

Blood Borne Pathogens Surveillance Project

Child Assent Information Sheet

Principal Investigator **Dr. B. Ritche** **@ 780 492 3550**

Co-Investigator: **Dr. R. Turner** **@ 780 407 8450**

Co-Investigator: **Dr. J. Akabutu** **@ 780 492 2397**

Nurse Coordinator: **Wilma McClure** **@ 780 407 6588**

Introduction

You and your child have been asked to take part in a research study. It is important to understand the purpose of this study and how it may affect you and your child. This information sheet and consent form is to help you decide if you and your child want to participate in this study or not. Taking part is entirely you and your child's choice. If you, or your child, have any questions that these sheets do not answer, please ask the research nurse and/or the investigator, and they will be happy to answer all your questions.

Background

Since the 1950's, patients with bleeding disorders have been effectively treated with blood and blood products. These treatments have been life saving, and have led to a dramatic improvement in the quality and length of life.

Unfortunately, these treatments have also been complicated by transmission of infectious diseases like Hepatitis and AIDs. The discovery of the blood borne viruses and the methods to remove them from the blood products has largely fixed this problem.

Patients, physicians, and government agencies remain concerned about the possibility of new and unknown agents entering the blood supply and causing problems in the future. There has been intense interest over the last 15 years in the blood clotting genes and their mutation which cause bleeding disorders. This knowledge has become more important recently with the development of genetic treatments for bleeding disorders. The Canadian researchers and Health Canada are interested in identifying the genetic mutation that causes different bleeding disorders as well as which other genetic factors modify the tendency to bleed.

Purpose

The government of Canada, through the Blood Borne Pathogens Division, Population and Public Health Branch of Health Canada has asked the Association of Hemophilia Clinic Directors of Canada (AHCDC) to develop a method to look for known and emerging blood borne diseases.

We want to create and develop a secure bank of blood samples to test for new viruses as they are discovered. We will also study your child's genes to find out what genetic factors cause or modify his/her bleeding disorder. We want to find out what inherited traits makes bleeding problems better or worse, as well as find out what causes his/her bleeding problem.

We require your consent and your child's assent (ages 10-17 years of age) to:

1. Collect and analyze your child's blood sample
2. Share clinical information obtained through the current data bank, CHARMS, with this study
3. Transfer data from the Blood Borne Pathogens Division, Population and Public Health Branch of Health Canada, to the coordinating laboratory center for the purpose of conducting this study.

Procedure

On the day of your child's annual visit, the study nurse and investigator will ask you and your child, if you would both like to participate in this research study. This information sheet and consent form will be reviewed at this time. If you both agree to participate, you will:

- Need to sign the consent form
- Allow the lab personnel to take an additional 3 cc (1/2 tsp) of blood from children 0 – 4 years of age. And 6-14.5 cc of blood (1.5-3 tsp) for all other participants greater than 4 years of age, at this time. This is the only additional test that is needed from your child.

As the results of your blood sample are analyzed, you and your child will be informed of the results. You, or your child, may reverse his/her decision to be involved in this study at any time, for any reason. If you request, any samples and clinical data that have been collected will be destroyed at that time. Please notify your doctor of all changes in your decision, regarding your participation in this study

Re-Consent

We plan to do serial testing of your blood samples. This means that we will need samples of your blood every year. If you agree to participate again next year we will contact you by mail or phone and book an appointment for you to give the next blood samples. We would like to do this every year, until you no longer wish to take part in this project, you expire, or the project ends.

Please remember it is your responsibility to keep the clinic, and your doctor, informed of any name, address, or telephone changes during your participation in this study.

Benefits

Identifying new blood borne agents and those persons affected by these agents is expected to lead to earlier treatment of these new disorders and prevention of further transmission. There may be no direct benefit to your child at this time. However in the future, the information gained in this study may benefit other children.

Discomfort

Your child may get a little pain or bruising where the blood was taken, or faint from having blood drawn.

Risk

Results of testing done in this study will go into your child's clinical record and you will be told of these results. As with any clinical or medical information, the information discovered by this study could make it difficult for your child to obtain an insurance policy in the future.

Confidentiality

All the information learned about your child and all their personal records will remain strictly confidential. Your child will never be named. All reports and documents will be coded with an I.D. number. In addition to the investigators, other appropriate regulatory agencies may have access to your child's records. If the results of this study are used for any type of publication, your child's identity will never be released.

By signing the consent form you give permission to the study staff to access any personally identifiable health information which is under the custody of other health care professionals as deemed necessary for the conduct of the research.

Freedom to withdraw

You and your child may choose to participate in this study, or not. You and your child may also withdraw from this study at any time, for any reason. These decisions will not affect your child's medical care at this, or any other facility.

If you and/or your child decide to withdraw from this study, at any time, for any reason, please call the doctor immediately and tell him so that the study center can remove and discard your child's blood sample, and stop any further participation.

Additional Contact

If you have concerns about your rights as a study participant, you may contact the Patient Relations Office of Capital Health, at 407-1040. This office has no affiliation with the study investigators.

If you have any questions about this study, please call one of the following individuals directly involved with this surveillance project.

<i>Principal Investigator</i>	<i>Dr. B. Ritche</i>	<i>@ 780 492 3550</i>
<i>Co-Investigator:</i>	<i>Dr. R. Turner</i>	<i>@ 780 407 8450</i>
<i>Co-Investigator:</i>	<i>Dr. J. Akabutu</i>	<i>@ 780 492 2397</i>
<i>Nurse Coordinator:</i>	<i>Wilma McClure</i>	<i>@ 780 407 6588</i>

**** This section may or may not be filled out by the child.**
CHILD'S CONSENT FORM: (*ASSENT is between the ages of 10-17)

- I wish to participate in this study: Age of child: _____ Yes No
(This is optional)

Child's Name

Child's Signature

- I am aware that the results of all-future testing will be given to me and my child. Yes No
- I consent my child, to participate in the development of a bank of plasma, DNA, and RNA, to look for known and new blood borne diseases. Yes No
- I consent my child to take part in the search for genetic features that affect the predisposition to disease caused by blood borne pathogens described above. Yes No
- I consent my child to allow the use of any samples left-over from other studies in this project. Yes No
- I consent my child to participate in the research to search for the genetic mutation causing my bleeding disorder, and for other genetic factors which affect my tendency to bleed. Yes No
- In event of death:
 - I wish to have my child's samples destroyed. Yes No
 - I wish to have my child's samples remain in this study for continued participation. Yes No
- Would you and your child be interested in participating next year? Yes No
- May we contact you and your child when the time comes? Yes No

Parent/Legal Guardian

Date

Parent/Legal Guardian signature

Witness Name

Date

Witness Signature

- Once you become of legal age, you are allowed to change this decision at any time, for any reason. Please call your doctor if you decide to change your decision.
- Please keep a copy of this form.

Title of Project: Blood Borne Pathogens Surveillance Project

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To be completed by the parent/legal guardian:

Do you understand that your child has been asked to be in a research study? Yes No

Have you and your child read and received a copy of the attached Information Sheet? Yes No

Do you understand the benefits and risks for your child in taking part in this research study? Yes No

Have you and your child had an opportunity to ask questions and discuss this study? Yes No

Do you and your child understand that you are free to refuse to participate or withdraw from the study at any time? You do not have to give a reason and it will not affect his/her care. Yes No

Do you understand who will have access to your child's records, including personally identifiable health information? Yes No

Do you want the investigator(s) to inform your family doctor that your child is participating in this research study? If so, please provide your doctor's name: Yes No

_____ .

This study was explained to me by: _____

Signature of Child

I consent for my child to take part in this study.

Signature of Parent/Legal Guardian Date Witness

Printed Name

Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily consents to have his/her child participate.

Signature of Investigator or Designee Date

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH SUBJECT