CONSENT FORM

Title of this Research Study
Serum POC Pregnancy Study

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Nebraska (CN).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

PURPOSE:
The purpose of this study is to determine if blood collected from your finger tip, instead of urine, can be used on a bedside pregnancy test.
METHODS:
The study personnel will use a lancet to obtain 1-2 drops of blood from your finger. Your blood will be put into a pregnancy test along with some saline. The test results will be available in 5-10 minutes.
RISK:
- There is the potential risk for pain or bleeding to the collection site
- There is the potential risk for collection site infection
- There is the potential risk for loss of confidentiality

BENEFITS:
There is not direct benefit to you for being in this study. This study may help us determine if finger stick blood is a usable specimen type for a bedside pregnancy test.
ALTERNATIVES:
Instead of being in this research study, you can choose not to take part.

Why are you being asked to be in this research study?
You are being asked to be in this study because you are 19 years or older and currently pregnant.

What is the reason for doing this research study?
The purpose of this study is to determine if blood collected from your finger tip, instead of urine, can be used on a bedside pregnancy test. The pregnancy test being studied has been approved by the Food and Drug Administration (FDA) for testing with a urine sample. The FDA has not approved the test for blood samples. For purposes of this research, the test is considered investigational.

What will be done during this research study?
If you decided to participate in this study, the study personnel will collect 1-2 drops of blood from the tip of your finger using a lancet. If you decided to participate in this study, your blood will be placed into a bedside pregnancy test cartridge then diluted with 1-2 drops of sterile saline. Your bedside pregnany result will be recorded within 5-10 minutes. The study personnel will then review your medical record to collect the result of your most recent beta-hCG result. At this point your participation is completed.

The sample(s) we collect will not be used for other research studies by us, or by any other investigator after this research is over.

There are no plans to perform any genetic tests (including whole genome sequencing) on your samples.

What are the possible risks of being in this research study?
- There is the potential risk for pain or bleeding to the collection site
- There is the potential risk for collection site infection
- There is the potential risk for loss of confidentiality

What are the possible benefits to you?
You are not expected to get any benefit from being in this research study.

What are the possible benefits to other people?
This study may help us determine if finger stick blood is a usable specimen type for a bedside pregnancy test.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to take part.

What will being in this research study cost you?
There is no cost to you to be in this research study.

Will you be paid for being in this research study?
You will not be paid to be in this research study.

Who is paying for this research?
This research is being paid for by the University of Nebraska Medical Center - Department of Emergency Medicine.

What should you do if you are injured or have a medical problem during this research study?
Your health and safety is our main concern. If you are injured or have a medical problem or some other kind of problem because of the study call someone listed at the end of this consent form.

How will information about you be protected?
In the course of this research we may collect information about you. This can be things that could be used to find out who you are (like your name, phone number, birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible.

The information will not be used for other research by us, or by any other researcher.

Who can see information about you?
We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:

- The UNMC Institutional Review Board (IRB)

- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)
- The Food and Drug Administration (FDA)

The Privacy Rule may not apply to all these groups. Once disclosed outside of UNMC federal privacy laws may no longer protect your PHI. Ask the investigator (or contact the Office of Regulatory Affairs at IRBORA@unmc.edu) if you have questions.

You are letting us use and share your PHI for as long as the research is going on.

How will results of the research be made available to you during and after the study is finished?

In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address: thang.nguyen@unmc.edu.

A description of this clinical trial will be available on 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.

What will happen if you decide not to be in this research study?

You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the organization. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?

You can stop being in this research (withdraw) at any time. If you decide to stop being in the research, please let us know.

If you stop being in the research study it will not affect your care or your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.

Will you be given any important information during the study?
We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?
We gave you a copy of *"What Do I Need to Know Before Being in a Research Study?"*

If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463.
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent
You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects You have had your questions answered.
- You have decided to be in the research study.
- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature

_____ _____
Signature of Subject Date

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate

_____ _____
Signature of Person Obtaining Consent Date

Authorized Study Personnel
Principal
* Nguyen, Thanh (Thanh)
phone: 402-559-7884
alt #: 402-559-7884
degree: RN

Secondary
Hergenrader, Alex (Alex)
phone: 402-559-6160
alt #: 402-559-4500
degree: MD

* Meyer, Isuzu
phone: 402-559-6150
alt #: 402-836-9549
degree: MD, MSPH

* Rimsza, Rebecca
phone: 402-559-6150
alt #: 520-981-0933
degree: MD

* Ukadike, John
phone: 402-559-6802
alt #: 402-559-6802
degree: DO

* Ukah, Obiaara
phone: 402-559-5413
alt #: 402-559-6802
degree: MD, PhD

Participating Personnel
* Giombetti, Natisha
degree: BSN

Lead Coordinator
* Zimmerman, Brooklin
phone: 402-559-5237
alt #: 402-836-9405
degree: MSN, BA, RN

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn't in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I've started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830
402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT ...

... to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

... to freely decide whether or not to take part in the research.

... to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

... to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

... to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

... to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

... to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.