

## ASSENT Form

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

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#### **Why are we doing this study?**

We are asking you to be in a research study. Research is a way to test new ideas. Research helps us learn new things. Being in research is your choice. You can say “yes” or “no”. Whatever you decide is ok. We will still take good care of you.

We are asking you and other kids/teens that we know or think may have intestinal disease to be in the research because we want to learn more about intestinal disease. Your intestinal tract is the tube that travels from your mouth (your gum) to your bottom (your bum). Sometimes it is also called your “gut” or “GI tract.” Intestinal disease is a condition that may cause inflammation (swelling, redness, or soreness) in different parts of your intestinal tract.

We also want to find out why intestinal disease affects some kids/teens in different ways than others.

The goal of this study is to help in the search to identify genes involved in intestinal disease. Genes are in every cell of our body. They tell each cell what to do, and how to function. For example, genes are what make some people have blue eyes, and some people have brown eyes. In some cases, they are also the reason why some kids are more likely to have a certain disease. Genes are also called DNA. We hope that learning more about genes and about bacteria in the gut will give us a better understanding of why someone develops intestinal disease.

#### **What will happen during the study?**

There are no extra hospital visits or special tests.

The next time you have bloodwork or a procedure at SickKids, we will collect 1-2 tablespoons of blood from you. This is a small amount of blood and your body will not miss it. We will use this blood sample to look at your genes.

We may also ask for other types of samples:

- We may ask you to collect a saliva (spit), stool (poop) and/or urine (pee) sample in containers we give to you. We may also give you a cotton swab (like a Q-tip) and ask you to rub it on the inside of your cheek. This can be done at SickKids or at home and given to the study coordinator.

Some kids/teens may already be coming to SickKids for a test called a “scope” (an endoscopy or colonoscopy). If you are having a scope, you will be given special medicine at the hospital to make you sleep during the test. While you are sleeping, a skinny tube is inserted in your mouth or bum to look for swelling, redness, or soreness in your intestinal tract.

**We won’t ask you to have a scope just for research.** If your doctor asks you to have one for your health, we may ask for some samples:

- During a scope, the doctor will spray salt water on the intestines to clean them, and will remove this water to better see the intestines. We may want to keep this leftover water to study.
- Often, your doctor will also want to collect biopsies. A biopsy is a very tiny piece of lining of the intestinal tract taken during a scope while the patient is sleeping. A biopsy can also be a very tiny piece of skin taken during a scope or an operation. Biopsies can give your doctor important information. It may tell your doctor if there is inflammation too small to see with the eye, if an area has been inflamed for a long or short time, and sometimes gives clues about the cause of inflammation. We may want to collect extra biopsies for research, too. These biopsies will only be taken if the doctor says it is ok for your health.

If you are not having a scope or an operation, we may ask if we can collect a skin biopsy during a SickKids’ visit. You can say “yes” or “no.” If you say yes, we will give you an anesthetic patch to put on your skin so that it does not hurt when we collect the sample. You do not have to give a skin biopsy during a visit if you do not want to. You can still be in the rest of the study.

Some kids may need an operation to help them feel better. **We won’t ask you to have an operation just for research.**

- If you are already having an operation, we may want to look at the part of the intestine the doctor took out to help you feel better. We would only look at this leftover part that is already removed. No extra part would be taken for research.

### **Are there bad things about the study?**

It will hurt a bit to have the needle placed in your arm to take the blood sample. We will try to get the blood at the same time your doctor collects your blood.

### **Are there good things about the study?**

This study may not help you directly. Being in the study may provide information that may result in better ways to treat kids/teens with intestinal disease. We hope that this research will someday lead to answers about why kids get intestinal disease and how we can better help them.

**Who will know about what I did in the study?**

Only our SickKids' GI research team will know your name. Once your samples are sent to the lab, they will have a code number and your name will not be on it. If we feel your health may be in danger, we may have to report your results to your doctor.

**Can I decide if I want to be in the study?**

Yes. Nobody will be angry or upset if you do not want to be in the study. We are talking to your parent/legal guardians about the study and you should talk to them about it, too.

**Assent:**

I was present when \_\_\_\_\_ read this form and said that he or she agreed, or assented, to take part in this study.

**Person who obtained assent:**

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date