

Blood Borne Pathogens Surveillance Project

Adult Patient Information Sheet

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Introduction

You have been asked to take part in a research study. It is important for you to understand the purpose of this study and how it may affect you. This information sheet and consent form is to help you decide if you want to participate in this study or not. Taking part is entirely your choice. If you 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. However 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 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 genes to find what genetic factors cause or modify your bleeding disorder. We want to find out what inherited traits makes bleeding problems better or worse, as well as find out what causes your bleeding problem.

We require your consent to collect blood samples, and to share clinical information obtained through the current data bank, CHARMS, with this study. We also require your consent to 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 annual visit, the study nurse and doctor will ask you if you would like to participate in this research study. This information sheet and consent form will be reviewed at this time. If you agree to participate, you will then be asked to:

- Sign the informed consent form
- Allow the lab personnel to take an additional 6-14.5 cc of blood (1.5-3 tsp) in addition to your routine blood tests

As the results of your blood sample are analyzed, you will be informed of the results. You may reverse your 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 you at this time. However in the future, the information gained in this study may benefit others.

Discomfort

The only associated discomfort is with getting your blood taken. There may be temporary pain and bruising at the puncture site.

Risk

Results of testing done in this study will go into your 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 you to obtain an insurance policy in the future.

Confidentiality

Personal records relating to this study will be kept confidential. Any research data collected about you during this study will not identify you by name, only by your initials and a coded number. Your name will not be disclosed outside the research clinic. Any report published as a result of this study will not identify you by name.

For this study, the study doctor may need to access your personal health records for health information such as past medical history and test results. He/she may also need to contact your family physician and your other health care providers to obtain additional medical information. The health information

collected as part of this study will be kept confidential unless release is required by law, and will be used only for the purpose of the research study. 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.

The health information collected in this study will need to be checked from time to time against your medical records by representatives from the sponsoring drug company (name, if applicable). In addition to the investigators(s) and the sponsor representatives, the Health Research Ethics Board, the Health Products and Food Branch of Health Canada (if applicable), the United States Food and Drug Administration (if applicable), and/or other foreign regulatory agencies may have access to your records to monitor the research and verify the accuracy of study data.

By signing the consent form you give permission for the collection, use and disclosure of your medical records. In Canada, study information is required to be kept for 25 years. Even if you withdraw from the study, the medical information which is obtained from you for study purposes will not be destroyed. You have a right to check your health records and request changes if your personal information is incorrect.

Freedom to withdraw

You are free to withdraw from the research study at any time, and your continuing medical care will not be affected in any way. If the study is not undertaken or if it is discontinued at any time, the quality of your medical care will not be affected. If any knowledge gained from this or any other study becomes available which could influence your decision to continue in the study, you will be promptly informed.

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

- I am aware that the results of all future testing will be given to me Yes No
- In event of death:
 1. I wish to have my samples destroyed Yes No
 2. I wish to have my samples remain in the study for future continued participation Yes No
- I consent 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 to search for genetic features that affect the predisposition to disease caused by blood borne pathogens described above. Yes No
- I consent to the use of any samples left-over from other studies in this project. Yes No
- I consent 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
- Would you be interested in participating next year? Yes No
- May we contact you and call you when the time comes? Yes No

Patients Name

Date

Patients Signature

Witness Name

Date

Witness Signature

