PARTICIPANT 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. B. Halloran
- Dr. D. Kao
- Dr. C. Karvellas
- Dr. K. Kroeber
- Dr. A. Lazarescu
- Dr. J. Liu
- Dr. M. Ma
- Dr. K. Madsen
- Dr. C. Teshima
- Dr. A. Montano-Loza
- Dr. G. Sandha
- Dr. E. Semlacher
- Dr. P. Tandon
- Dr. R. Sultanian
- Dr. A. Syed
- Dr. J. McKaigney
- Dr. A. Montano-Loza
- Dr. G. Sandha
- Dr. E. Semlacher
- Dr. P. Tandon
- Dr. R. Sultanian
- Dr. A. Syed

INTRODUCTION

You are being asked to participate in this study because you are going to be seen by one of the Gastroenterologist or Hepatologist during your clinic visit or are undergoing an endoscopic procedure. We are trying to develop a “bank” of human tissue, blood and other types of biological samples (for example: 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). These samples when studied in large enough numbers can help us to do research to examine the roles of bacteria and viruses in the cause and treatment of gastrointestinal and liver diseases.

This document will explain the study to you, to help you decide if you want to participate. It may contain words that you do not understand, so please 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

The study involves taking samples of a person’s blood, urine, stool, ascites fluid (if you have some drained) and DNA and storing them in a “repository” or bank. By collecting a large number of samples in a bank like this it allows researchers to study samples from several people at one time. In addition to these samples, we will also ask if we can look at your medical record, to collect some information about your past and current health status that will be “linked” to your samples. As stated above, the information and samples we collected (as above) will be used by various researchers (both here at the University of Alberta and some possibly at other Universities) to try to identify why some people develop these diseases and others do not.

Samples in this bank will be stored without any personal identifiers attached to them (this means things like your name will not be attached to your samples). When a sample goes into the bank we give it a special “code”. All samples and information about you will ONLY be identified by this code, so no researchers that ever use the sample now or in the future, will ever be able to know that the sample came from you. This also means that you will never receive any information about the results from the research on the samples. We will maintain a list that links your sample to your name, but only certain individuals in the research group will have this link, and they will only use it if you ask to have your sample(s) removed in the future.

As we said earlier, researchers from the University of Alberta and possibly even other Universities may ask to have some (de-identified) samples from this repository to use for research about gastrointestinal and liver diseases.
However, any future research using the samples that are stored in this bank will always have been reviewed by a Research Ethics Board before the samples can be accessed by researchers and the samples will never have any personal information about you attached to them.

**STUDY PROCEDURES**

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. We are also asking your permission to review of your hospital and clinic records for information such as age, gender, medical conditions, medications, surgical history and family history.

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, we are asking your permission to take additional biopsies from the stomach and/or bowel in addition to those taken for diagnostic purposes (these additional biopsies will be taken by your physician/specialist performing the biopsy procedure). After the biopsy are collected, the research intestinal tissue and DNA samples will be frozen and stored in the bio-bank in a de-identified manner (without your name/health information attached to them).

4. If you require a liver biopsy, we are asking your permission to take one tissue sample from the liver in addition to those taken for diagnostic purposes. After the biopsy, the research liver tissue and DNA samples will be frozen and stored in the bio-bank in a de-identified manner.

**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 which has already been explained to you. Taking biopsies is part of the routine 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. This study involves taking extra biopsy samples, which means that there is a risk of bleeding with each extra biopsy sample taken, over and above the normal biopsies taken.

**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.

You will not be allowed to be in this study if you are at an increased risk of bleeding from intestinal biopsies. This might occur if you have hemophilia, other blood clotting disorders and/or are chronically using Coumadin, heparin or...
other anticoagulant therapies. It is important to tell us if you have any bleeding disorders and/or are taking blood thinners.

**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 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 will 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. “Your samples and genetic materials, which will be de-identified and not contain any information that could allow them to be linked to you, may be shared with other scientists that we will collaborate with in the future”. If your samples leave the custody of any of the Doctors named on this consent form – it is for the purpose of research only and these samples will never come back to us.

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 CEGIIR Project Manager, Dr. Brian Reuter at (780) 492-3172
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 Research Ethics Office, at (780) 492-2615. This office has no affiliation with the study investigators.
PARTICIPANT 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. B. Halloran
Dr. D. Kao
Dr. C. Karvellas
Dr. K. Kroeker
Dr. A. Lazarescu
Dr. J. Liu
Dr. M. Ma
Dr. K. Madsen
Dr. A. Lazarescu
Dr. J. McKaigney
Dr. E. Semlacher
Dr. P. Tandon
Dr. R. Sultanian
Dr. A. Mason
Dr. J. McKaigney
Dr. A. Montano-Loza
Dr. G. Sandha
Dr. E. Semlacher
Dr. S. van Zanten
Dr. W. Wong
Dr. S. Zepeda
Ms. M. Carbonneau
Ms. M. Harriott
Ms. M. Carbonneau
Ms. M. Harriott
Dr. A. Syed

1) Do you understand that you have been asked to participate in this research study? ☐ ☐
2) Have you read and received a copy of the attached Information Sheet? ☐ ☐
3) Do you understand the benefits and risks involved in taking part in this research study? ☐ ☐
4) Have you had an opportunity to ask questions and discuss this study? ☐ ☐
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? ☐ ☐
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? ☐ ☐

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 Investigator or Delegate                      Date                          Printed Name

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

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