**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**FOR A MINOR**

**INFORMED CONSENT - PART I**

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

*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 participants.
3. You have the right to refuse to let your child 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 child’s participation is voluntary.
6. By signing this consent form, you agree to let your child 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. | | | |
|  | Day Phone: |  | | |
|  | 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 the 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?***

Provide inclusion criteria. (Use bullets for ease of reading and understanding and to reduce the grade level of the consent.) State the following: You may not qualify for this study based on other exclusion criteria not listed. The study coordinator will go over this information in detail.

Since this a minor consent use language like "Your child is eligible to participate in the study if:" (Use bullets for ease of reading and understanding.)

***5- What will happen to your child if he/she takes part in the study?***

The following table shows what will happen to your child at each visit if you decide to let your child take part in the study:

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

Tell the parent/guardian what to expect. Don't say "you" instead say "your child." "If you agree that your child can take part... 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.) If you are drawing blood, you must list the amount 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 any risks the child may encounter. **Refer to Study Procedures posted under the IRB section of PINE for approved language**)

In addition to the risks listed above, your child 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 parent/guardian's child, then any direct benefits to others, if applicable. If there are no direct benefits to the parent/guardian's child, state: We cannot promise any benefits from your child being in the study. However, possible benefits include      .

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

Describe alternatives to participation in the study.

You have the choice at any time to not let your child participate in this research study. If you choose to not let your child participate, any health benefits to which he/she is 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 child’s rights as a research volunteer, you should call the Institutional Review Board Office at 225-763-2693 or the Executive Director of Pennington Biomedical Research Center at 225-763-2513. If you have any questions about the research study, contact the Principal Investigator,       at      . If you think you have a research-related injury or medical illness, you should call the Medical Investigator,       at       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 child’s taking part in the study end early?***

Dr. Principal Investigator, Dr. Medical Investigator, or the study sponsor can withdraw your child from the study for any reason or for no reason. You may withdraw your child 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. (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 keep your child 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 your child’s 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 that your child can take part in this research study, 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 the check to arrive at Pennington.

***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 your child participates, he/she 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 your child require ongoing medical treatments, they must be provided by community physicians and hospitals. (DOD-funded research requires other language. Contact IRB Office.)

***16- Tissue/Specimen Storage for Future Research or Use (Optional)***

**If you are requiring tissue/specimens as participation in the study and this is not optional, please incorporate section 16 language into section 5 of the consent.**

***\*\*You cannot collect DNA with this consent, you must have a separate genetic consent. See the HRPP website for the genetic consent template\*\****

**Biospecimens for future research:**

You are being asked to allow some of your child’s (list biospecimen being stored) to be stored and used for research at a later time. These bodily materials are called biospecimens. The donation of biospecimens in this study is optional. No matter what you decide to do, it will not affect your child’sparticipation in this study. Your child will still be allowed to take part in the study even if you don't want his/her specimens to be collected and used for future research. 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 child’s samples stored, you can change your mind later.

The samples will be stored indefinitely. If you agree to donate your child’s 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 child’s 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 child’s 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.

**Making your choice about future research:**

Please read about each biospecimen below. It is your choice which samples will be collected, stored and used for future research for this study or future studies. After reading about each below, sign next to “Yes” or “No” to show your choice about the collections for this research study and for future research studies.

**Blood**

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

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

Signature of Parent/Legal Guardian Date

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

Signature of Parent/Legal Guardian Date

**Tissue**

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

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

Signature of Parent/Legal Guardian Date

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

Signature of Parent/Legal Guardian Date

**Urine**

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

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

Signature of Parent/Legal Guardian Date

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

Signature of Parent/Legal Guardian Date

If you decide you would like to withdraw your consent to use your child’s samples, you must provide a written request to have your child’s 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 child’s samples, you can contact the Principal Investigator at:

Principal Investigator Name

Pennington Biomedical Research Center

6400 Perkins Road

Baton Rouge, LA 70808

***17- Signatures***

If the study volunteer is a child, and the child is old enough to provide assent, an assent form must be completed by each subject. **Note: Section 17 must appear on one page.**

The study has been discussed with me and all my questions have been answered. If there is anything I don’t understand, I can ask the doctor. 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.

The study volunteer is a child. I certify that I am his/her legal guardian and legally authorized to enroll him/her in this research study. Misrepresentation of this authority could result in civil and/or criminal penalties.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | |  |  | | | |
| Printed Name of Child | |  | Date of Birth of Child | | | |
|  | |  |  | | | |
| Printed Name of Parent/Legal Guardian | |  | Relationship to Child | | | |
|  | |  |  |  |  | |
| Parent/Legal Guardian Signature | |  |  |  | Date | |
|  | | | |  | |  |
| 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’s Parent/Legal Guardian 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’s Parent/Legal Guardian has indicated to me that he/she is unable to read. I certify that I have read this consent form to the volunteer’s Parent/Legal Guardian and explained that by completing the signature line above the volunteer’s Parent/Legal Guardian has agreed to let his/her child participate.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |

Signature of Reader Date