Hatfield CONSULTANTS

Canadian International Development Agency | Agence canadienne de développement international

APPENDIX A2

Case ID #_____ Sample Id # _____

Informed Consent Document

Regional Capacity Building Program for Health Risk Management of Persistent Organic Pollutants (POPs) in South East Asia:

Blood Sampling

1 TITLE OF THE RESEARCH PROJECT

POPs Project ("POP1406")

2 SPONSOR OF STUDY

This study is sponsored by the World Bank, through the Canadian International Development Agency (CIDA) POPS Fund.

3 NAMES OF THE RESEARCHERS

All researchers are affiliated with Hatfield Consultants and Golder Associates:

- Principal Investigator: Thomas Boivin, M.Sc., R.P. Bio
- Co-Investigators: Sokhem Pech, M.A (Hons). LLM
- Grant Bruce, M.Sc.
- John Wilcockson, M.Sc., R.P. Bio
- Daniel Moats, B.Sc., R.P. Bio
- Jasmin Gee, B.Sc.
- John McKnight, M.Sc.

4 DESCRIPTION OF THE RESEARCH

The main objective of the *Regional Capacity Building Program for Health Risk Management of Persistent Organic Pollutants in South East Asia* is to improve the ability of government agencies in the South East Asia Region to manage POPs and POPs-like chemicals using a health risk-based approach.

A second objective is to improve inter-governmental cooperation on hazardous chemicals issues in the region.

Persistent Organic Pollutants are toxic chemical substances that persist in the environment and bio-accumulate through food webs. The release of these chemicals into the natural environment is increasing and poses a serious threat to human health and the global environment. The project team will use a risk management approach to assess the POPs situation in 4 South-East Asian countries: Lao PDR, Cambodia, Malaysia and Thailand.

The study will investigate the contribution of many potential sources of exposure to POPs chemicals, including: soils, sediments, fish and other food items. Residents living near the contaminated sites, or families of workers, will be the key focus of the study. Subjects invited to participate in this study will be asked to complete a questionnaire and provide a blood and/or breast milk sample. Blood and breast milk samples will be analyzed only for selected POPs chemicals (PCBs, and/or dioxins and furans along with serum lipids, i.e., fats in the blood).

Persons who complete the questionnaire and provide a blood/milk sample will be asked to allow soil or other food samples to be collected for analyses.

5 DESCRIPTION OF HUMAN SUBJECT INVOLVEMENT

You are being asked to participate in this study because you live or work in the vicinity of _____, and/or you were randomly selected.

To be eligible for this study, subjects must be at least 18 years old and must have lived at their current residence continuously for the last 5 years (except for vacations or other absences that total less than 6 months).

Subjects will be asked to complete an interview with a trained interviewer from Hatfield or national POPs focal point. The interview will include questions about residential history, occupational history, recreational activities (e.g., fishing), pregnancy history (for women only), and diet.

Subjects will be asked to provide a blood sample of 80 milliliters. Blood samples will be analyzed only for selected dioxins, furans, PCBs, and serum lipids. No other analyses will be performed on blood samples; any left over blood may be stored or 'banked' for future analyses.

Subjects must meet the following blood/milk sample eligibility criteria:

- Weigh at least 40 kg (90 pounds);
- No chemotherapy in the last 6 months;
- No history of bleeding or clotting disorders;
- Not currently taking blood thinner medications;
- Not currently pregnant;
- Not currently diagnosed or treated for anemia;
- Not currently diagnosed or treated for malaria or dengue fever;
- Not currently diagnosed or treated for Hepatitis A, B or C;
- Not currently diagnosed or treated for HIV Aids; and
- No blood donation within the last 8 weeks.

Please confirm whether you meet the blood sample eligibility criteria by initialing one of the following statements:

- I meet the blood/milk sample eligibility criteria _____
- I do NOT meet the blood/milk sample eligibility criteria _____

If you meet the blood sample eligibility criteria, please confirm whether you want to provide a blood sample for analyses in this study by initialing one of the following statements:

- I want to provide a blood/milk sample_____
- I do NOT want to provide blood/milk sample _____

6 LENGTH OF HUMAN SUBJECT PARTICIPATION

The interview will last approximately 20-30 minutes. There will be only one interview. The interview will be conducted at a time and place that is convenient to the subject. Some subjects may be re-contacted (usually by phone) to verify and/or clarify answers on the questionnaire. Blood sample collection will be scheduled for a time and place that is convenient to the subject. There will be only one blood sample collected, and this should take about 15 minutes.

7 RISKS & DISCOMFORTS OF PARTICIPATION

The only physical risk associated with participation in this study is related to obtaining the blood or milk sample. The blood sample will be obtained by a trained, professional phlebotomist using sterile, disposable equipment. The risks of bleeding, bruising, or infection are small, and similar to having blood drawn at your doctor's office. Some subjects report a feeling of faintness or brief dizziness upon blood donation. However, the volume of blood (80 milliliters) is small, and will be replaced quickly by your body. For comparison, donation of blood normally involves about 500 milliliters, and it is permissible for a healthy person to donate this much blood as often as every 8 weeks.

Breast milk samples (40-50 ml) will also be obtained by trained medical professionals. Samples will be collected by squeezing milk directly from the breast into a pre-cleaned glass jar; the mother can do this herself, with assistance from the medical personnel.

The interview will include questions about residential history, occupational History and diet. The interview does not include questions that might be considered potentially embarrassing (e.g., use of illegal drugs or other criminal behavior).

You are unlikely to benefit directly from participation in this study, except that you can choose to learn the results of tests for dioxins, furans, PCBs and lipids in your blood. However, this study will increase the scientific understanding of how dioxins, furans and PCBs get into people's blood or breast milk in South East Asia.

You should be aware that almost everyone has measurable levels of dioxins, furans and/or PCBs in their blood. And, there is no medical treatment for removing these chemicals from our bodies.

Please indicate whether you want to receive the results of analyses of your Blood/milk for dioxins, furans, PCBs and lipids by initialing one of the following choices:

- I want to receive results of analyses for dioxins, furans, PCBs and lipids in my blood/milk _____

- I do NOT want to receive results of analyses for dioxins, furans, PCBs and lipids in my blood/milk _____

You can change your decision about receiving results by notifying the Principal Investigator in writing.

8 MANAGEMENT OF PHYSICAL INJURY

Should you get physically injured as a result of research-related procedures, the POPS Project team will provide first-aid medical treatment. Additional medical treatment will be provided, if the POPS Project team determines that it is responsible to provide such treatment. However, the POPS Project team does not provide compensation to a person injured while taking part as a subject in research.

9 COSTS TO SUBJECT RESULTING FROM PARTICIPATION IN THE STUDY

There are no costs associated with participation in the questionnaire and blood sampling phase of this study.

10 PAYMENTS TO SUBJECT FOR PARTICIPATION IN THE STUDY

Subjects who agree to participate in this study will be paid $10 USD for completing the questionnaire and providing a blood and/or milk sample. Subjects who provide both a blood and milk sample will be paid $20 USD.

11 CONFIDENTIALITY OF RECORDS/DATA

Individual subjects will not be identified in any reports on this study. Research records will be kept confidential to the extent possible.

The researchers will not make any disclosure of information that would identify you as a participant in this research unless you provide written authorization to the Principal Investigator to do so.

12 CONTACT INFORMATION

If you have questions about this research, you may contact:

Thomas Boivin, M.Sc. R.P. Bio (tboivin@hatfieldgroup.com)

Sokhem Pech, M.A. (spech@hatfieldgroup.com)

13 VOLUNTARY NATURE OF PARTICIPATION

Your participation in this project is voluntary. Even after you sign this informed consent document, you may decide to stop further participation in the study at any time without penalty or loss of benefits to which you may otherwise be entitled. Data and specimens that have already been collected will remain in the study. You may skip or refuse to answer any survey question without affecting your study compensation.

14 DOCUMENTATION OF THE CONSENT

One copy of this document will be kept together with the research records of this study. Also, you will be given a copy to keep.

15 CONSENT OF THE SUBJECT:

I have read [or been informed] of the information given above. Mr. Boivin or his representative has offered to answer any questions I may have concerning the study. I hereby consent to participate in the study.

ADULT SUBJECT OF RESEARCH

_____ _____
Consenting signature Printed Name

_____ _____
Witness signature Printed Name

Date _____