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

Informed Consent Form

Program Title: Global Tissue Consenting (GTC) Program

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Introduction to the Global Tissue Consenting (GTC) Program

The Ottawa Hospital implemented a GTC program which provides all patients undergoing standard of care surgery with the opportunity to donate their leftover surgical tissue/body fluid **and/or** an additional sample of blood (4 tablespoons = 60 ml) for research purposes. The sample(s) will also be accompanied by some personal health information and personal identifiable information obtained from your medical record.

The GTC program will be explained to you by your clinical surgeon during your surgical consult visit. You will be asked to document your decision to participate, or to not participate, on the surgical consent form that will be given to you as a part of your usual/standard of care surgery.

We hope that this program will streamline the consent and collection process, in order to provide researchers with increased access to human samples and data for research purposes, which is critical to making new discoveries.

To learn more about the GTC Program, and for a list of research studies using samples and/or data from the GTC program, please visit: https://www.ottawahospital.on.ca/en/clinical-services/my-surgery/tissue-research/.

This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this program.

Please take your time in making your decision. If you would like to, you can talk about this program with other people. These people might include your family, your friends, Elders or trusted leader, and your usual doctor or health care provider.

Taking part in this program is voluntary. You have the option to not participate at all, or you may choose to leave the program at any time. The decision you make, whether to participate or not, will have no effect on your medical care.

Conflicts of Interest

The surgeon(s) involved in your care may also be involved in research studies that will use sample(s) and data from this program; however, your surgeon(s) will not have any influence over which studies your donated sample(s) and data will be used for – this will be determined by the program's priority distribution guidelines which were developed by a committee of researchers.

Collection of Sample(s) and Data

If you choose to participate in the GTC program, the applicable sample(s) and data will be collected and used in research studies or will be stored for future use. The types of samples and data to be collected for use/storage are outlined below. No extra time or visits to the hospital will be required because of your participation in this program.

Leftover tissue(s) and/or body fluid(s) (optional):
At the time of your usual/standard of care surgery, your surgeon will collect the tissue and/or body fluids that are required for clinical purposes. After clinical testing, any leftover tissue is either stored by the Department of Pathology for future clinical care and diagnosis or discarded. We are instead asking you to consent to donate any leftover tissue. Even if you agree, your leftover tissue will only be collected if your doctor feels it isn't needed for additional clinical testing, or storage for future clinical testing. Please note that if a clinical care need arises in the future and your sample was provided for research purposes, the sample may be exhausted (used up) and may not be returned for required clinical purposes.

Blood (optional):
A blood sample (4 tablespoons or 60 ml) will be taken from a vein with a needle at some point before your usual/standard of care surgery. If possible, this sample will be taken at the same time as a clinical related sample; however, it is possible that this may require an extra blood draw. Even if you agree at the time of consent to allow collection of blood for research you may still decline at the time of collection.

Information/Data Collection:
Information about you, your health and medical condition(s) may be collected from your medical records, including your personal identifiable information (e.g., full name, full date of birth, medical record number, phone number) and personal health information (e.g., demographics such as age and sex, health and medical history, treatment details, results of tests/procedures, etc.).

Use of Sample(s) and Data
Your sample(s) and data may be given to researchers and biobanks from The Ottawa Hospital as well as from other hospitals/health institutions, universities/academic institutions and commercial (for-profit) companies, in Canada and around the world.

A for-profit company could be a pharmaceutical or a biotechnology company that wants to make a new drug, test a currently approved drug and/or develop a new way to treat or diagnose disease. It could also be a diagnostic, medical device or digital health technology company that wants to develop new ways of detecting, diagnosing or monitoring a disease.

Your sample(s) and data may be used for 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;
- **biomarker research** (details below);
- **genetic research** (details below);
- to create **cell lines** (details below);
- to create **organoids** (details below);
- **Induced Pluripotent Stem Cell (iPSC) research** (details below);
- **transplanting human tissue/cells into animals** (details below);
- to develop, train and test **machine-learning models** (details below);
- for **biobanking** (details below);
- **other purposes, not yet identified**, as research and technology are continuously evolving.

Biomarker Research:
Researchers may look at biomarkers in your samples. Biomarkers are natural substances in your body that can give information about your health – such as a gene, protein, hormone or other molecule. For

example, blood sugar is a biomarker used to monitor diabetes. Biomarker research may help to better understand how diseases develop and progress, how your body responds to treatment, and which patients are more likely to benefit from certain therapies. These discoveries can lead to the creation of new tests that may help doctors find diseases sooner, choose better treatments or prevent diseases.

Genetic Research:
Researchers may look at your genes, which are made up of DNA. Genes carry information about features, such as hair or eye colour. Everyone's genes are unique, and sometimes small changes can be linked to certain diseases or conditions.

- **Non-hereditary genetic testing:** Researchers may look at the way that genes affect health and disease, or how your body responds to treatment.
- **Hereditary genetic testing:** Researchers may look at changes in genes specific to diseases and medical conditions that are passed on in families and populations larger than families.
- **Whole genome sequencing** is a type of genetic research that looks at almost all of a person's DNA — also called their genome. Your genome is like an instruction manual that tells your body how to grow, develop, and function. It includes all of your genes, as well as other parts of your DNA that help control how your genes work. Researchers use whole genome sequencing to better understand how genetic differences may affect health, illness, or how a person responds to treatment. By studying the full genome, researchers can look for both non-inherited and inherited (passed down in families) changes in DNA. This can help identify the causes of diseases, why some people respond differently to treatment, or why certain conditions run in families. In the long term, this research may lead to improved diagnosis, prevention, and treatments for various health conditions.

Creation of Cell Lines:
Researchers may take a small number of your cells and create a living tissue sample called a "cell line", which is a population of cells that can divide and grow in the lab. The cell line may be used to develop treatments for a variety of diseases and conditions.

A cell line can be created in different ways, including:

1. Cells are isolated without making changes and allowed to make copies outside of the body. These cell lines eventually end when the cells are no longer able to make copies of themselves, but this may be many years from now.
2. Cells are changed so that they can make an unlimited number of copies of themselves. This means the researchers will have an unlimited supply of your cells to do research on for a long time, maybe forever.

The cell lines will be identical or almost identical to the cells you originally provide and will contain some or all your genetic information.

Researchers may use the cell line created from your sample (or anything taken from it) in products or services that are sold for profit, or they may share your cell line with others, who may use it in products or services that are sold for profit.

Creation of Organoids:
Researchers may use the cells taken from your sample(s) to create what is called an "organoid". Organoids are small, three-dimensional cell structures that scientists grow in a lab from donated cells. They mimic some of the structure and function of a real organ (for example, intestine, liver or brain). Organoids are used to better understand how diseases develop and to test new treatments in a controlled setting. They are not whole organs and cannot function like a complete organ inside a person.

Induced Pluripotent Stem Cell Research (iPSC):
Sometimes researchers can take ordinary cells (for example, skin or blood cells) and “reprogram” them into a special type of cell called a stem cell. These are called induced pluripotent stem cells (iPSCs). iPSCs can be made to grow into many different kinds of human cells (such as heart, nerve, or liver cells) in the laboratory and the cells can be genetically altered. iPSCs are used to study how diseases develop and to test new treatments. They are not embryos and are not used to create a pregnancy.

Studying iPSCs may help researchers to:

- Understand how certain diseases develop and affect the body
- Test new drugs and treatments in the lab before trying them on people

Explore ways to repair or replace damaged tissue in the body

Transplanting Human Cells/Tissue into Animals:
Researchers may mix your human cells with animal cells, or put your human cells or tissue into animals, during research done on animal models. This helps to understand human diseases better before doing tests on humans directly. For example, a patient's cancer cells may be put into a mouse so researchers can test different drugs and treatments to see which ones are most effective against that specific cancer.

Machine Learning:
Your data may also be used to develop, train and test machine-learning models. Machine learning is a type of Artificial Intelligence (AI) where computer programs learn from data automatically to see patterns that would be difficult or impossible for humans to observe on their own. No directly identifying information, such as your name, will be used.

Biobanking:
A biobank is a type of facility that receives, stores, processes and distributes human body samples (e.g., blood, tissue, fluid, etc.) and related health information (i.e., data) to qualified individuals for future purposes, including research. Biobanking provides an important resource for health research.

Qualified researchers can submit a request to biobanks to use their stored samples and data for research purposes.

The biobank may be external to The Ottawa Hospital, but within Canada or it may be part of The Ottawa Hospital. If your sample(s) and personal health information are selected to go to an external biobank, your full name and your telephone number will be provided to the biobank team before samples are transferred.

If the biobank is part of The Ottawa Hospital your full name and your MRN (medical records number) will be provided to the biobank team.

The biobank team will contact you to provide you with a separate biobank consent form with additional information to consider. Should you be interested in donating your sample(s) and related health information to the biobank you may sign that consent. Your sample(s) and related health information will not be sent to the biobank unless you specifically consent to this separately.

<u>Research Results:</u>

Results of research tests done on your sample(s)/data will not be given to you, your doctor or other healthcare providers. The results will not be put into your medical records.

Study results obtained from research using samples and data from the GTC program will not be given to you.

However, if you would like to know where your sample(s) and data have been donated, you can contact the GTC Navigator listed on page 1 of this consent form.

Duration of Storage
Your sample(s) and data may be stored indefinitely, until they have been entirely used up or are no longer of scientific value. Your data will be stored indefinitely, or until your sample(s) have been used up.

Benefits
You will not directly benefit from your participation in this program. Your participation will however help to increase research activity, which may help researchers make discoveries, such as finding new ways to prevent, detect, understand, and treat diseases; this could benefit people in the future.

Risks
Risks related to sample collection:

- If you require an additional blood draw, the needle used for blood sample collection might be uncomfortable. You might get a bruise, or rarely, an infection at the site of the needle puncture.
- Since leftover clinical tissue and/or body fluid will be collected, no additional physical risks are expected related to this.

Risk related to future care:

- If you choose to donate your leftover tissue and/or body fluids for research purposes, there is a possibility that the sample may be exhausted (used up) and may not be able to be returned for clinical care, if necessary.

Risks related to personal health information:

- Although there are technical and physical safeguards in place, there is a risk that someone could get access to the personal information or other information researchers have stored about you.

Risks related to research involving genetic testing:

- When you donate your sample(s) you are not only sharing genetic information about yourself, but also about biological (blood) relatives who share your genes or DNA. Advances in technology could increase the risk that your genetic samples and results could be linked back to you or your relatives.
    - While current Canadian Federal Law provides certain protections from genetic discrimination in health insurance and employment, it is possible that if an insurer, a current or future employer, or law enforcement were to learn your genetic code it could result in loss of privacy and to possible future discrimination in employment or insurance against you or your relatives. Even though this risk is unlikely, we think you should be aware.
- You should be aware that genetic information cannot be protected from disclosure by court order.
- Due to the rapid pace of technological advances, the potential future use of genetic information is unknown and therefore the potential future risks also are unknown.

Other Risks:

- As your samples contain DNA, they can never be fully de-identified. Even with protections in place, there is a risk that your sample(s) or data could be traced back to you.
- If you agree to donate your sample(s) and data to the program, they could be used in a research project to which you might not agree to, if you were asked specifically about it. We think this consent form will give you a good idea of the kinds of research projects that might be done with your sample(s) and data.
- There may be other risks involved in participating in this program that are unknown, since your sample(s) and data are meant to be used for as-yet unknown purposes by researchers. The program will help to minimize these risks by reviewing all research proposals carefully before approving.

Voluntary Participation and Withdrawal

Taking part in this GTC program is voluntary. You have the option to not participate at all, or you may choose to participate now and change your mind later. Whatever you choose, it will not affect the usual medical care that you receive.

If you decide you no longer want your sample(s) or data to be used for research, please contact the GTC Navigator listed on page 1 of this consent form who will ensure your sample(s) are returned to The Ottawa Hospital or destroyed, and data is withdrawn.

If any of your samples or data have already been shared, or if tests have already been done and included in an analysis or publication, it will not be possible to withdraw those samples/data/results.

Privacy and Confidentiality

As a participant in this program, you will be assigned a unique code. Your code will not include any personal information that could directly identify you, such as your name. To keep your identity confidential, your sample(s) and data will only be labelled with your code, age and sex.

The list that links your unique code to your personal identifying information (such as your name) is in the control of GTC program. The list will be kept separate from your sample(s) and data in a secure location at The Ottawa Hospital. If you change your mind about participating in this program, this list will be used to locate your sample(s) and data.

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may come to the site or be given remote access to an electronic portal (via internet) to look at your original (identifiable) medical/clinical and program 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. These records to identify you, but everyone involved is responsible for making sure that your privacy, and the confidentiality and security of your records in maintained.

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

Information that is collected about you for this program may also be sent to the organizations listed above. The records received by these organizations may contain other information that may indirectly identify you (e.g., unique code, sex, and partial date of birth (month and year)).

Your sample(s) and data will not be sold; however, biobanks, researchers and industry partners may be charged a fee to help cover some of the costs of the overall operation of the GTC program.

If requested by a researcher within Canada, directly identifiable information (e.g., name, full date of birth, medical record number, health card number) may also be shared with the researcher so they can collect additional information about you and link it to your sample(s) and data. This will allow for a more accurate and comprehensive dataset. The least amount of identifying information will be shared to securely link the data. Whenever possible, files used to create the linkage by researcher will be deleted once the linkage is complete.

If it is determined that your samples and data are to be provided to a biobank, your name and telephone number will be provided to the biobank team, who may be external to The Ottawa Hospital, but within Canada.

All research projects utilizing sample(s) and/or data will be reviewed and approved by a Research Ethics Board.

Your sample(s) and data may be sent to researchers in other countries. Any samples and information sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all samples and/or information that are transferred outside of Canada will be coded. Coded means they will not contain your directly identifiable personal information such as your name, address, medical record number or contact information. All samples and information will be transferred in compliance with all relevant Canadian privacy laws. By agreeing to participate in the GTC program, you are consenting to the transfer of your coded sample(s) and coded information to organizations located outside of Canada.

External researchers who would like to do research using your sample(s) and data will sign agreements with The Ottawa Hospital Research Institute. These agreements will control how your sample(s) and data will be used. They will not be permitted to disclose or to transfer study samples or data to anyone else if not stated in the agreement. They will also not be permitted to use study data for purposes other than those included in the agreements.

Coded data resulting from analyses being done on samples may be pooled and shared with researchers from around the world for future studies that are unknown at this time. Data may also be added to central or public databases, published, or presented at scientific meetings. The goal of sharing is to make more research possible. Although your name and any other information that could directly identify you will not be included, there is a risk that someone could trace the information in a central or public database back to you. The chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.

Costs
Participation in this program will not involve any additional costs to you or your private health care insurance.

Payment
You will not be paid for taking part in this program.

In the case of program-related illness or injury, medical care will be provided by your doctor or you will be referred for appropriate medical care.

Commercialization:
Your sample(s) and health information may be used to help create new medical tests, treatments, and/or products. Some of these may later be further developed and sold by companies; this is called commercial use. This is a normal part of how medical research leads to real-world treatments. Even though your participation may contribute to these discoveries, you will not receive any money or ownership rights from any products that are made. Any profits or inventions will belong to the researchers, the hospital or research institutions, or the company responsible for the research.

Rights
You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this program. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By agreeing to participate, you do not give up any of your legal rights against the Principal Investigator or involved institutions for compensation, nor does this form relieve the Principal Investigator or their agents of their legal and professional responsibilities.

Questions
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 GTC Navigator at 613-737-8899 ext.73185. You may also email GTC@TOH.CA.

If you have questions about your rights as a participant or about ethical issues related to this program, you can talk to someone who is not involved in the program at all. Please contact The Ottawa Health Science Network Research Ethics Board at REBAdministration@ohri.ca or 613-798-5555, x16719.