CAMC Health Education and Research Institute, Inc. (CHERI)
Charleston, West Virginia

OUTCOMES RESEARCH
INFORMED CONSENT TO PARTICIPATE IN RESEARCH

DATE:

PLACE PATIENT IDENTIFICATION LABEL HERE

Patient Name:	APPROVAL

CAMC Health Education and Research Institute, Inc.
Center for Health Services and Outcomes Research
3200 MacCorkle Avenue, S.E.
Charleston, WV 25304

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Study Title: DEVELOPMENT OF AN EPIGENETIC BIOMARKER FOR PREDICTION OF FETAL ALCOHOL SPECTRUM DISORDERS

Protocol No.: 17-388

Sponsor: United States Drug Testing Laboratories, Inc. (USDTL), and The National Institute of Alcohol Abuse and Alcoholism at the National Institute of Health (NIH)

Investigator: Stefan Maxwell MD

Phone #: 304-388-2238

Statement that "you" refers to the study subject.
Throughout this consent "you" refers to the study subject.
For this study, you are consenting for your and your newborn's participation in this research study.

This consent form may have words you do not understand. Please ask the study doctor or the study staff to explain any words or information you do not clearly understand.

INVITATION TO PARTICIPATE
You are being asked to take part in this research study because you are currently pregnant, aged 18 years or older, and plan to deliver at Charleston Area Medical Center, Women and Children's Hospital.

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Your participation in this study is completely up to you. Research studies include only people who choose to take part. If you decide to participate, you are free to stop your participation at any time. Please take your time to make your decision.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to improve how we test if a baby was exposed to alcohol before birth. We are asking all women who are currently pregnant if they wish to be a part of this study.

Markers for prenatal alcohol exposure are needed. We have some tests for alcohol exposure, but we want to find better ones. This project will improve and re-test these methods to look for alcohol exposure before birth. We also want to learn more about the birth mothers and infants who are exposed to alcohol before birth.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 600 newborn infants and their birth mothers will take part in this study.

HOW LONG WILL YOU BE IN THE STUDY?

Your participation in the study is expected to last about from the time you deliver your infant until the time your infant receives a heel stick (~48 hours after delivery).

WHAT IS INVOLVED IN THIS STUDY?

We will test levels of a non-routine marker for alcohol, Phosphatidylethanol, also known as PEth, in your newborn baby. PEth detects episodes of heavy drinking (~3 or more drinks) in the last 30 days. Levels of this alcohol marker will be compared to changes in DNA (carrier of genetic information).

Both PEth and DNA changes can be measured using dried spots of blood that are put on a piece of special paper. Blood from the infant will be obtained at the time of birth from the umbilical cord and at ~48 hours after birth via a heel stick. At both of these times blood and tissue is routinely collected.

Additionally, your and infant records medical records from CAMC will be examined so we can learn more about you and your infant. These study activities described above are in addition to CAMC's routine testing for drug and alcohol exposure before birth.

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Study Activities	Prior to delivery	Delivery	Post Delivery (approximately 48 hours)
Consent for study participation	X		
Obtain umbilical cord blood		X	
Obtain blood from infant heel stick			X

WHAT ARE THE RISKS?

The blood obtained taken for this study will be taken as part of routine care. The risk of the study includes those associated with having blood taken. The amount of blood drawn will be minimal (less than half a teaspoon) and will be obtained by trained professional in a sterile fashion as to minimize any additional pain, bleeding, bruising, or infection.

PARTICIPANT RESPONSIBILITIES:

As a participant, your responsibilities include:

- Follow the instructions of the study doctor and study staff.
- Ask questions as you think of them.
- Tell the study doctor or study staff if you change your mind about staying in the study.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

If you agree to participate in this study, we cannot guarantee or promise that you will get any direct benefit. We hope the information learned from this study will help other people in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:
The alternative is to not participate. Your child will not receive PEth testing or testing for changes in DNA. Standard care will be provided for you and your infant, including CAMC's routine testing for prenatal drug and alcohol use regardless if you choose to participate in this study.

WHAT ABOUT CONFIDENTIALITY?

Your records while participating in the study will be kept private. If this study falls under FDA regulations, authorized representatives of the Food and Drug Administration (FDA) and other legally permitted people may have access to medical records that contain your identity. However, information that identifies you will not be released or published. Information will be sent to the study sponsors (United States Drug Testing Laboratories, Inc. (USDTL) and the National Institute of Health (NIH), but they will not be able to identify you or your infant.

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If PEth testing comes back positive for alcohol exposure, then a letter will be provided from the study's doctor to the baby's pediatrician listed in the medical records. The letter will state that the infant took part in this research study and a non-routine test suggests that the infant was exposed to alcohol before birth. The letter will also state that increased observation, testing, or intervention for symptoms linked to alcohol exposure may be needed.

USDTL will receive information about prenatal alcohol testing and infant characteristics. In addition, USDTL will receive the cards with the dried blood spots and performed the tests for PEth levels and DNA changes. The cards and infant information will be coded with an anonymous study number so all information sent to USDTL will be de-identified. Researchers at CAMC will have a key linking these anonymous codes to your infant. This key will be maintained securely and only accessible to members of the research study team at CAMC. USDTL will keep the anonymous dried blood spot cards indefinitely for possible future research on prenatal substance exposure.

Confidentiality of the participants in the study will be protected at all times. All identifying patient information will remain at CAMC in a locked cabinet/drawer in a locked office and if electronic, on a password protected computer in a password protected file. Protected health information collected for this study will be destroyed at the conclusion of the study unless you give us permission to contact you in the future, and then the information will be keep indefinitely.

WHAT ARE THE COSTS?

Research-required tests or procedures which are considered routine care (meaning you would receive the tests whether or not enrolled in the study) will not be covered by the sponsor, Charleston Area Medical Center, Inc. or CAMC Health Education and Research Institute, Inc. and will be the responsibility of you and/ or your insurer. You will be responsible for all co-pays and deductibles associated with routine care billable to insurance and/or yourself.

WILL YOU GET PAID FOR PARTICIPATING?

No, you will not get paid to participate in this study.

WHAT HAPPENS IF YOU ARE INJURED?

In the case of injury or illness resulting from this study, emergency medical treatment is available from Charleston Area Medical Center (CAMC).

The fact that you are voluntarily participating in this research study does not guarantee you will receive monetary compensation or payment for the costs associated with research-caused side effects or complications.

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For more information concerning this research study and related risks or injuries, you may talk with your study doctor, Dr. Maxwell, at *304-388-2238.*

Signing this consent form does not waive or limit your legal rights.

CAN YOU BE REMOVED FROM THE STUDY?
For your safety, your study doctor may remove you from the study at any time without your consent. You and your infant will be removed from the study if:

- You do not deliver your baby at CAMC Women and Children's Hospital.
- Your baby is stillborn.

WHAT IF YOU CHANGE YOUR MIND - CAN YOU STOP PARTICIPATING?
You may choose to stop participating at any time. No one will be mad at you and you will continue to receive care. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop for any reason, it is important to let your study doctor know as soon as possible so you can stop safely. You are free to seek care from a doctor of your choice at any time.

NEW INFORMATION
You will be told of any important new information that is learned during the course of the study that may affect your health, welfare, or willingness to stay in this study.

CLINICAL TRIAL REGISTRY
A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS?
For questions about the study or a research-related injury, contact the study doctor or a member of the study team at *304-388-2238.* In the event of a serious injury, go the Emergency Room.

If you have questions about your rights as a participant of this study, you may contact the Office of Research Compliance at **(304) 388-9975**.

GINA (Genetic Information Nondiscrimination Act) Law Statement

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

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- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

This federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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VOLUNTARY CONSENT TO PARTICPATE IN RESEARCH

I have read, or have had read to me, all of the above. I have asked questions and received answers concerning areas I did not understand. With my signature below, I indicate that I willingly give my consent to participate in this study.

SIGNATURE (Required as written)

_____

Signature of participant OR participant's legal authorized representative / State relationship Date

_____ _____

Signature of person obtaining or verifying consent Date

_____ _____

Witness Signature Date

(A witness signature is only required if the consent form is to be read to the subject. In all other instances the witness signature should be left blank.)