IRB-Approved
19 Feb 2026

CARILION CLINIC
CONSENT TO TAKE PART IN A BIOMEDICAL RESEARCH STUDY

TITLE:

Evaluation of Innovative Placental Imaging Techniques in Fetal Growth Restriction

IRB#: 24-2156

INVESTIGATOR:

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SUMMARY

This consent form contains important information to help you decide whether to take part in a research study. You should read and discuss all the information in this consent form with the research study doctor. A brief summary of the study is provided below.

- Being in this research study is voluntary; it is your choice.
- If you join this study, you can still stop at any time.
- Do not join this study unless all of your questions are answered.
- The study is being done to see whether new ultrasound techniques can improve the detection and management of fetal growth restriction, a condition where a baby weighs or has a body size less than 90% of other babies at that week of pregnancy.
- Ultrasounds will be performed that take roughly 15 minutes with measurement of the fetus as well as obtaining additional information at 3 places on the placenta. These are not part of your normal ultrasounds.
- These ultrasounds will be performed every 3 weeks during your pregnancy in addition to your normal ultrasounds.
- Your participation is expected to last until you deliver
- It is not expected that you will personally benefit from this research, but the results may benefit other people in the future.
- The most likely risks to you are discomfort during the ultrasound exam. There also may be important incidental findings that could be discovered during the ultrasound. More rare risks could include the potential for privacy breaches, skin reactions to the ultrasound gel or fainting during the ultrasound.
- Your options other than participating are routine prenatal care without research ultrasounds.
- Being in the study will not cost anything

IRB NUMBER: IRB-24-2156
IRB APPROVAL DATE: 02/23/2026

The study staff will explain this study in detail to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

DETAILED RESEARCH CONSENT

Please read this entire consent form carefully.

WHAT IS INFORMED CONSENT?

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to volunteer should be based upon knowing what will take place in the research study and how it might affect you. Informed consent begins when the research staff explains the facts to you about the research study.

The research staff will assist you with the informed consent form that goes over these facts so you can decide whether or not you want to take part in the research study. These facts include details about the research study, tests or procedures you may receive, the benefits and risks that could result and your rights as a research volunteer.

This research is sponsored by Carilion Clinic and Virginia Tech. The person running this study locally is Megan Whitham, M.D. Before you can decide whether to take part in the research, you should be told about the possible risks and benefits with this study. This process is known as informed consent. This consent form will give you information about this study and your rights as a research participant. Being in this study is voluntary. Your record has been reviewed for possible involvement in the study because you are a patient who has been receiving care for pregnancy in the OB CMC clinics.

Be aware that the role of your doctor as a researcher is different from the role of your personal doctor in clinical care. In clinical care, your doctor decides how to treat your specific problem in order to help you. Your doctor as a researcher treats all participants under a specific protocol to obtain general knowledge that may or may not benefit you. Be sure to ask your doctors questions to help you know more about these different roles.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to determine whether new ultrasound techniques can improve the detection and management of *fetal growth restriction*, a condition where a baby weighs or has a body size less than 90% of other babies at that week of pregnancy. This is a common cause of complications during pregnancy and affects about

10% of babies. This complication can increase the risk of a pregnancy being lost or stillborn. There will be 60 participants included for participation at one research site, Carilion Clinic.

The 60 participants will be divided into two groups. The first group will be 30 participants that have been already diagnosed with fetal growth restriction. The second group of 30, or the control group, will be participants that do not have a diagnosis of fetal growth restriction.

One of the ultrasound machines being used in this research has been approved by the U.S. Food and Drug Administration (FDA); the second research ultrasound machine being used in this research is investigational, which means the device has not been approved by the FDA and is still being tested in research studies.

The length of time you can expect to be in this research is until delivery. Your electronic health record will be accessed after your delivery for data regarding your pregnancy outcome.

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

You will be given a brief questionnaire to make sure you qualify for the study. This questionnaire is 8 questions long and asks about your health, past pregnancies, and the history of this pregnancy.

If you choose to participate in the research, a member of the research team will perform ultrasounds of your baby every 3 weeks. These ultrasounds are in addition to your regular ultrasounds. The research ultrasounds cannot be used in place of your regularly scheduled ultrasounds. The researcher will try to schedule this research visit at the same time or right after your routine pregnancy check-ups, but you may need to come to Carilion Clinic Maternal Fetal Medicine for these research visits on weeks you do not have a check-up. If your baby has already been diagnosed with fetal growth restriction, you may have routine standard of care ultrasounds in addition to the research ultrasounds.

An Ultrasound is a procedure that uses sound waves to create an image of things inside the body. First, a gel that helps the machine get clearer images will be applied to your stomach area. Then the ultrasound probe will be applied to your stomach area and the images will be collected. Once all of the images are collected, you will be able to wipe off the gel with a towel.

At each of your research ultrasounds, the sonographer will ask if you want to continue to participate.

The sonographer will then perform research ultrasounds which are composed of obtaining some measurements of your baby to determine the estimation of the baby's weight, and then she will obtain images of the placenta. She will obtain 3 images of the placenta at 3 locations for a total of 9 images.

The research ultrasounds will take about 15 minutes and estimate your baby's size, weight, and the health of the placenta which provides blood to the baby, using new ultrasound techniques. These new ultrasound images of the placenta will show how well blood is flowing through the placenta to the baby and take several other measurements that may indicate the overall health of the placenta's tissue. At the end of the research visit, you will receive an ultrasound photo of your baby.

The images will be stored on the research ultrasound machine and sent to the researcher at Virginia Tech, Dr. Han, for analysis. These images will not contain any of your personal information.

Some specific participants may also receive additional color ultrasounds on the standard ultrasound machine used for your routine care at Carilion Clinic. This will add approximately one minute to the research-related part of your appointment. These images will be used to compare the clarity of the picture to that obtained with the research ultrasound machine.

All research visits will occur at Carilion Clinic Maternal Fetal Medicine.

You will not be told immediate information about the placental imaging because this is the imaging under investigation. You may be told the estimation of your baby's weight, but this does not replace the clinical ultrasound estimation of fetal weight from your normal prenatal care appointments.

We also would like to have permission to look at your medical records. We will review and collect your medical history by accessing your medical records. The information will include your demographic information like age, medical history, diagnosis, treatments, medications, and diagnostic images as well as the outcome of your pregnancy. This helps researchers link their research results and their meaning to different aspects of human disease and the effects of treatment. The confidentiality section below provides details about how we will keep your information private.

Following the conclusion of this research you will not be contacted again by our study team for research-related purposes.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to:

- Come to all of your scheduled research visits or contact the research team if you cannot make it to an appointment for any reason.
- Follow instructions as provided by the study team and give them any new information about any new medical issues
- Seek immediate medical attention if you develop a severe rash from the ultrasound gel – please note, it is the same gel as we use in routine OB ultrasounds.

WHAT ARE THE RISKS OF BEING IN THIS RESEARCH STUDY?

- There may be risks of stress, emotional distress, embarrassment, or inconvenience
- There may be risks of discomfort with ultrasound exam (uncommon): If you experience this, the sonographer study team member will stop the exam, discuss the discomfort with you and discuss whether alterations in positioning can be made to improve comfort. The sonographer will assess your willingness to continue the research ultrasound on that day, reschedule or whether you wishes to forgo the research ultrasound altogether. Should you wish to be rescheduled, this will be coordinated directly with study personnel.
- There may be risks of fainting episodes with ultrasound exam (rare event): If this happens the sonographer will stop the exam and alert clinical staff members of the MFM Clinic. You will be provided rest and water, and evaluated by a clinical team member. After resolution of your symptoms, the sonographer will assess your willingness to continue the research ultrasound on that day, reschedule or whether you want to forgo the research ultrasound altogether. Should you wish to be rescheduled, this will be coordinated directly with study personnel.
- There may be risk of Allergic Dermatitis / Rash (rare event): Ultrasound gel used during examination may contain propylene glycol or isothiazolinone chemicals. A small number of people may have an allergy or sensitivity to one or more of these chemicals. This allergy or sensitivity usually manifests as a localized skin reaction such as mild erythema [redness] or itching. Should this occur, the ultrasound gel will be removed from the skin by the sonographer and the area cleansed with soap and water. Members of the clinical team will be alerted. Dr. Whitham will provide clinical care if needed. Should you wish to be rescheduled, this will be coordinated directly with Dr. Whitham or with study personnel.
- There may be a risk of incidental ultrasound findings (uncommon): Should your sonographer see something on ultrasound that is unexpected, the images will be directly reviewed by a Maternal Fetal Medicine specialist and the appropriate follow up and clinical care will be coordinated for you based on the condition encountered. This may preclude you from further participating in the study.
- As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures

in place to lessen the possibility of this happening (see "What about confidentiality?" section below).

The study may have additional risks that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

WHAT ARE THE RISKS TO A PREGNANCY OR TO A NURSING CHILD?

The ultrasound machine used in this study is specifically programmed to have the same settings for ultrasounds performed during routine obstetric care. With any obstetric ultrasound, there is theoretical heat exposure to the fetus. The risks of ultrasound exposure are also minimized by minimizing scan time.

WHAT ARE THE BENEFITS OF BEING IN THIS RESEARCH STUDY?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include developing new technologies to help improve care for unborn children and pregnant patients. This study hopes to be an early step in developing technologies to improve detection of fetal growth restriction and prevent stillbirth.

ARE THERE ANY OPTIONS TO BEING IN THIS RESEARCH STUDY?

If you do not wish to participate in this study, you will still receive your standard prenatal treatment and ultrasounds.

WILL I RECEIVE NEW INFORMATION ABOUT THIS RESEARCH STUDY OR ABOUT MY STUDY RESULTS?

In general, we will not give you any individual results from the study because the clinical significance may not be known. It is possible though that we will discover information of medical importance that is unrelated to the purpose of this study. If we believe that the information is of urgent medical importance, we will share this information with you.

Depending on the type of incidental finding, we may contact you by mail or by phone. If you want, we can give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation. An incidental finding may cause you to feel anxious. Since an incidental finding will be part of your medical record, it may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

Sometimes new information comes out during a research study that may affect your health, welfare, or willingness to stay in a study. If that happens, the researchers will tell you about the new information. If you decide you no longer wish to participate, they will also tell you about other options for your care. You may need to sign another form with your consent to continue in the study.

In general, we will not give you any individual results from the study other than what we have discussed earlier in this consent form because the ultrasounds are for research purposes only and are not a clinical test intended for diagnostic or therapeutic purposes.

We are therefore asking your permission to re-contact you in case we need to notify you of unexpected events in the future. We may also contact you to ask about follow-up information about your health or medical care.

WHAT ABOUT CONFIDENTIALITY?

The research ultrasounds will be coded with your research ID number and there will be no private health data or identifying information on the ultrasounds. The ultrasound images will be stored on the ultrasound machine and periodically uploaded to the researchers at Virginia Tech. Data about your health, prenatal records, and pregnancy outcomes as well as identifying information will only be accessed by the research personnel at Carilion Clinic and this will be stored on a Carilion Clinic secure server, which is HIPAA-compliant. The ID number from your ultrasound studies will pair with the data stored on the server to link the data.
Questionnaires will be completed in a private, confidential room. The completed questionnaires will be kept private in a locked office and in a locked filing cabinet. The questionnaires will be coded with the same unique number. The ID number from your questionnaires will pair with the data stored on the server to link the data.

Your identity will not be used in any sort of published report.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION:

There is a federal law that protects the privacy of health information. This law is known as HIPAA. HIPAA stands for the "Health Insurance Portability and Accountability Act." Because of this law, your health information cannot be looked at, collected or shared with others without your permission.

Signing this consent and authorization form means you allow the Principal Investigator for this study and members of the investigator's research team to create, get, use, store and share information that identifies you for the purposes of this research.

This is the information about you that researchers will use:

- Personal identifiers such as name, address, telephone number, or medical record number
- Demographic information such as age, race, gender
- Images that will be obtained during the study
- Other personal health information that will be obtained from other sources to use in the research, including past medical history, and tests
- The following information specific to this study:
    - Results of aneuploidy screening, if performed
    - History of hypertension, gestational hypertension or preeclampsia
    - History of small-for-gestational age baby or fetal growth restriction
    - Nicotine use
    - In-vitro fertilization history
    - History of diabetes
    - History of vascular diseases or lupus
    - History of anemia and Hemoglobin levels

The investigator and research team may share information about you with:

- The Carilion Clinic Institutional Review Board, a research protection group that provides ongoing review of the research project.
- Authorized employees of Carilion Clinic who need the information to perform their duties to provide treatment, to ensure the integrity of the research or to do accounting and billing.
- The Office of Human Research Protections (OHRP), Food and Drug Administration (FDA), or other government agencies that oversee research with humans.
- Committees that monitor research data and safety or other groups authorized to monitor the study.
- Researchers at the following non-Carilion facilities: Virginia Tech and Virginia Tech Carilion School of Medicine

Health information that could allow you to be identified is called protected health information or PHI. The investigator and research team will share only the PHI listed above with the individuals/agencies listed above. If the investigator needs to share other PHI or needs to share PHI to other individuals/agencies not listed above, then you will be asked for your permission in writing again.

Carilion Clinic and its affiliates are required under law to protect your PHI. However, the individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it. They could share your PHI with others without your permission, if permitted by the laws governing them.

You will not be eligible to participate in this study if you do not sign this consent and authorization form. Refusing to sign will not affect the present or future care you receive at Carilion.

You have the right to stop sharing your PHI. To end your permission to share your PHI, you must do so in writing to the Principal Investigator at the address listed on the first page of this form. If you want the researchers to stop collecting your PHI for the research, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or any other benefits you are entitled to receive. PHI collected for the research study prior to you ending your permission will continue to be used for the purposes of the research study. Also, the FDA (if involved with your study) can look at your PHI related to the study even if you end your permission.

You may not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

Research information continues to be analyzed or monitored after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

WILL IT COST ME MONEY TO TAKE PART IN THIS RESEARCH?

Taking part in this research will not cost you any money.

Taking part in this research may lead to added costs to you, such as: transportation costs, or time away from work.

WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?

For taking part in this research and to compensate you for the time and effort of participating, you may be compensated up to a total of $50 in the form of Amazon Gift Cards. Your compensation will be broken down as follows:

- You will be paid $5 for completion of each research ultrasound performed every three weeks. At the end of your pregnancy, upon confirmation of completion of the research ultrasounds, you will receive the remainder of the balance up to $50. For example, you will receive $5 for your first ultrasound, $5 for your second ultrasound and then after delivery, you will receive $40 if you only needed to have 2 research ultrasounds.

If you do not complete all of the study visits, you will be paid only for the number of research ultrasounds you completed.

Payments made to you as compensation for your participation will be tracked by the research team. This information will be submitted to Carilion's financial department for central tracking. If you receive greater than $600 from Carilion in a calendar year, this is considered taxable compensation and will be reported to the Internal Revenue Service (IRS). You will be issued a 1099 tax form by Carilion if you meet this reporting threshold.

This research may lead to new medical knowledge, tests, treatments, or products. This research could have some financial value and result in commercial profit. There are no plans to provide financial payment to you or your relatives should this occur.

WHAT IF I WANT TO STOP BEING IN THE STUDY BEFORE IT IS FINISHED?

Being in this research is voluntary. You may refuse to take part or you may withdraw at any time. Your decision not to take part or your decision to withdraw will not affect your ability to get care from your doctors or from Carilion.

If you decide to leave this research because you do not wish to have further ultrasounds performed, contact the research team so that the investigator can confirm with you whether or not we may access your records following delivery.

CAN I BE REMOVED FROM THIS RESEARCH WITHOUT MY APPROVAL?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- The research is canceled by the Investigator or the Review Board
- You are unable to keep your scheduled appointments

The reason for any exclusion will be explained to you.

WHAT WILL HAPPEN IF I HAVE COMPLICATIONS OR IF I AM INJURED BY THIS RESEARCH STUDY?

If you have a medical problem that happens because you are in this study, you will be able to get treatment. If you need emergency care, call 911 or go to your nearest hospital or emergency room right away. It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

The treatment will be billed to you or your insurer at the usual charge. The study does not make any provisions for the payment of these costs. You will not receive any other financial compensation, nor payment for any wages you may lose due to your injury. However, you do not give up any legal rights to seek compensation for injury by signing this consent form.

Call the person in charge of this study as soon as you are able. They will need to know that you are hurt or ill.

ARE RESEARCHERS BEING PAID TO DO THIS STUDY?

This study is being supported by an internal grant sponsored by Carilion Clinic. The research support personnel's time to conduct the study is supported by that grant. There is no additional compensation to the research team being granted for your agreement to participate in the study beyond that of the time involved for conducting study procedures.

WHO ARE THE CONTACT PERSONS?

If you encounter complications or have any questions about the study, you may call:

Megan Whitham, M.D.
102 Highland Ave, Suite 455
Roanoke, VA 24013
(540)266-6146 daytime phone
(703)819-7703 nights and weekends

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (540) 224-5878 if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

IRB SURVEY:

The IRB committee is a group of people that reviews research to protect the rights of research participants. One job of the IRB is to make sure the research is done in a way

that is respectful to participants. If you agree, the Carilion IRB may select you to receive a survey asking about your experiences while taking part in this research study. If your name and address are given to the Carilion IRB in order to mail the survey, the Carilion IRB will keep this information confidential. You do not have to put your name or other identifying information on the survey unless you choose to do so or request to be contacted regarding your experiences. You do not have to give permission to allow the Carilion IRB to send you this survey. Please check below whether you agree to allow the Carilion IRB to send you a survey:

_____ Yes, I agree to Carilion IRB sending me a survey about my experiences while taking part in research.
_____ No, I do not want Carilion IRB to send me such a survey.

ClinicalTrials.gov

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. 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.

CONSENT SIGNATURES:

- **Research Participant Box** must always be completed.
- **Person Obtaining Consent Box** must always be completed.
- **Signatures must be obtained/documented on the same date, prior to enrollment.**
- **Participants** must receive a signed copy of this consent form.

ADULT RESEARCH PARTICIPANT (WHEN THE RESEARCH PARTICIPANT IS ABLE TO CONSENT FOR THEMSELVES): The research study as described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered. I consent to take part in this research study. My consent is given willingly and voluntarily. I may withdraw my consent at any time.

_____
Printed Name of Research Participant (**18 years or older**)

_____ _____
Participant's Signature Date

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RESEARCH TEAM MEMBER OBTAINING CONSENT (<u>WHEN THE RESEARCH PARTICIPANT IS ABLE TO CONSENT FOR THEMSELVES</u>): I certify I was present for the informed consent discussion. The participant had an opportunity to ask questions about and appeared to understand the information presented. The participant agreed to take part voluntarily in the research and I obtained the signature. I will give the participant a copy of the signed consent.

_____
Printed Name of Research Team Member Obtaining Consent

_____ _____
Signature of Research Team Member Obtaining Consent Date

WITNESS TO SIGNATURE: As an impartial third party, I witnessed the authorization process and the participant's signature on this form. I confirm that this entire form was read to the participant named above. The participant voluntarily agreed to be in this study.

_____
Printed Name of Witness

_____ _____
Witness' Signature Date