The Ottawa Hospital | L'Hôpital d'Ottawa
Global Tissue Consenting (GTC) | Consentement global au don de tissu (CGT)

Patient Information Sheet

Consent for Program of Global Tissue Collection from Surgical Specimens

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INTRODUCTION

At the time of consenting for your surgery, you were (will be) asked if you would like to consent to the collection of leftover tissue(s) or body fluid(s) and a blood sample for research purposes. This document describes the purpose and procedures associated with the Global Tissue Collection Program at The Ottawa Hospital in more detail.

Your participation in the Global Tissue Collection program is voluntary. If after reading the details of the program you wish to end your participation you may contact the program coordinator, at 613-737-8899 ext. 73185 to withdraw your consent.

WHY ARE TISSUE/ BODY FLUID AND BLOOD COLLECTIONS BEING DONE?

The goal of the Global Tissue Collection (GTC) Program is to offer everyone undergoing a surgical procedure at The Ottawa Hospital the opportunity to consent to the collection of their leftover tissue(s) and/or body fluid(s) plus an additional blood sample (three tablespoons = 40 ml) to be collected, used, and stored for future research studies. Your treating surgeon may or may not be involved in one of these research studies. We hope that this program will help us carry out many research studies and in turn may lead to new directions in the individualized care of patients.

HOW MANY PEOPLE WILL TAKE PART IN TISSUE/BODY FLUID AND BLOOD COLLECTION?

All patients having surgery at The Ottawa Hospital are asked to allow use of their leftover tissue, body fluid and/or a blood sample, at the time of their surgery, for research purposes. No extra time or visits to the hospital are required by you because of your participation in this program.

WHAT IS INVOLVED IN THE TISSUE COLLECTION AND BLOOD COLLECTION?

After the surgery the tissue(s) and/or body fluid(s) (from here forward referred to as " Sample(s)") removed from your body are sent from the operating room to the hospital laboratory for closer examination and testing necessary to find out more about your condition. This is part of standard, or regular, care and not research.

For research purposes we have asked your permission to send the portion of your Sample(s), not needed for testing, from the hospital laboratory to a research laboratory(ies) to be used in variety of Research Ethics Board (REB) approved research studies. There is no extra tissue and/or body fluid, removed from your body during the surgery and there will be no other tests or procedures required from you.

These Sample(s) are collected from the hospital laboratory only after the adequate tissue(s) that are necessary for your treatment have been obtained. If you agreed to a blood sample collection, roughly three tablespoons of blood will be collected at some point before your surgery and will be sent to a research laboratory(ies). This may require an extra blood draw.

Your clinical/diagnostic test results will be reported back to you by your surgeon but, in most cases, any results related to research conducted with the collected Sample(s) are not normally reported back to you.

The Samples and/or Data from the Samples will be made available to researchers according to priority distribution guidelines developed by a committee of researchers.

WHAT WILL HAPPEN TO THE SAMPLE(S) / WHAT TYPE OF RESEARCH MAY BE DONE?
The collected Sample(s) and/or Data will be sent to a research laboratory(ies) and may be used for any approved research purpose, including any of the following purposes:

- to find out more about the causes and progression of diseases and conditions;
- to find out how new treatment options affect diseases and conditions;
- to develop and test methods to diagnose different diseases and conditions;
- for research involving whole genome sequencing (meaning that your entire personal genetic code will be identified) as well as other molecular sequencing technologies;
- for specific genetic research looking at diseases and medical conditions that are passed on in families and among populations larger than families. This is referred to as hereditary genetic testing;
- to create cell lines by growing cells from your Sample(s), including cells that can be used to create different types of tissue that could become basis for new cell lines, products, diagnostic or therapeutic agents:
    - cell lines are living tissue samples that can be grown in a lab. They allow researchers to have an unlimited supply of your cells and a source of your DNA, without collecting more samples from you.
- to change the genes in cells or putting human cells into animals;
- to do genetic manipulation of cells or mixing human and non-human cells in research done on animal models, to develop treatments for variety of diseases and conditions;
- to develop, train and test machine-learning models:
    - Machine learning is a type of Artificial Intelligence where computer programs learn from data automatically to see patterns that would be difficult or impossible for humans to observe on their own for example;
- other purpose, not yet identified, as research and technology are continuously evolving.

The collected Sample(s) will be made available to researchers according to priority distribution guidelines developed by the committee of researchers.
Information regarding you, your health and medical condition may be collected from your medical chart by researchers as a part of approved and linked research projects to better understand the results of Sample analysis, but information that may directly identify you (such as first name, last name, full date of birth or address) will not be released outside of any approved research protocols.

The Sample(s) and/or data from the Sample(s) will be used for academic and commercial medical research and may be sent to third parties to perform the research, including researchers at other academic and commercial institutions across Canada and internationally, such as the Terry Fox Research Institute and the Ontario Tumor Bank. Data from your samples may be shared on other online databases for further study by medical researchers. However, we will never share your name or any contact information, outside of the linked and REB approved research protocols, that would identify you directly without your explicit permission.

The examples listed above should give you a good idea of the kinds of research projects that might be done. If any of these examples of research use of your tissue or blood are not acceptable to you then you should withdraw from participation.

WHAT ARE THE RISKS?
There are no health risks to you to have leftover Sample(s) collected after the surgery and used in research. Only excess Sample(s) not needed for diagnosis of your condition will be used for research. No test results

from this study will be put into your medical record. You may read more about the GTC Program on the website: www.ottawahospital.on.ca/en/clinical-services/my-surgery/tissue-research/.

You may experience some temporary discomfort when the blood Sample is taken. There is a small risk of bruising, infection or swelling at the site where the needle is inserted, and some people may feel faint or dizzy.

We require all investigators and organizations involved in research using these samples to agree not to attempt to re-identify samples for the purpose of linking them or the information to you, unless required by law. While extremely unlikely, it is possible that the Sample(s) and genetic information could be re-identified and linked back to you. In this case, personal information about you, your health and your risk of disease could become known to others. This could present unknown risks. However, current federal law provides certain protections from genetic discrimination in health insurance and employment that may apply in these circumstances.

ARE THERE BENEFITS TO TAKING PART IN THE GLOBAL TISSUE COLLECTION PROGRAM?

There is no direct benefit to you for participating in this program. Your participation will help us increase research activities and greatly increase our ability to study a variety of new treatments and help to determine which types of diseases respond to which treatments. Your participation may help researchers gain new knowledge that may help others with similar condition or other diseases in future. If your Sample(s) or cells are used to create a new cell line, therapy or medical test, it could be commercialized and potentially generate revenue for The Ottawa Hospital Research Institute or another party such as a company. You will not benefit financially from these potential revenues and will not have rights to the potential product or its usage.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Excess tissue(s), blood, body fluid(s) and/or Data collected after your surgery will be labeled by a random sample identification (ID) number. The link between your identity and random sample ID number will be kept confidential and securely saved to protect your privacy, in accordance with the REB approved protocol(s).Your information may also be stored at the Ontario Tumour Bank (OTB). OTB is a provincial tissue bank of the Ontario Institute for Cancer Research (OICR), a not-for-profit organization funded by the Government of Ontario. More information about the OTB can be found at www.ontariotumourbank.ca .

Your name will not be disclosed in any report or publication resulting from any research conducted on your Sample(s) or in any documents leaving The Ottawa Hospital, unless required by law.

Authorized representatives of the following organizations may look at your original (identifiable) medical records at the site where these records are held, to check that the information collected for the program is correct and follows proper laws and guidelines:

- The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this program,
- Ottawa Hospital Research Institute, to oversee the ethical conduct of research at this location.

Your Sample(s) and/or Data may be shared with organizations located outside of Canada. Any Sample(s), and Data, that may be sent outside of Canadian borders may increase the risk of disclosure of information because the laws and ethical guidelines in those countries dealing with protection of information may not be as strict as in Canada.

WHAT ARE THE COSTS?

There will be no cost to you for taking part and there are no extra visits to the hospital if you decide to participate in this program.

WILL I RECEIVE ANY COMPENSATION OR BE PAID FOR MY TISSUES?
You will not receive any compensation now or in future for your Sample(s). Any income earned from distribution of Samples(s) to commercial medical researchers will be used to support research at The Ottawa Hospital.

VOLUNTARY PARTICIPATION
Your participation in the GTC Program is voluntary. If you choose not to participate or to withdraw your consent, your decision will not affect the care you receive at The Ottawa Hospital now or in the future. You will not have any penalty or loss of benefits to which you are otherwise entitled.

If you agreed to participate and then change your mind later and no longer wish to allow use of your leftover Sample(s) and/or Data in research simply contact the Global Tissue Collection Program coordinator, Edita Delic, at 613-737-8899 ext. 73185 to withdraw your consent. Verbal withdrawal is sufficient. If you decide to withdraw consent, any sample(s) already collected, but not yet analyzed by research, will be disposed of and any Data already collected will be deleted.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
If you have questions about taking part in this program you may talk to your surgeon or surgeon in charge of this program, Dr. Rebecca Auer, 613-737-7700 ext 72791, or you may contact the Global Tissue Collection program coordinator, Edita Delic at 613-737-8899 ext.73185.

If you have any questions regarding your rights as a research participant, you may contact the Chairperson of the Ottawa Health Science Network Research Ethics Board (OHSN-REB) at 613-798-5555, ext. 16719.