future research by this study?

Yes, I give permission \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature Date

No, I do not give permission \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature Date

If you decide you would like to withdraw your consent to use your samples, you must provide a written request to have your samples destroyed. In the event you withdraw your consent, it will not be possible to destroy samples that have already been given to researchers.

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

Principal Investigator

Pennington Biomedical Research Center

6400 Perkins Road

Baton Rouge, LA 70808

***7- What are the possible risks and discomforts?***

*If there are risks or discomforts to participation, describe them for each procedure and drug. (Please use bullets to emphasize to the volunteer any risks he/she may encounter.* ***Refer to Study Procedures posted under the IRB section of PINE for approved language for standard procedures****).*

*If medications are being used (approved or investigational), risks for each medication must be provided.*

*If this is a placebo-controlled study, include the risk that the participant’s condition may not be treated and that the participant’s condition may worsen.*

*If the study includes a washout period, describe the possible risks of discontinuing medications.*

*In addition to physiological risks/discomforts, describe psychological, emotional, financial, social, and legal risks that might result. For example, address the risk of loss of confidentiality of sensitive information.*

*If the research involves genetic material, include the following:* Genetic information is unique to you and your family, even without your name or other identifiers. Pennington Biomedical Research Center follows procedures to prevent people who work with your DNA information from being able to discover it belongs to you. However, new techniques are constantly being developed that may in the future make it easier to re-identify genetic data, so we cannot promise that your genetic information will never be linked to you.

*If the research involves interviews or questionnaires, include the following:* You do not have to answer any questions you do not want to answer.

In addition to the risks listed above, you may experience a previously unknown risk or side effect. *(This sentence is not necessary for no risk or minimal risk studies.)*

***8- What are the possible benefits?***

*Describe any direct benefits to the subject, or the possibility of direct benefits, that are likely for subjects. If there are no direct benefits, state:* We cannot promise any benefits from your being in the study.

*Describe the generalizable or societal benefits and use a sentence such as:* If you take part in this study, you may help others in the future.

*Do not include compensation in this section. Results of tests given to participants and study-related medical care are not considered benefits. If results will be provided, this should be explained in Section 5 (What will happen to you if you take part in the study?).*

***9- If you do not want to take part in the study, are there other choices?***

*Describe alternatives to participation in the study.* You have the choice at any time not to participate in this research study. If you choose not to participate, any health benefits to which you are entitled will not be affected in any way.

***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- What information will be kept private?***

Every effort will be made to maintain the confidentiality of your study records. However, someone from the Food and Drug Administration *(if applicable*), the National Institutes of Health *(if applicable*), the Pennington Biomedical Research Center, and sponsor(s)'s name(s) and/or the contract research organization (the sponsor) may inspect and/or copy the medical records related to the study. Results of the study may be published; however, we will keep your name and other identifying information private. Other than as set forth above, your identity will remain confidential unless disclosure is required by law.

*If the study will be registered on ClinicalTrials.gov, include the following:* A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

*If you have a Certificate of Confidentiality for this study, include the following information:*

Agency Name has given us a Certificate of Confidentiality for this study. This Certificate provides some additional protection for research information that identifies you. The Certificate allows us, in some circumstances, to refuse to give out information that could identify you as a research subject without your consent, when such information is sought in a federal, state, or local court or public agency action. Still, we may disclose identifying information about you if, for example, you need medical help.

We may also disclose identifiable information about you as described in the Informed Consent document Part II or in other cases. For example, the government may see your information if it audits us, and the research team will voluntarily comply with reporting requirements to the appropriate local or state authorities:

* if they suspect abuse, neglect or abandonment of a child or vulnerable or dependent adult;
* if certain diseases are present; and
* if the team learns that you plan to harm someone. In this case, the team also may warn the person who is at risk.

Even with this Certificate in place, you and your family members must continue to protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the Certificate to withhold this information.

This Certificate does not mean the government approves or disapproves of this research project.

*If you will be submitting genomic data to an NIH designated repository, include the following:*

Genomic studies, including genome-wide association studies (GWAS), examine genetic differences in the entire human genome (the complete set of human genes) and the association between these genetic differences and health conditions.

As part of this study, we will collect information about your health and your individual genes. This information will be sent to a National Institutes of Health (NIH) designated data repository that includes all kinds of genomic data from studies funded by the NIH.

The aim of collecting this information is to look for genetic connections that:

* may increase the likelihood of getting a certain disease (such as asthma, cancer, diabetes, heart disease or mental illness) or a condition (such as high blood pressure or obesity)
* may affect the progress of a certain disease or condition
* may affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others.

We will remove direct identifiers (such as your name) and instead code your information before sending it to the repository. NIH will never get this code or the identifiers we have removed.

The repository is a controlled-access repository. Controlled-access data is only available to researchers and companies who apply to the NIH. The NIH will review data requests for scientific merit and for methods to protect data and methods to ensure data will be used for the approved purpose. We will not know what types of health-related research will be done with the data that are sent to the repository.

**What are the risks to your privacy?** There may be risks to your privacy and the privacy of your relatives from storing your information in the repository. Although the NIH takes measures to protect privacy, we do not know how likely it is that your identity could become re-connected with your genetic and health information.

If your genetic information were re-identified, personal information about you, your health and your risk of disease could become known to others. This could present unknown risks. Current federal law will help protect you from genetic discrimination in health insurance and employment.

**Are there benefits to sharing your genetic information?** There is no direct benefit to you from placing your genetic information in the repository. Allowing researchers to study your genetic information may lead to a better understanding of how genes affect health. This may help other people in the future.

***12- Can your taking part in the study end early?***

Dr. Principal Investigator, Dr. Medical Investigator, or the study sponsor can withdraw you from the study for any reason or for no reason. You may withdraw from the study at any time without penalty; however, all data Pennington Biomedical has previously collected cannot be removed from the study. Possible reasons for withdrawal include add additional reasons why the subject may be withdrawn, if appropriate. The sponsor of the study may end the study early. *If applicable, information should be added here to describe any adverse effects on the volunteer’s health or welfare, or follow-up that may be requested if they decide to withdraw from the study.*

***13- What if information becomes available that might affect your decision to stay in the study?***

During the course of this study there may be new findings from this or other research which may affect your willingness to continue participation. Information concerning any such new findings will be provided to you.

***14- What charges will you have to pay?***

*If there are no charges, state “None”.*

***15- What payment will you receive?***

*If there is no payment involved, state “None”.*

*If the volunteer will be compensated for participating, state:* If you agree to take part, we will pay you up to       *(indicate amount; also indicate if the amount is pro-rated for study visit completion).* Your check will be requested from the LSU payroll department when you complete the study or at the appropriate milestone if you are compensated during the course of the study. It usually takes about 3-4 weeks for it to arrive at Pennington Biomedical Research Center.

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

(If the study sponsor will cover subject injury, ensure this section matches language in the contract.)

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.

*(DOD-funded research requires other language [see Department of Defense Instruction 3216.02 for guidance]).*

***17- Signatures***

***(Note: Signatures of volunteer and person administering informed consent must appear on same page)***

The study has been discussed with me and all my questions have been answered. I understand that additional questions regarding the study should be directed to the study investigators. I agree with the terms above and acknowledge that I will be given a copy of this signed consent form.

With my signature, I also acknowledge that I have been given either today or in the past a copy of the Notice of Privacy Practices for Protected Health Information.

Printed Name of Volunteer

Signature of Volunteer Date

***If the subject is unable to consent due to cognitive impairment and requires consent by a Legally Authorized Representative, include the following:***

Printed Name of Legally Authorized Representative

Signature of Legally Authorized Representative Date

Representative’s Authority to Act for Subject

(e.g., relationship to subject): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Administering Informed Consent

Signature of Person Administering Informed Consent Date

# Insert Name of Principal Investigator

Principal Investigator

Insert Name of Medical Investigator

Medical Investigator

***If the study volunteer is unable to read, please include the following signature lines, as appropriate. If not applicable, do not include as part of the consent form.***

The study volunteer has indicated to me that the volunteer is unable to read. I certify that I have read this consent form to the volunteer and explained that by completing the signature line above the volunteer has agreed to participate.

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

Signature of Reader Date