

**RESEARCH SUBJECT INFORMATION AND CONSENT FORM****TITLE:** Mechanisms of pregnancy vascular adaptations

**This consent form contains important information to help you decide whether to participate in this research study.**

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may discuss this consent form with family or friends. Take as much time as you need to decide if you want to be in this research.

- **Being in a study is voluntary – your choice.**
- **If you join this study, you can still stop at any time.**
- **No one can promise that a study will help you.**
- **Do not join this study unless all of your questions are answered.**

**Before signing this consent form you should be able to answer the following questions.**

- Why is this research study being done?
- What will happen to me during the study?
- What are the possible risks to me?
- What other options could I choose instead of being in this study?
- How will my personal health information be treated during the study and after the study is over?
- Will being in this study cost me anything?
- What to do if I have problems or questions about this study?

**Please read this consent form carefully.**

# CONSENT TO BE PART OF A RESEARCH STUDY

## INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. *Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.*

## 1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

### 1.1 Study title:

Mechanisms of pregnancy vascular adaptations

**1.2 Company or agency sponsoring the study:** National Heart, Lung, and Blood Institute

### 1.3 Names, degrees, and affiliations of the researchers conducting the study:

Sathish Kumar, DVM

Comparative Biosciences

School of Veterinary Medicine

## 2. PURPOSE OF THIS STUDY

Preeclampsia is a pregnancy complication. It features high blood pressure and signs of damage to another organ system. Blood vessels may be at the root of preeclampsia. We want to study these blood vessels to learn more about how they work in a person with preeclampsia, compared to a person without preeclampsia.

## 3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

### 3.1 Who can take part in this study?

Pregnant women between the ages of 18 and 40 who are not expected to have multiple births and may deliver their baby via Caesarean section (C-section) can take part in this study. You will only have a C-section if it is medically necessary.

### 3.2 How many people (subjects) are expected to take part in this study?

104 women who are delivering at UnityPoint Health – Meriter are expected to take part in this study.

## 4. INFORMATION ABOUT STUDY PROCEDURES

### 4.1 What exactly will be done to me in this study? What kinds of research procedures will I receive if I agree to take part in this study?

This study asks you to provide two tissue samples: (1) Omental biopsy (2) Placental donation. You can choose to provide one or both of these samples. Additionally, a research team member will review your medical record for health data that is relevant to the research.

#### (1) Omental Biopsy:

- a. **What is the omentum?** The omentum, an abdominal fat layer that acts like an apron covering your organs, helps your immune cells reach an injury or inflammation in the abdomen. Omentum assists the healing process by isolating the injury until healing occurs. If you have a C-section to deliver your baby, you are eligible to donate omental tissue.
- b. **Who will collect the omentum?** In most cases, the surgeon performing your C-section will also collect your omental tissue. When this is not the case, you will be informed before your C-section starts that another surgeon will be doing this collection. You will be introduced to this surgeon before your C-section starts.
- c. **What will be collected?** When you deliver your baby via C-section, several layers of your abdominal wall are cut open. Once your baby and placenta are delivered, the surgeon closes these layers. The omentum is not usually cut, but is near the opening. If you consent, the surgeon will remove a small triangular piece of the omentum to study the blood vessels. Each side of the triangular piece will be about 2.5 inches long. After tissue removal, the surgeon will repair and suture the site to prevent any bleeding. The surgeon will then close your incision in layers.

- (2) **Placental Donation:** After your baby is delivered via C-section, your placenta is delivered. The placenta is often discarded, or sent for examination. If you consent and if no examination is required, then the researchers will take the placenta to study the blood vessels.

### 4.2 How much of my time will be needed to take part in this study? When will my participation in the study be over?

The omental biopsy will take about 10 minutes in addition to usual C-section procedures. The placenta collection will be done after your baby is delivered. It will not add any time to your delivery or treatment. The medical record review will be done after you are discharged from the hospital.

## 5. INFORMATION ABOUT RISKS AND BENEFITS

### 5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

There is a risk of physical harm from the omental biopsy, similar to having a standard C-section because both involve an incision. However, because the omentum is not ordinarily cut in a regular C-section, this an additional risk, which is described below.

When you have an incision or inflammation, the omentum works to 'isolate' the area of injury from the rest of the abdomen. In this process, omentum will surround the injury, but, in rare cases, will attach to the site of injury. These attachments are known as adhesions and are more

likely to occur because of other clinical conditions such as an infection, rather than removal of omentum.

The main risks are a small risk of bleeding, infection, and adhesions (abnormal attachments of tissue within the abdomen) at the site of the omentum incision.

An obstetrician will be present for your biopsy, ensuring that you are well cared for. After the C-section you will be monitored and cared for as any new mom who delivered by C-section. If complications arise, appropriate medical care will be provided.

Additionally, there is a risk of breach of confidentiality. The research coordinators that handle your data are trained to do so in a secure manner. Additionally, the data must remain secured both electronically and physically throughout the study. There is more about the Confidentiality of Subject Records in section 9 below.

As with any research study, there may be additional risks that are unknown or unexpected.

## **5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?**

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even when the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers listed in Section 10 of this form.

In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Dr. Sathish Kumar at (608) 265-1046 if you are injured or for further information.

## **5.3 If I take part in this study, can I also participate in other studies?**

If you agree, you can donate any leftover placenta with any attached umbilical cord to other research within UW Ob/Gyn. The research staff will coordinate sharing of tissue samples if you consent. You should not take part in more than one study at the same time without approval from the researchers involved in each study.

## **5.4 How could I benefit if I take part in this study? How could others benefit?**

You will not receive any personal benefits from being in this study. However, this research may benefit future women's care for conditions like preeclampsia.

## **5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?**

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

## 6. OTHER OPTIONS

### 6.1 If I decide not to take part in this study, what other options do I have?

You do not have to participate in this study to receive a C-section or other treatment related to your delivery. You will receive the routine treatment provided by your obstetrical provider. Participation in this research study is voluntary. There is no penalty if you choose not to participate.

## 7. ENDING THE STUDY

### 7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please notify one of the persons listed in Section 10 “Contact Information” (below). You can also tell your nurse or doctor who will inform the research study team that you want to leave the study.

### 7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No. There are no risks to you if you decide to leave the study before it is finished.

### 7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

## 8. FINANCIAL INFORMATION

### 8.1 Will taking part in this study cost me anything? Will I or my insurance company be billed for any costs of the study? If so, which costs? What happens if my insurance does not cover these costs?

You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you take part in this study, such as your C-section and hospital care. If your insurance company does not cover these treatments or procedures, you will have to pay for them.

**There are no fees or costs for participating in this study.**

### 8.2 Will I be paid or given anything for taking part in this study?

You will not be paid or given anything for your participation in this study.

### 8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of the study.

## 9. CONFIDENTIALITY OF SUBJECT RECORDS

UnityPoint Health - Meriter policies require that private information about you be protected. This is especially true for your personal information.

On the other hand, sometimes the law allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

### 9.1 How will the researchers protect my privacy?

With any research study, there are risks related to loss of confidentiality. Your information will be protected by storing research data written on paper in a locked cabinet in a locked office. All electronic information is password protected and stored on a secure server. Your identifiable information will be kept until the study is completed. Your specimens and data will be labeled with a code instead of your name to protect your privacy.

### 9.2 What information about me could be seen by the researchers or by other people?

#### Why? Who might see it?

There are many reasons why information about you may be used or seen by the researchers or others during this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- UnityPoint Health - Meriter IRB, Food and Drug Administration [FDA], and other government officials may need the information to make sure that the study is done properly.
- Organizations that are funding the study may need the information to make sure that the study is done properly.
- Safety monitors or committees may need the information to make sure that the study is safe.
- Insurance companies or other organizations may need the information in order to pay your medical bills.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- UW Madison Research Oversight Offices

The results of this study could be published in an article, but would not include any information that would let others know who you are.

## 10. CONTACT INFORMATION

### 10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- 
- Express a concern about the study

Dr. Sathish Kumar, DVM,  
UW School of Veterinary Medicine  
Veterinary Medicine Building  
2015 Linden Dr  
Madison, WI 53706  
608-417-6099

Study Coordinator  
UW Ob/Gyn – Clinical Research  
McConnell Hall – 4<sup>th</sup> Floor  
1010 Mound Street  
Madison, WI 53715  
608-417-4232

You may also express a concern about a study by contacting the– UnityPoint Health - Meriter Institutional Review Board at:

**608-417-6411**  
UnityPoint Health - Meriter  
202 South Park Street  
Madison, WI 53715

*When you call or write about a concern, please provide as much information as possible, including the name of the researcher and details about the problem. This will help UnityPoint Health - Meriter officials look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

## 11. RECORD OF INFORMATION PROVIDED

### 11.1 What documents will be given to me?

After you sign in the next section, you will receive copies of all of the following documents:

- This consent document to be part of a research study.

*Note: A copy of this document will be stored in a separate confidential research file. We will enter this consent into your medical record.*

- HIPAA Authorization for the release of medical record information

## 12. EMAIL COMMUNICATION

We are requesting your email address so we can send you study information and reminders. We will do everything we can to protect the privacy of your information.

Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the lead researchers, Dr. Laura Cooney or Dr. Kathleen Antony, at 608-824-6160 or the research coordinator at 608-417-4232. You do not have to provide your email address to participate in this study.



### 13. SIGNATURES

This study provides the option to choose which samples you would like to provide. Please mark with your initials which specimens you would like to provide for this study. If you would like to provide both specimens, please mark both options.

\_\_\_\_\_ **Omentum:** I agree to allow a surgeon to collect an omental biopsy during my C-section and I donate that tissue to this research study.

\_\_\_\_\_ **Placenta and any umbilical cord attached to the placenta:** I agree to donate my placenta and any attached umbilical cord to this research study, once it is no longer clinically useful.

Additionally, please decide whether you would like to donate any leftover placenta with any attached umbilical cord to other research within UW Ob/Gyn. Mark the option you prefer.

\_\_\_\_\_ I **agree to donate** my placenta and any attached umbilical cord and some of the medical history data collected for this study. My name and other identifying information will not be included in this additional research.

\_\_\_\_\_ I do **not want to donate** my placenta and any attached umbilical cord and some of the medical history data collected for this study.

#### Research Subject:

*I have discussed this study, its risks and potential benefits, and my other choices. My questions so far have been answered. If I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I will receive a copy of this form at the time I sign it and later upon request.*

Signature of Subject: \_\_\_\_\_ Date: \_\_\_\_\_

Name (Print legal name): \_\_\_\_\_

Person Explaining Consent: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of Person Explaining Consent:  
\_\_\_\_\_

**Researcher: Enter a signed copy of this consent in the subject's electronic medical record.** Use the same method you would use for other signed consent forms.