**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 red 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 future patients.
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.       directs this study, which is under the medical supervision of Dr.      . We expect about       people from       sites will be enrolled in this study. 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 how this study is designed to solve the problem.

***4- Who is eligible to participate in the study? Who is ineligible?*** Provide inclusion and exclusion criteria. (Use bullets for ease of reading and understanding and to reduce the grade level of the consent.)

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

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

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

Tell the subject what to expect. Give a time-line description of the procedures that will be performed, the drugs that will be administered, and all visits. Describe all procedures in lay language, using simple terms and short sentences (**refer to Study Procedures posted under the IRB section of PINE for approved language**). Provide a lay description of the randomization procedure, if applicable, and describe the chances of being assigned to any one group.(Use bullets for ease of reading and understanding.)

***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 posted under the IRB section of PINE for approved language**)

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, then any direct benefits to others, if applicable. If there are no direct benefits to the volunteer, state: We cannot promise any benefits from your being in the study. However, possible benefits include       (receiving information about your blood cholesterol, for example).

***8- 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.

***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 Dr. Steven Heymsfield, 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 (indicate the sponsor’s name 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.

[FDA and NIH require, for applicable trials, the following be included in the confidentiality section of the informed consent] 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 your child. At most, the web site will include a summary of the results. You can search this web site at any time.

***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. You may withdraw from the study at any time without penalty. 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. (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.)

***12- 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.

***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 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 2-3 weeks for it to arrive at Pennington Biomedical Research Center.

***15- 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. (DOD-funded research requires other language. Contact IRB Office.)

***16- HIPAA***

Records that you give us permission to keep, and that identify you, will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in records disclosed outside of Pennington Biomedical Research Center. For records disclosed outside of Pennington Biomedical Research Center, you will be assigned a unique code number.

***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 have been given a copy of the 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

Date of Birth of Volunteer

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