Appendix C - Consent forms

CONSENT FORM

PARENT'S INFORMATION AND CONSENT FOR CHILD'S PARTICIPATION

TITLE: Follow-up Evaluation of Lead Exposure in Children (under 7) in Flin Flon, Manitoba and Creighton, Saskatchewan

SPONSOR: Hudson Bay Mining and Smelting Ltd. (HBMS)

INVESTIGATORS:

Principal Investigator: **Murray Lee, MD, MPH**, Clinical Assistant Professor, University of Calgary Faculty of Medicine (Department of Community Health Sciences) and Partner, Habitat Health Impact Consulting

***Co-Investigators*:** **Celine Pinsent, PhD**, Senior Associate, Goss Gilroy Inc.
Elliot Sigal, President, Intrinsik Environmental Sciences Inc.

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. Please take sufficient time to carefully read this document, and to understand any accompanying information. If you would like more detail about something mentioned within this consent form or information not included in this form please ask. You will receive a copy of this form.

BACKGROUND

As you may be aware, in 2009 a large soils study was recently conducted in Flin Flon and Creighton. The Flin Flon Soils Study had many different parts. Each piece focused on collecting information that could be used to understand how Flin Flon area residents are potentially exposed to metals in their everyday lives. The largest part of the study was a Human Health Risk Assessment which predicted how people are exposed to metals and whether or not these exposures could affect people's health. Another part of the study was the Evaluation of Exposure which measured the actual levels of metal in the blood and urine of children. Although measured blood lead levels in children from the Flin Flon area did not indicate immediate health concerns, the risk management plan that resulted from the 2009 study recommended that a follow-up blood lead study be completed in 2012.

Like the Flin Flon Soils Study, this study is being paid for by Hudson Bay Mining and Smelting Ltd. and is being overseen by a Technical Committee who reviews the technical aspects of the project and a Community Advisory Committee that provides guidance on the participation of the community, what types of questions are viewed as important, and things to consider when

conducting the study. This study will focus on a random sample of children under the age of 7 who live in Flin Flon or Creighton, and who agree to participate in the study. We anticipate that approximately 250 children will participate in the study.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to answer three questions that have been identified as being important to answer in order to understand how much children in Flin Flon and Creighton are exposed lead, and if that level of exposure has changed since 2009. The three specific questions that this study will try to answer are:

1. What is the current level of internal exposure to lead in the child population residing in the Flin Flon Area?
2. Compared to the lead exposure levels measured in 2009, have levels in Flin Flon Area children increased, decreased, or remained the same in 2012?
3. Are the personal factors associated with children's lead exposure measured in 2009 (e.g., place of residence, age, gender) similar in 2012?

WHAT WOULD MY CHILD HAVE TO DO?

Participation in the study will include the following components:

- Interview/questionnaire
- Collection of environmental samples by the study team (household dust, tap water, yard soil)
- Capillary blood sample (collected at a scheduled time at a local clinic)

Interview:
If you and your child decide to participate in this study, you will be asked to participate at your convenience, in an interview at your home or at an alternate location that suits your needs. During the interview, you will be asked questions about the recreational and play activities of your child, hand washing practices, occupations of adults in the home, smoking, household cleaning practices, child's use of medication and vitamin, child's diet and common foods they eat, and various characteristics of your house such as water source, age of house, or renovations. All questions are voluntary, so if you do not wish to answer a question indicate this and the interviewer will just skip to the next question. On average, the interview should take between 30 and 45 minutes, depending on the number of children that are participating in the study from your family.

Environmental Samples:
During the household visit for the interview a study team member will collect samples of paint, house dust, tap water and yard soil for lead analysis. Standard collection protocols will be utilized. Sample collection will be done in a manner to ensure minimal household disruption. Sample collection will occur concurrent to the interview and will not extend the duration of the interview. Environmental sampling results will be provided to the home owner and/or occupant of the house unless otherwise requested.

Capillary blood sample (finger or heel prick)
If your child is under 7 years old (less than 84 months) as of October 31, 2012 he or she will be asked to provide a capillary blood sample at a clinic. A trained medical person will draw the sample from the child's finger (for those over 12 months old) or from the heel (for those under 12 months old). A small sample will be collected and analysed at the same public health laboratory in Quebec. The blood sample will be analysed for lead. We will schedule an appointment with you for the clinic, so you will not have long wait times.

WHAT ARE THE RISKS?

The research team and the ethics review committee have assessed the potential risk associated with your child's participation in this study as ***minimal***. If your child is under the age of seven, the research team will collect a finger-prick or heel-prick (capillary) blood sample from your child to measure the level of lead in their blood. Capillary blood testing is a small prick using a one-time use lancet to collect a small blood sample from your child. Most children will only feel a small prick or stinging sensation, while others may feel more pain. Some children may experience throbbing at the site of the prick.

WILL MY CHILD BENEFIT IF HE/SHE TAKES PART?

No direct benefit is guaranteed to your child from taking part in this study. A possible benefit of participating in the study is identifying the actual level of your child's exposure to lead. You will receive a mailed copy of your child's blood test. We will also send a copy to your child's physician if you provide his/her contact information on this form.

If your child's level of lead is determined to be in a range that requires some type of follow-up we will discuss the results with your child's physician, if you provide consent to do so. The initial recommended follow-up step will be re-testing. In addition, we will request consent to release the initial and follow-up blood test results to the local Medical Officer of Health. This would allow the principal investigator (Dr. Lee) to discuss your child's result directly with your physician and public health officials to arrange proper follow-up (e.g., house inspection; additional sampling of dust, soil, paint; periodic monitoring of child's blood lead levels). If your child does not have a physician, Dr. Lee will be working with a local physician in the community to provide appropriate follow-up for your child, if required. In addition, we will ask permission to use the results from follow-up for study-level reporting. If you choose to provide permission, the results would be grouped together with other results for reporting and no names or other identifiers will be attached.

The community may also benefit by increased awareness of what exposure is occurring among children in the community and what changes may have occurred in exposure levels between 2009 and 2012. In addition, more information about the issue of environmental exposure will help in planning any additional necessary interventions to reduce the health risks associated with exposure to lead.

DO WE HAVE TO PARTICIPATE?

Your child's participation in any or all parts of this study is voluntary. You or your child may decide to withdraw or refuse to answer certain questions or provide samples without penalty or explanation.

WHAT ELSE DOES MY PARTICIPATION INVOLVE?

There are no other requirements for your child's participation in the study, other than what has been described above.

WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?

There is no cost or fee to enter your child into the research study. There is no cost to you, your private medical insurance (if any), or the public health insurance plan for study procedures. If you agree to have your child take part in the study you will not be reimbursed for any personal costs such as transportation costs, parking, etc.

WILL MY CHILD'S RECORDS BE KEPT PRIVATE?

Any personal information collected from you about your child and your child's sample results will remain strictly confidential to the extent permitted by law. Individual information will be available only to your child's physician or a designated local physician (if you complete the information about the physician below), the research team, the research ethics board – IRB Services (an independent committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants) during the course of the study. The researchers will be permitted to share this information beyond those listed above **only** if you provide a separate written consent to release it.

Individuals or households will not be identified in any publication or report resulting from this study. Within seven years of completion of the study, all personal identifiers for the collected information will be destroyed. The individual results (without personal identifiers) will remain in the possession of Goss Gilroy Inc., one of the companies contracted to work on this study.

You have the right to check your study records and request changes if the information is not correct.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing this information and consent form, you consent to the collection, access, use and disclosure of your information as described above.

IF MY CHILD SUFFERS A RESEARCH-RELATED INJURY, WILL HE/SHE BE COMPENSATED?

In the event that your child suffers an injury as a result of participating in this research, you will receive appropriate medical care. The sponsor will cover necessary medical costs not covered by the provincial health plan or your private medical insurance (if any). No compensation will be provided to you by Hudson Bay Mining and Smelting Ltd, or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation and your child's participation in the research project and agree to have your child participate. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities.

If you complete the information about your child's physician or agree to have results forwarded to a designated local physician, this is considered consent to forward a copy of your child's blood sample results, along with the child's name, date of birth, your name, your address, and telephone number to the physician. As well, if you complete this information, you are providing consent to have the Principal Investigator, Dr. Murray Lee, contact the child's or designated physician to discuss his or her results.

You are free to withdraw from the study at any time. If you have further questions concerning matters related to this research, please contact the Principal Investigator, Dr. Murray Lee or the Study Manager, Blair Jackson, at the project office to obtain additional information at (204) XXX-XXXX.

If you have any questions about your rights as a research subject, please contact the committee that reviewed the ethical aspects of this study at: The Director, Human Research Protection Program, IRB Services, 372 Hollandview Trail, Suite 300, Aurora, ON L4G 0A5. You may also call IRB Services, at 1-866-449-8591, or contact IRB Services by email at subjectinquiries@irbservices.com.

A copy of this consent form has been given to you to keep for your records and reference.

Child's Name: _____

Date of Birth: **Day:** _____ **Month:**_____ **Year:** _____

Street Address: _____

Community: _____

Postal Code: _____

Primary Phone Number: _____

Alternate Phone Number: _____

PARENT/GUARDIAN

Name: _____

Signature: _____

Relationship to Child: _____

Date: **Day:** _____ **Month:**_____ **Year:** _____

SIGNATURE OF WITNESS

Name: _____

Signature: _____

Date: **Day:** _____ **Month:**_____ **Year:** _____

SIGNATURE OF INVESTIGATOR/DELIGATE

Name: _____

Signature: _____

Date: **Day:** _____ **Month:**_____ **Year:** _____

CHILD'S PHYSICIAN
Please check one:

- ❑ I do not give my consent to have my child's test results provided to any physician.
- ❑ My child does not have a physician. I give my consent to having my child's test results provided to the local physician in the community who has agreed to follow-up with study participants, if required. I give my consent for Dr. Lee to contact the designated physician to discuss my child's test results, if required.
- ❑ I give my consent to have my child's test results provided to my child's physician and for Dr. Lee to contact the physician to discuss my child's test results, if required. Please see information below.

Physician's Name: _____

Physician's Address: _____

Physician's Phone: _____

ENVIRONMENTAL SAMPLING

- ❑ I do not wish to receive a copy of my environmental test results.