Attachment 2 - LOI-3-RT-01-N: Exemplar Consent Form

Title of Study: RT-01-M GC/MS methods to determine environmental factors on fetus and new born

Parental Permission/Research Informed Consent

Principal Investigator (PI): William D. Lyman, PhD
Children's Research Center of Michigan
Children's Hospital of Michigan
3901 Beaubien
Detroit, MI 48201
313 745 2400

Funding Source: National Institute of Child Health and Human Development

When we say "you" in this consent form, we mean you or your child;
"we" means the doctors and other staff.

Purpose

You are being asked to be in a research study that will help us figure out how best to study the possible effects of chemicals found in the environment on the cells in children's bodies. We believe that these chemicals can enter a baby's body through the mother before it is born. This study will not be able to tell us if such chemicals have or will affect your child's health. This is the first step in many years of work. This study is being conducted at Wayne State University and Hutzel Hospital. You are being asked to be in this study because you either have delivered, or could possibly deliver a baby boy. The estimated number of study participants to be enrolled at Hutzel Hospital is about 800, which includes 400 mothers and 400 babies.

Please read this form and ask any questions you may have before agreeing to be in the study.

In this research study, we will determine if chemicals commonly found in plastics, called phthalates, are in your and your baby's urine, and if there are changes in one of your baby's genes that is involved in sexual development in relation to exposure to phthalates. These genetic changes could potentially cause abnormal hormonal effects. Being asked to take part in this study does not necessarily mean that you or your baby have abnormal levels of phthalates in your body.

Study Procedures

If you agree to take part in this research study, we will collect a sample of your urine given before delivery of your baby. We would like to collect a second sample of your urine (as much as we can collect into a small container), as well as a sample of your baby's urine (we will collect the diapers to obtain the urine), and your child's foreskin if he is circumcised. We will provide a bag for you to save your baby's diapers in and we will pick them up at least twice per day. These procedures will not make your time in the hospital longer or in any way negatively affect you. We will examine your and your baby's urine to measure for the phthalates, and his foreskin to look for gene changes. We will also measure your baby's finger length using a caliper, because there is evidence that the chemicals we are studying can alter these distances. In addition to finger length, we will measure the distance between your baby's anus and scrotum using a soft, sterile tape measure. This would provide additional information about how we should study the possible effects of these environmental chemicals.

Benefits

There will be no direct benefit to you or for your child; however, information from this study may benefit other people now or in the future.

Risks

There are no known risks at this time to participation in this study.

Alternatives

You have the right not to participate in this study.

Study Costs

There is no cost to participate in this study.

Compensation

You will receive a $25 gift card for your participation in this study.

Research Related Injuries

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Care for such will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Wayne State University the Detroit Medical Center, University Physician Group, sponsor, and any other facility involved with this study. If you think that your child has suffered a research related injury, contact the PI right away at 313 745 2400.

Confidentiality

All information collected about your child during the course of this study will be kept confidential to the extent permitted by law. Your child will be identified in the research records by a code name or number. Information that identifies your child personally will not be released without your written permission. However, the study sponsor, the Human Investigation Committee (HIC) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your child's identity. If photographs, videos, or audiotape recordings of your child will be used for research or educational purposes, your child's identity will be protected or disguised.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to allow your child to take part in this study. If you decide to allow your child to take part in the study you can later change your mind and withdraw from the study. You and/or your child are free to only answer questions that you want to answer. You are free to withdraw your child from participation in this study prior to collection of samples. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you or your child are entitled to receive.

Questions

If you have any questions about this study now or in the future, you may contact Dr. William Lyman or one of his research team members at the following phone number 313 745 2400. If you have questions or concerns about you or your child's rights as a research participant, the Chair of the Human Investigation Committee can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call (313) 577-1628 to ask questions or voice concerns or complaints.

Consent to Participate in a Research Study:
To voluntarily agree to have your child take part in this study, you must sign on the line below. If you choose to have your child take part in this study, you may withdraw them at any time. You are not giving up any of your or your child's legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

Name of Participant	Date of Birth
Signature of Parent/ Legally Authorized Guardian	Date
Printed Name of Parent Authorized Guardian	Time
*Signature of Parent/ Legally Authorized Guardian	Date
*Printed Name of Parent Authorized Guardian	Time
**Signature of Witness (When applicable)	Date
Printed Name of Witness	Time
Oral Assent (children age 7-12) obtained by	Date
Signature of Person Obtaining Consent	Date
Printed Name of Person Obtaining Consent	Time
Signature of translator	Date
Printed name of translator	Time

***** Both parent's signatures should be obtained however both are **required** for level 3 studies

****** Use when parent/guardian has had consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

Continue to HIPAA Authorization on next page

HIPAA Authorization

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and his research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and his research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI's research office and can take place anytime during the study or after the study has ended.

The PHI that will be "USED" for this research includes the following: name, elements of dates, medical record number, biometric identifiers and any unique identifying numbers, characteristic or code.

The PHI that will be "DISCLOSED" or shared with others includes any unique identifying numbers, characteristic or code.

Your study information may be **used** or **shared** with the following:

- The PI, co-investigators, and key personnel of WSU associated with the research project
- WSU's HIC and the Institutional Review Boards (IRB)
- Authorized members of WSU and DMC workforce who may need to access your information in the performance of their duties. For example, to provide treatment and services, and/or ensure integrity of the research.
- The study Sponsor or representative, including companies it hires to provide study related services, which include: National Institute of Child Health and Human Development.
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records.

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

- During your participation in this study you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center and/or the WSU School of Medicine Practice Plans.

Authorization to use and disclose PHI

- By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

_____ _____

Signature of participant Date

_____

Printed name of participant

- For participants unable to give Authorization, the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.).

_____ _____

Signature of authorized representative Date

_____ _____

Printed name of authorized representative Relationship to the participant

_____ _____

Signature of person obtaining Authorization Date

_____

Printed name of person obtaining Authorization