BIRTH OUTCOMES AND WATER (BOW)

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INFORMED CONSENT FORM
Project Name: **Birth Outcomes and Water (BOW)**
IRB# 17044

Purpose of the Research:
The purpose of this research project is to study how mothers' health and environmental factors are related to the health of their children. If you agree to participate, you will be asked to complete a questionnaire about your demographics, residential and water use history, health, diet, and your child's health history. You (as the mother) will be asked to provide saliva and blood samples for measurement of biological markers. You will also be asked to allow collection of a drinking water sample at your residence. A second purpose of this research is to understand the reasons or barriers affecting a decision to participate or not participate in studies such as this one. If you agree to participate in interviews or focus groups concerning your motivations for participating/not participating in the study you will be asked questions about those motivations or barriers. If you agree, a separate consent form will be used for that part of the study.

Procedures: When you return this consent form with your signature, the Bureau of Sociological Research (BOSR) at the University of Nebraska-Lincoln (UNL) will send you a package. The package will contain a saliva sample collection kit, blood sample collection kit, and the necessary packaging to return those materials. If you elect to complete a paper questionnaire rather than one that is web-based, it will be included in the package.

You will be asked to provide a saliva sample using the sample collection kit we send you. The saliva sample will be used to measure levels of nitrate and nitrite, which are indicators of chemical reactions in your digestive tract.

You will be asked to allow a water specialist to collect a sample of your drinking water. The water sample will be used to determine the age of your drinking water and test for nitrate and nitrosatable compounds.

We will ask you to visit a healthcare provider in your area to collect your blood sample. Two tubes of blood, 2-3 milliliters (less than one teaspoon) each, will be collected. We will cover the cost of the blood draw, and your healthcare provider will submit the sample (instructions for the provider are included in the kit). DNA extraction will be performed on the entire sample in one tube to examine differences in Cytochrome P450 2E1 (CYP2E1) and NAD(P)H dehydrogenase (quinone) genes. Genotyping for the CYP2E1 c1/c1, c1/c2 and c2/c2 alleles will be performed. These genes make enzymes that metabolize chemicals in your body. The second tube will be cultured and processed to evaluate chromosomal differences (breakage/translocation) among the participants. The cost for these tests will also be paid for by the BOW study.

Your samples will be assigned code numbers that cannot be traced back to you by anyone not working for the study. The samples will be stored at UNL or the University of Nebraska Medical Center (UNMC) and destroyed after the related research is completed and published. Your biological samples may be stored up to 10 years to allow for confirmation studies or additional analyses based on the results of the research described to you for this study. You may also request that your samples be destroyed earlier and they will be destroyed as soon as possible after your request.

The questionnaire is expected to take about an hour to complete. Collecting the saliva sample may take up to 5 minutes. The amount of time needed to take your blood sample will depend on your proximity to the nearest health care center and availability of appointment times. The actual blood draw should take less than five minutes. Up to an hour will be required for personnel to collect a drinking water sample at your residence. In total, your participation in this study is estimated to require less than 5 hours of your time.

Benefits: If requested, we will send your water test results to you. These results will provide information about the quality of your drinking water. At your request, we will send you the test results of your blood and saliva analyses. These results will provide some genetic information (Cytochrome P450 2E1 and NAD(P)H dehydrogenase (quinone) genes) and the levels of nitrate and nitrite in your system.

Risks and/or Discomforts:
You may experience distress when recalling pregnancy-related events. The questionnaire has been designed to minimize these feelings. You can skip any question that you do not care to answer. Additionally, we can provide suggestions for a reputable support group/counselor at your request.

The potential risk of giving a blood sample includes a bruise and/or infection where the blood was collected on your arm. To avoid these complications, we ask you to have your blood drawn by a trained phlebotomist in the office of your trusted health care provider.

Confidentiality:
All information that could be traced to you will be kept strictly confidential. We will use a study code number rather than your name or any identifying information to label your completed questionnaire, water, saliva and blood samples. This information will be stored on secure computer servers and in locked cabinets in the lead investigator's office, and will only be accessed by authorized personnel during the study and for two years after the study is completed. The results of this study may be used for teaching, research published in scientific journals or presented at scientific meetings, but never in a way that could identify you. We will never share any of your individual results or personal information with anyone. Your biological samples will be used only by researchers associated with this project.

Compensation:
If you agree to participate, we will send you a $25 check in the mail after the completed questionnaire and saliva sample are received and the water sample collected. You will also receive a $50 check after your blood sample is returned. In addition, as part of the evaluation of our procedures, you may be contacted and ask if you are willing to share your experiences relating to participating in this study. If you are contacted and agree to participate in those additional activities, you will be given a separate consent form an offered an additional $25 for your participation.

Opportunity to Ask Questions:
You may ask any questions you have about this study and have those questions answered before agreeing to participate in or continue participating in the study. You may call the project leader (Dr. Martha Rhoades) at any time at (402) 472-1633. You may leave a message and she will return your call.

Sometimes study participants have questions concerning their rights as a study participant. If you have such questions, you may contact the University of Nebraska-Lincoln Institutional Review Board at (402) 472-6965.

Freedom to Withdraw:
You are free to choose whether to participate in this study and can stop participating at any time, without affecting your relationship with the investigators or the University of Nebraska. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

Consent, Right to Receive a Copy:
You are voluntarily making a decision whether or not to participate and provide information about you and your child for this research study. Your signature certifies that you have read and understand the information presented, have decided to participate, and agree to provide information about your child through the questionnaire. The second copy of this consent form is for your records. If you have questions at any point after you sign this form or want to receive additional copies of this form, please contact Dr. Rhoades at (402) 472-1633.

Please mark the type of questionnaire you prefer

_____ **Paper**

_____ **Electronic**

If you selected electronic, please provide your email address below. A link to the questionnaire will be emailed to you.

Email address_____

Please mark if you consent to providing a drinking water sample.

_____I consent to providing a drinking water sample. I understand that personnel from the University of Nebraska-Lincoln will call to schedule an appointment to collect the sample and they will present identification at the scheduled appointment.

Please mark if you consent to providing a blood sample and a saliva sample.

_____I consent to providing a sample of my blood. I understand that my blood sample may be stored up to 10 years from today's date to allow for confirmation studies or additional analyses based on the results of the research described to you for this study. I also understand that my blood sample will be destroyed as soon as possible upon my request at any time during this time period.

_____I consent to providing a sample of my saliva. I understand that my saliva sample will be destroyed as soon as possible upon completion of the nitrate/nitrite analysis.

Please mark if you would like a copy of your water/saliva/blood analysis reports.

_____I would like a copy of my water analysis results.

_____I would like a copy of my saliva analysis results.

_____I would like a copy of my blood analysis results.

By signing below, you agree to participate in this research.

Signature of Participant:

_____
(Name: Please Print)

_____ _____
(Signature) *(Date)*

The University of Nebraska-Lincoln wants to know about your research experience. This 14 question, multiple-choice survey is anonymous. The survey should be completed after your participation in this research. Please complete this optional online survey at http://bit.ly/UNLresearchfeedback.

Names and phone numbers of investigators:

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Enclosure: Return envelope