

Columbia University Consent Form

Attached to Protocol: IRB-AAAA1411

Protocol Approval Date:

**Principal Investigator: patrick louchouarn
(pl2065)**

Protocol Expiration Date:

**IRB Protocol Title: Assessing the Differential Impact of Exposure to
Arsenic in Hopewell Township, NJ**

Consent Number: CF-AAAA1105

Participation Duration: 15-20 mins

Anticipated Number of Subjects: 100

Contact

| <u>Contact</u> | <u>Title</u> | <u>Telephone</u> | <u>Pager</u> | <u>CellPhones</u> |
|--------------------|---------------------|------------------|--------------|-------------------|
| patrick louchouarn | Associate Professor | 212-854-0479 | | |
| Williams Bryan | Associate Professor | 520-626-3406 | | |

Research Purpose

This aim of this research is to determine the quality of the drinking water sources with a particular emphasis on naturally occurring heavy metals found in certain ground water systems. We will attempt to relate observed levels of heavy metals (i.e. arsenic and related metals) to aquifer conditions (pH and alkalinity) and hydrogeological conditions within your community. We will also determine the source and amount of water used by individuals within your community and relate that to metal levels in drinking water sources. This project has been originally designed in coordinatin with researchers from the NJ Department of Environmental Protection and scientists from Columbia University's School of International and Public Affairs, University of Tennessee's Medical School, and Rutgers University's Environmental and Occupational Health Science Institute.

Statement of the Research

You are invited to participate in a research study.

The purpose of this consent form is to provide you with the information that you need to decide whether to participate in this research study and to inform you, as completely as possible, of the nature, purpose and risks involved in the study.

The Principal Investigator, or authorized member of the study team will explain to you the purpose of the project study, the procedures to be used, and the potential benefits and risks of your participation. Please ask the investigator or study team member to explain anything that you do not understand.

The consent form is your record of what was discussed, and informs you of your rights as a participant in this research. We ask that you read this consent form completely and ask any questions you may have before agreeing to participate in the study. Do not sign this consent form unless you have received satisfactory answers to all of your questions. You will be given a copy of the consent form to keep.

Risks

Risks

Risks, Stress, or Discomfort: Researchers do not foresee any personal risks associated with participation in this study.

Benefits

Benefits

You will receive a report that details the quality of your drinking water.

Alternative Procedures

The information you provide will be kept confidential; no identifying information will be recorded on the questionnaires. If you participate in the study, your name and/or email address will not be associated with your questionnaire. After the study, all identifying information will be destroyed. No identifying information will be kept or used for any other purposes.

Confidentiality

Although every effort will be made to protect the confidentiality of your records, absolute confidentiality cannot be guaranteed. By signing this document you grant permission for information about you obtained during the study to be made available to:

- The investigator, study staff and other health professionals (if applicable) who may be evaluating the study;
- Authorized representatives of the sponsor of this research (if applicable);
- Columbia University;
- New York Presbyterian Hospital (if applicable);
- Authorized representatives of the National Institutes of Health (“NIH”), Food and Drug Administration (“FDA”), the Office of Human Research Protections (“OHRP”) or other government regulatory agencies (if applicable); and
- Applicable Institutional Review Boards (“IRBs”) that independently review the study to assure adequate protection of research participants, as required by federal regulations.

The investigator, regulatory authorities, IRB and study sponsor may keep the research records indefinitely. If the results of the study are published or presented at a medical or scientific meeting, you will not be identified.

Questions

If you have any questions or concerns about the study, you may contact the Principal Investigator or the emergency contact person listed on this consent form.

If you have any questions about your rights as a subject, you may contact:

Health Sciences Institutional Review Board
Columbia University Health Sciences
722 West 168th Street, 4th Floor
New York, NY 10032

Telephone: (212) 305-5883

OR

Morningside Institutional Review Board
2910 Broadway at West 114th Street
A3-#15 Hogan, Mail Code 4330
New York, NY 10025
Telephone: (212) 854-1324

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.

Voluntary Participation & Early Withdrawal

Your participation in the study is voluntary. You may decide not to participate in the study. If you decide to participate, you are free to withdraw from the study at any time. For your safety, we advise you to tell the investigator if you intend to withdraw. You may be asked to return any unused study drug or return for a follow-up visit.

Your refusal to participate, or your early withdrawal, will not affect any benefits to which you are otherwise entitled from Columbia University or the Sponsor.

Compensation

Financial Incentives

No monetary compensation will be provided for participation in this study.

Additional Information

The information you provide will be kept confidential; no identifying information will be recorded on the questionnaires. If you choose to participate in the study, your name and/or email address will not be associated with your questionnaire. After the study, all identifying information will be destroyed. No identifying information will be kept or used for any other purposes.

Signature

Study Subject

Print Name _____ Signature _____ Date _____

Person Obtaining Consent

Print Name _____ Signature _____ Date _____