Consent Form Approval: This form is approved by the New Mexico State University (NMSU) Institutional Review Board (IRB), which was utilized by the New Mexico Department of Health (NMDOH), effective July 27, 2015 and valid through August 31, 2019.

State-based Public Health Laboratory Biomonitoring Program for the Four Corners States (Arizona, Colorado, New Mexico, Utah) Biomonitoring Consortium

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CONSENT FORM FOR ADULT (≥ 18 YEARS OLD) PARTICIPANTS

1. Project Description

In partnership with the Four Corners States Biomonitoring Consortium (4CSBC), the New Mexico Department of Health (NMDOH) is conducting this study to better understand how people may be exposed to some chemicals. When you are exposed to chemicals, your body will release those chemicals (for example, metals) or their break down products (also known as metabolites) into your urine. We will measure the amount of metals and metabolites in your urine. This will then tell us how much chemical you were exposed to. Your laboratory results along with the results of all the other participants in the study will help us understand how people are exposed to those chemicals. This, in turn, will help us understand what needs to be done to prevent high exposures and protect your health. The chemicals we are interested in checking for include: [Check those that apply]

□ Heavy metal (arsenic, cadmium, manganese, mercury, selenium, uranium) contaminants in private well drinking water

Metabolites: arsenic, cadmium, manganese, mercury, selenium, uranium

□ 2,4-dichlorophenoxyacetic acid (2,4-D) containing herbicide

Metabolite: 2,4-dichlorophenol (2,4-DCP)

□ p-dichlorobenzene (p-DCB), a contaminant found in disinfectants, deodorants and some kinds of pesticides

Metabolite: 2,5-dichlorophenol (2,5-DCP)

□ Phthalate contaminants in food and domestic products

Metabolites (up to 17): mono-benzyl phthalate (MBzP), mono-n-butyl phthalate (MnBP), mono-isobutyl phthalate (MiBP), mono-ethyl phthalate (MEP), mono-isonoyl phthalate (MiNP), mono-methyl phthalate (MMP), mono-n-octyl phthalate (MOP), mono-(3-carboxypropyl) phthalate (MCPP), mono-2-ethylhexyl phthalate (MEHP), mono-(2-ethyl-5-hydroxyhexyl) phthalate (MEHHP), mono-(2-ethyl-5-oxohexyl) phthalate (MEOHP), mono-(2-ethyl-5-carboxypentyl) phthalate (MECPP), mono-(carboxyoctyl) phthalate (MCOP), mono-(carboxynonyl) phthalate (MCNP), cyclohexane-1,2-dicarboxylic acid- monocarboxy isooctyl esther (MCOCH), cyclohexane-1,2-dicarboxylic acid-mono(oxo-isononyl) esther (MONCH), cyclohexane-1,2-dicarboxylic acid-mono(hydroxy-isononyl) esther (MHNCH)

□ Pyrethroid-containing insecticides

Metabolites (up to 3): 3-phenoxybenzoic acid (3-PBA), 4-Fluoro-3-phenoxybenzoic acid (4-F-3-PBA), trans-3-(2,2-Dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (trans-DCCA)

□ Creatinine. This metabolite is used to measure how concentrated your urine is. It helps us interpret your results.

2.
Procedures

Before we include you in this study, we have asked you some questions. Those questions helped us know if you are eligible for this study. Based on those questions you are eligible to participate. If you agree to take part in this study, we will ask you to:

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

2.2 Answer the eligibility questions.

2.3 Answer the questions about your home and play activities. This will include questions about your health, habits, and activities inside your home and outdoor. This will take about 30-35 minutes.

2.4 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 metals and 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. Any remaining urine will be destroyed when the project is finished.

2.5 Store the urine sample in your refrigerator, until we pick it up. [Cross out if not applicable]

2.6 Be home at the time we agree to pick up your urine and water samples. [Cross out if not applicable]

2.7 Be at the scheduled time at a sample collection location to give us your urine and water samples. [Cross out if not applicable]

3. Discomforts and Risks

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

The questions we will ask you are personal, but you may refuse to answer any questions you do not wish to. Giving a urine sample will take a few minutes and should not be uncomfortable to you.

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.

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

This study may result in new knowledge about chemicals exposures in your home. That knowledge may result in some unintended consequences. Examples of things that you might experience are listed below but 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: [Cross out if not applicable]

- Install a water treatment system to remove metals from the water. We will send you some information about water treatment systems that are effective in removing the metals from your well water. You may want to verify the results we send you with some additional testing. You will be responsible for the cost of additional testing to determine what type of water treatment 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 for working 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 offer your health care provider some recommendations on what kinds of additional evaluation and testing you may need to have as a follow-up. You will be responsible for setting 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 high amounts of 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.

4.
Benefits

We will learn more about how people are being exposed to chemicals in the environment. This will help us make better policies to protect public health, including your health.

Being in this project may benefit you and others around you, as a result of what we learn from this project. We will send you a copy of your personal results so you will know the levels of chemicals/metabolites in your urine and your water. [Cross out “and your water” if not applicable]

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

5. 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 5U88EH001153. The study period is from September 1, 2014 through August 31, 2019.

6. 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. If you perform any actions to improve your water quality, you will have to pay for those improvements [Cross out if not applicable]. Those costs are not covered by this study.

7. Analytical Results

After we analyze your urine and water, we will provide you a copy of the results. [Cross out "and water" if not applicable] 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 for reducing your exposure to the chemicals that have been described in this form, which may lead to improved health.

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.

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.

8. Right to Refuse or Withdraw 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 and sign this form, you have the right to stop at any time without any negative effects to you. You may refuse to answer any of the questions on the survey. 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 principal 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 study director is Heidi Krapfl. You may ask any questions you have now. If you have questions later, you may call Dr. Chaudhuri at (801) 965- 2470 or Ms. Krapfl at (505) 476-3577. You may also call our office at 505-476-1734.

If you have any questions about your rights as a research subject, please contact the Institutional Review Board (IRB) Chair, through the Office of Research Compliance at New Mexico State University at (575) 646-7177 or at ovpr@nmsu.edu.

You/your full legal guardian [Cross out if not applicable] must sign the consent form to be part in this study. You/your full legal guardian [Cross out if not applicable] will be given a copy of this form to keep.

9. Confidentiality
Protection

If you participate in this study, we will keep your individual information confidential. The survey answers and water and urine sample test results will be linked to your name and contact information, so we will be able to provide results back to you, and then the information will be de-identified, as stated in the paragraph below. No one else will have the right to look at your information.

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

10.
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 not be penalized or lose my benefits and 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:

_____ the eligibility survey, as described in Section 2.2 above. (initial)

_____ the exposure assessment questionnaire, as described in Section 2.3 above. (initial)

_____ collect, store and provide a urine sample to the study staff as described in Sections 2.4 (initial) through 2.7 above, to be analyzed for the metals and metabolites of the environmental

contaminants indicated in Section 2.

_____ collect, store and provide an additional urine sample for laboratory quality control (initial) purposes, as described in Section 2.4 above.

_____ collect, store and provide a water sample from your private drinking water well, to (initial) study staff as described in Sections 2 above. The drinking water will be analyzed for

heavy metals and will be used to relate drinking water exposure risk to the level of urinary metal levels. [Cross out if not applicable]

Participant Certification

Participant's Name:_____

Participant's Street

Address:_____

_____

_____

Participant's Mailing Address (if different):_____

_____

_____

Well Coordinates:

_____

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:_____

signatur e

Print name:

_____