Informed Consent Form

Measurement of Agricultural and Dietary Glyphosate Exposure among Pregnant Women

NCT04155463

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BOISE STATE UNIVERSITY

INFORMED CONSENT

Study Title: Measurement of Agricultural and Dietary Glyphosate Exposure among Pregnant Women
Principal Investigator: Dr. Cynthia Curl
Sponsor: National Institute of Environmental Health Sciences (NIEHS) / National Institute of Health (NIH)

This consent form will give you the information you will need to understand why this research study is being done and why you are being invited to participate. It will also describe what you will need to do to participate as well as any known risks, inconveniences or discomforts that you may have while participating. We encourage you to ask questions at any time. If you decide to participate, you will be asked to sign this form and it will be a record of your agreement to participate. You will be given a copy of this form to keep.

➢ PURPOSE AND BACKGROUND

The purpose of this research is to understand whether and how pregnant women may be exposed to a common pesticide called glyphosate. Glyphosate (pronounced: Gly-Foh-Sate) is the active ingredient in Roundup, which is a pesticide that people use at home to kill weeds and that farmers use in growing crops. We want to understand how much glyphosate pregnant women in Idaho are exposed to, and we also want to understand whether this exposure comes from where they live or what they eat. We are recruiting pregnant women who either live close to or far away from agricultural fields where glyphosate is used. We will then collect urine samples from these women and measure glyphosate levels in those samples. Finally, women will be provided two weeks of free food: one week of organic food and one week of regular (non-organic) food. Then, we will collect additional urine samples to understand the effect of these different diets on exposure to glyphosate. More specifics are provided throughout this form. You are being asked to participate because you are a pregnant woman in your first trimester who is 18 – 35 years old and currently consumes a conventional diet.

➢ PROCEDURES

Participation in this study involves the following:

- Complete brief questionnaires
- Provide up to 36 urine samples
- Eat one week of organic food and one week of regular (non-organic)food

If you agree to participate in this study, we will ask you to answer some basic questions about your life and about possible interactions you may have with pesticides, and we'll collect weekly urine samples from you throughout the rest of your pregnancy. We aim to collect one urine sample per week for 22 weeks, which is about 5 months. We'll also provide you with two weeks of free food that you will get to choose and order, and the food will be delivered to your home. We'll also ask you to keep track of what you eat during that two-week period. During this two-week period, we'll collect daily urine samples.

If you agree to participate in this study, these will be required activities. In order to provide these urine samples, we will give you 4 oz. polypropylene specimen cups. We will ask you to leave the sample in a cooler outside your home for us to collect. This process should take no longer than five minutes.

After collection, your urine samples will be transferred into several vials for storage and analysis. One (or more) of these vials will be analyzed for glyphosate and other pesticides and pesticide metabolites as a part of this study. With your consent, we will also store the remaining vials in a long-term storage system, called a biorepository. As with all of your samples, these stored vials will not be labeled with your name or any other identifying information. They will be labeled with an ID number that does not indicate your identity. These stored urine samples may be used for future research, to analyze other compounds (for example, additional pesticides) in a future study.

- **RISKS**

All interactions between you and study personnel will be completed over the phone or through videos, and urine samples will be collected from a cooler outside your home. No face-to-face interaction is required. There are no known risks to providing a urine sample. There are also no known risks for consuming either organic or conventionally grown food. For this research project, the researchers are requesting demographic information. Due to the make-up of Idaho's population, the combined answers to these questions may make an individual person identifiable. The researchers will make every effort to protect your confidentiality. However, if you are uncomfortable answering any of these questions, you may leave them blank.

- **BENEFITS**

The information that you provide will help us understand the degree to which pregnant women are exposed to glyphosate and the pathways through which this exposure occurs. However, you may not directly benefit from your participation in this study.

- **EXTENT OF CONFIDENTIALITY**

We will employ a series of measures to safeguard your confidentiality and the confidentiality of any data we collect from you. First, your name will be assigned a specific ID at the beginning of the study, and only that ID will be used on the urine sample collection containers and the urine collection log. This way, the research team at Boise State University will be the only group that can connect your data to your name. We will not share the results of your individual biological sample analysis with anyone. Any identifiable information obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by law. All data collected from this study, including this signed consent form, will be kept in the research team's secure, locked file cabinets in locked offices on the Boise State University campus. Only the members of the research team, the site conducting urine sample analysis, and the Boise State University Office of Research Compliance (ORC) may access the data. The ORC monitors research studies to protect the rights and welfare of research participants.

Your name will not be used in any written reports or publications which result from this research, and any data presented will be de-identified and presented in aggregate. Data will be kept for three years (per federal regulations) after the study is complete and then destroyed.

- **PAYMENT/COMPENSATION**

If you choose to participate in this study, you will receive two weeks of free food (up to $150 per week for a total of up to $300). You will also receive a $10 gift card each week you provide a urine sample (up to 22 weeks, for a total of up to $220), and up to $50 in gift cards for the daily urine samples you provide during the two-week dietary intervention ($50 prorated over the number of samples provided during that 14 days). Finally, you will receive an additional $50 gift card at the completion of the study if you provide all 36 urine samples throughout the duration of the study.

- **PARTICIPATION IS VOLUNTARY**

You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time without consequences of any kind or loss of benefits to which you are otherwise entitled.

- **QUESTIONS**

If you have any questions or concerns about your participation in this study, you may contact the Principal Investigator, Dr. Cynthia Curl: 986-224-7120 or cynthiacurl@boisestate.edu.

If you have questions about your rights as a research participant, you may contact the Boise State University Institutional Review Board (IRB), which is concerned with the protection of volunteers in research projects. You may reach the board office between 8:00 AM and 5:00 PM, Monday through Friday, by calling (208) 426-5401 or by writing: Institutional Review Board, Office of Research Compliance, Boise State University, 1910 University Dr., Boise, ID 83725-1138.

DOCUMENTATION OF CONSENT

I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks have been explained to my satisfaction. I understand that some of my de-identified urine will be stored in a biorepository for possible additional analyses in future studies. I understand I can withdraw at any time.

Printed Name of Study Participant	**Signature** of Study Participant	Date

Signature of Person Obtaining Consent	Date