

Magee-Womens Hospital of UPMC

Department of Obstetrics, Gynecology, & Reproductive Sciences

Summary of Key Information on the Relationship between Plasma Concentration of 17-OHPC and Preterm Birth (PTB)

Participation is voluntary: You are being asked to participate in a research study. Research studies include only people who choose to take part. The study team members will explain the study to you and answer any questions you might have. You should take your time to make your decision.

Study Summary: A prior preterm birth (PTB) increases your chances of having another PTB. The only treatment that has been shown to reduce that risk is weekly injections 17-hydroxyprogesterone caproate (17-OHPC). Researchers at Magee-Womens Hospital (MWH) have shown that in many women the standard 250 mg dose approved by the Food and Drug Administration (FDA) may be too low to prevent another PTB. The purpose of this study is to determine if higher blood levels of 17-OHPC will further reduce the risk of PTB. Some women in this study will receive the standard 250 mg weekly dose whereas others will receive a 500 mg weekly dose. If you decide to participate, you will attend a screening visit where you will be asked questions to determine if you are eligible to participate. If you choose to participate, you will be randomly assigned to receive either the 250 mg or 500 mg dose. You will receive weekly injections administered by the research staff, your personal physician, or by someone trained to give the injections at home. You will be seen at MWH at least every 6-9 weeks and we will collect blood samples during 3 of these visits and at delivery. We will also collect umbilical cord blood and a sample of the placenta after delivery to determine the concentration of 17-OHPC.

Risks of being in the study: The side effects of the 250 mg and 500 mg dose will be similar but the larger dose may cause more discomfort at the injection site and may increase the likelihood of the uncommon side effects such as pain at the injection site, itching, swelling, bruising, or hard lump at the injection site. Hives from an allergic reaction are possible, but uncommon. Other uncommon risks include nausea, diarrhea, fluid retention, decrease in glucose tolerance, clotting disorders and depression among those with a history of clinical depression. There are minimal risks associated with the other study procedures. There is a minimal risk of breach of confidentiality regarding the collection of medical record information. All research information about you will be handled in a confidential (private) manner consistent with other hospital medical records.

Benefits of study participation: You and your baby may not benefit clinically from participation in this study if the higher dose does not reduce the risk of preterm birth. However, we anticipate with the higher dose of 17-OHPC that there may be an improvement in your risk for preterm births; meaning that your pregnancy may last longer which may offer better outcomes for your baby. If you participate in this study, you may benefit financially since you will not have a co-pay for the medication. Many insurance companies require a co-pay with this medication.

Alternative Treatments: The alternative to this study is not to participate. If you decide not to participate, then you will continue to receive routine prenatal care and 17-OHPC injections by your health care provider.



TITLE: Relationship between Plasma Concentration of 17-OHPC and Preterm Birth (PTB)

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Introduction

You are invited to take part in a research study. This consent form provides information about the risks and benefits of the study. A member of the study team is available to answer your questions and to provide further explanations. You are free to choose whether or not you will take part in the study. If you agree to take part in the research, you will be asked to sign this consent form. This process is known as informed consent.

Your doctor may be involved as an investigator in this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

Why is this research being done?

Preterm or premature birth remains one of the most important problems in obstetrics today. It is the leading cause of newborn death and a major cause of lifelong disability. A prior preterm birth (PTB) increases your chances of having another PTB. The only treatment that has been shown to reduce the risk of having another PTB is weekly injections of a medication called 17-hydroxyprogesterone caproate (17-OHPC). This medication is approved by the Food and Drug Administration (FDA) and is standard of care for all women who experienced a spontaneous PTB in the past. The medication is administered weekly from 16 0/7-21 6/7 weeks through 36 6/7 weeks of gestation. The standard dose is 250mg weekly but researchers at Magee-Womens Hospital have shown that in many women the amount of medicine in the mother's blood is too low to prevent another PTB. Women who had higher blood levels had lower rates of PTB. Another study however, found no relationship between the amount of medicine in the blood and risk of PTB birth.

The purpose of this study is to determine if higher blood levels of 17-OHPC will reduce the risk of PTB; some women in this study will receive the standard 250 mg weekly dose whereas others will receive a 500 mg weekly dose. This 500 mg dose does not have FDA approval but this study has been reviewed and approved by the FDA. Additionally, we will determine if maternal weight or race or genetic makeup impacts blood concentration and the placental transport of the drug.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.



How many people will be studied?

We expect about 300 women to participate in this research study. This study is sponsored by the National Institutes of Health (NIH) Obstetric-Fetal Pharmacology Research Center Network (OPRC) and has been reviewed by the FDA. It will take place at 3 sites: Magee-Womens Hospital (MWH) (Pittsburgh, PA), Northwestern University (Chicago, IL), and the University of Texas Medical Branch (Galveston, TX).

Who is being asked to take part in this research study?

You are asked to take part in this study because you meet all of the following conditions:

- You are between 18-45 years old and currently pregnant with one baby.
- You are in your second trimester, between 16 weeks and 21 weeks of gestation.
- You had a previous pregnancy that ended before 36 weeks of pregnancy.
- You are currently considered to be at increased risk for another spontaneous preterm birth.

How long will my participation in this research last?

If you decide to participate in this study and are found to be eligible, your participation will start at the time of enrollment and will continue until you are discharged from the hospital after your delivery.

What procedures will be performed for research purposes?

Whether or not you choose to participate in this research study, your prenatal care will remain the same. If you decide to take part in this study and once you sign this consent form, the following tests and procedures will occur:

Screening Visit (approximately 30-45 minutes):

- The Screening Visit will occur at MWH, and should take about 30-45 minutes to complete. When possible, the Screening Visit will be performed during a day on which you have a routine visit to your caregiver at MWH already scheduled.
- A member of the study team will review the study with you. If you are eligible and agree to participate, you will sign this consent form.
- You may be asked to sign a routine medical record release form to provide more information to see if you are eligible to participate in this study.
- We will review your medical record and ask you questions about your pregnancy; medical history, including depression; obstetrical history, including outcomes of all prior pregnancies; any medications you are taking; and your social history (such as your marital status, years of education, and alcohol, tobacco, and other drug use).
- We will ask if you are feeling depressed. If necessary, we will ask additional questions to assess your current level of depression.
- From your medical record, we will record your height and weight.
- You will be randomized to one of two drug treatments (explained below) and given instructions about your study drug.
- You will be administered the first injection of 17-OHPC at MWH by a trained member of the research study team.
- Procedures for the upcoming study visits will be reviewed.

Study Drug Treatment

You will be randomly (like a coin flip) assigned to be treated with either a dose of 250 mg or 500 mg of 17-OHPC injected intramuscularly, every week from 16 0/7-21 6/7 weeks of gestation until 36 6/7 weeks of gestation. Those assigned to the weekly 500 mg dose will receive either a single 2 ml



injection or two 1 ml injections while those assigned to the 250 mg dose will receive a 1 ml injection of the same medication into the hip/buttocks area. You will have an equal chance of receiving either of the two study treatments. You, your doctor, and the study staff will know whether you are receiving a 250 mg or 500 mg 17-OHPC injection. Once you are assigned to a group, you will stay in that group as long as you are participating in the study. The objective of this study is to determine if higher blood concentrations result in lower rates of PTB than is currently seen with the 250 mg weekly dose. Doses as high as 1000 mg weekly of 17-OHPC have been used in pregnant women in the past for other clinical indications including twins, short cervix and other high-risk conditions without any significant complications.

The medication will be provided free without cost to you or your insurance company. The medication is provided by the company that distributes the FDA-approved medication.

Study Visits

You will receive your first injection from a trained member of the research study team. After that, you will be given enough medication to last 6-9 weeks and the injections can be given by the research staff at Magee, your Obstetrical provider's office if they offer that service or by other qualified medical personnel, or a friend or family member that is trained to administer the medication. That friend or family member must come to a study visit conducted prior to the start of home injections to be instructed on how to administer the medication and how to draw up the medication from the vial in order to maintain sterility. When possible, we will coordinate your study visits with your regular prenatal visits. The research team will contact you weekly and ask about any side effects that you may have experienced since your last injection and any other medications you are taking. The team will also ask you if you had an episode of preterm labor or were hospitalized for any other reason since the last injection. Weekly communication with the study team will occur until the delivery of your baby.

As a requirement of the study, you will be asked to allow us to draw a blood sample on 3 occasions during your regularly scheduled visits with the study team. These blood samples will measure how much 17-OHPC is in your blood. The first blood specimen (7 mL, 1½ teaspoons) will be taken 1 week after your first injection and the second specimen (7 mL, 1½ teaspoons) will be taken between 26 and 30 weeks of pregnancy. The third sample will be taken 6-9 weeks after the 26-30 week sample. Although not a requirement for this study, we ask that you allow us to take an additional 7 mL of blood (1½ teaspoons) during one of these 3 times that we are collecting a blood sample in order to perform genetic studies related to the medication's metabolism and preterm birth risk. Your genes are unique and they may determine how well the medication works, how much reaches the baby and how great your risk of premature birth is. This genetic blood specimen can be taken at the same time as the other blood specimens.

At the second and third sample collections, we will ask if you are experiencing any depression. If necessary, we will ask additional questions to assess your current level of depression. You will be offered a referral to a mental health provider, if necessary. We ask that you inform the research team if you begin to experience symptoms of depression during the study.



PERMISSION TO COLLECT AND STORE MATERNAL DNA:

I give my permission to have my blood samples and genetic material (DNA) be collected and stored.

_____ YES _____ NO _____ INITIALS

Labor and Delivery

The following procedures will occur, when you deliver your baby at MWH:

- We will collect data during your hospital stay by reviewing your medical chart. Your weight and a list of medications that you are taking will be recorded. You will be asked about any side effects that you have had since the last 17-OHPC injection.
- Prior to delivery, 7 mL (1½ teaspoons) of blood will be drawn to measure the concentration of 17-OHPC in your blood.
- After the birth of your baby, blood will be collected from the umbilical cord that is still attached to the placenta but separated from the baby. The umbilical cord is usually discarded at delivery, but we would like to collect a blood sample from it for this study. Samples of this cord blood will provide information from your baby. 7 mL (1½ teaspoons) will be collected from the umbilical cord to measure how much 17-OHPC and its breakdown products are present.
- From the cord blood collected, we may also study certain genes directly or indirectly involved in how the body handles and responds to medications. Although not a requirement of this study, we ask that you allow us to collect another blood specimen (7 mL, 1½ teaspoons) from the cord for DNA studies of the baby. These studies will focus on the babies' genes that are involved in the metabolism of the 17-OHPC and genes that may be involved in factors regulating the timing of birth.

Please note:

- The labor and delivery samples (maternal blood, umbilical cord blood and placenta) will only be collected when possible.
- If you intend to store cord blood in a family bank, that collection will take priority over the collection for this research study. We still will collect cord blood for research purposes, if there is enough remaining after your donation to a family bank.

PERMISSION TO COLLECT AND STORE CORD BLOOD:

I give my permission to have my baby's de-identified cord blood samples and genetic material (DNA) be collected and stored.

_____ YES _____ NO _____ INITIALS

- After delivery of your baby, about a 3 x 3 cm sample of the placenta (after birth) will be collected, when possible, and stored for testing on how much 17-OHPC is present and how well the placenta handles 17-OHPC.



- After you deliver your baby, we will collect information from your medical records on your pregnancy, labor, and the status of you and your baby until you are both discharged from the hospital.

The maximum amount of blood that will be collected from you during this entire study for full participation is about 35 mL (approximately 7 teaspoons). The maximum amount of umbilical cord blood collected is 14 mL (3 teaspoons) No blood or other biological specimens will be collected from your baby.

Future Contact

We will ask your permission to contact you in the future to update your contact information, including your address and telephone numbers. If a new research study comes up for which you may be eligible, we may contact you to see if you would be interested in participating. For instance, we would also like to have your permission to contact you in the future if research funding becomes available to evaluate long-term outcomes for this study. This may involve collecting information from your medical records and from you regarding your health and/or that of your child. If research into the long-term outcomes for this study occurs, then you will be contacted and asked to sign an additional consent form.

<p>PERMISSION TO COLLECT FOLLOW-UP INFORMATION</p> <p>I give permission to have a member of the study team contact me to update my contact information. I also give permission for the study team to obtain medical record information regarding my health or the health of my child.</p> <p>_____ YES _____ NO _____ INITIALS</p>

<p>PERMISSION TO BE CONTACTED FOR FUTURE RESEARCH</p> <p>I agree to be contacted for future research studies.</p> <p>_____ YES _____ NO _____ INITIALS</p>

Use and Storage of Biological Samples

Analyses of samples (e.g., blood, DNA, placenta, and cord blood) will be performed at the University of Pittsburgh or another NICHD-supported laboratory. Samples will be stored indefinitely in secured freezers, and Dr. Caritis will be responsible for control of the storage areas at MWH, MWRI, and the University of Pittsburgh. Only authorized researchers will have access to the stored samples.

Samples will be stored with assigned code numbers, and the information linking these code numbers to your identity will be kept in a separate, secure location. De-identified samples (samples that do not indicate your identity) may be made available to investigators from the other OPRC Network sites for future research on pregnancy. You will not share in any commercial profit that may result from the future use of your de-identified samples.

If you decide to withdraw consent for this study, and your samples have already been de-identified, your samples will continue to be used for analysis and future research. If you decide that you want your

stored samples to be destroyed, please notify Dr. Caritis in writing and we will destroy the samples that are labeled with your study ID.

Genetic tests, study drug measurements, and other research test results will not be reported to you or your care provider and will not be put in your medical record. These tests are being done entirely for research purposes and are not known to predict clinical outcomes.

What are the risks of participating in this research study?

Although unlikely, it is possible that participation in this study could involve risks to you or your baby that are currently unknown. As with any research study, there may be adverse events or side effects that are currently unknown and it is possible that certain of these unknown risks could be permanent, serious, or life-threatening. You will be promptly notified if, during the conduct of this research study, any new information develops that may cause you to change your mind about continuing to participate.

Risks of 250 mg 17-OHPC Injections

The risks associated with the weekly 250 mg 17-OHPC injections include pain at the injection site, itching, swelling, bruising, or hard lump at the injection site. Hives from an allergic reaction are possible, but uncommon. Other uncommon risks include nausea, diarrhea, fluid retention, decrease in glucose tolerance, clotting disorders and depression among those with a history of clinical depression.

Risks of 500 mg 17-OHPC Injections

The only difference between the 250 and 500 mg injection is that the 250 mg injection is a 1 mL injection while the 500 mg injection is a 2 mL injection. The side effects will be similar but the larger injection volume may cause more discomfort at the injection site and may increase the likelihood of the uncommon side effects listed below. The common risks include pain at the injection site, itching, swelling, bruising, or hard lump at the injection site. Hives from an allergic reaction are possible, but uncommon. Other uncommon risks include nausea, diarrhea, fluid retention, decrease in glucose tolerance, clotting disorders and depression among those with a history of clinical depression.

In order to minimize the discomfort associated with the 500 mg dose, you will have the option of receiving either a single 2 ml injection (500 mg) or two 1 ml injections (250 mg each), administered at the same time, for a total dose of 500 mg.

Risks to your Fetus (unborn baby) and Neonate (Newborn)

To further limit the risk to your fetus, we will not be collecting any blood or other specimens directly from your fetus while you are pregnant. Only umbilical cord samples will be collected after delivery of your baby, and after clamping and cutting the umbilical cord. Other risks to your neonate include loss of confidentiality, as it could possibly occur during the collection of data for this study.

Risks of Collection of Blood Samples

The common risks include bruising, bleeding, swelling, and pain at the injection site. Infection at injection site, blood clot at the injection site, fainting, and lightheadedness are possible, but uncommon. The amount of blood to be drawn in this study should not affect your blood count.



Risks of Answering Study Questions

There is minimal risk from answering the study questions. You do not have to answer any questions that you do not want to answer. You may stop answering questions at any time without affecting your medical care. All of your answers will remain confidential.

Risks of Genetic Testing

Genetic (DNA) testing involves the potential for breach of confidentiality that could impact your insurability, employability, or reproduction plans, or have a negative impact on family relationships, and/or result in paternity suits or stigmatization. Although your genetic information is unique to you, you will share some genetic information with your children and other blood relatives. So, it may be possible that genetic information from them could be used to help identify you. It also may be possible that genetic information from you could be used to help identify them. It is possible that people may develop ways in the future that would allow someone to link your genetic or medical information back to you.

The risk that the tests we do could be used against you is very small. First, the study investigators will be very careful to ensure that only authorized researchers can use study samples, study information (including test results), and your personal information. Second, research information and test results will not be placed in any medical records.

A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies and group health plans to use genetic information in making decisions regarding eligibility or premiums. GINA also makes it illegal for employers with 15 or more employees to use genetic information when making decisions regarding hiring, promoting, firing, or setting the terms of employment. This federal law does not protect against genetic discrimination by companies that sell life, disability, or long-term care insurance.

Risks of Collection of Medical Record Information

There is a minimal risk of breach of confidentiality regarding collection of medical record information. All research information about you will be handled in a confidential (private) manner consistent with other hospital medical records.

Risks of Collection of Umbilical Cord Blood Samples

There is no risk associated with collecting an umbilical cord blood sample since the umbilical cord will be separated from you and your baby.

Risks of Placental Collection:

There is no risk to you or your baby associated with collecting a sample of the placenta.

Risks of Randomization

Because study treatment will be randomized, it is possible that a different study treatment group will have more benefit or lower side effects than the group to which you are assigned.

Will I benefit from participating in this study?

You and your baby may not benefit clinically from participation in this study if the higher dose does not reduce the risk of preterm birth. However, we anticipate with the higher dose of 17-OHPC that there may be an improvement in your risk for preterm births; meaning that your pregnancy may last



longer which may offer better outcomes for your baby.

If you participate in this study, you may benefit financially since you will not have a co-pay for the medication. Many insurance companies require a co-pay with this medication.

We hope that the results of this study will help health care providers in the future to offer treatment that may prevent preterm births, better than the current treatment, reducing health care burdens and their associated costs. Therefore, your participation could potentially benefit many mothers and their babies in the future and perhaps even yourself if you again become pregnant.

What treatments or procedures are available if I decide not to take part in this research study?

The alternative to this study is not to participate. If you decide not to participate in this study, then you will continue to receive routine prenatal care and 17-OHPC injections by your care provider. Your decision about taking part in this study will not affect your eligibility for any health plan, any health plan benefits or payments, or any medical care options at any UPMC hospital or doctor's office.

What if I change my mind about participation?

You can change your mind at any time. If you chose to withdraw from the study but still wish to be treated with the standard 250 mg weekly dose of 17-OHPC, the medication will need to be ordered by your provider and you may have to pay a co-pay depending on your insurance. The research team will continue to provide the standard 250 mg weekly dose until treatment can be transitioned to your healthcare provider to ensure there is no lapse in your care. The medication used in the study cannot be used for women who do not remain in the study. To formally withdraw your consent for participation in this research study or to withdraw your authorization to allow the research team to review medical records, you should provide a written and dated notice of this decision to Dr. Caritis at the address listed on the first page of this form. Even if you cancel this authorization, the study team may still use and disclose protected health information (PHI) and use the biological samples they already have obtained about you as necessary to maintain the integrity or reliability of the research. However, no new PHI or biological samples will be collected from you after you revoke your authorization. Withdrawing permission for your PHI to be used for the research study will not change the medical care you receive and will not affect your eligibility for any health plan, any health plan benefits or payments, or any medical care options at any UPMC hospital or doctor's office.

How much will it cost to participate?

There will be no cost to you for taking part in this research study, as none of the research procedures that you receive will be billed to you or your insurance company. You and/or your health insurance will be charged, in the standard manner, for services and procedures provided for your routine prenatal care, such as your labor and delivery with associated hospital services.

Will I be paid to take part in this research study?

If you agree to take part in this research study, you will be compensated at the end of each study visit via a reloadable debit card. You will receive \$25 for completing the screening visit and every time blood and/or delivery samples are collected for this research study. You will receive an additional \$50 if you and your baby complete all parts of this study. You also will receive a voucher for free parking for each study visit in which blood is drawn at MWH.

Some of the research conducted using your and your baby's samples or information could lead to the



development of new diagnostic tests, new drugs, or other commercial products. Should this occur, there is no plan to provide you with any part of the profits.

Who will pay if I am injured as a result of taking part in this study?

UPMC and MWH investigators and their associates recognize the importance of your voluntary participation to their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as the result of the research procedures being performed, please immediately contact Dr. Caritis. Emergency medical treatment for injuries solely and directly relating to your participation in this research will be provided to you by UPMC and MWH. It is possible that UPMC and MWH may bill your insurance company for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care, unless otherwise specifically stated in this consent. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

How will my privacy be protected?

Your privacy is very important to us. Protected Health Information (PHI) is medical record information about a person's health that includes information that would make it possible to figure out whose it is. According to federal law, you have the right to decide who can see your PHI. All information obtained from this research study that can be identified with you or your baby will remain confidential within the limits of the law.

When choosing to take part in this research study, you are giving us permission to see and use all medical information and personal identifiers from your medical records and from information that you give to a researcher, such as information related to your eligibility for this study; demographic information; medical history; obstetrical history; labor, delivery, and discharge information; and treatments of whatever kind related to or collected for use in this research study. From your baby's medical records, we will get information about your baby's health up to the time that your baby is discharged from the hospital. Identifiable medical record information will be made available to members of the study team for an indefinite period of time.

The information collected for this research study will be held at MWH in a database consisting of information from all the participants in this study. The information will include your PHI such as hospitalization dates and the date of delivery (which is your baby's date of birth). In all other cases, we will use a study ID number to identify your study information. Records linking your name to the study ID will be securely stored in a locked file cabinet in the office of the research staff at MWH.

Any research information that identifies you will not be voluntarily released or disclosed without a separate consent, except as specifically required by law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

General de-identified information from this research may be published in medical journals, shared with secondary investigators, and placed in a public data set so that health care providers might learn to provide better care to women in the future.



What is a Certificate of Confidentiality?

To further protect the privacy of you and your baby, the researchers will obtain a Certificate of Confidentiality from the NICHD. This Certificate means that the researchers cannot be forced (for example, by court order) to disclose any information that might identify you to any federal, state, or local court. A Certificate of Confidentiality does not prevent you from voluntarily giving information to others about your participation in this research study. We will not release any information collected as part of the research study regarding use of illicit drugs. However, information gathered and tests done as part of your routine clinical care, are not protected by the Certificate of Confidentiality that we will obtain for this research study.

Who will have access to my PHI related to my participation in this research study?

In addition to Dr. Caritis and his research staff, the following individuals may have access to your PHI related to your participation in this research study:

- 1) Authorized representatives from the sponsor (NICHD) may look at or copy study records for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. The results of this research study also will be provided to the sponsor.
- 2) The Office for Human Research Protections (OHRP) may look at your study records to protect your safety and welfare.
 - a. Persons who receive your PHI may not be required by federal privacy laws to protect it. Some of these persons may be able to share your information with others without your separate permission. By taking part in this study, you are giving your permission for these persons to collect, use, and share your PHI. If you choose not to let these persons, collect, use, and share your PHI as explained above, then you will not be able to participate in this research study.
 - b. While NICHD and OHRP understand the importance of maintaining the confidentiality of your PHI, the University of Pittsburgh, UPMC, and MWH cannot guarantee the confidentiality of this information after it has been obtained by them.
- 3) Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your PHI for the purpose of monitoring the appropriate conduct of this research study.
- 4) Authorized representatives of UPMC hospitals or other affiliated health care providers may have access to your PHI related to your participation in this research study for the purpose of: fulfilling orders, made by the investigators, for hospital and health care services associated with research study participation; addressing correct payment for tests and procedures ordered by the investigators; and/or for internal hospital operations (such as quality assurance).

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The link to identifying information about you and your baby's de-identified neonatal delivery outcome data will be destroyed seven years after study completion. After that time, study identifiers will be destroyed, and your information will be coded and retained anonymously indefinitely.

Can I be removed without my permission from this study?

Dr. Caritis or the study sponsor may choose to stop your participation without your approval. This could happen, for example, if it is determined not to be in your best interest to continue in the study, or if the study is stopped early by the sponsor.



VOLUNTARY CONSENT AND PARENTAL PERMISSION

I certify that I have read the above information, or it has been read to me. All of the above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspects of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this consent document. The Human Subject Protection Advocate of the Institutional Review Board (IRB) Office, University of Pittsburgh (1-866-212-2668), will answer any questions that I have about my rights as a research participant.

By signing this form, I agree to participate in this research study and give my authorization for the University of Pittsburgh, UPMC, and Magee-Womens Hospital to allow the individuals listed above to use my medical records and my child’s medical records for this research study for an indefinite period of time. A copy of this consent form will be given to me.

Printed Name of Participant

Signature of Participant

Date

Time

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and a member of the study team will always be available to address future questions, concerns, or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

Time

