

Transplant Biobank Registry

Why do some children develop complications after transplant? Why do some transplant recipients respond to medicines better than others? These are some questions we are trying to answer by studying blood and tissue samples (biospecimens) from affected patients through the research described here. Our goal is to develop better ways to improve outcomes and prevent complications after transplant.

Transplant Biobank Registry

Collecting and storing biospecimens and clinical information to help research outcomes after transplant.

Participation

You will be approached by a coordinator to give consent. Participation is voluntary.



Samples

Here are some things that will be collected from you:

- Blood or saliva
- Leftover tissue from surgery
- Medical and family history

What will you do with my samples?

Samples will be stored for research in organ transplant and other health disorders.



How will you keep me informed of findings?

- Newsletters
- Website updates at www.transplantbiobank.com
- Publication Links
- Email communications
- Education days and symposia
- Advocacy groups

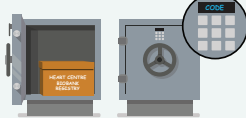
Are there any risks?

- Small amount of blood
- Slight discomfort
- Your identity will not be revealed when research findings are presented or published without your permission unless required by law



Storage and Privacy

All data will be securely stored with a study code so that your identity will be protected.



Data and Sample Sharing

Samples and data will be shared with researchers in Canada and internationally.



What if you find something from my samples/ what if I want to know what you found?

During the course of research, if we find something that is important to you and/or your family's health, we will contact you and/or your physician to share the findings.



What if I change my mind?

You can ask to withdraw at any time. Please call or email us and we can help with this.



Why be part of the Transplant Biobank?

While the research from the biobank may or may not directly benefit you, it will help future generations by helping find ways to improve outcomes in patients after transplant.



What is the Transplant Biobank?

The purpose of the Transplant Biobank is to collect and store biospecimens and clinical information from individuals with organ failure, and from organ donors and recipients to help researchers study how to improve transplant outcomes, prevent complications and treat it. The samples and data are shared with Canadian and international researchers who are approved to do this type of research.

What do you need to know?

If you are a patient being seen in the SickKids Transplant Centre or another SickKids clinic, you may be approached by a clinical researcher regarding your interest in participating.

Who can participate?

Patients who have organ failure and /or are being evaluated for, or, have received an organ transplant are eligible to participate. Relatives and living and deceased organ donors are also eligible to participate.

What will be asked of you?

A research coordinator will explain the terms of consent to you and ask you to read through the form and make an informed decision about your willingness to participate. The coordinator will answer any questions you may have at this time, or later if you need more time to make a decision.

What will be collected from you?

Blood: A small blood sample (between 2–4mL) which equals about ½ a teaspoon will be taken by a trained professional, usually at the time of a clinical blood draw, or from a blood sample left over after clinical testing. This will minimize additional needle pokes that can cause discomfort. If you are having a procedure, small blood samples may be taken before and at a few time points (3–4) after.

Saliva: If you do not want to provide a blood sample, we can also collect a sample of saliva for testing instead of a blood sample. This can be collected during your hospital visit or by mail.

Tissue: If you are undergoing a procedure, we may collect tissue that is removed during the procedure. Only tissue that is removed as part of the clinical procedure and left over from what is needed by pathology will be stored for future research. No additional tissue will be removed for this research.

Skin: If you are undergoing a procedure, we may collect a small piece of skin (about 3–4 mm) from the incision site for making stem cells. Alternatively, we may collect a blood sample for this purpose.

Medical and family history: Your medical records will be reviewed to obtain information about your condition, your medical and surgical history, and how you are doing. We will also provide you with a short questionnaire to collect some additional information including your family history. If medical records are available at other institutions or clinics, you may be asked for permission to access this information. You may be recontacted in the future to follow up on your health, or for additional information, and/or sampling.

If you are not interested in providing all the samples, just inform the staff approaching you so that they can make a note of your preferences. If your doctor indicates that providing a sample is not in your best interest, we will not collect that sample at that time.

What will your samples be used for?

We will use your samples to extract DNA, RNA, protein and/or cells for biological research. These samples will be used for current research and stored for future use. This includes searching the whole genome for defects linked to transplant and other medical conditions. Cells isolated from your blood or skin will be used to make stem cells, known as pluripotent cells, which can then be changed into any cell type for studying disease and testing medicines. In some cases, the investigators may wish to use the blood 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 in the long-term future for research. The importance of these samples increases over time as we track the cause or outcome of the disease and treatment.

Are there any risks to participating?

With any blood draw, there may be a small amount of bleeding, and slight discomfort or bruising when blood is taken from a vein. There is no risk with collecting a skin sample since it will be taken from the incision site as part of routine surgery.

How will your information be kept private?

Medical history, samples and all other data will be de-identified, meaning that any information that can identify you will be replaced with a study code which is a set of letters and numbers. Any data or samples that are shared with other researchers will use a study code so that the person receiving them cannot identify you. All records are stored securely and will only be accessible to approved research staff for approved research. Research findings from this study will not be part of your medical record.

How will we keep you informed of findings?

Studies supported by the biobank and their findings will be shared via newsletters and our website. Individual results will not be shared with you unless researchers identify a finding that may be important to you or your family's health. In these situations, we will try to contact you directly or be in touch with you through your physician or a genetic counselor.

What if you change your mind?

If you change your mind, you can withdraw from the study at any time by letting us know and we will remove any unused data and samples from the biobank.

Why be part of a biobank?

Organ transplant in children is a relatively rare condition. Being part of a biobank helps researchers to study a large number of affected patients than would otherwise not be possible. While the research from the biobank may or may not directly benefit you, it will help future generations by helping us find ways to improve outcomes, prevent complications and develop new treatments for individuals with organ transplant.

This brochure provides a quick overview of the Transplant Biobank Registry. A research coordinator may speak to you about this study in more detail.

We hope that this will help you understand the purpose of the biobank and how to participate in it. More details will be provided by the person approaching you with the informed consent.

For more information: 416-813-8428 | E: transplant.biobank@sickkids.ca | Visit our website at: www.transplantbiobank.com