CellCAN

Regenerative Medicine and
Cell Therapy Network

Mobilizing knowledge and stakeholders across Canada to significantly advance regenerative medicine and cell therapy research and clinical development

CellCAN
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CENTRE OF EXCELLENCE IN CELL THERAPY (CETC)

Hôpital Maisonneuve-Rosemont, Montréal (Québec)

Specialities

- Immuno-oncology
- vision health
- orthopedics and translational platform

Rooms

- 13 environmentally controlled rooms (clean rooms) for the manufacture of cell products
- Quality control laboratory
- Storage room primarily used for the preservation of cellular products

Equipment

- Bioreactors for increasing the number of cells
- Lamps for performing cell photodepletion operations
- Immunomagnetic selection devices
- All equipment necessary for safe handling of cellular products

Features

- GMP, more than minimally manipulated
- Access restricted to qualified personnel
- Highly secure and regulated
- Highest standards of quality according to Quebec, Canadian, European and American standards

Area

- 3,500 m2 spread over four floors

Key investigator

Dr. Denis Claude Roy, MD, FRCPC

Chief Executive Officer of CellCAN and Scientific Director of the Hôpital Maisonneuve-Rosemont Research Centre, he is a renowned researcher in the field of haematopoietic stem cell therapy, Scientific Director of the HMR Research Centre, he has initiated and chaired more than 15 phase I-II clinical trials involving ex vivo manipulation of haematopoietic stem cells for transplantation. He has also participated in more than 60 clinical research protocols.

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Crtc-hmr.org

Groundbreaking Projects

The proven expertise and noted achievements of the CECT Hôpital Maisonneuve-Rosemont have made it a world leader in stem cell transplantation since the turn of the century.

Stem cells were first successful in the treatment of **blood cancers.** Today some 200 bone-marrow transplants are done every year at Hôpital Maisonneuve-Rosemont to treat blood cancers.

The CETC is also working on modifying cell genes called lymphocytes-t. These veritable anti-cancer missiles attack patient cancer cells with more force and precision than ever before. Ongoing advances in research will soon make it possible to boost donor immune systems in order to better fight leukemia in recipients.

Major **immunotherapy** work is also underway to reduce the incidence of rejection in stem cell transplants by modifying the behaviour of donor cells so they no longer attack recipient organs, such as the liver, intestines, eyes or lungs.

Also, in collaboration with the CHUM cardiovascular centre, the CETC is working to strengthen muscles weakened as a result of myocardial infarction or chronic failure by injecting them with stem cells. These treatments can help the heart regain enough of its strength to allow patients to do things that had become became difficult or impossible for them to do. Other research centre projects focus on **ophthalmology**, **nephrology** and **orthopedics**.

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CENTRE MULTIDISCIPLINAIRE DE DÉVELOPPEMENT
DU GÉNIE TISSULAIRE (CMDGT)
Université Laval, Québec (Québec)

Specialities

- Cell and Tissue Culture
- Primary cells (fibroblasts, keratinocytes, endothelial cells, epithelial cells, etc.)
- Tissue Engineering and organ reconstruction
- Regenerative Medicine (Eye; Skin; Cardiovascular; Adipose tissue; Urology, etc.)
- Urology
- ASCs
- Cardiovascular (blood vessels and valves)

Rooms

- Clean room suite of 3 separate cell culture areas comprised each of an airlock, an incubator room, and a cell culture room. In addition the clean room suite encompasses an instrument and cold storage room, a preparation room and other spaces such as gowning, a corridor and an airlock entrance

Equipment

- Each cell culture area: incubators, flow hood, microscope, centrifuge and cell counter.
- Access to microscopes, histology and other analytical services through the research center

Features

- Development and production of novel 3D reconstructed tissues that are ready for the clinical trial phase (contract manufacturing of tissue)
- Engineered human tissue: Reconstructed bilamellar skin and cultured epidermal autografts
- Cornea

Area

- The clean room suite covers a total area of 185.5 m^2, within a research center of 5000 m2, for tissue reconstruction and stem cell research

Key investigator

Dr. Lucie Germain, PhD

Scientific Director of the CMDGT and head of the The Cell Regenerative Medicine Network, Dr. Germain was directly involved in the successful development of the technique to generate skin substitutes and corneal replacement.

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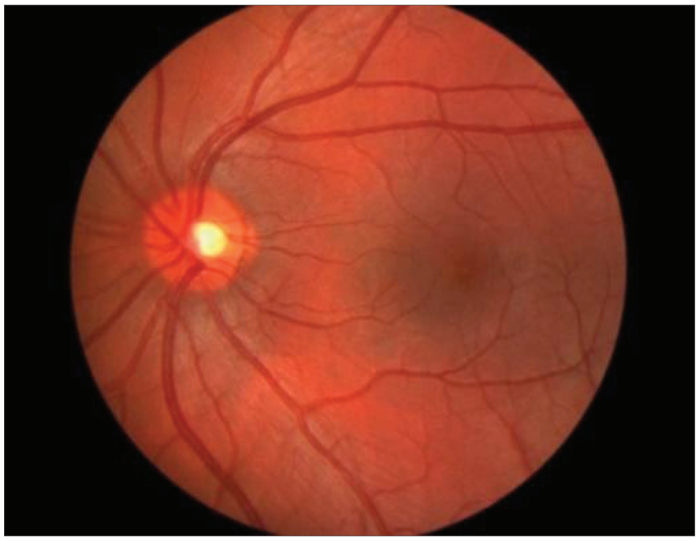
loex.qc.ca

Groundbreaking Projects



The Centre Multidisciplinaire de Développement du Génie Tissulaire is a renowned leader in the treatment of **occular diseases**. It is the first medical facility in Canada to have transplanted a patient's own living tissues (autologous) to replace a corneal epithelium (the tissues covering the front of the cornea).

It was also in Quebec that the first **skin graft** was performed on a large burn area in 1986 using skin tissue made in a laboratory, a Canadian first. The method developed in Quebec is unique in the world, using only the patient's natural cells to create the dermis and the epidermis. This is a very major advance since the reconstructed skin has the proper elasticity and resistance to grow with the patient. Another advantage of producing skin this way is that it can be reconstructed as needed for testing and for developing treatments.

In addition, the CMDGT carries out important work on the construction of natural **valves** (such as heart valves), on the manufacture of **blood vessels** and on the reconstitution of **fat** that will one day enable the natural reconstruction of breasts by grafting. It is also developing **ligaments** and **bronchial tubes**, as always using the same cell culture process.

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GMP ALBERTA CELL THERAPY MANUFACTURING

University of Alberta, Edmonton (Alberta)

Specialities

- MSC production
- Viral production
- CAR-T cells
- Xenotransplantation – porcine islet production

Rooms

- 6 Class B cleanrooms : 5 positive pressure and 1 negative pressure

Equipment

- Biological Safety Cabinets equipped with continuous particle counters
- Tri-gas Incubators
- Refrigerated centrifuges, high-speed and ultracentrifuges
- Controlled rate freezer and automated liquid nitrogen storage system
- Designated refrigerators, freezers and ultralow freezers for each cleanroom
- GMP autoclaves and Plasma Sterilization System
- Cell isolation and separation systems
- Cell encapsulation equipment
- Bioreactor systems
- Quality Control instrumentation
- Facility Monitoring System to continuously monitor all equipment and cleanroom conditions (particle counts, differential pressure, temperature, humidity)

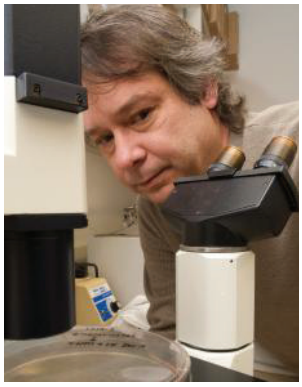
Features

- New 10,000 square foot GMP facility designed for production of cell and gene therapies for clinical trials
- Served by 4 different air-handling systems
- 4 rooms designated for human cell processing, one room for gene therapy and a segregated xenotranslantation wing for porcine islet processing.
- Unidirectional movement of personnel and materials through gowning rooms, intermediate entry rooms, airlocks, intermediate exit rooms and degowning rooms
- Support areas including a quality control laboratory, sterilization room, archive room and storage room with a secure quarantine area

Area

- 10,000 square feet

Key investigator



Dr. Greg Korbutt, PhD

Dr. Korbutt is a Professor in the Department of Surgery at the University of Alberta, Canada. He has been actively involved in islet transplant research for the past 25 years. Dr. Korbutt is the project leader of CFI award to build the GMP Cell and Tissue Innovation Research Centre in Alberta.

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Groundbreaking Projects

University of Alberta researchers made an international breakthrough with the transplantation of islets from cadaveric donors to treat **type 1 diabetes**. The method consists of infusing islets into the patient's portal vein, improving blood glucose control and reducing the amount of insulin needed. Insulin independence is not usually sustainable in the long term, but the transplanted islets still function enough to provide protection from severe hypoglycemic episodes and fainting. This discovery, the Edmonton Protocol, has paved the way to the construction and establishment of the ACTM to build on these findings and implement usage of alternative sources of islet cells. A third of all the islet transplantation are done in Edmonton.

Researchers in Edmonton are also at work on developing gene therapies to correct **blindness** as well as on the culture of **cartilage** from human cells.

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OTTAWA HOSPITAL RESEARCH INSTITUTE

Ottawa (Ontario)

Specialities

- Hemato-oncology
- Immunotherapy
- MSCs and bioprocess optimisation

Rooms

- Fully equipped with sate of the art equipment involved in the manufacture, testing, and packaging of cell therapy products
- Highly controlled and regulatory compliant manner

Equipment

- Custom designed modular isolator units each capable of housing all of the equipment necessary (microscopes, centrifuges, incubators etc) to independently manufacture cell therapy products

Features

- The facility is operated within the Ottawa Hospital Research Institute (OHRI) under the guidance of: two scientific directors for viral and cell production respectively.
- The facility is governed by an operations committee composed of scientists, clinicians, and senior administrators and; a steering committee composed of OHRI senior management, scientists, and external consultants.
- Cell therapy clinical trials either single or multi-institutional are run through the facility and are further supported at the OHRI by an ad hoc translational research committee (composed of clinicians, scientists, and research ethics board members) that provides advice on clinical trial design and ethical aspects of the studies.

Area

- 200 square meters

Key investigator

Dr. Duncan Stewart, MD

Dr. Stewart is a pioneering Canadian cardiovascular researcher, recognized for his many important discoveries in blood vessel biology as well as his dedication to translating these discoveries into benefits for patients and society. He has started his career in academic cardiology at McGill University and Toronto.

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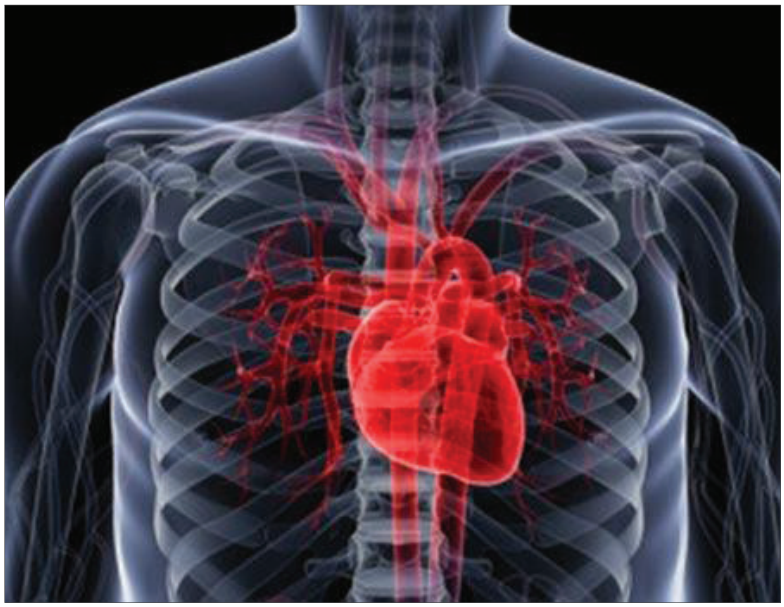
Groundbreaking projects



The multidisciplinary approach of the Ottawa Hospital Research Institute has made possible some impressive breakthroughs, such as using a patient's own cells (autologous cell gene therapy) in a trial for the treatment of **pulmonary hypertension**, a fatal disease, which affects the lungs' functioning. Gene therapy can restore the function of a crucial enzyme found in diseased lungs. The hypertension can now be reduced by sending cells with a mission to reopen the vessels.

A similar trial for the treatment of a specific type of **heart disease** (ischematic) has also been initiated. In cases where heart attacks are caused by arteries that have become blocked, it is essential to open the vessels by dilating them. But the smallest microscopic vessels cannot be treated mechanically. The Ottawa team has developed new methods to work around this problem using cellular therapies. In such cases, the patient is injected with vascular stem cells that promote the development of blood vessels, to create new access routes to the heart that allow blood to penetrate the heart muscle. In addition to this, a gene is introduced into the stem cells that encourages the vessels to remain open.

The Ottawa Research Institute is also working on **stiff person syndrome**, a rare neurological disorder that affects one person in a million, mostly women in their forties. The disorder of the immune system causes great suffering due to high rigidity of the trunk and limbs. The institute's treatment uses stem cells extracted from the patient's blood to eliminate deficient cells. The patient is then subjected to chemotherapy to neutralize their immune system which is then re-injected with their own purified stem cells. The idea is to reboot the immune system once it's stripped of its bad cells. The first patients in the program are still in remission two years after treatment.

The Institute also hopes to find a treatment for people with **sepsis**, a general infection of the body syndrome, as well as **multiple sclerosis**, **loss of vision**, and **diabetes**, as well as **stroke**.

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PHILIP S. ORSINO FACILITY FOR CELL MANUFACTURING

Princess Margaret Cancer Centre, Toronto (Ontario)

Specialities

- Mesenchymal stromal cell (MSC) manufacturing in flasks/hyperflasks
- NK cell manufacturing
- T cell manufacturing
- DC vaccines
- Labelling cells
- LV transduction of CD34+ cells
- CD133+ cells

Rooms

- 3 rooms (2 positive pressure and 1 negative pressure)

Equipment

- 3 BSCs
- 1 Cell Processor - COBE 2991
- 1 Apharesis Optia
- 3 centrifuges
- 3 fridges; 10 incubators
- 3 microscopes
- 3 particle counters
- 2 peristaltic pumps
- 1 balance
- 2 tube sealers
- 3 vaccum pumps
- 2 welders
- Wave bioreactor

Features

- All class 10,000; 2 Positive pressure and 1 negative pressure
- 24-h environmental monitoring

Area

- Clinical translation and regulatory expertise for Health Canada and FDA filing
- Worked with industry and academia on 12+ projects
- Collaborate on grants and other funding mechanisms

Key investigator

Dr. Armand Keating, MD, FRCPC

Dr. Keating, a key founding member of CellCAN, is Chair of CellCAN Steering Committee as well as Director of the Cell Therapy Program at UHN. Dr. Keating is a former President of the American Society of Hematology and established the largest stem cell transplant program in Canada.

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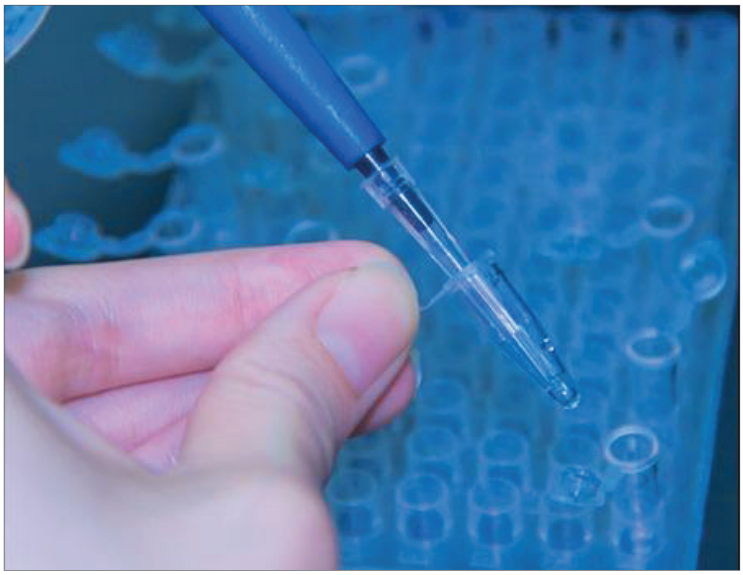
uhnres.utoronto.ca/facilities/psoctf

Groundbreaking Projects



As the birthplace of stem cell research, Toronto has always played a major role in the development of cellular therapies. This is due largely to the work of two researchers in the 1960s, Till and McCulloch, who discovered stem cells. Since then, Dr. Keating has implemented the country's largest stem-cell transplant program and continues his work on important research projects.

Ongoing research in Toronto focuses mainly on **vascular disease** (blood vessels), **organ transplants**, **lung disease**, and **immunotherapy**, which shows great potential for the treatment of certain cancers. Immunotherapy involves stimulating the immune system to induce it to attack cancer cells, rather than attacking the tumors with chemicals. Research is also being carried out to find better ways to treat a range of chronic diseases, including **arthritis** and **osteoarthritis**.

The world's first gene therapy clinical trial aiming to find a cure for **Fabry disease** is conducted in Toronto. This rare inherited enzyme deficiency can shorten lifespan by as much as 40 years. Researchers will remove a quantity of stem cells from a Fabry patient's blood. Then a working copy of a new gene will be inserted into the stem cells using a specially engineered virus. During the final phase of the trial, researchers hope to transplant these stem cells back into the donor patient and the new, working copy of the gene will create the missing enzyme.

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CENTRE OF GENOMICS AND POLICY

McGill University, Montréal (Québec)

TRANSVERSAL CORE: Ethical, Legal and Regulatory

The Centre of Genomics and Policy (CGP) is a world-renowned hub for multidisciplinary research at the crossroads of the legal, medical and public policy fields. It enables and facilitates national and international interoperability and harmonization of ethical, legal and regulatory requirements.

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genomicsandpolicy.org

Key investigator

Dr. Bartha M. Knoppers, PhD

Dr. Knoppers is director of the Centre of Genomics and Policy (CGP) at the Faculty of Medicine, Department of Human Genetics, McGill University in Montréal. She is also the Chair of the International Stem Cell Forum's Ethics Working Party (ISCF-EWP) and is also involved on two Public Core Grants by the Stem Cell Network of Canada (SCN) on international stem cell research, banking and clinical translation.

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MICHAEL SMITH LABORATORIES

University of British Columbia, Vancouver (British-Columbia)

TRANSVERSAL CORE: Biotechnology

The UBC-Biotechnology Core is a transversal bioengineering core facility to all cell and tissue manufacturing within CellCAN. This group led by Dr James Piret focuses on optimization of therapeutic cell bioprocesses through cellular physiology and engineering approaches. This aims to improve the design and operation of stem cell and tissue manufacturing and ultimately establish robust and non invasive culture process controls through analysis, prediction and validation of process performance for clinical grade production.

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Key investigator

Dr. James Piret, Sc.D., FCIC

Dr. Piret is a Professor and the Associate Head of the Department of Chemical and Biological Engineering at the University of British Columbia. He was the founding Stem Cell Bioengineering Theme Leader of the Stem Cell NCE.

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