**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**FOR AN ADULT**

**INFORMED CONSENT - PART I**

* *Text in blue is informational or sample text only and should be* ***deleted*** *before submitting to IRB.*
* *The Informed Consent process is not complete without participant signatures on both Informed Consents (Parts I and HIPAA Part II).*
* *The prospective subject or legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information: Key Information*
* *The version date in the footer must also match the version date in the footer of the corresponding HIPAA Authorization.*

***Title of Study:***

***Study Sponsor:***

***Key Information:***

* **Why am I being asked to review this form?**
  + You are being asked to take part in a research study. This form is provided so that you may read and understand the reasons why you might or might not want to participate in the research. Your participation is voluntary.
* **What is the purpose, duration, and procedures of this study?**
  + The purpose of this research study is…
  + Your expected time in this study will be \_\_\_\_\_ *days/months/years* consisting of \_\_\_\_\_ study visits.
  + The procedures involved in this study include… *include a bulleted list.*
* **What are the possible risks and discomforts?**
  + *Include reasonably foreseeable risks and side effects related to the procedures, drugs, interventions, or devices. This section should identify the most important and/or most likely risks, similar to the information that a doctor might deliver in the clinical context, but with a particular emphasis on how those risks are changed by participating in the study.*
  + A more comprehensive and detailed description of reasonably foreseeable risks to subjects are included later in Section 6 of the informed consent.
* **What are the possible benefits?**
  + *Include any benefits to prospective subjects or to the others that may reasonably be expected from the research. If there are no direct benefits, state:* We cannot promise any benefits from your being in the study. Your participation may help us gain knowledge that may help people in the future.
* **If you choose not to participate in the study, are there other choices?**
  + You have the choice at any time not to participate in this research study.
  + *If you decide not to participate in this study, your other choices may include:*
    - *Getting treatment or care for* *[disease] without being in a study*
    - *Taking part in another study*
    - *Getting no treatment*

***Detailed Information:***

***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” and/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.*

*Provide the following language after the bulleted inclusion criteria:* 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 and any procedures that are experimental.*

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.*

*If each visit or group of visits is separated into sub-headings, include the following to each sub-heading if applicable: approximately how long the visits will be and any fasting details (fasting visit; how long to fast).*

***Refer to “Study Procedures with Associated Risks” document for approved language for standard procedure******descriptions.*** ***Document can be found on the IRB/HRPP website at*** [***http://www.pbrc.edu/hrpp/forms/***](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 ‘ like 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).*

***6- 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 with Associated Risks” document for approved language for standard procedure risks. Document can be found on the IRB/HRPP website at*** [***http://www.pbrc.edu/hrpp/forms/***](http://www.pbrc.edu/hrpp/forms/)***.***

*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 pregnant women or women of childbearing potential and the risk to fetuses of the drugs, devices, or other procedures involved in the research is not well known, include the following statement:*

**Unforeseeable Risks Involving Pregnant Women**

If you are pregnant or become pregnant, [the particular treatment or procedure] may involve risks to the embryo or fetus, which are currently unforeseeable.

*If the research involves genetic material, include the following:*

**Genetic Information**

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:*

**Interviews/Questionnaires**

You do not have to answer any questions you do not want to answer.

*If the research involves prepared meals for research, include the following:*

**Food Allergies**

Because of the way our meals are prepared for research, and the possibility that the ingredients in the foods we get from commercial vendors could change at any time without our knowledge, it cannot be guaranteed that allergens will be identified and removed from the foods used in our research studies. If you have a food allergy, and you are participating in a study where foods are provided, there is a risk that you could have an allergic reaction. All participants with known life-threatening food allergies must inform staff of their allergies.

Include the following regarding any incidental or unexpected findings and information about notifying the subjects:

**Will I be notified if my** **[information, samples or images] result(s) in an incidental finding?**

During a research study, a researcher may notice something that he or she was not looking for. This is called an “incidental” or “unexpected” finding. These incidental findings are not directly related to the research. However, they may show important information about the health of a research volunteer.

Researchers may share some or all of their findings with you. However, you may not learn about any findings for a very long time. If such findings occur, you will be notified by the medical investigator or trained study personnel and referred to a treatment facility for further testing and/or treatment.

Risks: It can be very upsetting to learn unexpected information about your health. This is especially true if you learn that you have or will develop a condition that has no treatment or cure. There is a chance that unexpected findings could affect your family or social relationships, change your family planning decisions, or affect you financially. You might need more tests and procedures to find out what the information really means. It’s also possible that the information might be incorrect, so you would worry without cause.

*[This should be the default language in regard to incidental findings. If you object to notifying subjects of such events if they occur in your study, you will need to provide the IRB with a rationale and have the language (explaining why you wouldn’t notify them) approved by the IRB]*

*Include this sentence at the end of this section for ‘more than minimal risk’ studies:*

**Unknown Risks**

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.)*

***7- 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?).*

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

*Describe alternatives to participation or other courses of treatment, if any, that might be advantageous to the subject.*

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. You have the right to take part now and change your mind later on.

***9- 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.

***10- 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.

*Please include the following regarding information (data) or biospecimens:*

**Identifiable Private Information or Identifiable Biospecimens**

Any identifiers might be removed from your identifiable information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or given to another investigator for future research without additional informed consent from the subject or legally authorized representative.

*If sponsor requires MMSEA information such as Social Security Numbers, include the following:*

**Medicare/Medicaid Mandatory Reporting**

If the study sponsor covers costs associated with a study-related injury or medical illness, they will need to know some information about you like your name, date of birth, and Medicare Health Insurance Claim Number, or, if you do not have one, your Social Security Number. This information will be used to check to see if you receive Medicare, and, if you do, report the payment they make to Medicare. The study sponsor will not use this information for any other purpose.

*If the study will be registered on ClinicalTrials.gov, include the following:*

**ClinicalTrials.gov**

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:*

**Certificate of Confidentiality**

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.

*For research involving biospecimens, a statement must be added regarding (even if identifiers are removed) whether the biospecimens may be used for commercial profit and whether the subject will or will not share in the commercial profit.*

**Biospecimens and Commercial Profit**

Your [specific samples] may be used to develop new drugs or other products that may result in commercial profit that will not be shared with you.

*For research involving biospecimens, a statement must be added regarding whether the research will (if known) or might include whole genomic sequencing (i.e. sequencing of human germline or somatic specimens with the intent to generate the genome or exome sequence of that specimen).*

**Whole Genomic Sequencing**

Your [specific samples] collected for this research will be analyzed for the study. As

part of the analysis, the research [will OR might] include [whole genomic, germline, somatic, and/or exome sequencing]. This means that the researchers [will OR might] look at your sample to learn about your genes (DNA). There are different ways to look at your DNA. Researchers often use a technology called sequencing to look at your DNA. Sequencing “reads” each letter of the DNA and finds changes (also called “variations” or “mutations”) in your genes that may cause disease or affect how your body reacts to a certain disease. 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.

**OR**

Your [specific samples] that are collected for this research study will not include [whole genomic, germline, somatic, and/or exome sequencing]. This means that the researchers have no plans to look at or try to “read,” the protein information that makes up your genes (DNA) from your sample.

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

**Genetic Information**

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.

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

**Genomic Data/NIH Repository**

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.

*If this is a consent for a Trial Partner/Caregiver of an elderly subject, please include the following:*

**Trial Partner/Caregiver**

During the consenting process, enrollment or Research activities, PIs, Investigators and/or Research staff may become aware of conditions that gives them cause to believe that potential Abuse or Neglect may exist of elders. The PI (or delegate) is responsible for reporting all instances of Abuse and Neglect to the appropriate authorities.

***11- 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. Possible reasons for withdrawal include add reasons why the subject may be withdrawn, if appropriate. The sponsor of the study may also end the study early.

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. Early withdrawal from the study could result in include possible consequences if a subject decides to withdraw from the research (e.g., adverse consequences).

If your participation in the research ends early because of the investigator or by your choice, termination procedures may need to be completed or follow-up data may need to be obtained to ensure your safety. If there are specific procedures for this study that may be required at an early termination, include here. The study staff will go over the details with you.

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

*Must include the statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject:*

**Significant New Findings**

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.

*Must include one of the following statements regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions:*

**Clinically Relevant Research Results**

*If clinically relevant research results will be shared, include the following statement.*

In this study, you will be informed of any clinically relevant research results, including your individual results, that may be discovered. *Include conditions here.*

*If no clinically relevant research results will be shared, include the following statement*

In this study, you will not be informed of any clinically relevant research results, including your individual results that may be discovered.

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

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

***14- 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 compensate you       *(indicate amount) for completion of the study. If you do not complete the entire study, you will be compensated*       *(indicate amount) for visits (etc.) Indicate if the amount is pro-rated for study visit completion; Make it clear if the subject will or will not be compensated for any screening visits if applicable).* 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.

U.S. citizens, legal resident aliens, and those who have a work eligible visa will need to provide their social security number to receive payment.

You are subject to a 1099 for receiving compensation. Payments in excess of $600 per calendar year are considered taxable income. If you will be paid more than $600, Pennington Biomedical/LSU will report this income to the IRS.

Non-US citizens are subject to having taxes withheld from payment and will need a passport, visa and 1-94 for payment to be processed.

I authorize that all information provided on this Informed Consent form and HIPAA Authorization form, including any and all personal and financial data may be shared with the Internal Revenue Service (IRS) for tax reporting. This data will be securely retained indefinitely.

***15- 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]).*

***16- Signatures***

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

By signing this consent form, I agree to participate in the study as it is described. 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 signature lines, as appropriate. If not applicable, do not include as part of the consent form.*

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

***17- What you need to know about future research with your information, biospecimens or imaging.*** *Remove this Section if you are not storing information (data), biospecimens or imaging for future research. However, if you are, please include the following:*

*If information (data), biospecimens or imaging for future research is not optional for this research study, include a criterion in Section 4 and remove the signature portions of this section.*

*If the research involves collection and/or sharing of de-identified information (data), biospecimens, or images to other researchers include the following:*

Your [information, samples or images] may be sent to researchers outside of the Pennington Biomedical Research Center. Any personal information that could identify you will be removed before the [information, samples or images] are shared.

*OR*

*If the research involves collection and/or sharing of identifiable information, biospecimens, or images to other researchers include the following statement:*

Your [information, samples or images] may be sent to researchers outside of the Pennington Biomedical Research Center. The [information, samples or images] that are sent to these researchers may contain identifiable information. Identifiable information is being sent to these researchers because [explain the purpose of sending identifiable information, samples or images to researchers outside PBRC].

*If your research involves biospecimens, add the following:*

What you should know about your biospecimens:

* The samples will be stored indefinitely.
* If you agree to have your samples stored, you can change your mind later.
* For privacy and confidentiality, your samples will be labeled with a unique series of letters and numbers. Pennington Biomedical will store your samples with this unique identifier and the minimum number of personal identifiers to meet laboratory standards.
* The future research may or may not take place at Pennington Biomedical and may or may not involve Pennington Biomedical Researchers.
* You will not be compensated for any research studies that might be conducted in the future.
* You will not be informed of the details of any specific research studies that might be conducted in the future.
* 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.
* The research done with your specimens may also 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 your research involves blood, add the following:*

**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 used in future research?

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

Signature Date

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

Signature Date

*If your research involves tissue, add the following:*

**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 used in future research?

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

Signature Date

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

Signature Date

*If your research involves urine, add the following:*

**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 used in future research?

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

Signature Date

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

Signature Date

*If your research involves imaging or MRI scans, add the following:*

**Imaging or MRI Scans**

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

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

Signature Date

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

Signature Date

*If there is a* ***possibility*** *that future research will involve gene sequencing or creation of cell lines, include the following appropriate statement(s):*

**Genetic Testing**

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.

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.

If you give permission, your stored samples may be tested at Pennington Biomedical Research Center or other locations used in future research. Do you give permission for your biospecimens to be used in future research that may involve genetic testing?

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

Signature Date

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

Signature Date

*This withdrawal language below must still be included at the end of this section for information, biospecimens, or imaging. It also must be included even if the future research isn’t optional.*

**Withdrawal of Consent**

If you decide you would like to withdraw your consent to use your information, biospecimens or imaging, 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 the information, samples or imaging that have already been given to researchers.

For destruction of your information, biospecimens or imaging, you can send a request to the Principal Investigator at:

Principal Investigator

Pennington Biomedical Research Center

6400 Perkins Road

Baton Rouge, LA 70808