State-based Public Health Laboratory Biomonitoring Program for the Four Corners States (AZ, CO, NM, UT) Biomonitoring Consortium

Project Lead: Katherine A. James, Ph.D. MSCE
Assistant Professor University of Colorado, Anschutz Medical Campus
303-724-8169 : Kathy.James@ucdenver.edu

PARTICIPANT CONSENT FORM

1. Consent for Children

When this form is completed for a child, the word "you" applies to that child and to the parents, guardian or caretaker of that child.

2. Project Description

We ask you to be part of a study. This study is about how you may be exposed to some chemicals common in the environment of the four corner states. When you are exposed to chemicals your body will release metabolites from them into your urine. We will measure the amount of those metabolites in your urine. This will tell us how much chemical you are exposed to. Your results along with the results of all the other participants in the study will help us understand how people are exposed to those chemicals. The chemicals we are interested in checking for include: [check those that apply]:

□ Heavy metals (those that are higher risk to be contaminates in private well drinking water)
Metabolites: arsenic, cadmium, lead, manganese, mercury, selenium, uranium, and possibly other metals

□ 2,4-dichlorophenoxyacetic acid (2,4-D) containing herbicide
Metabolite: 2,4-dichlorophenol (2,4-DCP)

□ p-dichlorobenzene (p-DCB) contaminates found in disinfectants, deodorants and some kinds of pesticides
Metabolite: 2,5-dichlorophenol (2,5-DCP)

□ Phthalate contaminates in food and domestic products
Metabolites (12): monoethyl phthalate (MEP), mono-isobutyl phthalate (MiBP), mono-n-butyl phthalate (MnBP), monobenzyl phthalate (MBzP), mono-3-carboxypropyl phthalate (MCPP), mono-carboxyoctyl phthalate (MCOP), mono-carboxyisononyl phthalate (MCNP), di-(2-ethylhexyl) phthalate (DEHP), mono-(2-ethylhexyl) phthalate (MEHP), mono-(2-ethyl-5-oxohexyl) phthalate (MEOHP), mono-(2-ethyl-5-hydroxyhexyl) phthalate (MEHHP), mono-(2-ethyl-5-carboxyphenyl) phthalate (MECPP)

□ Pyrethroid-containing insecticides
Metabolite: 3-phenoxybenzoic acid (3-PBA)

□ Creatinine. This metabolite is used to measure the concentration (dilution) of your urine. It helps us interpret your results.

We will only test your urine for the metabolites listed above.

Our study partners are the Centers of Disease Control and Prevention (CDC), the 4-Cornors States Biomonitoring Consortium (4CSBC), Colorado Department of Public Health and Environment (CDPHE), and University of Colorado-Anschutz Medical Campus (UCD-AMC). The CDC is paying for this study. We want to know more about how people are exposed to chemicals. That information will help us make better policies to protect your health.

Before we include you in this study, we will ask you some questions. Those questions will help us know if you are eligible for this study. If you are selected for this study, you will be asked to:

_____
Initial

(1) Answer some questions about your home, work and/or play activities.

(2) Give us a sample of your first-morning urine. You will need to follow the instructions we give you about taking samples.

(3) Give us a sample of your water. You will need to follow the instructions we give you about taking water samples. [Cross out if not applicable].

You will not have any risk from providing us urine sample or a water sample. The cups or bottles we give you to collect the samples may have a preservative in them. The preservative is not harmful to your health.

You will not need to take any medications nor will you need to stop taking any medications that you are now taking for this study.

Your participation is voluntary. We request that you participate in all the activities of this study. However, you may choose to not to participate in any of the activities. The activities are listed in the next section.

3. Procedures

If you agree to take part in this study, we will ask you to:

3.1 Fill out the form on the last two pages of this consent form.

3.2 Answer the eligibility questions.

3.3 Answer the questions about your work, home and play activities. This activity will include questions about your health, habits, and activities inside, outdoor, and at work or school.

3.4 Give us a urine sample using either of the two following methods below. Your urine sample will be tested for the metabolites listed above. You may be asked to give two samples. We will use the second urine sample to make sure our laboratory is doing the test right.

3.4a. Provide specimen at health clinic: You will be asked to provide a sample as soon as you arrive at the clinic.

Or

3.4b. Provide specimen at home: For the tests to be accurate, you will need to follow the instructions we give you. You will need to schedule a time for transfer of sample using one of the two options in 3.5 below.

3.5 Store the sample in your refrigerator and do one of two options to transfer the sample to our study personnel:

3.5a We pick it up, and ask that you be at home at an agreed upon time for pick up

or

3.5b Deliver the sample to your clinic during clinic operation hours.

4. Discomforts and Risks

There are no anticipated discomfort or risks to you for participating in this study.

All of the information you give us will be kept confidential. Water and urine results will only be released to you through a postal mailed letter. No results will be released to any other person, business, or agency other than you. For analysis and research, the urine and water data will be de-identified (removal of name and contact information). Data will be stored in a password protected file on a secure server at the UCD-AMC.

_____
Initial

As part of the 4CSBC, each state will provide a summer of all the data. This summary will be completely de-identified and data will only appear as summary data (counts or averages). No person will be individually identifiable.

This study may result in new knowledge about chemicals exposures in your home which may result in some unintended consequences.

5. Benefits

We will learn more about how people are being exposed to chemical common in the environment. This will help public health agencies and community action groups make better local level policies to protect the health of children.

This study is not designed to diagnose or treat any illnesses you may now have. We will not be collecting any health information.

6. Source of Funding

To do this study we were given a grant. CDC is funding this study. CDC is part of the US Department of Health and Human Services. The title of the grant is "The 4 Corner States are Collaborating to Develop and Enhance Biomonitoring Capability to Assess Human Exposure in this Region." The award number is 1U88EH001153-01. The study period is September 1, 2014 through August 31, 2019.

7. Cost to Participants

You will not have to pay to be part of this study. The results will be free to you. You will not receive any monetary incentive for being part of the study.

If you choose to follow-up with your health care provider after you get your results back, you will have to pay for that follow-up. Those costs are not covered by this study.

If you choose to modify your exposure level (example: add a water filtration system or buy bottled water), there may be costs incurred by you and these are not covered by this study.

8. Analytical Results

After we analyze your urine and in some cases water, we will provide you a copy of the results. The results will be for those tests that are checked above. We will also send you a fact sheet for each test we do. The fact sheet will help you understand what your results mean. The fact sheet will also give you some suggestions to reduce your exposure.

This study is designed to help public health understand exposure. The laboratory procedures that will be used may not be approved for diagnosis. After you get your results you may want to do some follow-up testing with your health care provider using testing methods which can more describe exposure level and associated health effects. You will be responsible to set up an appointment with your health care provider for any additional testing you choose to have. You will be responsible for the costs of your appointment, testing and treatment.

The study is designed so that the four states will work together. Each state will be able to do some of the tests but not all of the tests. Some of the urine sample you provide us may be sent to other states for testing.

Because we have a limited budget, we may choose to wait until we have a large batch of samples before doing the tests. It may be several months before you get your results back.

Should you receive results that indicate exposure levels higher than the 90^{th} percentile of a similar aged child in the United States, we will offer to you the option to receive results via the mode you wish. Research team members can contact you via telephone, postal mail, or meet in person at a location at your convenience. You can also request to have your results forwarded to your health care provider.

9. Withdrawal from Study

_____
Initial

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, your doctor will still take care of you. You will not lose any benefits or medical care to which you are entitled. If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them. The study principle investigator or study director may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm, or for any other reason. The sponsors may also stop the study at any time.

The principal investigator carrying out this study is Dr. Sanwat Chaudhuri (Utah State Epidemiologist) and the study director for Colorado is Dr. Katherine James. You may ask any questions you have now. If you have questions later, you may call or email Dr. Katherine James at kathy.james@ucdenver.edu or 303-724-8169. You will be given a copy of this form to keep.

10. Confidentiality Protection

If you participate in this study, we keep your individual information confidential. The CDC, CDPHE, and the UCD-AMC Institutional Review Board (IRB) has the right to examine your information. They do this to make sure we are doing the work properly. No one else will have the right to look at your information. The CDC, CDPHE, and UCD-AMC IRB will keep your information confidential.

The information you provide us, along with the information from other participants, will be summarized into counts, rates and other statistics. We will share the summarized data with our partners at CDC and the 4CSBC. You cannot be identified through the summary information. We may use the summary data to make presentations at meeting and publish reports. You will not be identified at those meetings or in those reports.

11. Authorization

I have read this consent form about the study or it was read to me. I understand the possible risk and benefits of this study. I know that participating in this study is voluntary. I choose to participate in this study. I know I can stop participating in any or all activities of this study. I know that if I stop participating, I will still get my usual medical care. I will get to keep a copy of this consent form.

Please initial all the previous pages of this consent form.

I agree to participate in all activities of the study that I have initialed below:

_____ (initial) the eligibility survey, as described in Section 3.2 above,

_____ (initial) the exposure risk questionnaire, as described in Section 3.3 above

_____ (initial) collect, store and provide a urine sample to the study staff as described in Sections 3.4 through 3.6 above, to be analyzed for the metabolites to the environmental contaminants indicated in Section 2.

_____ (initial) collect, store and provide an additional urine sample for laboratory quality control purposes, as described in Section 3.7 above.

_____ collect, store and provide a water sample from the primary drinking water source in the home, to

_____
Initial

(initial) study staff as described in Sections 2 above. The drinking water will be analyzed for heavy metals and will be used to correlate drinking water exposure risk to the level of urinary metal levels. (cross out if not applicable)

_____ (initial) if results indicate exposure at a level greater than the 90th percentile of a similar aged child in the United States, please contact me via

_____ telephone
_____ postal mail
_____ in person meeting

_____ (initial) if results indicate exposure at a level greater than the 90th percentile of a similar aged child in the United States, please forward a copy of results to my health care provider (contact information below)

_____ Name
_____ Address
_____ City, State, Zip
_____ Phone

_____
Initial

Participant Certification

Participant's Name:_____

Participant's Street Address:_____

_____

Participant's Mailing Address (if different):_____

_____

Participant's Phone Number:_____

Participant's Email (optional):_____

Signature:_____ Date: _____
Participant, or participant's parent, guardian or caretaker

Print name of person signing:_____

Investigator Certification

Consent form explained by:_____ Date:_____
signature

Print name: _____

_____
Initial