This informed consent applies to: Adults over the age of 18

Name of participant (please print):_____Date: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in Project PLACENTA is voluntary and unrelated to the consent you have given for any prior procedure. There is no cost to you for taking part in this study. You may choose to not participate; your records will not be linked to tissue samples. Your decision to participate will not affect your medical care in any way. You are free to withdraw from this study at any time. This form describes the purpose of the study, and the risks and possible benefits of participating in the study.

1. **What is the purpose of Project PLACENTA?**

Pregnancy tissue is the tissue left over after delivery of your child. After a typical delivery, the placenta and leftover pregnancy tissues are thrown away. We would like to collect samples from left over pregnancy tissues and fluids after your delivery. With your permission, these tissue will be linked to your medical records, in order to create a bank (or library) of samples for use in many types of health research studies. This will allow us to better understand the causes of diseases in women and families during pregnancy and childhood. Our ultimate goal is to improve the treatment and prevention of prematurity, diseases, and pregnancy related conditions.

2. **What am I being asked to do?**

With your permission, we will collect and store tissue and fluid samples obtained after your delivery at Labor and Delivery and link them with your medical records. Project PLACENTA will only use pregnancy tissues and fluids that are left over and going to be thrown away. If your doctor wants to send your tissues for further testing, your tissues will not be affected. After our team collects the samples, samples are processed and stored in a special way to preserve them.

We are asking you to share your medical records:

With your permission, we will link these tissues to your medical records, so they can be used for research. Your medical records contain information about your health problems, test results, medical procedures, images (such as X-rays), and medicines you take. Your records may have information on your mental health, use of alcohol or drugs, or on infections you have had, including HIV status. Researchers may request this information be identified, meaning the information may contain things like your medical record number, name and date of birth. At all times, your information will only be used for research purposes, will be kept private, and your information will never be made public.

We are asking you to share your child's medical records:

These tissues may also be linked to the medical records of your child. An important part of research on pregnancy is knowing about any medical conditions that your child develops later in life. For example, by examining the pregnancy tissue of children who develop asthma, we may be better able to understand why a child is diagnosed with that condition.

What happens after my tissue has been collected?

Samples and data on your medical record history will be made available to qualified, approved researchers for use in research on pregnancy tissue and health.

Examples of research that may be conducted on your tissues:

In some cases, researchers may want to use your tissues to study your DNA and genes. Genes are the instruction manual for our bodies and can determine the way we look or the conditions we develop. They can also tell us a person's risk for certain diseases and how they will respond to treatment. Researchers may also want to use your tissues to grow cells in a laboratory. Examining how cells from your pregnancy interact with other cells and chemicals cells can be important to research. Researchers may make discoveries by studying the information they gathered from testing your samples.

There may be a study that requests to contact you to ask if you would like to take part in other research studies.

They would be required to give you information about the study and ask your permission to participate. You do not have to participate if you do not want to. We would like to know if you would like to be contacted to learn more about these studies.

_____Yes, I would like to be contacted to learn more about research studies.
(if YES)Please enter your preferred contact method:
(if YES)Phone _____
(if YES)Email _____

_____No, please DO NOT contact me

3. **What are the risks of taking part in Project PLACENTA?**

The main risk of taking part in Project PLACENTA is to your privacy. We will make every effort to protect your information, however there is a chance that there could be a data breach and someone could get access to the information we have about you. If this happens, your information could be misused. We believe the chance of this is very small.

Your privacy is very important to us. We have several steps we will take in order to protect that privacy.

- Your information will be stored on protected computers. We will limit and keep track of who sees the information.
- We will only share identified information with specific researchers that have gone through strict institutional review board (IRB) approval and have signed agreements forbidding them from releasing any identifying information publically.
- Many researchers will not need your name or identifying information, and in those cases your data will be kept de-identified. These researchers still need IRB approval and to sign a form promising not to misuse the data.

There is very little risk associated with collection of the tissues, all samples are taken after delivery and are a part of leftover waste that is normally discarded.

Taking part in Project PLACENTA may have risks that we don't know about yet. We will tell you if we learn anything that may change your decision to take part.

4. **What are some good things that might happen if I join Project PLACENTA?**

Research done on your tissues and records may benefit science and humankind. Donated tissue samples from your pregnancy can help our researchers make discoveries that may benefit future pregnancies, mothers, and children; help understand what causes prematurity or diseases during pregnancy, or even health effects of young children, like asthma and obesity. You will not receive any personal benefit from this study. You will not receive any medical results or money from experiments performed on your tissues.

5. **What will happen if you decide to participate in this study?**

To participate in this study, you must sign this consent form. Your tissue will be linked to your electronic medical records. You do not need to take any further steps. You will not receive any results from experiments done on your tissue. Your tissue is for research purposes only, and no clinical information will be returned to you or placed in your medical record.

6. **Who to call for any questions or concerns or if you change your mind:**

If you should have any questions about this study or if you have any concerns or if you would like to withdraw your consent, please call 615-343-3646 or email projectplacenta@vumc.org.

7. **HIPPA Authorization:**

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI.

As part of this study, Project PLACENTA and approved investigators may share the results of experiments on your tissue as well as parts of your medical records to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Medical Center Institutional Review Board, and the National Institutes of Health (including the Database of Genotypes and Phenotypes, dbGaP). Federal privacy rules may not apply to these groups, they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact us at 615-343-3646 or projectplacenta@vumc.org in writing to let us know that you withdraw your consent. The mailing address is: Pathlink c/o Jodell Jackson, 2525 West End Avenue, Suite 600; Nashville TN 37203-8820. At that time, we will stop getting any more data about you. The health data we stored before you withdrew your consent may still be used for reporting and research quality.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

I consent to having left over gestational tissues be part of Project PLACENTA and linked to my and my baby's medical records.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____ _____
Date Signature Printed Name and Title