



PATIENT INFORMATION SHEET

The Collection Of Blood, Urine, Stool, DNA, Ascites Fluid, Liver Tissue And Intestinal Tissue Samples Deposited Into A Secure Bio-Bank Along With Subject Demographics And Health Information Deposited Into A Secure Data-Bank That Will Collectively Be Used To Examine The Roles Of Bacteria And Viruses In Gastrointestinal And Liver Diseases.

Principal Investigator: Dr. Richard N Fedorak (780) 248-1037

Sub-Investigators: Dr. V. Bain, Dr. A. Bala, Dr. D. Cox, Dr. L. Dieleman, Dr. K. Gutfreund, Dr. D. Kao, Dr. E. Lalor, Dr. A. Lazarescu, Dr. J. Liu, Dr. M. Ma, Dr. K. Madsen, Dr. A. Mason, Dr. J. McKaigney, Dr. A. Montano-Loza, Dr. G. Sandha, Dr. E. Semlacher, Dr. P. Tandon, Dr. S. van Zanten, Dr. K. Wong, Dr. W. Wong, Ms. M. Carbonneau

INTRODUCTION

This study is about the collection and banking of human blood, urine, stool, deoxyribonucleic acid (DNA; tissue for genetic testing), ascites fluid, (obtained during routine paracentesis) liver tissue (obtained during routine liver biopsies) and intestinal tissue samples [obtained during routine gastrointestinal endoscopy] and data-banking of your de-identified demographic and clinical information. This is being done to examine the roles of bacteria and viruses in the cause and treatment of gastrointestinal and liver diseases.

This document may contain words that you do not understand. You should feel free to ask the study doctor or the study staff to explain any words or information that you do not clearly understand.

PURPOSE OF THIS STUDY

You are being asked to participate in this study because you are going to be seen at the portal hypertension clinic. Intestinal biopsies that may be taken during the endoscopy, and liver biopsy that may rarely be required, can be used by researchers to study the roles of bacteria and viruses in gastrointestinal and liver diseases. You will be asked to donate a sample of blood, urine, stool, ascites fluid (if you have some drained) and DNA that will help researchers identify why some people get the diseases from bacteria and viruses and other people don't. The purpose of storing the blood, urine, ascites fluid, DNA, liver and intestinal tissues is to allow the study of groups of samples, from several patients, at one time.

The Health Research Ethics Board at the University of Alberta will be asked to review and approve any use of your intestinal tissue, blood, urine, ascites fluid and DNA samples for future research studies

DESCRIPTION OF THIS STUDY

If you take part in this study three things will happen:

- 1. You will be asked to answer questions regarding your past and current health status. The information from these questions will be kept de-identified and stored in a locked data-bank.
2. You will be asked to have 20mls (4 teaspoon) of blood drawn from a vein in your arm. You will also be asked to provide a sample of urine, stool and ascites fluid (if you have some drained). The blood, urine, stool, ascites fluid and DNA samples will be sent to our bio-bank and de-identified storage for study at a later time.

3. If you require an endoscopy, you will be asked to have up to 32 intestinal biopsies taken from the stomach and/or bowel in addition to those taken for diagnostic purposes (this is the usual number of biopsies taken for this procedure). After the biopsy, the intestinal tissue and DNA samples will be frozen and stored in the bio-bank in a de-identified manner.
4. If you require a liver biopsy, you will be asked to have one tissue sample taken from the liver in addition to those taken for diagnostic purposes (this is the usual number of biopsies taken for this procedure). After the biopsy, the liver tissue and DNA samples will be frozen and stored in the bio-bank in a de-identified manner.
5. You will be asked to permit a review of your hospital and clinic records for information such as age, gender, medical conditions, medications, surgical history and family history. This will help us to determine the cause of inflammatory bowel diseases.

The information in the data-bank and samples in the bio-bank will be used to discover the role of bacteria and viruses in the cause and treatment of gastrointestinal and liver diseases.

POSSIBLE RISKS

Blood Testing: It is possible you may experience mild pain, bleeding, discoloration or bruising, and/or an infection at the place where the needle enters the vein for the blood test. It is therefore important that you immediately notify one of the individuals listed in the "Contacts" section on page 4 if you experience a worsening of any of the above listed side effects or have any concerns.

Endoscopy and Routine Biopsy: You are undergoing a routine endoscopy required by your doctor. As part of this routine test you may have a feeling of pressure, bloating, or cramping. The doctor may give you medication through a vein to help you relax and better tolerate any discomfort from the procedure. Endoscopy is generally very safe. Intestinal biopsies are performed as a routine during endoscopy. One very rare complication of biopsies is bleeding that may occur from the site of the biopsy. It is usually minor and stops on its own or can be controlled through the endoscope. Extremely rarely, blood transfusions or surgery to stop bleeding may be required.

Ascites Fluid: You may be undergoing a routine therapeutic paracentesis (draining of ascites fluid from your abdomen through a needle) required by your doctor. As part of this routine test you may have a feeling of pressure or some pain. The doctor may give you medication injected under the skin to help you better tolerate any discomfort from the procedure. Paracentesis is generally very safe and fluid is routinely removed. One very rare complication of paracentesis is bleeding that may occur from any area inside that the needle may contact. It can be minor and stop on its own or in extremely rare cases, blood transfusions or surgery to stop bleeding may be required. Some other rare complications are infection, low blood pressure and kidney dysfunction. If any of these happen, you may be admitted to hospital and be required to take antibiotics to treat the infection or have other treatments depending on the complication.

Liver Biopsy: You may be undergoing a liver biopsy (removing a sample of liver tissue through a needle) required by your doctor. As part of this routine test you may have a feeling of pressure or some pain. The doctor may give you medication injected under the skin to help you better tolerate any discomfort from the procedure. In most instances, a liver biopsy is obtained quickly with no problems. As noted, you may feel some discomfort in the right side or shoulder. Internal bleeding can sometimes occur, as can a leak of bile from the liver or gallbladder. These problems are rare and can usually be handled without the need for surgery. Another complication that is rare is infection. If this happens, you will likely be admitted to hospital and be required to take antibiotics to treat the infection.

Patients will not be included in this study if they are at an increased risk of bleeding from intestinal biopsies. This includes patients with hemophilia, other blood clotting disorders and patients chronically using coumadin, heparin or other anticoagulant therapies.

POSSIBLE BENEFITS

Participation in this study may be of no direct benefit to you personally. However, it is hoped that what is learned here will be of future benefit to others suffering from gastrointestinal and liver diseases.

COMPENSATION FOR INJURY

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. By signing this consent form you are not releasing the investigator(s), or institution, from their legal and professional responsibilities.

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 may need to be checked from time to time against your medical records by the Health Research Ethics Board.

By signing the consent form you give permission for the collection, use and disclosure of your medical records. At the University of Alberta we will keep all study documents for a period of twenty-five (25) years. Even if you withdraw from the study, the medical information which is obtained from you for study purposes before you withdraw your permission will not be destroyed. You have a right to check your health records and request changes if your personal information is incorrect.

RIGHT TO WITHDRAW FROM STUDY

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. You may request that your de-identified samples be destroyed at any time but you need to be aware that information already obtained from the study and or analysis of these samples will not be destroyed.

INFORMATION REGARDING GENETIC/DNA TESTING

Part of this study involves the collection of one additional blood sample (2 teaspoons) and extracting the DNA from the tissue for genetic (DNA) testing and health information for other related research. Doctors named on this Consent Form will conduct the genetic research described in this document. The genetic testing is critical to the success of the project. However, to preserve your identity, your name and identification will not be attached to the genetic testing.

Cells in the human body contain genes composed of deoxyribonucleic acid (DNA). The genes contain key instructions for cell function and help determine the characteristics of each individual. Genetic research uses DNA samples from healthy and ill individuals to do the following:

- a) study the causes of human diseases
- b) help understand how different individuals respond to medicines and to bacteria and viruses in the environment
- c) obtain information to help develop new methods to diagnose and treat diseases

The study doctor/nurse will replace your name and other identifiers with a code number and the code will be kept in a separate location available only to the study doctor/nurse. The coded blood and tissues DNA samples and your de-identified health information that you will provide when you answer the questionnaire will be securely stored in a blood and tissue bank and data bank located here at the University of Alberta for up to 25 years, for use in genetic studies. These future studies will be important in the discovery of new treatments for gastrointestinal disorders.

The study doctors have adopted strict privacy and confidentiality procedures for this research.

The DNA obtained from your blood/tissue sample may be used for the development of new therapies, diagnostic methods, medicines, treatments, information materials and other developments which may be patented or otherwise have commercial value to the study doctors and the University of Alberta.

By consenting to participate in this research, you authorize the use of your sample blood and tissue for the research described above. You will not receive financial benefits or compensation should this occur. Further research projects must be reviewed by the local Research Ethics Board.

We will not ask you to give further consent for the use of your, coded de-identified samples. There is no direct benefit to you in having these tests performed. Results of the tests will be available to the research team and will not be provided to you, or any other physician who is treating you or may treat you in the future.

Although results from this research may be published, or otherwise disclosed to outside parties within Canada, the European Union, the United States or other countries, for review or analysis by authorized personnel the results will not identify you in any way. You will never be contacted by any of the above mentioned parties.

When (or before) the 25 year period ends, your blood and tissue DNA sample will be destroyed. Your coded de-identified health and medical information collected for the study will be retained.

CONTACTS

If you have any questions about the study, you may contact:

Dr. Richard Fedorak or the GI Research Nurse: Wanda MacDonald, LPN, at (780) 248-1037
or Liver Nurse Practitioner: Michelle Carbonneau, NP at (780)492-3052

If you have concerns about your rights as a study participant, you may contact the Patient Relations Office of the Alberta Health Services, at (780) 342-8080. This office has no affiliation with the study investigators



PATIENT CONSENT FORM
The Collection Of Blood, Urine, Stool, DNA Ascites Fluid, Liver Tissue And Intestinal Tissue Samples Deposited Into A Secure Bio-Bank Along With Subject Demographics And Health Information Deposited Into A Secure Data-Bank That Will Collectively Be Used To Examine The Roles Of Bacteria And Viruses In Gastrointestinal And Liver Diseases.

Principal Investigator: Dr. R. N. Fedorak (780) 248-1037

Sub-Investigators: Dr. V. Bain, Dr. A. Bala, Dr. D. Cox, Dr. L. Dieleman, Dr. K. Gutfreund, Dr. D. Kao, Dr. E. Lalor, Dr. A. Lazarescu, Dr. J. Liu, Dr. M. Ma, Dr. K. Madsen, Dr. A. Mason, Dr. J. McKaigney, Dr. A. Montano-Loza, Dr. G. Sandha, Dr. E. Semlacher, Dr. P. Tandon, Dr. S. van Zanten, Dr. K. Wong, Dr. W. Wong, Ms. M. Carbonneau

- 1) Do you understand that you have been asked to participate in this research study? YES NO
2) Have you read and received a copy of the attached Information Sheet? YES NO
3) Do you understand the benefits and risks involved in taking part in this research study? YES NO
4) Have you had an opportunity to ask questions and discuss this study? YES NO
5) Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care? YES NO
6) Has the issue of confidentiality been explained to you, and do you understand who will have access to your medical records including personally identifiable health information? YES NO

Who explained this study to you? _____

I agree to take part in this study: YES [] NO []

Signature of Research Subject Date Printed Name

Signature of Witness Date Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator Date

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