University of California, Los Angeles
Afshar's Lab

INFORMED CONSENT FORM
FOR PARENT AND PARENTAL PERMISSION FOR FETUS/ MINOR TO PARTICIPATE IN RESEARCH

The UCLA Perinatal Biospecimen Repository

Dr. Yalda Afshar, Principal Investigator, Assistant Professor, Lab Director, and colleagues from the Maternal Fetal Medicine, Department of Obstetrics and Gynecology and Molecular Cell and Developmental Biology at the University of California, Los Angeles (UCLA) are conducting a research study.

The purpose of this study is to establish the UCLA Perinatal Biospecimen Repository (collection) for collecting and studying biospecimens related to pregnancy, and different pregnancy outcomes. We want to learn more about birthing people and their babies/ fetus health status.
Perinatal health problem are diseases and disorders relating to the period before and soon after birth. By collecting and analyzing the biospecimens and related clinical information of the study participants, we will know more about why these disorders happen in some pregnancies. The interaction with the study team will only be during routine clinical care.

You were selected as a possible participant in this study because you have a perinatal health problem or you do not have perinatal health problem, but you are pregnant, or you are an adult person with childbearing potential.
Your participation in this research study is completely voluntary.

The researchers will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

Why is this study being done?

According to the US Centers for Disease Control and Prevention, complications of pregnancy involve the mother's health, the baby's / fetus' health, or both. Some birthing persons can have perinatal disorders that arise during or after pregnancy. Other patients have health problems before they become pregnant that could lead to pregnancy complications. It is very important to know the risk factors of perinatal disorders to prevent non-favorable pregnancy outcomes.
Therefore, by conducting this study, we hope to improve the pregnancy-at-risk outcomes for both – for mother and for baby.

What will happen if I take part in this study?

If you agree to participate, there will be **no difference in your pregnancy management**.
The researchers will ask you to do the following:

Enrolment/ Baseline Visit: You will be asked to donate your blood (maternal blood) or/ and urine specimen to the Repository. We would like to draw additional small amount (less than 2 teaspoons) of your blood using a needle in your arm vein. These blood samples will be drawn during your routine blood testing. The blood will not be drawn for research more often than twice in a single week. The researcher will ask you to allow access to your health records to link clinical information to your biospecimens. We need clinical data regarding medical history, your pregnancy status and outcomes, concomitant medication, and your baby/ fetus status.

Follow-up Visits: Collection of the biospecimens and clinical data during the pregnancy follow-up visits is optional. It will depend on your pregnancy status and the researcher decisions. You may be asked to donate your blood and/ or urine samples once per pregnancy trimester:

- 1st Trimester (from conception to 12 weeks);
- 2nd Trimester (from week 13 to week 27);
- 3rd Trimester (from week 28 until birth).

Delivery/ End of Pregnancy Visit: You will be asked to donate your blood (maternal blood), urine, cord blood (less than 2 teaspoon), placenta, umbilical cord, and amniotic fluid. After delivery of your baby, within 30-minutes your placenta delivers. After it is delivered, we will take the umbilical cord and the small pieces of placenta for research. Both the umbilical cord and the placenta are considered temporary fetal tissues, and both are usually disposed after delivery. We will also collect a small amount (less than 2 teaspoons) of blood from the umbilical cord after the baby is born and the umbilical cord is cut. Clinical information will be linked to your biospecimens.

In case of a miscarriage, abortion, or stillbirth, we will ask if you would be willing to donate non-viable fetus tissue to the research study.

Postpartum Visit: You will be asked to donate your blood, urine, and breastmilk (2-3 teaspoon) to the Repository.

If you are non-pregnant healthy volunteer, participation in the project is limited for you to the one-time biospecimens donation (blood and urine) and granting access to your medical records.

The biospecimens collected will be processed and stored at the Afshar`s Lab Repository.

Clinical information will be collected from your medical record and your baby`s medical record. You will be asked to sign a separate HIPAA authorization form for the release of personal health information.
We will also look at data available from your prenatal genetic testing that was done.
Additionally, participants will not be provided with any study results since the collection of biospecimens and laboratory tests will be conducted for only research purposes.
Study medical procedures (blood drawing, assessment, physical examinations, medical record, etc.) will be performed by appropriately licensed / credentialed study site personnel working within the scope of their licenses and credentials.

How long will I be in the study?

Duration of participation in the study varies from 1 day to 10 months. Follow-up period: from study enrollment to the birth of child / outcome of pregnancy and further to postpartum visit.

Are there any potential risks or discomforts that I can expect from this study?

Risks of drawing blood:
Blood drawing may cause fainting or lightheadedness or some discomfort. Other risks include bleeding or bruising where the needle enters the body. A small blood clot may form where the needle enters the body or swelling of the surrounding skin may occur. There is also a small risk of a minor infection at the blood draw site. This will be done with a needle and if we are having difficulty in obtaining the blood sample, we will attempt the blood draw no more than two times per one day.

Risks Associated with Loss of Privacy in Genomic Research:
• Since some genetic variations can help to predict the future health problems of your child, this information might be of interest to health providers, life insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/ her blood relatives. Therefore, your fetus/newborns genetic information could potentially be used in ways that could cause you or your family distress. There also may be other privacy risks that we have not foreseen.

• Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record.

• In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about your fetus/neonate. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your child's genetic information. However, it does not protect your child against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Are there any potential benefits if I participate?

Possible benefits to me:
You will not benefit directly from participating in the study. It is possible that your participation in the study may help future patients with pregnancy complications. Your decision to donate biospecimens to the Repository may help researchers learn ways to identify and treat perinatal disorders in the future. Information learned from the biospecimens may help researchers find ways to decrease the risks of pregnancy complications and prevent non-favorable pregnancy outcomes.

Will I be paid for participation in this study?

No, there is no payment for participation in this study.

What other choices do I have if I don`t want to participate?

You are free to decide not to be part of this study. Your clinical care will not be affected if you decline.

Will information about me and my participation be kept confidential?

The researchers will do their best to make sure that your private information is kept confidential. Information about you and your baby/ fetus will be handled as confidentially as possible but participating in the study may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. A random code will be assigned to your study ID. Data and biospecimens collected for this study will be added to a research Repository. In the future, data and biospecimens collected for this study may be shared with other researchers for other projects that are unknown at this time. Any data and biospecimens shared with other researchers, will not include your name or other personal identifying information.

Public Information about this Study: 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.

Use of personal information that can identify you:
Information and biospecimens from the study will be used for education or research purposes. No names or identifying information will be used.

What are my rights if I take part in this study?

- The collection of a small amount of venous blood poses minimal risk to the women participating in the study. Blood drawing may cause fainting or lightheadedness or some discomfort. Other risks include bleeding or bruising where the needle enters the body. A small blood clot may form where the needle enters the body or swelling of the surrounding skin may occur. There is also a small risk of a minor infection at the blood draw site. This will be done with a needle and if we are having difficulty in obtaining the blood sample, we will attempt the blood draw no more than two times per one day.
- The collection of a small amount of cord blood poses no real risk to the baby participating in the study.
- The collection of fetus tissue (e.g. placenta, umbilical cord) poses after birth no risk to the baby.
- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you and your baby/ fetus, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

- You may refuse to donate any biospecimens that you do not want to donate and still remain in the study.
- Of note, not agreeing to participate will not change your labor management.

What other things should I consider before participation?

Any biospecimens (e.g., placenta, umbilical cord, blood, urine, breastmilk) obtained for the purposes of this study will become the property of the University of California. Once you provide the biospecimens you will not have access to them. The University may share your biospecimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of UCLA. The biospecimens and research data will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the research material.

Who can I contact if I have questions about this study?

- **The research team:**
  If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact:

Dr. Yalda Afshar, phone: (747) 254-2558, email: AfsharLabUCLA@gmail.com

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights as a study participant, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: 10889 Wilshire Blvd, Suite 830; Los Angeles, CA 90095-1406

You will be given a copy of this Informed Consent Form to keep for your records. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you want to participate in this study, you should sign and date below.

SIGNATURE OF THE PARTICIPANT

_____
First Name, Last Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

First Name, Last Name, Title of Person Obtaining Consent	Contact Number
Signature of Person Obtaining Consent	Date

SIGNATURE OF WITNESS (IF APPLICABLE)

First Name, Last Name of Witness	
Signature of Witness	Date