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 asked you to be part of a study. This study is about how you may be exposed to some chemicals. 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 metal (arsenic, cadmium, lead, manganese, mercury, selenium, uranium) contaminates in private well drinking water**
  Metabolites: arsenic, cadmium, lead, manganese, mercury, selenium, uranium, and creatinine

- ☐ **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 of your urine. It helps us interpret your results.

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

Our study partners are the 4-Cornors States Biomonitoring Consortium (4CSBC) and the Utah Department of Health (UDOH). The Center for Disease Control and Prevention (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.

Participant Consent Form

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:

(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 for this study. You will not need to stop taking any medications that you are now taking either.

Your participation is voluntary. We request that you participate in all the activities of this study. However, you may choose 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 two last 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. For the tests to be accurate, you will need to follow the instructions we give you. 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.

3.5 Store the urine sample in your refrigerator, until we pick it up.

3.6 Be home at the time we agree to pick up your urine sample.

4. Discomforts and Risks

We don't think you will have any discomfort or risks by participating in this study.

All of the information you give us will be kept confidential.

Participant Consent Form

We will share the results we get from analyzing your urine with you. We will not share your results with anyone else. A summary of all of the results will be shared with our partners. That summary will include counts and averages. No person will be individually identifiable.

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

5. Benefits

We will learn more about how people are being exposed to chemicals in the environment. This will help us make better policies.

This study is designed to help us learn more about how the public is exposed to chemicals in the environment. We will use what we learn to make better policies regarding public health.

This study is not designed to treat any illnesses you may now have.

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 from 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.

8. Analytical Results

After we analyze your urine, 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 improve your health.

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 that are approved for diagnosis. 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.

Participant Consent Form

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.

9. Withdrawal from Study

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 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 and the project coordinator is Carrie Butler. You may ask any questions you have now. If you have questions later, you may call Dr. Chaudhuri at (801) 965-2470 orCarrie at (801) 347-6739 You may also call our office at 801-538-6191. 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 UDOH 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 UDOH IRB will also 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 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.

Participant Consent Form

Basic Rights of Public Health Investigation Participants

Any person asked to take part as a participant in a public health investigation, or any person asked to consent to such participation on behalf of another, is entitled to receive a list of rights written in a language in which the person is fluent.

The rights below are the rights of every person who is asked to be in this public health investigation. As an investigation participant, I have the following rights:

1. To be told what the investigation is trying to find out,

2. To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,

3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for investigation purposes,

4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be.

5. To be told of other choices I have and how they may be better or worse than being in the investigation,

6. To be allowed to ask any questions concerning the investigation both before agreeing to be involved and during the course of the investigation,

7. To be told what sort of medical treatment is available if any complications arise,

8. To refuse to participate at all or to change my mind about participation after the investigation has started. This decision will not affect my right to receive the care I would receive if I were not in the investigation,

9. To receive a copy of the signed and dated consent form,

10. To be free of pressure when considering whether I wish to agree to be in the investigation.

Participant Consent Form

Possible Unintended Consequences

This document provides some examples of things that you might experience by participating in the Four Corners States Biomonitoring Consortium studies. These examples are not all of the possibilities. If your experiences are different from those listed here, please let us know about them.

After reviewing your laboratory results you may choose to:

- Install a water treatment system to remove metals from the water. We will send you some information about water treatment systems that are affective in removing the metals from your system. You may want to verify the results we send you with some additional testing. You will be responsible for the cost for additional testing to determine what system you need. You will be responsible for the costs to install and maintain a water treatment system.

- Connect to a public water system and stop using your well for drinking water. This may require some changes in your home plumbing and the installation of underground pipes to make the connection. You will be responsible to work with your local public water service to make this connection. You will be responsible for the costs of switching to a public water system and any plumbing that needs to be done to make that switch.

- Work with your health care provider for some additional testing and treatment. We will send you some recommendations on what kinds of additional evaluation and testing you may want to have as a follow-up. You will be responsible to set up appointments with your health care provider for any additional medical evaluation you may want to have. You will be responsible for all of the costs of testing, evaluation and treatment that you get from your health care provider.

- Change household food and water storage containers because the containers contain excessive amounts of free phthalates. We will send you some information on how to identify phthalate free containers. You will be responsible for acquiring new phthalate free containers. You will be responsible for discarding old containers.

- Change your use of personal and lawn care products and services that result in exposure to hazardous chemicals. You will be responsible for any changes in the costs of alternative products and services.

- Work with your community to change agricultural or industrial practices that are resulting in your exposure to hazardous chemicals.

- Identify and avoid high risk areas that you typically like to visit due to the use of hazardous chemicals in those areas.

This list of unintended consequences of participation in our study was prepared on December 8, 2014. This list may change as we become aware of additional consequences and add those to the list.

Participant Consent Form

PARTICIPANT ID LABEL

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.

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

I have read and understand the participant consent, potential unintended consequences and participant rights.

_____ Signature

_____ Date

Participant Consent Form

Participant Certification

PARTICIPANT ID LABEL

Participant's Name:_____

Participant's Street Address:_____

_____

Participant's Mailing Address (if different):_____

_____

Participant's Phone Number:_____ Participant's DOB: ____/____/_____

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: _____