1. Project Consent Form – SAMPLE

Part I – Research Participant Information sheet:

A: Purpose of the study:

You are being asked to participate in a research study. The purpose of the study is:

(three sentence description of purpose)

You qualify for this study because you are a healthy adult.

B. Description of the research:

In the ….. Project, we will enroll xx… volunteers. You will be asked to complete a brief questionnaire about your age, residence, work history, exposure to…(list of chemicals)….

Once during the study, a blood sample will be taken to test for YYYY, and a urine sample will be taken to determine levels of ….. Any remaining unused blood and urine will be discarded. The samples and the measurement results will be identifiable, that is they will be labeled with a code number which may be linked to your name only on a single master list kept by Dr. …. . No identifiers will be included in the analysis of the results of this investigation. You will be informed by Dr. …. or one of the investigators of the results of your testing and counseled about the significance of these results. As a volunteer for this study, you may decide that you wish to make public the pooled results of the study as a group or as individuals.

C. Costs/Reimbursements:

None

D. Potential risks and Discomforts:

Participation in this study will not expose you to any significant risks. Blood will be collected by medical staff trained in appropriate blood drawing and safety procedures. You may experience some minor discomfort and may develop a small black and blue mark on your arm. There is also a small chance of infection from blood drawing. There is little or no risk associated with collecting urine samples.

E: Potential Benefits

The direct benefits to you from participation in this study are knowledge about your own blood and urine levels of those chemicals being studied in this project. You will also

receive counseling and an explanation by a physician of the significance of the chemical levels detected in your biospecimens. In addition, your participation will help us better understand the process whereby communities can become engaged in biomonitoring studies.

F: Alternatives to participation

The alternative is your decision not to participate.

G. Confidentiality

Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. Your medical record in connection with this study will be kept confidential to the extent permitted by law.

H: Compensation/Treatment

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr. XXX at telephone number XXX

I. Voluntary participation

Participation in the study is voluntary. If you decide not to participate, this will not affect your ability to receive medical care you would normally receive or to receive any benefits to which you are otherwise entitled.

Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately.

A signed copy of this consent form will be given to you.

J: Termination of Participation

1. You may discontinue participation in the study at any time. Such withdrawal will not affect your ability to receive any benefits which you might otherwise be entitled.

K: Contact person(s)

If you have any questions, at any time, about this research, please contact XXXX.

(Name of Project) Consent for Research Authorization to Participate in Project

This form must be signed by the participant/surrogate and the investigator/delegate

Participant _____(print Name)

2. I hereby volunteer to participate in a biomonitoring project under the supervision of Dr.XXX.
3. 2. I acknowledge that I have read, or had explained to me in a language I understand, the attached consent document and that _XXX has explained to me the nature and purpose of this project. This explanation included a description of the parts of the project that are experimental, the possible discomforts, symptoms, side effects and risks that I might reasonably expect and the possible complications, if any, that I might reasonably experience from both known and unknown causes as a result of my participation in these studies. I have had the opportunity to ask questions I had about the study and all the questions I asked were answered to my satisfaction.

4. I understand that I am free to withdraw this authorization and to discontinue my participation in these studies at any time. The consequences and risks, if any, of withdrawing from the study while it is ongoing have been explained to me. I understand that such withdrawal will not affect my ability to receive any benefits which I might otherwise be entitled.

5. I confirm that I have read, or had read to me, this entire authorization and that all blanks or statements that require completion were, in fact, properly completed before I signed this authorization.

Project volunteer/surrogate_____Date_____

Name_____time_____

Relationship:_____(if signed by surrogate)

Attestation of Principal investigator/delegate:

I have fully explained to the above volunteer the nature and purpose of the above-mentioned project, the possible complications which may arise from both known and unknown causes as a result of thereof and the consequences and risks, if any, if the volunteer decides to discontinue participation. I believe that he/she understands the nature, purposes, and risks of these studies. I have also offered to answer any questions relating to these studies and have fully and completely answered all such questions.

PI/Delegate_____Date_____

Name printed _____Title_____