

## PARENT Consent For A Child

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

<b>Principal Investigator:</b>	Dr. Aleixo Muise	416-813-7735	
<b>Co-Investigators:</b>	Dr. Anne Griffiths	416-813-7735	
	Dr. Thomas Walters	416-813-7734	
	Dr. Peter Church	416-813-6171	
	Dr. Eileen Crowley	416-813-6184	
	Dr. Amanda Ricciuto	416-813-6184	
<b>Research Manager:</b>	Karoline Fiedler	416-813-6858	karoline.fiedler@sickkids.ca

#### **Purpose of the Research:**

Your child is being invited to participate in a research project because he or she 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 child's genes and certain information stored in your child's immune system (called biomarkers), along with bacteria in your child's gut (called microbes), 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 child to the extent that he or she is able to participate, and with your family and friends.

#### **Description of the Research:**

We may ask that your child provide one or more of the following samples, as applicable. All requested samples will be collected during a routine office visit, procedure, or admission. There are no additional visits to the hospital or extra time commitments required.

1. **Blood Sample:** A small blood sample (about 1-2 tablespoons) will be taken from your child once. This can be done when he/she is already going for regular bloodwork at SickKids, or when at SickKids for a routine office visit, procedure, or admission.
2. **Saliva:** Your child may be asked to provide a saliva (spit) sample.
3. **Buccal (Cheek) Swab:** Your child may be asked to provide a buccal swab sample. This is done using a cotton swab to gently brush the inside of your child's cheek.
4. **Stool:** Your child may be asked to provide a stool sample.
5. **Urine:** Your child may be asked to provide a urine sample.

6. **Intestinal Aspirate:** *If your child will be undergoing an endoscopy for his/her health, it is often part of standard medical care during the scope to spray saline (a salt water solution) on the intestines to clean them, and then remove these fluids (called “intestinal aspirate”) to better see the intestine. When intestinal aspirates are collected, we may store these leftover fluids for future research.*
7. **Tissue:**
  - a.) **Endoscopy (biopsies):** *If your child will be undergoing an endoscopy for his/her health, we may collect additional research biopsies. Understand that the endoscopy will not be an additional procedure, and that clinical biopsies are taken as part of routine care. Even with your consent, the gastroenterologist performing the procedure will only collect research biopsies if appropriate.*
  - b.) **Surgical Procedure:** *If your child will be undergoing a surgery or transplant for his/her health, we may collect tissue that is removed during the course of the procedure. Only tissues that are leftover after pathologic analysis will be stored for future research. Understand that this will not be something additional, but rather will be obtained during a clinically-indicated procedure and that no additional tissues will be removed specifically for this research.*
  - c.) **Skin Biopsy:** *If your child will be undergoing a biopsy or other surgical procedure for his/her health, we may collect fibroblasts (skin cells) from an incision site. Understand that the surgery will not be an additional procedure, and that a clinical skin biopsy may be taken as part of routine care. There is no additional risk when the skin biopsy is collected during a surgical procedure.*

If a surgical procedure is not scheduled, you may be asked if you would like for your child to provide a skin biopsy. If you do not want your child to provide a sample at that time, you may refuse and say “no.” Your child can still be in the rest of the study.

*If you choose for your child to provide a skin biopsy and do not have a surgical procedure scheduled, 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. Your child 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. When collected outside of a surgical procedure, 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. Remember, there is no additional risk to a skin biopsy collected during a surgical procedure; and this sample would only be collected outside of a surgical procedure if you agree.*

8. Samples will be used to extract DNA/RNA/plasma/biomarkers/protein/cells and analyze gut bacteria 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.
9. If a sample is unusable for technical reasons, or depleted, your child may be asked to provide another sample at his/her next routine office visit, procedure, or admission to SickKids. As always, it will be your choice if you wish for your child to provide another sample in future.
10. **Medical Records:** Your child’s medical records at SickKids and/or other institution(s) will be reviewed as needed to obtain information about his/her condition and medical history.

11. You will be re-contacted if needed to obtain follow-up information on your child's health, although how much of your child's 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 child's vein, and there may be slight discomfort and bruising or redness that will usually disappear in a few days.

**Potential Discomforts or Inconvenience:**

Your child 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 during your child's routine office visit or inpatient admission.

**Potential Benefits:**

**To individual participants:**

There may be no direct benefit to your child 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 your child and your child's health care team to make decisions about his/her care, or may immediately affect your child's health, these findings will be reported to your child's 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 child's 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 your child 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 child's privacy. No information about who your child is 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 your child if a child has been abused, if your child has an illness that could spread to others, if your child or someone else talks about suicide (killing themselves), or if the court orders us to give them the biobank papers.

Your child's 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 your child may be taking for intestinal disease, or your child's symptoms associated with intestinal disease.

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

Any genetic information obtained during this research and associated with your child 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 child's name or any other information identifying your child with the sample(s) he/she provides. 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 child's 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 child's identity with his/her 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 child's identity.

### **Storage of Research Samples**

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

### **Reimbursement:**

There will be no costs to your child, or payments made to your child, 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 for your child to take part in this biobank. If you give your consent for your child to be in this biobank and then change your mind, you can end your child's participation at any time and no further samples will be collected. You may also request (verbally or in writing) that your child's stored genetic and tissue samples be destroyed. The care your child gets at SickKids will not be affected in any way by whether he/she takes part in this biobank.

Your child's health is more important to us than participating in this biobank. If any changes are needed to protect his/her 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 for your child 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 your child 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 or your child any of this money now or in the future because your child took part in this biobank.

If your child becomes ill or is harmed because of biobank participation, we will treat your child for free. Your signing this consent form does not interfere with your child's 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 my child taking part in this biobank. I understand that I have the right for my child 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 child’s 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 child’s medical records will be kept private. You will give no one information about my child, unless the law requires you to.
6. I understand that no information about who my child is will be given to anyone or be published without first asking my permission.
7. I will be asked to provide consultation of my child’s medical record for any information related to intestinal disease and related disorders.
8. My child will be asked to provide a blood sample and any leftover fluid or tissue sample obtained during the course of a clinically-indicated procedure. My child may also be asked to provide a saliva, buccal (cheek swab), stool, urine, and/or skin biopsy sample; and I may be asked for my permission to collect research biopsies from my child during a standard care endoscopy.
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 child’s 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 child’s health.
12. You will attempt to contact my child’s physician in the future if any information about my child’s health that is specifically relevant to him/her 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 my child may need.
13. I have read and understood pages 1 to 5 of this consent form. I agree, or consent, for my child to take part in this biobank.

<b>Parent/Legal Guardian:</b>		
_____		
Print Child’s Name		
_____		
Print Parent/Legal Guardian’s Name	Signature	Date
_____		
Relationship to Child		

<b>Person who explained consent:</b>		
_____		
Print Name	Signature	Date

<b>Witness (if parent/legal guardian does not read English):</b>		
_____		
Print Name	Signature	Date

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