Attachment 5. Example Consent/Assent Form and Sample Collection Instructions

# **U.S. Department of Health and Human Services**

# **Agency for Toxic Substances and Disease Registry**

# **Exposure Investigation**

# **Lane County, Oregon**

# **Adult Consent Form for Urine Testing**

WHO ARE WE AND WHY ARE WE DOING THIS EXPOSURE INVESTIGATION (EI)?

We are from the Agency for Toxic Substances and Disease Registry (ATSDR), a sister agency to the Centers for Disease Control and Prevention (CDC). The purpose of the EI is to determine whether people who live near a Highway 36 herbicide spray area are being exposed to herbicides. The purpose of the EI is to determine whether people who live near a Highway 36 herbicide spray area are currently being exposed to the herbicides, 2,4-D and atrazine.

We are inviting you to have your urine tested for 2,4-D and atrazine and six of its breakdown products.

We will only test your urine for these chemicals.

#### WHAT IS INVOLVED IN THIS TESTING?

We will give you a plastic cup to collect a urine sample. We will tell you how to collect your sample. It should take 5 minutes or less for you to collect your urine sample.

#### WHAT ARE THE BENEFITS FROM BEING IN THIS EI?

By being part of this EI, you will find out if you may have been recently exposed to these herbicides and how your exposure compares to others in the U.S.

This test will not tell you if your health may be harmed by these exposures.

There is no cost to you for this testing.

#### WHAT ARE THE RISKS OF THIS EI?

There is no risk from donating a urine sample

Some people may feel uncomfortable about having their urine tested for chemicals. Some people may be concerned over their test results.

#### WILL I BE PAID?

You will not be paid for being in this EI.

#### WHAT ABOUT MY PRIVACY?

We will protect your privacy as much as the law allows. We will give you an identification (ID) number. This number, not your name, will go on your urine sample. We will not use your name in any report we write. We will keep a record of your name, address, and ID number so that we can send you the test results. Your name and address will be kept in a password-protected computer. Copies of your consent form will be kept in a locked file cabinet.

After we complete the EI, your urine sample will be destroyed.

#### HOW WILL I GET MY TEST RESULTS

We will mail your test results to you 3-4 months after your sample is collected. We will also give you a telephone number that you can call to discuss your test results or request a copy for your family doctor. ATSDR does not provide any follow-up medical care or evaluation.

#### MAY WE SHARE YOUR TEST RESULTS?

Sharing the test results with other agencies may help us to understand how people might be exposed to these herbicides. May we share these test results with other Federal and State health and environmental agencies?

YES	_ NO	

#### WHAT IF I DON'T WANT TO DO THIS?

You are free to choose whether or not you want to be part of this testing. If you agree to be tested, you may change your mind at any time and drop out without penalty. You must sign this consent form to be tested.

## WHOM DO I CONTACT IF I HAVE QUESTIONS?

If you have any questions about this testing, you can ask us now. If you have questions

later, contact the Project Officer, Dr. Kenneth Orloff, at ATSDR at 770-488-0735 or 888-232-4636 or send him an e-mail at KEO1@CDC.GOV.

If you have questions about your rights as part of this EI, please call the CDC Human Research Protection Office at 1-800-584-8814. Leave a message with your name and telephone number and say that you are calling about the Highway 36 EI. Someone will return your call.

# **VOLUNTARY CONSENT**

about this testing and my questions have been at any time. I will be given copy of this form t	answered. I know I can change my mind
Participant's Signature	Date
Participant's Printed Name	
Age Gender	
Address	
Telephone number	
Lab ID Number	
I have read the consent form to the person nanabout the investigation and had the questions a	
Signature of person administering consent for	m
Printed name of person administering consent	form
Date	

# **U.S. Department of Health and Human Services**

# **Agency for Toxic Substances and Disease Registry**

### **Exposure Investigation**

# Lane County, Oregon

# Parental Permission Form for Urine Testing for Children Less than 7 Years of Age

WHO ARE WE AND WHY ARE WE DOING THIS EXPOSURE INVESTIGATION (EI)?

We are from the Agency for Toxic Substances and Disease Registry (ATSDR), a sister agency to the Centers for Disease Control and Prevention (CDC). The purpose of the EI is to determine whether people who live near a Highway 36 herbicide spray area are currently being exposed to the herbicides, 2,4-D and atrazine.

We are inviting your child to have his/her urine tested for 2,4-D and atrazine and six of its break- down products.

We will only test your child's urine for these chemicals.

#### WHAT IS INVOLVED IN THIS TESTING?

We will give you a plastic cup to collect your child's urine sample. We will tell you how to collect the sample. It should take 5 minutes or less for you to collect the urine sample.

#### WHAT ARE THE BENEFITS FROM BEING IN THIS EI?

By being part of this EI, you will find out if your child may have been recently exposed to these pesticides and how those exposures compare to others in the U.S.

This test will not tell you if your child's health may be harmed by these exposures.

There is no cost to you for testing your child.

#### WHAT ARE THE RISKS OF THIS EI?

There is no risk from donating a urine sample. However, your child may feel uncomfortable about having their urine tested for chemicals. Some people may be concerned over their test results.

#### WILL I BE PAID?

Neither you nor your child will be paid or receive any type of compensation for being in this EI.

#### WHAT ABOUT MY CHILD'S PRIVACY?

We will protect your child's privacy as much as the law allows. We will give your child an identification (ID) number. This number, not your child's name, will go on the urine sample. We will not use your child's name in any report we write. We will keep a record of your child's name, address, and ID number so that we can send you the test result. Your child's name and address will be kept in a password-protected computer. Copies of your child's consent form will be kept in a locked file cabinet.

After we complete the EI, your child's urine sample will be destroyed.

#### HOW WILL I GET MY CHILD'S TEST RESULTS

We will mail your child's test results to you 3-4 months after the sample is collected. We will also give you a telephone number that you can call to discuss the test results or request a copy for your child's doctor. ATSDR does not provide any follow-up medical care or evaluation.

#### MAY WE SHARE YOUR CHILD'S RESULTS?

Sharing the test results with other agencies may help us to understand how people might be exposed to these herbicides. May we share these test results with other Federal and State health and environmental agencies?

YES	NO	
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#### WHOM DO I CONTACT IF I HAVE QUESTIONS?

If you have any questions about this testing, you can ask us now. If you have questions later, contact the Project Officer, Dr. Kenneth Orloff, at ATSDR at 770-488-0735/888-232-4636 or send an e-mail to KEO1@CDC.GOV.

If you have questions about your rights as part of this EI, please call the CDC Human Research Protection Office at 1-800-584-8814. Leave a message with your name and telephone number and say that you are calling about the Highway 36 EI. Someone will return your call.

#### PARENTAL PERMISSION

I have read this form or it has been read to me. I have had a chance to ask questions

about this testing and my questions have been answered. I agree that my child can be part of this testing. I know I, or my child, can change our minds at any time. I will be given a copy of this form to keep.

# **SIGNATURE** I give permission for my child to be tested. Printed Name of Child Signature of Parent Date Printed Name of Parent Age of child Gender of child Address of child: Telephone number \_\_\_\_\_\_ Lab ID Number \_\_\_\_\_ I have read the consent form to the person named above. He/she has asked questions about the investigation and had the questions answered. Signature of person administering consent form Printed name of person administering consent form

Date

# **U.S. Department of Health and Human Services**

# **Agency for Toxic Substances and Disease Registry**

## **Exposure Investigation**

## **Lane County, Oregon**

# Assent Form for Urine Testing for Children 7 to less than 18 Years of Age

# WHO ARE WE AND WHY ARE WE DOING THIS EXPOSURE INVESTIGATION (EI)?

We are from the Agency for Toxic Substances and Disease Registry (ATSDR), a sister agency to the Centers for Disease Control and Prevention (CDC). The purpose of the EI is to determine whether people who live near a Highway 36 herbicide spray area are currently being exposed to the herbicides, 2,4-D and atrazine.

We are inviting you to have your urine tested for 2,4-D and atrazine and six of its breakdown products.

We will only test your urine for these chemicals.

#### WHAT IS INVOLVED IN THIS TESTING?

We will give you a plastic cup to collect a urine sample. We will tell you how to collect your sample. It should take 5 minutes or less for you to collect your urine sample.

#### WHAT ARE THE BENEFITS FROM BEING IN THIS EI?

By being part of this EI, you will find out if you may have been recently exposed to these pesticides and how your exposure compares to others in the U.S.

This test will not tell you if your health may be harmed by these exposures.

There is no cost to you for this testing.

#### WHAT ARE THE RISKS OF THIS EI?

There is no risk from donating a urine sample. Some people may feel uncomfortable about having their urine tested for chemicals. Some people may be concerned over their test results.

#### WILL I BE PAID?

You will not be paid for being in this EI.

#### WHAT ABOUT MY PRIVACY?

We will protect your privacy as much as the law allows. We will give you an identification (ID) number. This number, not your name, will go on your urine sample. We will not use your name in any report we write. We will keep a record of your name, address, and ID number so that we can send you the test result. Your name and address will be kept in a password-protected computer. Copies of your consent form will be kept in a locked file cabinet.

After we complete the EI, your sample will be destroyed.

#### HOW WILL I GET TEST RESULTS

We will mail your test results to you 3-4 months after the sample is collected. We will also give you a telephone number that you can call to discuss the test results or request a copy for your family doctor. ATSDR does not provide any follow-up medical care or evaluation.

#### **ASSENT**

Your parents said it is all right for you to have this test. You don't have to if you don't want to.

#### MAY WE SHARE YOUR TEST RESULTS?

Sharing the test results with other agencies may help us to understand how people might be exposed to these herbicides. May we share these test results with other Federal and State health and environmental agencies?

YES	NO	

#### WHAT IF I HAVE QUESTIONS?

If you have questions, you can ask us now. You can talk with your parents if you want. If you have questions later, ask your parent. They can call us for answers.

#### **SIGNATURE**

I have read this form or it has been read to me. I have had a chance to ask questions about this testing and my questions have been answered. I agree to be part of this testing. I know I can change my mind at any time. I will be given a copy of this form to keep.

Signature of Minor		Date
Printed Name of Minor		
Signature of Parent		
Age of Participant	Gender of Partic	cipant
Address:		
Telephone number		
Lab ID Number		
I have read the consent form to the about the investigation and had the		He/she has asked questions
Signature of person administering o	consent form	_
Printed name of person administeri	ng consent form	_
Date		_

#### **Urine Collection Instructions**

Urine collection cups (which hold at least 120 ml) will be provided for each participant. Label each cup with a bar-coded specimen ID label. Instruct each study participant to do the following for a clean-catch urine collection.

- Wash hands and air dry.
- Do not remove the cap from the specimen cup until ready to void.
- Place the cap turned inside-upwards on a clean and stable surface while collecting urine.
- Collect at least 30-40 ml of urine in the cup; do not touch the inside of the cup or cap at any time.
- Recap the specimen cup.
- Return the cup to the ATSDR/OPEH staff person.