



## Information Brochure for Participants

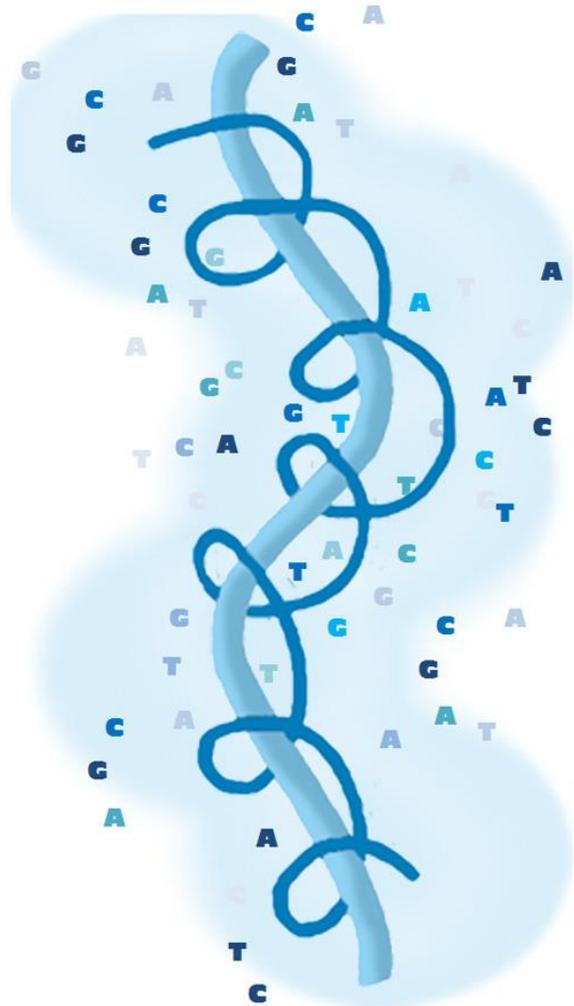
You received this brochure because you expressed your interest to participate in the CARTaGENE project.

**Participation in CARTaGENE is completely voluntary.**

Take the time to carefully read and understand the following information.

We invite you to visit the CARTaGENE website ([www.cartagene.qc.ca](http://www.cartagene.qc.ca)) or communicate with the call center (1-866-366-4249) for any additional information or explanation.

**This project is funded by the Canadian Partnership Against Cancer (CPAC) and Genome Quebec.**



## Table of contents

- p.3 - What is CARTaGENE?
- p.4 - Phase A: CARTaGENE cohort
- p.4 - Currently: Second wave of recruitment
- p.4 - Participation in CARTaGENE
- p.4 - How are participants selected?
- p.5 - What does participation in CARTaGENE involve?
- p.6 - Storage of data and samples
- p.7 - Consent Form
- p.7 - Freedom to participate and right to withdraw
- p.7 - Compensation
- p.8 - Confidentiality
- p.8 - Possible risks and benefits of participation
- p.8 - Commercialization
- p.9 - Access to data and samples
- p.9 - Access by researchers
- p.9 - Internal quality control and the production of aggregated data
- p.9 - Government Health Administrative data
- p.10 - Collaboration between biobanks and researchers
- p.10 - Monitoring and Governance
- p.10 - Public and expert consultation
- p.10 - Ethical oversight of CARTaGENE
- p.10 - Information Access Commission
- p.11 - Knowledge transfer
- p.12 - Consent Form
- p.14 - For more information on CARTaGENE

## What is CARTaGENE?

Our health depends on numerous factors including our environment, our lifestyle, and the genetic predisposition we inherited from our parents. Scientists have long been trying to establish the causes of chronic diseases that affect a large proportion of the population. So far, limited by the inaccessibility of people's genetic data, or by the inability to collect complete information about their health and environment, scientists have only partially uncovered the causes of these diseases.

CARTaGENE is a scientific project of the Centre Hospitalier Universitaire Sainte-Justine (CHU Sainte-Justine) and a research infrastructure developed in order to offer researchers the means to successfully conduct their health investigations. This resource is constituted by a health database and a bank of biological samples. In the long term, this could lead to better prevention, diagnosis and treatments of chronic diseases, such as heart diseases, diabetes and cancer, and thus to the improvement of Quebec's healthcare system.

Data and samples collected will be coded (depersonalized), in order to guarantee confidentiality.

CARTaGENE is part of a larger Canadian endeavor called the Canadian Partnership for Tomorrow Project (CPTP), funded by the Canadian Partnership Against Cancer (CPAC). The CPTP aims to reduce the incidence of cancer and other chronic diseases in Canada, and improve the quality of life of people affected by these conditions. The CPTP wishes to harmonize and coordinate the various provincial biobanks, in order to set a national platform allowing to share data and samples from 300 000 Canadians, including those of CARTaGENE.

For more information about the CPTP, visit the website:  
[www.partnershipagainstcancer.ca](http://www.partnershipagainstcancer.ca).

**The data and biological samples will be kept as long as the CARTaGENE team can ensure an adequate management of the project, unless the body responsible for the ethical evaluation and monitoring decides otherwise.**

## • PHASE A : CARTaGENE COHORT

Over 20 000 women and men residing in Quebec participated to the initial phase of CARTaGENE (Phase A) from June 2009 to October 2010. These participants form the baseline cohort, which can potentially be traced long term. Every participant provided information about his health and lifestyle, and gave blood and urine samples.

## • CURRENTLY : SECOND WAVE OF RECRUITMENT

**CARTaGENE is now beginning a new recruitment phase.  
This project aims at recruiting 20,000 additional participants.**

You are invited to join this new CARTaGENE cohort. This recruitment of new participants will not only cover new regions of the province of Quebec which have not yet been included during the first phase of the project, but will also enlarging our cohort of participants, thus ensuring the durability of the project.

*Note : The use of the masculine form is to simplify the text.*

## PARTICIPATION IN CARTaGENE

### • How are participants selected?

Potential participants are randomly selected among persons aged 40 to 69 years and residing in certain metropolitan areas of the province of Quebec in order to obtain a representative sample of this segment of population.

CARTaGENE has been authorized by the Commission de l'accès à l'information (CAI) to receive from the Régie de l'Assurance Maladie du Québec (RAMQ) coordinates from potential candidates. CARTaGENE also selects potential participants from a random list of phone numbers.

## • What does participation in CARTaGENE involve?

### **1- Filling the Health and Lifestyle Questionnaire**

Participation to CARTaGENE involves completing a questionnaire about health and lifestyle. Instructions to access the online questionnaire are included in the invitation email or in the envelope you received by mail if you requested it.

These instructions include information about your login and password to connect to the call center website, in order to fill out the consent form which is also available for viewing at the end of this information brochure. Once the consent form has been signed, you will be invited to complete the health and lifestyle questionnaire. It should take between 60 and 90 minutes to complete. It is possible to interrupt and resume the questionnaire at any time.

*If you have any questions or encounter any technical difficulties while completing the questionnaire, please contact the call center between 9h and 20h on weekdays, between 12h and 17h on Saturdays and between 13h and 18h on Sundays (1-866-366-4249).*

### **2- Biological Sample Collection**

Participation to CARTaGENE also involves providing a blood sample. The blood sample will enhance the scientific value of your participation in this project. Blood allows not only having sufficient quantity of genetic material (DNA) but also blood derivatives such as plasma and serum, which will be very useful to researchers for performing biochemical and immunological analyses.

You will receive by mail the list of the collection centers, colored labels for your samples, and a medical prescription. To accelerate the process, please bring these documents to your visit. You will need to book an appointment for your visit at the collection center. All the information will be provided in the letter you will receive

A set of contraindications will be checked in order to make sure that it is safe to draw blood. A total of 43 ml of blood (three tablespoons) will be collected, taking approximately 15 minutes.

## BALSAC Genealogical Option BALSAC

**If you wish, you can also participate in CARTaGENE's genealogical option, conducted in collaboration with the BALSAC project at the Université du Québec à Chicoutimi (UQAC).**

BALSAC is a digitized registry constructed from vital events records of Quebec. It allows automatic reconstruction of genealogies across Quebec by tracking ancestors up until the early 17th century. Genealogical information is useful to researchers in order to understand the demographic and historical factors that have shaped Quebec's genetic heritage, and allow us to better understand the distribution of genes or diseases in the current Quebec population.

Participation in the BALSAC option involves:

- Receiving information about the genealogical option by e-mail;
- Signing a specific consent form for the genealogical option;
- Filling in an electronic genealogical questionnaire by providing, to the best of your knowledge, information about yourself and your ancestors (last names, first names, places and dates of birth, of marriage and death, etc.) and returning it by e-mail to BALSAC .

**If you are interested in receiving, without any obligation, information about CARTaGENE's genealogical option by e-mail, you can make this request after signing the CARTaGENE consent form**

**BALSAC website: [www.uqac.ca/balsac/](http://www.uqac.ca/balsac/)**

### • Storage of data and samples

Data and samples collected from participants will be stored as long as the CARTaGENE team can ensure the adequate management of the project, unless the body responsible for the ethical evaluation and monitoring decides otherwise. These samples and data will be coded.

#### - Data from the health questionnaire

The data obtained from the health questionnaire will be coded and transferred to CARTaGENE's health database, where it will be stored until the end of CARTaGENE's activities.

## - Biological Samples

Biological samples collected will be coded and sent from the collecting centers to the “*Biobanque Génome Québec, Centre hospitalier affilié universitaire régional de Chicoutimi*” (GQ-CAURC Biobank) in Saguenay. Samples will then be stored in the GQ-CAURC Biobank for future analyses. DNA analyses will include genome sequencing\*. The samples will be kept until the end of CARTaGENE’s activities.

*\* Sequencing is a technique to determine the order of units that build the DNA and consists of the bases C, T, A and G. DNA is the genetic material that underlies heritability and is found in all cells of almost all living organisms.*

## • Consent Form

The consent form is the only document where the participant’s name appears. It will be securely stored by the CaG-CHUSJ Unit, or, in the future, any other independent entity designated by CARTaGENE and approved by the Commission d’Accès à l’Information, until the end of CARTaGENE’s activities.

The CaG-CHUSJ Unit is a separate body, independent from CARTaGENE, which is under the authority of the Executive Director of Sainte-Justine Hospital.

**Nominative information contained in this document will never be disclosed to the researchers using CARTaGENE data and samples.**

## • Freedom to participate and right to withdraw

**Participation in the CARTaGENE project is free and voluntary.  
You can end your participation at any time.**

If you want to withdraw from the project, you can do so by simply calling the CaG-CHUSJ Unit at **1-877-263-2360**. CARTaGENE will be informed of this withdrawal in a coded form. Data and biological samples from a participant that has withdrawn from the project will be destroyed. However, data and samples that have already been used by researchers cannot be withdrawn from current or completed studies. The death of a participant does not imply that their data and samples will be withdrawn from CARTaGENE, unless clear instructions to do so have been made in the participant’s will or other legal document.

## • Compensation

Each participant has an equal and fair probability **to win one of ten two hundred twenty-five dollars (225\$) prizes**. The draw, organized by CARTaGENE and the call center, will take place at the end of the project (scheduled for late 2014).

## • Confidentiality

**All the information collected for this project will be treated as confidential, unless otherwise stated by a judicial decision or an exception to the law.**

As so, the data and samples will be coded. However, for verification purposes and to ensure your protection, it is possible that delegates from the Research Ethics Board, from the CHU Ste-Justine, or from the Commission d'Accès à l'Information access your research data.

## • Possible risks and benefits of participation

The main inconvenience related to participating in CARTaGENE is the time spent for the participation.

### - Risks

The participant might feel discomfort with regard to certain personal questions asked or during blood draw performed by a **qualified healthcare professional**. Blood collection sometimes causes bruising, pain or, in rare cases, fainting.

Data and samples will be collected, coded and stored in secure and protected installations. Only staff authorized by CARTaGENE will have access to the data. Considering the great care taken for the protection of confidentiality of participants' data and samples, security risks and possible breach of confidentiality are minimized.

**All the research projects using CARTaGENE data or sample will be evaluated by ethic and scientific committees in order to ensure that the risks for the participants are minimized.**

### - Benefits

Participation in CARTaGENE will not bring any direct benefit to the participant. However, studies conducted using CARTaGENE data and samples **may lead to better medical knowledge and in turn improved health care.**

## • Commercialization

The CARTaGENE resource is not for profit. However, it could someday enable researchers to develop new tests or commercial products. **Should this be the case, participants will not receive any financial benefit from such commercialization**

## ACCESS TO DATA AND SAMPLES

- **Access by researchers**

The data and samples collected for the CARTaGENE project will be used for research on health and/or genomics. Researchers with projects that have been approved can ask to use certain samples and data. In this case, ethics committees will evaluate the research projects submitted and the scientific validity of these studies will be examined by an access committee independent from CARTaGENE.

**CARTaGENE will only grant access to data and samples to authorized researchers. Access will not be authorized to insurance companies and employers.**

- **Internal quality control and the production of aggregated data**

CARTaGENE will be able to use the data for quality control purposes and to produce aggregated data. Quality control is done to ensure the quality of the data and its use in future scientific research. Aggregate data is general data that enables CARTaGENE to describe the content of its biobank.

For example, aggregated data can indicate the number of female/male participants, the number of smokers, the number of participants with certain types of diseases, the number of participants by age group, etc. This type of data does not identify participants.

- **Government Health Administrative data**

Researchers will be able to request access to participant's data stored in the Quebec government administrative health databases by obtaining the approval of the *Commission d'Accès à l'Information*. Administrative health data going back as far as 1998 is accessible through the *Régie de l'Assurance Maladie du Québec* (RAMQ). This data may include, for example, hospitalizations, causes of death, types of cancer, and prescribed medications covered by the public health insurance regime. Governmental data sent to CARTaGENE for approved research projects will not contain any personal information because it will be transmitted in coded form. **CARTaGENE will never access participants' medical records.**

- **Collaboration between biobanks and researchers**

Sharing of data and samples makes it possible to increase the statistical power of studies so as to both gain a better understanding of complex genetic diseases and foster the transfer of knowledge to the healthcare system. Such data and samples (always coded) can be shared with researchers from other countries given their research projects abide by the measures put in place to protect CARTaGENE participants.

Researchers from outside Quebec who wish to use CARTaGENE data will have to follow the ethical and legal norms that apply to Quebec researchers and obtain approval from CARTaGENE's independent Access Committee and from the Research Ethics Board of the CHU Ste-Justine.

## Monitoring and Governance

- **Public and expert consultation**

Public consultations (focus groups and a survey) have been carried out to identify the concerns of the population regarding CARTaGENE. Also, workshops with ethics and legal professionals as well as policy decision makers were held. The results of these activities were taken into account in the conceptualization of the project.

- **Ethical oversight**

Ethical evaluation and monitoring of CARTaGENE is done by several Research Ethics Committees, under the umbrella of the CHU Ste-Justine's Research Ethics Board. This committee is independent from CARTaGENE. **Its goal is to protect the interests of participants.**

CARTaGENE and the CHU Ste-Justine follow the ethical norms applicable to research in Quebec and Canada.

- **Information Access Commission**

Personal information obtained by CARTaGENE is subject to surveillance by the Commission d'accès à l'information (CAI) (Information Access Commission) and governed by the "*Loi sur l'accès aux documents des organismes publics et sur la protection des renseignements personnels.*" **The CAI is an organization who has among its goals the protection of personal information held by public or private organizations.** The CAI also has the authority to undertake investigations and audits in order to verify that the collection, use, communication and storage of personal information are conform to the law.

- **Knowledge transfer**

Results obtained by researchers using data and samples from CARTaGENE will be returned to the database in order to enhance its content.

CARTaGENE will not communicate to participants, results from future research using their data and samples. Researchers who consulted or used CARTaGENE data will be invited to publish study results so that the scientific community and the general population may benefit from these. However, all intended publications will be reviewed by CARTaGENE before publication to ensure that there are no risks of identification or stigmatisation of any group of participants.

The summarized results from their studies will be available on the CARTaGENE website.

**Participants of the CARTaGENE project will not receive any individual results from their participation.**

List of health administrative data banks available for use by researchers :  
<http://www.ramq.gouv.qc.ca/en/data-statistics/Pages/data-statistics.aspx>

## CONSENT FORM

### SECOND WAVE OF RECRUITMENT OF CARTaGENE

**CARTaGENE Investigators:** **Philip Awadalla** (Principal Investigator), Ph.D., Professor and Researcher on Population Genomics, CHU Ste-Justine. **Guy Rouleau** (Co-principal Investigator) M.D., Ph.D., CHU Ste-Justine, Montreal Neurological Institute. **Catherine Boileau** (Research associate), Ph.D., Epidemiology, CARTaGENE.

**CARTaGENE Funding :** **The Second Wave of CARTaGENE is funded by the Canadian Partnership Against Cancer (CPAC).**

**The goal of CARTaGENE :** The goal of CARTaGENE is to collect data and samples to establish an infrastructure facilitating research in health and/or genomics.

**By signing this consent form, I agree to participate in CARTaGENE and I declare that:**

- I have read and understood the information brochure. I had the opportunity to ask all the questions I had and obtain answers. I agree to answer a detailed questionnaire regarding my health and lifestyle, and to provide a blood sample.
- I agree that the data collected from the questionnaire be transmitted, in coded form, to CARTaGENE.
- I accept that my blood samples collected will be transmitted, in coded form, to CARTaGENE and to the *Biobanque Génome Québec–Centre hospitalier affilié universitaire régional de Chicoutimi* (Biobank GQ-CAUR).
- I accept that my data and samples once coded, be used by researchers in Quebec or elsewhere, within a framework of biomedical research that have received the necessary approvals from scientific and research ethics committees.
- I accept that personal information about me contained in government health administrative databases be transmitted confidentially to CARTaGENE in coded form when needed for research in health and genomics. This information may cover the period from January 1st 1998 to the end of the CARTaGENE project.
- I understand that I will not receive any personal financial benefit from any possible commercialization of a test or product developed by using the data and samples from CARTaGENE.
- I understand that I will never have access to my data and samples stored in CARTaGENE.
- I understand that I will never receive any result regarding myself from analyses performed by CARTaGENE or researchers using CARTaGENE.

- I understand that after my death, my data and biological samples will not be withdrawn from CARTaGENE, unless clear instructions to that effect figure in my testament or any document with legal value.
- I understand that my participation is completely free and voluntary and that I can withdraw at any moment without giving a specific reason by calling (toll-free): 1-877-263-2360.
- I authorize the CaG-CHUSJ Unit and/or the call center to inform CARTaGENE about the end of my participation in the project if I should withdraw. In this case, I understand that my data and samples that have not already been sent to researchers will be destroyed.
- I agree that the data and samples stored by CARTaGENE will be destroyed at the end of the project unless otherwise specified by the body responsible for ethics review and monitoring.

## Recontact :

**Do you agree to be contacted by an instance acting on CARTaGENE's behalf in the future for additional questionnaires, physical measures and/or samples?** In such a case, you also agree that the CaG-CHUSJ Unit transmits your personal information to a call center designated by CARTaGENE in order to contact you.

I agree

I refuse

**By accepting to participate in this project, you do not waive any of your rights nor do you release the researchers or the establishments from their civil and professional responsibilities.**

Participant information (Application Web)

Last name :

First name :

Address :

Date :

## For more information on CARTaGENE

Visit CARTaGENE's website at: [www.cartagene.qc.ca](http://www.cartagene.qc.ca)

For more information about CARTaGENE, please contact the call center (from 9 a.m to 8 p.m during the week, 12 p.m to 5 p.m on Saturdays, and 1 p.m to 6 p.m on Sundays)

By phone : 1-866-366-4249

By email : [cartagene@advanis.ca](mailto:cartagene@advanis.ca)

Following your participation, if you want to withdraw your data and samples from CARTaGENE, please contact the CaG-CHUSJ Unit

By phone : 1-877-263-2360

To make an appointment for blood collection, please call 1-800-463-7674.

Any complaint regarding your participation in this research project can be addressed to the Commissaire aux plaintes et à la qualité des services du CHU Ste- Justine

By phone : (514) 345-4749

By mail : Commissaire aux plaintes et à la qualité des services

CHU Sainte-Justine, pièce 1102

3175, chemin de la Côte-Sainte-Catherine

Montréal (Québec) H3T 1C5

## Thank you for taking the time to think about CARTaGENE

- **Philip Awadalla**

Professor, Ph.D - Scientific Director and Principal Investigator

- **Guy Rouleau**

M.D, Ph.D., FRCP (c), OQ - Co-principal Investigator

- **External collaborators :**

BALSAC Project

Advanis Jolicoeur

Biron- Laboratoire médical