

Consent form for adult participants

Study Title: Crowdsourced Biomonitoring Study

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Sponsor: Silent Spring Institute

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. The reasons the researchers are asking you to participate in this study are described below. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate. If you decide to participate, you will be asked to sign this form, and you will receive a copy of it.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you.
- **You may benefit indirectly as a result of participating in this study.** Some participants may consider the opportunity to learn about chemicals in their bodies to be a benefit of participating in the study.

Introduction to crowdsourcing funded research

Most research participation in the United States is funded by government agencies or corporations. This study is organized by Silent Spring Institute which is a non-profit scientific organization that is concerned about the links between exposure to commercial chemicals and other pollutants and human health.

This study is unusual in that we are asking you to pay for this research. Silent Spring Institute wants to study people's chemical exposures as described below but does not have the funding from anyone to complete the work. The amount of the testing is \$299.00. This consent describes what will be done with this money and why it is important to you and Silent Spring Institute.

Why is this study being done?

This study is being done to learn about people's exposures to chemicals associated with household and personal care products. Our overall goal is to better understand sources that contribute to chemical exposures and ways to reduce those exposures.

How many people will take part in this study?

There is no limit on the number of people that can take part in this study. Enrollment is limited to people within the United States. We need a minimum of 100 participants before the study can

begin testing samples for chemicals. If fewer than 100 participants enroll, the study will end without testing the samples and your contribution will be fully refunded.

What will happen if I take part in this study?

On the project's crowdsourcing website, you will pay for the cost of processing your sample and enter your name and address so that we can mail you a sampling kit. The sampling kit will include two sterile urine collection cups and instructions on how to collect your samples.

You will be asked to follow the instructions to collect your urine and freeze it overnight in your home freezer, along with the freezer pack provided in the kit. The sampling kit will include a pre-addressed and pre-paid mailer that you will use to mail your frozen urine back to us. Your sample will be sent to a laboratory that holds accreditation for doing this kind of testing.

You will be asked to complete a questionnaire after you take your sample about the personal care products that you use. It will also ask for basic demographic information like your ethnic group, gender, and the state you live in. You will be able to skip any question that you do not want to answer. We can only process samples if you have filled out the questionnaire and provided payment.

We will measure your urine for 10 chemicals, including parabens, antimicrobials, and BPA. These are environmental chemicals with some known sources that individuals can choose to avoid (e.g. avoiding food in plastic wrappers). We will not do any targeted drug, alcohol, or genetic testing on your sample.

What will I be able to learn from the results?

After your urine is analyzed, you will have the option of learning the overall study results as well as your individual chemical levels. If you would like to access your results, you will create a password protected account on the study website using the unique identification number from your sampling kit as your User ID. You will have the option of providing your email address for the study team so we can let you know when your results are ready. When your results are ready, you will be able to view a report by signing into your account.

The report will tell you the levels of chemicals found in your urine. It will tell you what the chemicals are, where they may be coming from, and possible relationships to health. The report will also include personalized tips on how to reduce exposures based on your chemical levels.

The tests are not designed for diagnostic purposes. This means we can't draw conclusions from the tests about the specific health implications for you.

Even though the sample processing and laboratory methods are very carefully implemented, there is still a possibility of some error in these procedures.

If you would like to receive a paper copy of your report, you may request one to be mailed to you. You will also be able to download a printable version of your report from your online account.

How will these findings be reported?

A summary of the findings for all the urine measurements in the study may be published in scientific journals and reported in public meetings and news media. With your consent, the de-identified data may be shared with researchers, though your name and contact information will not be shared and will never be used in any reports, publications, or public meetings.

What happens to my samples?

We would like to ask your permission to store the urine samples we collect for an unlimited amount of time, or to throw them away, depending on our storage capacity and study objectives. The samples will be stored at a laboratory and labeled with a number. Your name and contact information will not be included on the label. With your permission, we may use your sample to study other chemicals of concern in the future, or use new scientific techniques that are not currently available to study links between environmental chemicals and health. If the new techniques produce informative results, we may offer you the opportunity to learn the results of the new analyses conducted on your sample through your online account. If any non-targeted methods we explore in the future detect indicators of illicit drugs or alcohol, this will not be reported to you.

How much time will it take?

Collecting the urine samples should take less than 15 minutes. You can either schedule a time for your prepaid return mailer to be picked up by the specific mail carrier, or drop the mailer off at the carrier's nearest location. Filling out the online questionnaire will take approximately 30 minutes.

Can I stop being in the study?

You can leave the study at any time. Leaving the study will not be held against you in any way. If you decide to leave the study, your samples will be destroyed. However, the data generated from your samples that have already been placed in research databases cannot be withdrawn.

What risks, side effects or discomforts can I expect from being in the study?

Breach of confidentiality is a small risk of participation. Direct identifiers, such as participant name or contact information will be held with the strictest confidentiality. This information will only be used to mail sampling kits, and to re-contact you for follow-up questions on your results if we have your permission to do so. Samples will be assigned unique identifying numbers, and questionnaire responses will only be linked to your identification number, not your personal identifying information

What benefits can I expect from being in the study?

You may benefit indirectly as a result of participating in this study. Some participants may consider the opportunity to learn about chemicals in their bodies and how to avoid them to be a benefit of participating in the study. You may benefit from the satisfaction of feeling that you are contributing to help researchers understand more about widespread environmental chemical exposures.

What other choices do I have if I do not take part in the study?

One alternative is to participate in another study that measures and reports these chemicals. We do not know of any other study beside this one that allows anyone in the U.S. to participate. There are private companies that will measure some of these chemicals for a fee. Some of these companies require that a doctor order the test for you.

Will my study-related information be kept confidential?

All participation in this study is voluntary and all information collected in the study will be held with the strictest confidentiality. Direct identifiers, such as participant name or contact information, will only be used to record your consent to participate in this study and to mail urine collection containers. Your payment will be processed through a third party provider and your confidential payment information (for example, credit card number) will not be available to the study team. We will use study ID numbers for all study samples and surveys. A link between the ID number and personal identifiers will be stored on a hard drive in a locked file cabinet only available to the PI, study manager, and database coders on the research team.

All data analyses will be done on de-identified data. Anonymized (no names or other identifying information) data will be eventually made available in a freely accessible, public database. The database will include the results of the tests performed on your urine sample, as well as your answers on the questionnaire. Your name or personal identifying information such as address, email, and phone number will not be included. There is a small risk that someone will be able to use the provided information in the database to identify you. We will reduce this risk by withholding any information that would easily identify you.

Study records, including personal identifiers, may be reviewed by Hummingbird IRB. An Institutional Review Board (IRB) is a group of people who review and evaluate studies to ensure that the study is as safe as possible before people become participants. Hummingbird IRB is required to make routine checks of the study.

What are the costs of taking part in this study?

The price of having your sample analyzed is \$299.00 This includes the price of shipping your sample to the laboratory, having the sample chemically analyzed at the laboratory, providing you with a report of your results, and associated administrative costs. If you know you would like to send us additional samples in the future, you may pre-pay for future measurements.

What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

We will provide you with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without worrying that it will be held against you or that you would lose benefits to which you are otherwise entitled.

Who can answer questions about the study?

For questions or concerns about the study, you may contact Herb Susmann at 617-332-4288 x241.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Hummingbird IRB toll free at 855-447-2123.

Part of Hummingbird IRB's responsibility is to help participants understand their rights both before deciding to participate in a study and to address any questions and concerns during the study.

Please initial after all the permissions below that you are willing to give the research staff to do this study. You may withdraw these permissions at any time through your online account or by sending a letter to Silent Spring Institute at 320 Nevada Street, Newton, MA 02460.

1 – Do you give permission for the questionnaire information and urine samples from you to be used by Silent Spring Institute for this study?

YES _____ NO _____

2 – Would you like to receive the results of your urine sample?

YES _____ NO _____

3 – Do you give permission for Silent Spring Institute to re-contact you to ask additional questions, if they so choose?

YES _____ NO _____

4 – Do you give permission for Silent Spring Institute to share your de-identified chemical measurements in urine and questionnaire data in a public online database (without your name or personal identifying information such as address, phone number, or email)?

YES _____ NO _____

5 – Do you give permission for your urine samples to be stored and then analyzed in future research about chemical exposures by Silent Spring Institute?

YES _____ NO _____

Your signature on this form indicates that you understand the information provided above and you agree to participate.

Participant's Signature

Date

Participant's Name (printed)

Mailing Address (this is where we will mail your Detox Me Action Kit):