

## **Study Consent Form**

The Community Health Impacts from Mining Exposure (CHIME) Study is being conducted as a collaborative effort between Joanne Hild and Jane Sellen, Sierra Streams Institute (SSI) and Peggy Reynolds, the Cancer Prevention Institute of California (CPIC), with funding from the California Breast Cancer Research Program.

### **Why am I being asked to participate in this project?**

This pilot project is being done to begin the process of learning whether residents of Gold Country have higher levels of certain metals, particularly arsenic and cadmium, in their bodies than people living in areas that do not have a history of gold mining. We will explore whether levels of these metals as measured in urine are related to your age, race or ethnicity, level of education completed, length of residency in Gold Country, daily activities, recreational activities, how far you live from mine waste, and other characteristics. We will also collect toenail clippings, which can reflect longer exposure for some metals, and store them for follow-up studies that may be suggested from the urine results.

Approximately 60 women residing in Western Nevada County will be asked to complete a questionnaire and provide an overnight urine specimen and clipped toenails. We are seeking women participants because research has shown that arsenic and cadmium may effect estrogen in women's bodies, and arsenic and cadmium are metals that may be at higher concentration near mining areas. The lab that will test for cadmium and arsenic in urine does so as part of a larger test for ten additional metals (chromium, cobalt, lead, manganese, mercury, molybdenum, selenium, thallium, tungsten, uranium). All these naturally occurring metals are present in the environment and are found in trace amounts in people. Some are necessary for good health, but in general little is known about potential health risks from the low levels found in most people. Very high levels of these metals, which can result from industrial accidents or other unusual circumstances, are known to cause health problems, but we do not expect to find very high levels of these metals in people simply because they live in a mining area.

With this background information, please keep in mind that all measurements from samples are for research only and not for the diagnosis, prevention or treatment of any disease. Based on results from national studies, we know that we all have chemicals in our bodies. For many chemicals there has not been enough research to make any predictions about potential health risks.

In this pilot study, participants can choose to be informed about the metals being measured in their urine. Returning individual results of this kind has not been common in past research in the United States for fear of causing distress in participants. However, after careful consideration, and in the spirit of respect for research participants and collaboration between researchers and communities that are concerned about their environment, this study is approved to return the results of the urine testing. As this is a pilot (preliminary) study, the researchers do not know at this

time if or when the toenail clippings will be tested for trace metals, so in considering participation, it is best to assume that those results will not be available. It is the intention of the researchers to provide a summary of individual results of future toenail testing, if feasible.

**What will I be asked to do?**

If you choose to participate in the project please do the following:

1. Sign this consent form indicating that you have read this form and agree to participate.
2. Complete a self-administered questionnaire, answering questions about your:
  - age
  - race/ethnicity
  - education
  - height and weight
  - cigarette smoking history
  - use of vitamin supplements
  - occupation
  - current residential address and addresses you lived at prior to current address
  - residence on a dirt road, consumption of well water
  - recreational activities such as dirt biking, OHV use, and hiking
  - home gardening and consumption of home-grown produce
  - consumption of locally-caught fish.

For the purpose of planning for further studies in the community, we will ask you about your willingness to provide a blood specimen in the future in order to obtain levels of metals in blood as well as genetic information.

3. Provide a sample from your first morning urine. This urine will be used to measure the levels of cadmium and arsenic, and other metals. We are providing instructions for the collection, storage, and mailing of your urine sample. In order to minimize potential interference from a nontoxic form of arsenic contained in seafood, you will be requested to refrain from consuming seafood 72 hours prior to the collection of your urine specimen. In the unlikely event that the laboratory results from your first sample could be unclear we may ask you to provide a second urine sample.

4. Provide a sample of your toenail clippings using the enclosed nail clipper. These clippings will be stored for follow-up studies if indicated by the study results from the measurements in urine.

5. Mail the consent form, completed questionnaire and toenail clipping samples in the provided pre-paid mailing envelope to the Cancer Prevention Institute of California. Drop off the urine sample in the provided addressed container to SSI, or, if you are

unable to deliver the urine sample, call SSI at the number provided to request pick up by study staff.

6. Participate in a community debriefing session where we will share with you the summary results of the study, give information on interpreting personal measures, and invite you to give feedback about your participation in the study. Individual results will be mailed to you after the debriefing session if you choose to receive them. You do not have to attend the debriefing session if you prefer to remain anonymous.

**Are there any risks involved with taking part in the project?**

- Providing a urine and toenail sample poses no physical risk. Some questions in the questionnaire may be sensitive and you have the right to choose not to answer any question. We will safeguard your personal information to minimize any risk of breach of privacy and confidentiality associated with participation.
- Based on the results of national and other studies, it is very likely that the metals we are testing will be detected in your urine. There has not been enough research to make any predictions about potential disease risks from exposure to arsenic or cadmium. If your urinary levels for the metals tested are found to be elevated, we will retest your urine specimen. The urine specimen measures short-term exposure and may change depending on your recent diet. If your retest level remains elevated, you will be contacted by study staff for further follow-up, who will help you locate resources and further information.
- The health implications of exposure to many metals, particularly arsenic and cadmium, are not well known. Just finding these metals in your urine does not mean that you will develop any disease, but you may experience some emotional distress as a result of learning these findings. You will have the opportunity to discuss your results with study staff. You may also contact your personal physician if you have questions or concerns about your findings.

**Do I have to pay anything to take part in the project? Will I be compensated?**

**What will I get out of taking part in the project?**

- There are no costs to you for participating. You will receive a \$40 check for completing the study. This will be sent 2-4 weeks after we receive your completed questionnaire and samples.
- You will not receive any other direct benefits from participating in this study. It is our hope that knowledge gained from this study will lead to a better understanding of the levels of cadmium, arsenic and other metals in Gold Country residents and factors related to measured levels of these metals. We also hope you will gain a sense of satisfaction for contributing to this research.

**Who will know that I took part in the project?**

- Your name will not be released to anyone and will only be available to study researchers Joanne Hild and Jane Sellen at Sierra Streams Institute and Dr. Peggy Reynolds at CPIC. All personal information obtained in this study will be kept confidential and will be available only to Dr. Reynolds and study staff at CPIC. A study identification number will be assigned to your questionnaire

information and urine and toenail clipping samples. Your personal information will never appear on any reports from the study. All materials containing information about human subjects will be stored in secure locked cabinets at CPIC. Electronic data files containing subjects' identifying information will be maintained on password-protected computers at CPIC.

**Do I have to participate? Can I stop being in the project whenever I want?**

- Your participation in this study is completely voluntary. If you enroll in the study, you will always have the right to withdraw at any time, to decline to answer any particular question and to not provide a urine or toenail-clipping sample. Your participation, your refusal to participate, or your withdrawal will not affect you or your rights in any way.

**How will my questionnaire information and urine and toenail clipping samples be used?**

- The questionnaire information you provide will only be used for the purposes of research. This information will not be given to anyone outside of the group of scientists conducting this study. In the future, your questionnaire information may be used for further study.
- Your urine and toenail clipping samples will only be used for the purposes of research. Individual results will not be given to anyone outside of the group of scientists conducting this study. The samples will be stored in locked freezers at CPIC and the State Environmental Health Laboratory for future use in further research. Samples will be labeled using a study identification number, not with your name.
- You will not be contacted for additional permission to use your questionnaire information or urine and toenail samples for future research. However, in the event these are used for future research, an Institutional Review Board (a committee concerned with the protection of research participants) will review any such research.
- The results of any future testing will not be given to you or to your doctor, and will not be added to your medical record.
- Samples will be stored until they are used up or destroyed. If you want us to destroy leftover samples, you can contact us and we will destroy what is left.

**Who should I contact if I have any questions about the project or my participation?**

- For any questions concerning this study or if you are not satisfied with the manner in which this study is being operated we encourage you to contact the Research Directors:
  - Joanne Hild (email: [joanne@sierrastreamsinstitute.org](mailto:joanne@sierrastreamsinstitute.org) or phone: 530-265-6090, ext. 200)
  - Jane Sellen (email: [jane@sierrastreamsinstitute.org](mailto:jane@sierrastreamsinstitute.org) or phone: 530-265-6090, ext. 202)
  - Peggy Reynolds (email: [peggy.reynolds@cpic.org](mailto:peggy.reynolds@cpic.org) or phone: 510-608-5000)

- You may also contact SSI investigators by mail: Sierra Streams Institute, 431 Uren Street, Suite C, Nevada City, CA 95959, or Dr. Reynolds at the Cancer Prevention Institute of California, 2201 Walnut Avenue – Suite 300, Fremont CA 94538.
- If you have questions regarding your rights as a study participant or want to report any complaints or injuries, please contact the Legal and Regulatory Affairs Office, Institutional Review Board of CPIC, 2201 Walnut Avenue, Suite #300, Fremont, CA 94538 or at (510) 608-5140 or by email at [IRBAdministrator@cpic.org](mailto:IRBAdministrator@cpic.org).

By signing below, you indicate that you have read this form (or someone has read it to you), received acceptable answers to your questions, and have agreed to participate in the study, as indicated above. You will receive a copy of this consent form.

Thank you for your participation.

Please check here if you might be willing to provide a blood sample in the future for further study

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date