



Platform of Global Consenting for Tissue from Surgical Specimens

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INTRODUCTION

This document describes the purpose and procedures associated with the Global Tissue Collection project at The Ottawa Hospital. Before agreeing to participate, it is important to understand what is involved. Feel free to discuss it with your friends, family and your doctor or community Elder. Please ask your surgeon to explain any words you do not understand and make sure all your questions have been answered to your satisfaction before signing the consent for leftover surgical tissue and/or body fluid collection.

You are being asked to voluntarily take part in the Global Tissue Collection project because you will be undergoing an operation or a procedure, at The Ottawa Hospital, where some tissue and/or body fluid, will be removed from your body.

WHY IS TISSUE COLLECTION BEING DONE?

The goal of this project is to help with collection of leftover tissue and/or body fluid, after surgery, for use in a variety of research projects. Your treating surgeon may or may not be involved in one of these research protocols. We hope that this Global Tissue Collection project will help us increase efficiency of 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 COLLECTION?

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

WHAT IS INVOLVED IN THE TISSUE COLLECTION?

After the surgery the tissue and/or body fluid removed from your body is sent from the operating room to 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 are asking your permission to send the portion of tissue and/or body fluid, not needed for testing, from hospital laboratory to a research laboratory/laboratories to be used in variety of Research Ethics Board (REB) approved research projects. 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.

The tissue and/or body fluid is collected from hospital laboratory only after tests necessary for your treatment have been completed. Any leftover tissue and/or body fluid that is not used for necessary testing or research will be destroyed in the hospital laboratory.

Your clinical/diagnostic test results will be reported back to you by your surgeon but any results related to research conducted with this tissue and/or body fluid collection will not be reported back to you.

WHAT WILL HAPPEN TO THE TISSUE?

The collected tissue and/or body fluid will be sent to a research laboratory/laboratories and will be used to find out more about disease and treatment. The de-identified tissue and/or body fluid sample will be made available to researchers according to priority distribution guidelines developed by committee of researchers. Information regarding you and your medical condition may be collected from your chart but information that may directly identify you (such as first name, last name, date of birth or address) will not be released to the researchers.

The de-identified or anonymized samples will be used for academic and commercial medical research, which may include provision of the de-identified or anonymized samples to third parties. This research may result in inventions or discoveries 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 and allow researchers to have an unlimited supply of your cells without collecting more samples from you and to have a source of your DNA. Cell lines may be used in genomic studies, genetic manipulation of the cells or mixing human and non-human cells in research done on animal models, and to develop treatments for variety of diseases and conditions. We may also use cells taken from your tissue to create a type of cell known as stem cell. These stem cells can be used to create different types of tissues and may be used in research involving genetic alteration of collected cells.

WHAT ARE THE RISKS?

There are no health risks to you to have leftover tissue and/or body fluid collected after the surgery and used in research. Only excess tissue and/or body fluid 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.

Your sample and your information are de-identified before being sent to researchers. 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. While extremely unlikely, it is possible that the tissue and genetic information could be re-identified and linked 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 THIS STUDY?

There is no direct benefit to you for participating in this study. 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 tissue and/or body fluid 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 and/or body fluid collected after your surgery will be labeled by a random study number. The link between your identity and random study number will be kept confidential and locked in a password protected file on a password protected computer and on a secure Ottawa Hospital Server. Your name will not be disclosed in any report or publication resulting from the study 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 study is correct and follows proper laws and guidelines.

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

WHAT ARE THE COSTS?

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

WILL I RECEIVE ANY COMPENSATION OR BE PAID FOR MY TISSUES?

You will not receive any compensation now or in future for your samples. Any income that may be derived from distribution of samples to commercial medical research will be used to support research at The Ottawa Hospital.

VOLUNTARY PARTICIPATION

Your participation in tissue collection is voluntary. If you choose not to participate, 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 agree to participate and then change your mind later and no longer wish to allow use of your leftover tissue in research simply contact the Global Tissue Collection project coordinator, Edita Delic, at 613-737-8899 ext. 73185 to withdraw your consent. Verbal withdrawal is sufficient. If you decide to withdraw your consent any tissue already collected, but not yet analyzed by research, will be disposed of.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about taking part in this study you may talk to your surgeon or surgeon in charge of this project, Dr. Rebecca Auer, 613-737-7700 x72791, or you may contact the Global Tissue Collection project 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.