

Attachment 5

Example Assent/Consent Forms

Anaconda Smelter EI Parental Permission/Assent/Consent/ Forms

PRIVACY ACT STATEMENT

FOR

Anaconda, Montana Exposure Investigation – Blood Lead and Urine Arsenic Testing

This statement provides the notice required by the Privacy Act of 1974 (5 USC § 552a(e)(3)).

- **Authority:** The Agency for Toxic Substances and Disease Registry (ATSDR) has the authority to collect this information under the “Comprehensive Environmental Response, Compensation, and Liability Act of 1980” (CERCLA) as amended by “Superfund Amendments and Reauthorization Act of 1986” (SARA) (42 U.S.C. 9601, 9604).
- **Purpose:** ATSDR is conducting this assessment to study your exposure to lead and arsenic in the Anaconda community as a result of past smelter activities. ATSDR is collecting this information on you or your child/ward for:
 - Adult consent, parental permission, and child assent to participate in questionnaires, and blood and urine collections.
 - Sending your or your child’s/ward’s testing results back to you.
- **Routine Uses:**
 - ATSDR may disclose these records to the local health department to provide follow-up, as needed, for blood lead results.
 - Other routine uses as described in Statement of Records Notice (SORN) No. 09-19-0001 - “Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances.” See <https://www.gpo.gov/fdsys/pkg/FR-2011-01-25/pdf/2010-33004.pdf>.
- **Disclosure:** Providing this information is voluntary. ATSDR needs this information for you or your child/ward to take part in the study. ATSDR may not include incomplete records in the data analysis. ATSDR needs up-to-date contact information to send your or your child’s/ward’s study results.

**Adult Consent Form for Blood and Urine Testing
ATSDR Exposure Investigation (EI)
Anaconda, MT**

Who are we?

- We are from a federal public health agency, the Agency for Toxic Substances and Disease Registry (ATSDR)

Who are we working with?

- Region 8 Environmental Protection Agency (EPA)
- Anaconda Deer Lodge County (ADLC) Health Department
- Montana Department of Public Health and Human Services (MDPHHS)

Why we are doing this Exposure Investigation (EI)?

- We are doing this EI to respond to community concerns about lead and arsenic in the environment and to help people find out if they are exposed
- We are testing lead in blood samples and arsenic in urine samples

What are we asking you to do?

- You are invited to have your blood tested for lead, and urine tested for arsenic.
- There is **NO COST** to you for the testing.
- Collect a urine sample at home and bring it to the blood collection location.
- Complete a brief questionnaire with that will ask questions regarding how you may be exposed to lead and arsenic.
- Allow a licensed phlebotomist to take a sample of your blood.

What is included in my participation?

There are three parts to your participation.

1. Urine Collection and Testing for Arsenic

- The first morning urine sample that you collected at home and froze was brought to the blood testing location.
- We will send your urine to a lab to test it for arsenic.
- **The urine will not be tested for drugs, alcohol or HIV.**

2. Answer a Short Questionnaire

- We will ask you some questions about your home and how you might be exposed to lead and arsenic.
- This should take about 20 minutes.

3. Blood Collection and Testing for Lead

- We will collect less than 1 teaspoon (3 milliliters) from a vein in your arm.
- This will take 10 minutes or less.
- We will send your blood to a lab to test it for lead.
- **The blood will not be tested for drugs, alcohol or HIV.**

What will happen to any leftover blood or urine after testing is finished?

- The blood and urine will not be used for anything else.
- The lab will throw out any leftover blood and urine.

When will you get the test results?

- You will get your test results by mail about 12 weeks after testing.

What are the benefits of being in this EI?

- You will know the levels of lead in your blood and arsenic in your urine.
- If you are found to have high levels of lead or arsenic, ATSDR and ADLC will recommend you follow-up with your physician and will provide you with information that will help you reduce contact with lead and arsenic.

What are the risks of this EI?

- The needle stick might hurt a little.
- Some bruising may happen where the blood is taken.
- You may feel a little lightheaded for a short time.
- If you are pregnant there is no risk to the pregnancy from the blood collection.

How will we protect your privacy?

- We will protect your privacy as much as the law allows.
 - Montana law requires that we report blood lead levels to the ADLC health department if the result is greater than 5 µg/dL.
 - Montana law requires that information given to the state may be made public if someone asks them for the information but your name and address will not be released.
 - We will share the results with other agencies only with your permission. We will require our government partners to treat your information as private.
- We will give you an identification (ID) number.
 - Your ID number, not your name, will go on the tube of blood and urine sample.
 - We will keep a record, under lock-and-key, of your name, address, and ID number. The information will be used by ATSDR to link the results to each person and send your blood and urine test results to you.
- We will not use your name in any report we write. Only group information that does not include individual names will be reported.

Lab ID Number _____

Certification of Consent Form Administrator:

I read the consent form to the person named above. He/she had the opportunity to ask questions about the Exposure Investigation and had the questions answered.

Signature of person administering the consent

Parental Permission Form for Blood and Urine Testing
Children younger than 18 years of age
ATSDR Exposure Investigation (EI)
Anaconda, Montana

Who are we?

- We are from a federal public health agency, the Agency for Toxic Substances and Disease Registry (ATSDR)

Who are we working with?

- Region 8 Environmental Protection Agency (EPA)
- Anaconda Deer Lodge County (ADLC) Health Department
- Montana Department of Public Health and Human Service (MDPHSS)

Why we are doing this Exposure Investigation (EI)?

- We are doing this EI to respond to community concerns about lead and arsenic in the environment and to help people find out if they are exposed
- We are testing lead in blood samples and arsenic in urine samples

What do we want you to do?

- Your child/ward is invited to have his/her blood tested for lead and urine tested for arsenic.
- There is **NO COST** to you for the testing of your child/ward.
- Collect your child's/ward's urine sample at home and bring it to the blood collection location.
- Complete a brief questionnaire with that will ask questions regarding how your child/ward may be exposed to lead and arsenic.
- Allow a licensed phlebotomist to take a sample of your child's/ward's blood.

What is included in my child's/ward's participation?

There are three parts to your participation.

1. Urine Collection and Testing for Arsenic

- a. The first morning urine sample from your child/ward that you collected at home and froze was brought to the blood testing location.
- b. We will send your child's/ward's urine to a lab to test it for arsenic.
- c. **The urine will not be tested for drugs, alcohol or HIV.**

2. Answer a Short Questionnaire

- a. We will ask you some questions about your home and how your child/ward might be exposed to lead and arsenic.
- b. This should take about 20 minutes.

3. Blood Collection and Testing for Lead

- We will collect less than 1 teaspoon (3 milliliters) from a vein in your child's/ward's arm.
- This will take 10 minutes or less.
- We will send your child's/ward's blood to a lab to test it for lead.
- **The blood will not be tested for drugs, alcohol or HIV.**

What will happen to any leftover blood after testing is finished?

- The blood and urine will not be used or tested for anything else.
- The lab will throw out any leftover blood and urine.

When will you get the test results?

- You will get your child's/ward's test results by mail about 12 weeks after testing.

What are the benefits of being in this EI?

- You will know the levels of lead in the blood and arsenic in the urine of your child/ward.
- If your child/ward is found to have high levels of lead or arsenic, ATSDR and ADLC will recommend you follow-up with your child's/ward's physician and will provide you with information that will help you reduce contact with lead and arsenic.

What are the risks of this EI?

- The needle stick might hurt a little.
- Some bruising may happen where the blood is taken.
- Your child/ward may feel a little lightheaded for a short time.

How will we protect your child's/ward's privacy?

- We will protect your child's/ward's privacy as much as the law allows.
 - Montana law requires that we report blood lead levels to the ADLC if the result is greater than 5 µg/dL.
 - Montana law requires that information given to the state may be made public if someone asks them for the information but your name and address will not be released.
 - We will share the results with other agencies only with your permission. We will require our government partners to treat your information as private.

- We will give your child/ward an identification (ID) number.
 - Your child's/ward's ID number, not their name, will go on the tube of blood and urine sample.
 - We will keep a record, under lock-and-key, of your child's/ward's name, address, and ID number. The information will be used by ATSDR to link the results to each person and send your blood and urine test results to you.
- We will not use your child's/ward's name in any report we write. Only group information that does not include individual names will be reported.

When can you ask questions about the testing?

- If you have any questions about this testing, you can ask us now.
- If you have questions later, you can call:
 - **Dr. Luly Rosales-Guevara at 770-488-0744**
 - **Dr. Matt Karwowski at 404-718-5867**
 - **The Anaconda Exposure Investigation toll free number (888) 892-1320**

Parental/Guardian Voluntary Permission

- I agree to have my child/ward tested.
 - I agree to answer questions about my child/ward.
 - I was given the chance to ask questions on behalf of my child/ward. I feel my questions have been answered.
 - I know that having these tests done is my choice for my child.
 - I know that even though we agreed to this testing, my child/ward may leave at any time without penalty.
- a. Regardless of the results, may we share the test result with other federal, state, and local health and environmental agencies? YES / NO**
(please circle one)
- b. If the results are 5 µg/dL or greater, can we provide your information to the Pediatric Environmental Health Specialty Unit (PEHSU), and may they contact you for follow-up? YES / NO (please circle one)**

Signature

I give permission for my child/ward to be tested and agree to answer questions about my child/ward.

Printed name of child

Age

Sex of child

Signature of parent/guardian

Date

Printed name of parent/guardian

Address of Child _____

Telephone _____

Lab ID Number _____

Certification of Permission Form Administrator:

I read the permission form to the person named above. He/she had the opportunity to ask questions about the Exposure Investigation and had the questions answered.

Signature of person administering permission

Attachment 5C:

Assent Form for Children younger than 18 Years of Age
Flesch-Kincaid Reading level – 6.6

Assent Form for Blood and Urine Testing
Children between 7 and 17 years of age
ATSDR Exposure Investigation (EI)
Anaconda, Montana

Who are we?

- We are from a federal public health agency, the Agency for Toxic Substances and Disease Registry (ATSDR)

Who are we working with?

- Region 8 Environmental Protection Agency (EPA)
- Anaconda Deer Lodge County (ADLC) Health Department
- Montana Department of Public Health and Human Service (MDPHHS)

Why we are doing this Exposure Investigation (EI)?

- We are doing this EI to respond to community concerns about lead and arsenic in the environment and to help people find out if they are exposed
- We are testing lead in blood samples and arsenic in urine samples

What are we asking you to do?

- You are invited to have your blood tested for lead and urine tested for arsenic.
- There is **NO COST** to you or your parents for the testing.
- Collect a urine sample at home and bring it to the blood collection location.
- Complete a brief questionnaire with that will ask questions regarding how you may be exposed to lead and arsenic.
- Allow a licensed phlebotomist to take a sample of your blood.

What is included in my participation?

There are three parts to your participation.

1. Urine Collection and Testing for Arsenic

- a. The first morning urine sample that you collected at home and froze was brought to the blood testing location.
- b. We will send your urine to a lab to test it for arsenic.
- c. **The blood will not be tested for drugs, alcohol or HIV.**

2. Answer a Short Questionnaire

- a. We will ask you some questions about how you might be exposed to lead and arsenic. Your parents can help you answer the questions on the form.
- b. This should take about 20 minutes

3. Blood Collection and Testing for Lead

- a. We will collect less than 1 teaspoon (3 milliliters) from a vein in your arm.
- b. This will take 10 minutes or less.
- c. We will send your blood to a lab to test it for lead.
- d. The urine will not be tested for drugs, alcohol or HIV.**

What will happen to any leftover blood after testing is finished?

- The blood and urine will not be used or tested for anything else.
- The lab will throw out any leftover blood and urine.

When will you get the test results?

- Your parents will get your test results by mail about 12 weeks after testing.

What are the benefits of being in this EI?

- You and your parents will know the levels of lead in your blood and arsenic in your urine.
- If you are found to have high levels of lead or arsenic, ATSDR and ADLC will recommend you follow-up with your physician and will provide you with information that will help you reduce contact with lead and arsenic.

What are the risks of this EI?

- The needle stick might hurt a little.
- Some bruising may happen where the blood is taken.
- You may feel a little lightheaded for a short time.

How will we protect your privacy?

- We will protect your privacy as much as the law allows.
 - Montana law requires that we report blood lead levels to the ADLC if the result is greater than 5 µg/dL.
 - Montana law requires that information given to the state may be made public if someone asks them for the information but your name and address will not be released.

- o We will share the results with other agencies only with your permission. We will require our government partners to treat your information as private.
- We will give you an identification (ID) number.
 - o Your ID number, not your name, will go on the tube of blood and urine sample.
 - o We will keep a record, under lock-and-key, of your name, address, and ID number. The information will be used by ATSDR to link the results to each person and send your blood and urine test results to your parents.
- We will not use your name in any report we write. Only group information that does not include individual names will be reported.

When can you ask questions about the testing?

- If you have any questions about this testing, you can ask us now.
- If you have questions later, you can call:
 - o **Dr. Luly Rosales-Guevara at 770-488-0744**
 - o **Dr. Matt Karwowski at 404-718-5867**
 - o **The Anaconda Exposure Investigation toll free number (888) 892-1320**

Child Assent

- Your parent/guardian said it is all right for you to have the blood and urine tests.
- Your parent/guardian said it is all right for you to answer some questions.
- You don't have to have these tests to answer questions if you don't want to.

Voluntary Assent

- I agree to be tested.
- I agree to answer questions.
- I was given the chance to ask questions and feel my questions were answered.
- I know that having these tests done is my choice.
- I know that even though I have agreed to this testing, I may leave at any time without penalty.

Signature

I agree to be tested and to answer questions.

| | | |
|---|--------------|--------------|
| Printed name of child | Age of child | Sex of child |
| Signature or written name of child in child's handwriting | Date | |

Printed name of parent/guardian

Address of child _____ Telephone _____

Lab ID Number _____

Certification of Assent Form Administrator:

I read the assent form to the person named above. He/she had the opportunity to ask questions about the Exposure Investigation and had the questions answered.

Signature of person administering the assent

