Summary of Protocol: Blood Borne Pathogens Surveillance Project


Association of Hemophilia Clinic Directors of Canada (AHCDC)

Overview:

The government of Canada, through the Blood Borne Pathogens Division, Population and Public Health Branch of Health Canada has asked that the Association of Hemophilia Clinic Directors of Canada (AHCDC) develop a method to look for known and emerging blood borne diseases. The project described here will establish a secure bank of samples to test for known blood borne infectious agents, and genetic changes causing or modifying the clotting disease and to be available for testing for newly discovered viruses and clotting gene changes as they are found.

Study Objectives

The objectives of this project are:

1. To collect blood samples for a sample bank of plasma, DNA, and RNA to screen for known and emerging blood borne diseases.

2. To identify the mutation leading to each consenting patient’s bleeding disorder, and to characterize other known and yet to be discovered genes that affect blood coagulation.

3. To collect encoded, non-nominal data into a central database from an electronic chart known as CHARMS, which is currently kept in each hemophilia clinic in Canada to correlate with results from 1 and 2.

Hypothesis

We hypothesize that discovering the new and emerging blood borne diseases and their clinical significance will be beneficial to patients and our healthcare system. This requires access to samples and clinical data in a timely fashion. Identifying these new agents and their significance is critical to providing a safe and valid tool for developing a system to remove these viruses before transmission may occur, which will enable many patients to receive safer blood products.

Sample Size

The sample size will be based on the total number of hemophiliac patients documented here in Canada with the help of the Blood Borne Pathogens Division, Population and
Public Health Branch of Health Canada. We expect to enroll 3,500 patients throughout Canada.

**Study Population**

**Patient Inclusion Criteria**

To participate in this surveillance project, the patient must have:

- A diagnosed hereditary bleeding disorder.
- Be between the ages of 0 – 85.
- Consent to be informed of all future testing results as they are discovered through this surveillance project.

A person must be willing to be informed of all the results which may be available as testing is done. Participation is not accepted if the participant refuses this. This is not an option. Therefore consent reads:

> I am aware that the results of all-future testing will be given to me.

**Patient Exclusion Criteria:**

The following is the list of the exclusion criteria:

- Persons who are unable to consent due to mental inability will not be able to participate in this study.
- Person who is known/diagnosed alcoholic may not participate in this study.
- Person that the investigator, and/or the co-investigator deems as unfit for this trial may not be enrolled in this study.
- Patients, who refuse to consent or participate, will not be enrolled in this study.
- Patients, who do not consent to be completely informed of all testing results as they are discovered, will not be eligible for this study.

**Study Design**

**Consent**

Patients are sent a letter, approximately one month before their Annual Comprehensive Hematology Clinic appointment to remind them of their appointment date and time. At this time, we will attach an introduction letter to inform them of the Blood Borne Pathogens Project.

We will also include the patient information sheet and the informed consent form. There will be clear instructions not to sign the informed consent sheet, until the participant is at
the Annual Comprehensive Hematology Clinic on the day of their annual visit, either with the nurse coordinator, or the physician investigator. On the scheduled day of their Annual Comprehensive Hematology Clinic appointment, the research nurse will be present to obtain consent from the persons who wish to participate in this study. The patient may also be enrolled on any visit to the clinic or associated hospital.

The patient information sheet and consent form will be completely reviewed and then signed at this time.

The Physician Investigators and/or the Nurse Coordinator may obtain and receive telephone consent for minors.

If the patient does not consent to participate in this study, at this time, we would like to ask them a few questions regarding their decision. They have the choice to either answer these questions or not. Please see attached Refusal Form.

**Laboratory Evaluation**

In addition to the routine blood sample, qualified, and certified personnel will take an additional sample of blood.

For infants and children between the ages of 0 - 4 years of age, only 2.5 cc of blood will be taken, an equivalent of 1/2 teaspoon.

For all other participants age five or greater, 5-12.5 cc of blood will be taken, an equivalent of 1.0-2.5 teaspoons. The sample will be obtained at this visit, and will be labeled and shipped (Per Protocol/ Lab Manual/ Standard of Practice) to the study centre:

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**Length of Study**

In order to conduct serial testing of the blood samples for the purpose of this Surveillance Project, we would like to request re-consent every year for all participants, until such time as:

1. Patient no longer wants to participate in this project.  
2. The project ends.  
3. Patient expires.
Re-consent

i. We would like to ask all participants, if they are willing to re-consent to continued yearly participation in this surveillance project.

ii. If they re-consent, their participation would require additional blood samples every year during their annual visit.

iii. If they agree, they will be contacted by phone or mail when the designated time has expired, (no less than 8 months after the blood samples have been given) and an appointment will be booked for the participants to visit the clinic and give the blood samples.

iv. When the participant arrives at the clinic, the nurse coordinator will review the study and have them re-consent by way of signing the Re-Consent form. (See attached form)

v. If the participant, changes his/her mind at this time and refuses continued participation, then the nurse/or physician will document this and ask if the study may keep the previous samples of blood and any clinical information collected and proceed as they had initially consented for, one year prior.

vi. If the person refuses to allow continued use of their samples, this will be documented. Then the samples and any clinical information collected are destroyed. This will be documented on the Destruction of Samples Form.

All documentation will be maintained with the patient’s case report forms.

Sample Collection/Identification

Blood collected from people with bleeding disorders will be labeled with a registry number and sent to a central surveillance lab, currently in Edmonton. No other identifying information will be on the tubes, so that the sample bank will know no information that can identify the patient. In the lab, the blood will be processed to collect plasma (the liquid that the cells float in), DNA and RNA (the genetic material of the cells). These samples will be given a new number known as an inventory number, which will be used for further testing, (so that no information that can link the sample to a patient) when samples are made available to any testing facility.