National Institute on Drug Abuse (NIDA) / “NEXUS - NEXt generation health through 2D & 3D fetal UtraSound; building connections to support maternal-fetal health”

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HM20025280/**NCT05814575**

IRB approval 4/25/2024

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**National Institute on Drug Abuse (NIDA) / "NEXUS - NEXt generation health through 2D & 3D fetal UtraSound; building connections to support maternal-fetal health"**
Protocol Number:	**HM20025280**
Principal Investigator:	**Amy Salisbury, PhD, APRN**
Telephone:	**804-250-1112 (24 Hour)**
Address:	**Virginia Commonwealth University School of Nursing 1100 East Leigh St Richmond, VA 23298**

NOTE: In this consent form, "you" always refers to the research participant.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this research study is to determine if fetal ultrasound observations can help pregnant persons to feel more connected to babies and if these observations help to enhance

self-care. The study will test if additional feedback and educational content during a fetal ultrasound observation will help pregnant persons more than ultrasound alone to feel connected to their fetus and pregnancy, engage in routine prenatal care, and or reduce substance use, such as smoking, alcohol, or marijuana. We hope that this study will help us to develop interventions and/or improve existing medical care practices and lead to better health outcomes for mothers and babies. For example, we will be looking at ways to help pregnant persons to obtain healthcare in new ways or in new locations, such as locating ultrasound services in the local community, and if this also helps with pregnancy health outcomes.

What will happen if I participate?

You will be asked to fill out surveys and answer some interview questions at your enrollment visit. Once this is completed, you will be randomly assigned (like the flip of a coin) to one of two types of non-diagnostic fetal ultrasound assessments. Both types of ultrasound sessions will provide you with 2D fetal ultrasound and pictures of your baby. We will also be observing your baby in 3D mode, which gives better images, however, these images are very dependent upon your baby's position and how much fluid is near your baby's face; we cannot guarantee that we will be able to see your baby's face in a 3D image. You have an equal chance of being assigned to either of the ultrasound groups.

In this study, you will be asked to do the following things:

1. Visit the NEXUS mobile or stationary clinic for 2 prenatal ultrasound study visits.
2. Have weekly or every other week (depending on your available time and preference) brief telephone check-ins with a care navigator
3. Meet with the care navigator in your home around 6 and 12 weeks after delivering your infant for a brief interview and an assessment of your infant (for example, movement, reflexes, eye contact).
4. Take surveys and answer questions about your health, mood, treatment, infant's health, and family support
5. Give permission for the researchers to collect information about your health and your infant's health from your medical records.

Your participation in this study will last up to 16 weeks after you deliver your infant. Approximately 60 individuals will participate in this study.

What alternative treatments or procedures are available?

If you decide not to enter this study, you can receive the usual care from other health providers that you would receive even if you were not in the study. This includes routine prenatal care, one diagnostic fetal ultrasound at mid-pregnancy (usually 17-20 weeks), and treatment for

mental health, and/or substance use disorders. The study staff will discuss these options with you. You do not have to participate in this study to receive prenatal care or to be treated for mental health or substance use disorders.

You have the option to take paper surveys instead of electronic ones. Ask the study staff if you would like a paper survey.

What are the risks and benefits of participating?

There are both risks and benefits to participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?" section.

Risks and Discomforts	Benefits to You and Others

There is a risk that you could experience inconveniences or side effects from participating in this study. Below are some of the most common risks and discomforts (these will be described in more detail below):
• Legal Risks if you disclose information that requires mandatory reporting by law
• Psychological risks such as discomfort or anxiety when completing study questionnaires
• Social/Economic risks including embarrassment, loss of respect of others, labeling in a way that will have negative consequences
• Breach of Privacy or Loss of confidentiality
  ○ Audio recordings
  ○ Sharing your information
• Although the risk from fetal ultrasound is minimal, and the procedures we are using minimize risks to you and your fetus, there may be unknown risks that we are not yet aware of that may be associated with ultrasound.
	You may or may not benefit from taking part in this study. We cannot guarantee or promise that you or your infant will receive any direct benefit by participating in this study. However, it is possible that by being in this study, you may increase your engagement in treatment. This may provide improved support for less substance use or prevention of relapse into drug use; which may increase your overall health.

• There may be some risks that the investigators do not know about yet, so we will let you know of any new findings. • There may be a risk of mild discomfort to your infant while completing the infant assessment after delivery. This level of discomfort is not more than your infant would experience during a clothing change or during a routine physical examination.	

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read the rest of this document or have someone read it to you. If there is anything you don't understand, be sure to ask the study staff.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

The following table is a summary of the study visits planned for this study.

PREGNANCY			**AFTER BIRTH**	
< 32 weeks *May occur on the same day*		**32+ Weeks**	**6-11 Weeks**	**12-16 Weeks**
Enrollment Visit (30 Minutes) < 32 weeks	**Ultrasound Visit (60 minutes) 21-32 Weeks**	**Ultrasound Visit (60 minutes)**	**Post-birth Visit 1 (60m)**	**Post-birth Visit 2 (60m)**
Introduction	Randomization	New/repeat ultrasound	Interview	Interview
Review Consent, ask questions, sign consent	Standard or enhanced Ultrasound	Standard or enhanced ultrasound based on randomization	Brief Infant Assessment	Brief Infant Assessment
Complete baseline surveys and interviews	Meet Care Navigator	Care Navigator Check-In	Care Navigator Check-In	Care Navigator Check-In
	Brief surveys	Brief surveys	Surveys	Surveys
Weekly or Bi-Weekly text, telephone check-ins, and brief questions with the care navigator				

There will be up to 4 visits for this research study.

Pregnancy

At your first study visit (Enrollment), we will explain the study to you, give you time to read this consent form, and ask questions. This visit may take place virtually or in person. Once we confirm that you are eligible to participate in the study, and you decide that you would like to participate in the study, you will be interviewed by the study staff and asked to fill out questionnaires about your community, pregnancy, prenatal care, mood, health history, medications, and history with substance use (smoking, alcohol, marijuana, for example).

The first ultrasound visit may take place on the same day as the enrollment visit if your appointment is in person. Otherwise, we will schedule your first ultrasound visit on another day that is convenient for you, either in the mobile clinic or at the VCU School of Nursing research clinic. At the time of your appointment, you will be randomly assigned (like the flip of a coin) to receive one of two types of ultrasound sessions; each type of ultrasound will provide 30-minutes of intermittent non-diagnostic ultrasound observation of your baby to obtain basic health information including estimated weight, 2D pictures, and short video clips.

A non-diagnostic ultrasound means that we will not be looking for the things that are observed during a standard, diagnostic ultrasound. We will only be measuring your baby's general well-being, estimated weight, and movements.

You will not be told which group you have been assigned. Only the study nurse will know the group to which you have been assigned. The care navigators and other research assistants will not know the assigned group.

If you are less than 29 weeks pregnant when you enroll in the study, you will be asked to attend up to two ultrasound sessions, once before 29 weeks and once after 32 weeks of pregnancy. The 2nd ultrasound visit will take place about 4 weeks (3 to 8 weeks) after the first ultrasound visit. If this is a 2nd ultrasound visit, you will have the same ultrasound study plan as the first session.

Each ultrasound will follow the schedule shown in **the following figure:**

The surveys will ask you about your experiences with your health, pregnancy, prenatal care, family support, experiences, and treatment since your last visit.

Post-delivery

There will be two visits after you deliver your infant, one at 6 weeks (range 4-8 weeks) and one at 12 weeks (range 10-14 weeks post-delivery). At each visit, you will be asked to describe your experiences with your health, pregnancy, newborn care, mental health and substance use, medical treatment and any resources you feel would be helpful to your postpartum journey.

The final post-delivery visit will include an interview with the study staff to ask about your overall experience during the study. The investigators will collect information from you and your infant's medical and mental health records about your current health status, physical and mental health history, and infant birth. This information will only be collected for the time during your participation in the study.

WHAT ALTERNATIVES ARE AVAILABLE?

You may choose not to take part in this study; participation in this study is voluntary. You have the option to take a paper survey instead of an electronic one. Ask the study staff if you would like a paper survey.

If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study. This includes ultrasounds at your routine prenatal visits.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

There is no guarantee that you will receive benefits by participating in this study. However, it is possible that by being in this study, you may increase your engagement in treatment. This may provide improved support for less substance use or prevention of relapse into drug use; which may increase your overall health.

WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to the study staff, investigator, or your own healthcare provider.

The risks associated with taking part in a research study have been carefully considered and we take every precaution to protect you and your infant from these risks. However, we cannot guarantee that you will not experience any risks from taking part in this study. While in this study, you are at risk for the following side effects:

Breach of Privacy and Confidentiality:
As with any study involving the collection of data, there is the possibility of a breach of confidentiality of data. Loss of confidentiality includes having your personal information shared with someone who is not on the study staff and was not supposed to see or know about your information. Every precaution will be taken to secure your personal information to ensure confidentiality. Upon entry into the study, you will be assigned a study identification number. This number will be used on all data collection forms in the database instead of names and other private information. A separate list that is not stored with the data will be maintained that will link your name to the study identification number for future reference and communication.

During the study interviews, your voice will be recorded. Anything that you discuss in the interview will remain completely confidential. We will keep recordings in secure study files only accessible to our study staff. Also, in order to ensure all ultrasound sessions are given in the correct ways, the sessions will be audio recorded. Please note that no information about you will be collected during the ultrasound session recordings; we will only record the audio of the study nurses and not record you during the ultrasound. Your voice might be on the audio recordings of the ultrasound session if you talk or ask questions, but we will not maintain a record of anything you say because, once the sessions are checked by our study staff and the interviews are transcribed, we will destroy the recordings. No one other than study staff directly involved with the research will have access to the data. These recordings are a requirement for being part of this study.

Legal Risks:
This study has a certificate of confidentiality that prevents us from releasing information about substance use. However, there are laws that require reporting child or elder abuse, some communicable diseases, and threats to harm yourself or others.

Psychological:
In some circumstances, you may feel anxious about seeing your fetus through ultrasound. If you have any discomfort about the ultrasound study plan, you may ask to stop at any time. You may feel temporary discomfort in answering questions about the sensitive personal information (for example, substance use). Study staff from this project will have links to resources to assist

participants in these situations. In addition, participants may refuse to answer any study questions.

If at any time you feel uncomfortable, please let the study staff know, you do not have to answer questions if they cause you distress. If you are feeling upset after the study visit, we will assist you with treatment referrals and access to medical services.

You may become upset during the interview about your current and past moods or history. Study staff members are here to help as needed.

There may be an inconvenience to you from the amount of time involved to participate in the study, time burden has been purposely minimized in this study.

Some pregnant persons in this study will be clinically depressed, have other mental health conditions, or trauma history. There are risks associated with not treating depression or other mental disorders during pregnancy, such as lack of productivity, inability to concentrate, poor sleep, lessened social functioning, inadequate compliance with prenatal care, poor appetite, or overeating, low energy, feelings of hopelessness, and suicidality. Study staff will assist you with obtaining medical care for any of these concerns.

You must tell your investigator right away if you have any thoughts about hurting yourself.

If you are having suicidal thoughts or feel in crisis, call the investigator at the telephone number listed on the first page of this form. You can also call or text the National Suicide & Crisis Lifeline at 9-8-8 or 1-800-273-TALK (8255). The Lifeline numbers are answered 24 hours a day every day of the year by a skilled, trained counselor. You can also present to a healthcare provider, your local emergency room, or call 9-1-1 to be connected to local emergency services.

Study Plan-Related Risks and Incidental Findings

Ultrasound observation:
Although there are no known risks to humans from standard fetal ultrasound, and we follow all standard guidelines, we cannot guarantee that there are no associated risks that we are not yet aware. Our ultrasound machines are set to the standard guidelines that provide additional safety for your baby. We also use limited scanning times (7 minutes on/3 minutes off) with a scanning time of 60 minutes or less. Our study nurses are trained and certified in obstetrical ultrasound for medical personnel.

There may be rare situations in which disclosure of information to your health care providers is necessary. Examples include:

- Unintended discovery of a problem with your baby, such as low fetal weight, or a low fluid level
- Your blood pressure or temperature is higher than the typical level.

Risks associated with Interviews:
The main risk of the Interviews is that you may feel emotional or upset when answering some of the questions. Tell the interviewer at any time if you want to take a break or stop the interview.

Risks associated with Surveys:

- There are no physical risks but you might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable.
- You might feel overwhelmed or burdened completing the infant sleep and feeding log. You do not have to complete this form if you are feeling overwhelmed.
- You will be asked to fill out surveys about your thoughts and feelings about yourself and your infant. If you tell us that you are feeling like you want to harm yourself, we will ask you to talk with the investigator or another trained healthcare provider to see how we can help. You may refuse the additional interview but we will need to make your chosen treatment providers know about how you are feeling.

Infant Assessments
There is a risk of mild discomfort to your infant while completing the infant assessment of movements and attention. This level of discomfort is not more than a routine physical examination of the baby.

Unexpected Findings:
Throughout the study there may be unexpected findings about you or your baby's health. This may result from questionnaires, surveys, ultrasounds, and other study procedures. You may experience stress as a direct result of receiving health findings/measurements that may indicate an underlying illness.

Unknown or Unforeseeable Risks
The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

Adverse events

Any adverse reaction occurring during the study either observed by the investigator or study staff or reported by the participant will be recorded. Other incidental serious adverse events unrelated to the study (such as trauma resulting from motor vehicle accidents or sport activities) will not be reported to the Institutional Review Board (IRB).

There are no guaranteed benefits to participation for the study participants. However, there is potential for participants to increase their engagement in treatment, improved support for less substance use or prevention of relapse into drug use; which may increase their overall health. Sharing of study results with community partners, study participants, and the community at large through venues such as publication and presentation may be perceived as a benefit.

WHAT ARE THE COSTS?

The sponsor is paying for everything in relation to this study. You will not be charged for any study visits, tests, or procedures.

We expect that you will continue to receive your routine prenatal and postpartum care throughout the study. The cost of your routine clinical care will be billed to you/your insurance company in the usual way.

VCU has programs to help uninsured and underinsured families see if financial assistance is available. If you need financial assistance, you can talk with a financial coordinator.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

We will compensate you, in the form of gift cards, based on the pay schedule below and the amount of visits/tasks that you complete.

Visit/Activity	We will pay you:
Enrollment	$20
Session 1	$40
Session 2	$40
Follow-Up calls with Care Navigator: **$5 each** (up to 16 calls before delivery)	$80
6-Week Postpartum Visit	$50
12-Week Postpartum Visit	$50

Follow-Up calls with Care Navigator: **$5 each** (up to 4 calls after delivery)	$20
TOTAL COMPENSATION	**$300**

We will pay you *up to* a total of **$300** if you complete every study visit and activity. If you do not complete the entire study, we will pay you for each visit/task that you complete. You will be paid following each completed visit.

You can also be an ambassador for this NEXUS study! You have the opportunity to receive a "recruitment bonus" if you share information about this study to potentially eligible people. You can receive a $10 gift card per each referral, up to three times per year. You can receive this bonus if: the person identifies you during the screening survey as the way they heard about the study and they are eligible to participate.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participating in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?

If you are injured by, or become ill, from participating in this study, please contact your investigator immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your investigator will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the investigator without your consent. The reasons might include:

- The investigator thinks it necessary for your health or safety
- You are found to not be eligible for the study
- You have not followed study instructions
- Administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

We will keep the records of this study confidential by assigning you and your infant a unique identification number. All information we collect from you will have your identification number. We will not put names on any study related materials. We will use date of birth and dates/times (such as discharge date, date of treatment, etc.) on some data abstraction forms.

This information will be entered into the secure online study database. All study files and computers are locked and secured with passwords. We will make every effort to keep your records confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The following people or groups may review your study records (stored by ID number only and not your name) for purposes such as quality control or safety:

- The investigator and any member of the study staff
- Representatives of Virginia Commonwealth University and VCU Health System, who may need to see your information, such as administrative staff members and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study)
- Federal and state agencies that oversee or review research (such as the Health and Human Services (HHS) Office of Human Research Protection or the US Food and Drug Administration, if applicable)
- Virginia Commonwealth University whom creates and maintains the study database

Physical study data will be stored at the VCU School of Nursing at 1100 East Leigh Street, Richmond, VA 23298.

The results of this study may also be used for teaching, publications, or presentations at professional meetings to inform other doctors and health professionals. We will keep your

identity private in any publication or presentation about the study. If your individual results are discussed, your identity will be protected by using a code number or pseudonym rather than your name or other identifying information.

By law, VCU is required to protect your private information. The investigator and study staff involved in the study will keep your private information collected for the study strictly confidential. Please refer to the section at the end of this document titled "HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?" that explains more specifically how your personal information will be protected.

If, during your participation in this study, we have reasonable cause to believe that **child or elder** abuse is occurring, this will be reported to authorities as required by law. The investigator will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court will demand the release of identifiable research information.

If, during your participation in this study, we have reason to believe that you are at risk for harming yourself or others, we are required to take the necessary actions. This may include notifying your doctor, your therapist, or other individuals. If this were to occur, we would not be able to assure confidentiality.

It will be noted in your protected electronic health record at VCU Health that you are in this study. Information about the study will be included in the record. This information is protected just as any of your other health records are protected.

In general, we will not give you any individual results from the study. If we find something of medical importance to you or your baby, we will inform you, although we expect that this will be a very rare occurrence.

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

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value.

In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples could be used for other research studies by this study staff or another researcher without asking you for additional consent.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires and added to your healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?
The following types of information may be used for the conduct of this research:

☒ Complete health record	☒ Diagnosis & treatment codes	☒ Discharge summary
☒ History and physical exam	☐ Consultation reports	☒ Progress notes
☒ Laboratory test results	☐ X-ray reports	☐ X-ray films / images
☒ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☒ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	
☒ Information about mental health	☐ Information about sexually transmitted diseases	
☐ Other physical or mental health information (specify):		

Who will use or share protected health information about me?
VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- The Investigator and Study Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research study, whichever is later.

Statement of Privacy Rights

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the investigator at the address listed on the first page of this form.

If you decide not to sign this form, you will not be able to take part in the study.

OPTIONAL STORAGE FOR FUTURE RESEARCH STUDIES

To advance science, it is helpful for researchers to share information. They do this by putting data or samples into one or more scientific databases (called registries or repositories), where it is stored along with information from other studies. Researchers can then study the information in other ways and combine information from many studies to learn even more about health and disease.

As part of this study, we would like to keep the information that you provide, along with your unidentifiable health information (data will be stored by your study number only) in a registry/repository to be available for other research studies in the future. Your information and samples would be stored at VCU by the investigator and could be used for other research studies about any topic. Your data will be protected, but there is always a possibility that information could be accessed by individuals without authorization. There is no limit on the length of time we will store your information/samples.

In the future, if you decide that you don't want to be part of this registry, you can request that your information/samples be removed and destroyed by contacting the investigator. However, information that has already been shared with other researchers will continue to be used.

Permission to Store Data for Future Research Studies

Please circle your answer: I agree that my data may be stored and used for future research as described above.

YES NO

OPTIONAL STORAGE FOR FUTURE RESEARCH STUDIES (NON-REGISTRY)

To advance science, it can be helpful for researchers to contact participants later to ask additional or follow-up questions after the completion of this study. We do this by storing your contact information in our password-protected files. This is NOT a registry or repository. Rather, this is a method for us to contact you if we have additional questions about how you are doing. Your data will be protected, but there is always a possibility that information could be accessed by individuals without authorization. There is no limit on the length of time we will store your information. In the future, if you decide that you do not want to be contacted, you can request that your contact information be removed from our files by contacting the principal investigator.

Permission to Store Contact Information for Future Research Studies
Please check your answer: I agree that my contact information may be stored and used for future research as described above.

YES NO

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participant. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  VCU Human Research Protection Program
  800 East Leigh Street, Suite 3000
  BioTech One Building
  Box 980568
  Richmond, VA 23298
- or call **toll free**: (804) 828-0868
- or by **email**: HRPP@vcu.edu

Please reference the following number when contacting the VCU HRPP: HM20025280.

STATEMENT OF CONSENT AND AUTHORIZATION AND PARENT/LEGAL GUARDIAN PERMISSION

I have been provided with an opportunity to read this consent and permission form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which my baby or I am otherwise entitled. My signature indicates that I freely consent to participate in this research study and that I understand the procedures related to my and my baby's participation in this study. I will be asked to sign this consent for my baby once he or she has been delivered. I will receive a copy of the consent form for my records.

_____	
Participant Name (Printed)	
_____	_____
Participant's Signature	Date
_____	
Name of Person Conducting Consent Discussion (Printed)	
_____	_____
Signature of Person Conducting Consent Discussion	Date
_____	_____
Investigator Signature (if different from above)	Date

My infant was delivered and my signature below indicates that I give my permission for my baby to participate in this research study.

_____	
Infant's Name (Printed)	
_____	_____
Parent's Signature	Date
_____	
Name of Person Conducting Consent Discussion (Printed)	
_____	_____
Signature of Person Conducting Consent Discussion	Date
_____	_____
Investigator Signature (if different from above)	Date