SickKids®
THE HOSPITAL FOR SICK CHILDREN

Participant Name:

DOB:

HSC#:

RELATIVE Consent

Intestinal Disease Biobank: *Genetic, Functional, and Microbial Studies in Intestinal Disease*

Principal Investigator:	Dr. Aleixo Muise	416-813-7735	
Co-Investigators:	Dr. Anne Griffiths	416-813-8757	
	Dr. Thomas Walters	416-813-7734	
	Dr. Peter Church	416-813-6184	
	Dr. Abdul Elkadri	416-813-6184	
	Dr. Cornelia Thöeni	416-813-7654 x328848	
	Dr. Neil Warner	416-813-7654 x328848	
Research Coordinators:	Karoline Fiedler	416-813-6858	karoline.fiedler@sickkids.ca
	Suzan O'Donnell	416-813-8665	suzan.odonnell@sickkids.ca
	Michelle Ouzounis	416-813-8665	michelle.ouzounis@sickkids.ca
	Meagan Perry	416-813-7554	meagan.perry@sickkids.ca
	Jhananiee Subendran	416-813-7654 x201561	jhananiee.subendran@sickkids.ca

Purpose of the Research:

You are being invited to participate in a research project because you have a relative that has been diagnosed with or is suspected to have intestinal disease. The purpose is to create a biobank of biological samples from people with intestinal disease and healthy people for future research. We want to look at your genes and certain information stored in your immune system (called biomarkers) to find the causes of intestinal disease in children.

Knowing about these genes, biomarkers, and how the immune system reacts to gut bacteria will help us find ways to prevent intestinal disease in the future, as well as improve diagnosis, better predict treatment response and long-term outcomes, and develop new treatments that may help children with intestinal disease.

Please take your time to make your decision. Discuss it with your family and friends.

Description of the Research:

1. **Blood Sample:** A small blood sample (about 1-2 tablespoons) will be taken from you once. This can be done when you are already at SickKids with your relative for a routine office visit, procedure, or admission.

2. **Saliva:** You may be asked to provide a saliva (spit) sample.

3. **Buccal (Cheek) Swab:** You may be asked to provide a buccal swab sample. This is done using a cotton swab to gently brush the inside of your cheek.

4. **Stool:** You may be asked to provide a stool sample.

5. **Urine:** You may be asked to provide a urine sample.

6. **Skin Biopsy:** You may be asked to provide a skin biopsy. If you choose to provide this, we will arrange a convenient time to collect the sample. At collection, the area of skin will be sterilized and a small amount of topical anesthetic will be applied with an anesthetic patch. You may feel some pressure or a twisting sensation, but no pain. The area will be in a location where it will not be easily seen and a small bandage will be applied afterwards. The risks (which are extremely rare) include allergic reaction to the local anesthetic, infection at the site of the biopsy or bleeding. Generally, the skin heals easily within 1-2 weeks. In most cases, the area will heal completely over time and will not leave a scar. For some people, the procedure may leave a tiny scar similar in size to a chicken pox scar.

   If you do not want to provide a sample at that time, you may refuse and say "no." You can still be in the rest of the study.

7. Samples will be used to extract DNA/RNA/plasma/biomarkers/protein/cells for genetic and microbial research in intestinal disease. These samples may be stored indefinitely so that as additional genes, biomarkers, and gut bacteria are discovered, their role in intestinal disease can be assessed. In some circumstances, the investigators may wish to use the sample to create a cell line (cells that can continue growing and dividing over time in the laboratory) for the purpose of using the sample over an indefinite period for research. The importance of these samples increases over time as we track the outcome of intestinal disease and treatment.

8. If a sample is unusable for technical reasons, or depleted, you may be asked to provide another sample the next time you are at SickKids. As always, it will be your choice if you wish to provide another sample in future.

9. **Medical Records:** If you have intestinal disease or a related condition, your medical records at SickKids and/or other institution(s) will be reviewed as needed to obtain information about your condition and medical history.

10. You will be re-contacted if needed to obtain follow-up information on your health, although how much of your health information you share with us is entirely optional.

Potential Harms:

Minimal—Blood drawing: There may be a small amount of bleeding when blood is taken from your vein, and there may be slight discomfort and bruising or redness that will usually disappear in a few days.

Potential Discomforts or Inconvenience:

You will not be required to make any extra visits to the hospital or provide extra time commitment to participate in this biobank. All samples can be provided when you are with your relative during a routine office visit or inpatient admission.

Potential Benefits:

To individual participants:

There may be no direct benefit to you or your relative for participating in this biobank. The results of the research will not be provided to you individually. Currently, the significance of the vast majority of variations in these genes is not known. However, genetic testing is ongoing and new research may mean that the interpretation of the test results may change over time. Also, on occasion, in the process of testing for one genetic condition, another genetic alteration may be identified. This is called an incidental finding. If we

discover information that would help you and your health care team to make decisions about your care, or may immediately affect your health, these findings will be reported to your health care provider to discuss with you. Should this happen, repeat testing in a clinical laboratory is recommended to confirm any research results. (If you do not wish to be told about incidental findings that will not immediately affect your healthcare, please tell your doctors. Please also let a biobank team member know. You can do this by writing us a note indicating this choice.)

To society:
Although you may not benefit directly from this biobank, results of the research will be published as a group and will improve the understanding of intestinal disease and may benefit patients in the future. The research may help in developing diagnostic tests and better therapies that can improve the long-term health and well-being of patients with intestinal disease. The results from the research may also result in the development of genetic tests that can be used for screening as well as planning future pregnancies. If such genetic tests become available in future, we will refer the family for appropriate genetics counseling if requested.

Confidentiality:

We will respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless required by law. For example, the law could make us give information about you if a child has been abused, if you have an illness that could spread to others, if you or someone else talks about suicide (killing themselves), or if the court orders us to give them the biobank papers.

If applicable, your health record will be accessed as described above for the purpose of this research. Only information related to intestinal disease will be reviewed. For instance, this may include test results for procedures related to intestinal disease, treatment you may be taking for intestinal disease, or your symptoms associated with intestinal disease.

SickKids Clinical Research Monitors may see your health record to check on the biobank. By signing this consent form, you agree to let these people look at your records. We will put a copy of this research consent form in your patient health record and give you a copy as well.

Any genetic information obtained during this research and associated with you will remain strictly confidential. Once we take a sample, we will assign it a unique identifier (a combination of letters and numbers) to be used for the duration of the biobank. It will not be possible for anyone other than the research team to link your name or any other information identifying you with the sample(s) you provide. Only the de-identified sample will be sent to the laboratory for analysis. Results of genetic tests related to this biobank will not be entered in your medical record.

The data produced from this biobank will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. This could include external research team members. The biobank researchers will keep records linking your identity with your sample(s) for an indefinite period. Following completion of the biobank, the data will be kept as long as required then destroyed as required by SickKids policy. Published results will not reveal your identity.

Storage of Research Samples

All samples will be stored for research in intestinal and related disorders. We may also want to analyze your sample(s) as part of other research activities or share portions of it with other researchers working in other institutions. If we distribute your sample to other researchers, the sample will be coded and sent anonymously without your name, medical record number, or other identifiers.

Reimbursement:
There will be no costs to you, or payments made to you, for participating in this biobank. There are no special visits to the hospital expected during this project. All samples will be taken at the time of a routine clinic visit, procedure, or hospital admission.

Participation:
It is your choice to take part in this biobank. If you give your consent to be in this biobank and then change your mind, you can end your participation at any time and no further samples will be collected. You may also request (verbally or in writing) that your stored genetic and tissue samples be destroyed. The care your relative gets at SickKids will not be affected in any way by whether you take part in this biobank.

Your health is more important to us than participating in this biobank. If any changes are needed to protect your health, we will talk with you about them before they are made.

New information that we get while we are doing this project may affect your decision to take part in this biobank. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the biobank.

During this research we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you any of this money now or in the future because you took part in this biobank.

If you become ill or are harmed because of biobank participation, we will treat you for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the biobank and the hospital is still responsible, legally and professionally, for what they do.

Sponsorship:
The sponsor/funder of this research is Dr. Muise and the Hospital for Sick Children.

Conflict of Interest:
Dr. Muise and the other research team members have no conflict of interest to declare.

Open Consent: By signing this form, I agree that:

1. You have explained this biobank to me. You have answered all my questions.
2. You have explained the possible harms and benefits (if any) of this biobank.
3. I know what I could do instead of taking part in this biobank. I understand that I have the right to not take part in the biobank and the right to stop at any time. My decision about taking part in the biobank will not affect my health care at SickKids.
4. I am free now, and in the future, to ask questions about the biobank.
5. I have been told that my medical records will be kept private. You will give no one information about me, unless the law requires you to.
6. I understand that no information about who I am will be given to anyone or be published without first asking my permission.
7. I will be asked to provide consultation of my medical record for any information related to intestinal disease and related disorders.
8. I will be asked to provide a blood sample. I may also be asked to provide a saliva, buccal (cheek) swab, stool, urine, and/or skin biopsy sample.
9. Such samples may be used as a source of DNA, RNA, plasma, biomarkers, protein, or cells and stored indefinitely for research into intestinal disease and other medical conditions after all identifying information has been removed.
10. My sample can be used in this laboratory or sent to other laboratories for research into intestinal disease and other medical conditions after all identifying information has been removed.
11. I agree to be re-contacted to provide follow-up information about my health.
12. You will attempt to contact my physician in the future if any information about my health that is specifically relevant to me becomes known through this research. I understand it is my responsibility to notify the GI/Nutrition department of any change of address, and to check with the department for updated genetics information and counseling that I feel I may need.
13. I have read and understood pages 1 to 5 of this consent form. I agree, or consent, to take part in this biobank.

Participant:

Print Name	Signature	Date
Maiden Name or Alternate Names (if applicable)	Date of Birth (month/year)	
Print Name of Child (Patient)	Relationship to Child (Patient)	

Person who explained consent:

Print Name	Signature	Date

Witness (if participant/legal guardian does not read English):

Print Name	Signature	Date

If you have any questions about this biobank,
*please contact **Karoline Fiedler at 416-813-6858, karoline.fiedler@sickkids.ca.***

If you have questions about your rights as a participant in a study or injuries during a study,
please call the Research Ethics Manager at 416-813-5718.