

The world within you



**Information
brochure
for participants**

**ENVIRONMENT AND
NUTRITION COMPONENT**

Production of this brochure has been made possible through a financial contribution from Health Canada, through the Canadian Partnership Against Cancer.



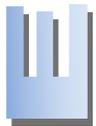
Introduction

CARTaGENE, a research infrastructure consisting of a database and a biobank of biological samples, was designed to facilitate research in the field of health and genomics.



Purpose of this Recontact

CARTaGENE is again seeking your collaboration for a new component called “Environment and Nutrition.” This new component will allow CARTaGENE to add data to its database and thus provide new data for health and genomics research. This new component will allow the collection of detailed information on your eating habits and exposure to the environment.



Environment and Nutrition

We now know that the food we consume and the environment where we live are related to our state of health. However, we still know relatively little about these relationships and their impact on the health of individuals. The Environment and Nutrition component aims to increase our knowledge on this subject.



The Environment and Nutrition component is divided into two modules. The Environment module comes first, and the Nutrition module will follow. Your consent given for the first phase of CARTaGENE’s data and sample collection included this option to be recontacted for further studies. The Environment and Nutrition component is such a study. Your participation remains voluntary however. Before making your decision, it is important that you read this brochure and the consent forms included so as to understand the implications of participating in either or both modules of this component. Your decision whether or not to participate in these modules will not affect any data or samples that you have already given for the first phase of CARTaGENE. Any data or samples already collected will remain in CARTaGENE’s database and biobank.



Collaboration with Canada’s other biobanks

As we informed you in the first phase’s Information Brochure, CARTaGENE has forged links with other Canadian organizations, for instance, the Canadian Partnership for Tomorrow Project (“CPTP”) funded by the Canadian Partnership Against Cancer (“CPAC”). The CPTP’s objective is to reduce the number of new cases of cancer and other chronic diseases in Canada, as well as improve the quality of life for people currently suffering from disease. CPTP aims to harmonise and coordinate different provincial biobanks to create a national platform that will enable the sharing of the data and samples of 300,000 Canadians, of which 20,000 are CARTaGENE participants.



CARTaGENE is proud to be the Québec partner for this large-scale project by making available the data and samples gathered, including the ones from this Environment and

Nutrition component. CARTaGENE will permit access by researchers to its data and samples in accordance with CARTaGENE's policies and commitments to its participants.

For more information on the CPTP project, visit the website:

www.partnershipagainstcancer.ca

AIM OF THE ENVIRONMENT AND NUTRITION COMPONENT

The purpose of the **Environment** and **Nutrition** component is to enrich the data on the environmental exposures and eating habits of CARTaGENE participants. Our eating habits, the quality of our natural environment and our surrounding infrastructures all impact our state of health. A person's genetic code alone cannot explain the causes of disease. CARTaGENE is interested in factors which, like our genes, can influence the development of chronic diseases. A better knowledge of the links between environmental factors, eating habits and the genes of each individual, as well as the repercussions each of these factors has on health, could help develop programs better adapted to the needs of the population. It may also improve personalized interventions based on an understanding of the role of different genes.

PARTICIPATING IN THE ENVIRONMENT AND NUTRITION COMPONENT

The collection of the **Environment** and **Nutrition** component will begin with the module on the **Environment** and will be followed by the module on **Nutrition**. If you wish to participate in this component of CARTaGENE, you have the choice of filling out questionnaires on both the **Environment** and **Nutrition** modules in either paper format or online.

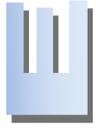
CARTaGENE has mandated the firm Jolicoeur et associés (The Call Center) to ensure communication and technological support to its participants for the **Environment** and **Nutrition** component. If you do not reply, you will receive up to two reminders by phone after the initial issuance. If you no longer wish to participate in this component, we ask that you notify us by contacting the Call Centre.

If you decide, at any time, to complete the questionnaires and consent forms in paper format, you may request the Call Center (Jolicoeur et associés) to send them to you by mail.

To contact the Call Centre:

1. Call: 1-800-636-3106 ext. 104
Or
2. E-mail: cartagene@etudesondage.com

Visit the CARTaGENE website at: www.cartagene.qc.ca



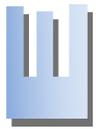
Environment Module

The **Environment** module consists of a questionnaire about your residential and work environments. You will be receiving this module's documents first.



Questionnaire about residential and work environments

This questionnaire includes questions relating to your residential and work environments. With regard to the residential environment, you are asked to provide the addresses (including your postal code) of all the places where you have lived, the years of construction of all of your homes, the number of people living at the same address as you, your main source of heating, etc.



The questions pertaining to your work environment concern information about your employers, the period and duration of different jobs you have had, tasks at work, type of transport used to get to and from work, etc.



The addresses we request in this questionnaire are only to determine your postal code in case you cannot remember it. This information will not be integrated into the CARTaGENE database and therefore not transmitted to researchers. This information is only requested to better identify environment-based factors regarding where individuals live or work that can impact health.



You have the choice to indicate either only the first three (3) characters of your full postal code, or all six (6) characters. Complete postal codes may, in certain circumstances, inadvertently help identify an individual, a family or a community. If you do not wish to share your full postal code, we ask that you give only the first 3 characters.



In any event, complete postal codes will not be given to researchers. The information relating to the environment associated with a geographic area defined by a particular postal code will be able to be linked to the data collected in CARTaGENE. Only researchers who demonstrate that such information would be necessary and pertinent to a research project linked to health will have access to this data.



As a general rule, any pairing of data with the CARTaGENE database will be carried out within CARTaGENE and only the results of the pairing will be given to researchers (excluding postal codes). However, researchers may, in some cases, consult the CARTaGENE databases, including postal codes, but only on secure workstations in the CARTaGENE offices. This is used particularly in data analysis. CARTaGENE ensures that only aggregated results from these analyses (excluding full postal codes) be provided to researchers at the end of their work session at the CARTaGENE offices.



In addition, all researchers requesting access to CARTaGENE's data and samples undertake not to attempt to identify any participant and, if they inadvertently manage to do so, undertake to destroy all identifying information.

This Environment questionnaire should take approximately one (1) hour to complete.

Nutrition Module

The **Nutrition** module includes a questionnaire relating to eating habits.

Questionnaire on eating habits

The questionnaire used in this module about **Nutrition** was adapted from the *Diet History Questionnaire* of the *National Institutes of Health* (United States)

This questionnaire includes questions relating to eating habits, regarding the consumption of different types of food from a predetermined list (ex: fruits, vegetables, grains, meat, fish, dairy products, alcoholic beverages...). The questions pertain to the frequency of consumption of these foods as well as portion size consumed during the last 12 months.

This Nutrition questionnaire should take approximately one (1) hour to complete.

RISKS AND BENEFITS LINKED TO PARTICIPATION

The main inconvenience caused by participation in either the modules of the **Environment** and **Nutrition** component is the time spent participating.

Risks

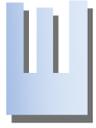
The data will be collected, coded and stored in secured facilities. Only a limited number of people authorized by CARTaGENE will have access to it. Considering the great care put into the protection and confidentiality of participants' data, security risks or breach of confidentiality are minimized.

Information available through CARTaGENE's **Environment** module may allow links to be drawn between characteristics of certain neighbourhoods and the health of its residents.

All the research that will make use of the data provided by CARTaGENE will be evaluated by ethics and scientific committees to ensure that any risks associated with this research will be minimized for participants.

Benefits

Participation in the **Environment** and **Nutrition** component of CARTaGENE will not directly benefit the participants, but may allow to improve scientific knowledge, through analyses done with CARTaGENE's data.

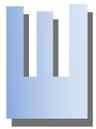


Links that may be made between characteristics of certain neighbourhoods and the health of its residents, in the **Environment** component, could lead to new solutions for health problems that concern specific sub-divisions of the population, particularly those living in certain neighbourhoods; for example, a link between obesity and the presence of fast food shops or green spaces in a neighbourhood.



COMMUNICATION OF RESULTS

No results deriving from the data collected will be communicated to participants. However, an annual newsletter aimed at informing the public about research projects using CARTaGENE will be available on CARTaGENE's website (www.cartagene.qc.ca).



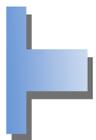
RIGHT TO WITHDRAW



Participants are free to withdraw from the **Environment** and **Nutrition** component of CARTaGENE at any time. To withdraw, simply call the *Régie de l'assurance maladie du Québec* (RAMQ) toll-free at (1-877-263-2360). The request will be forwarded to CARTaGENE, identifying the participant with a code, and the participant's data in the CARTaGENE database will be destroyed. However, data already used in either completed research or research that is already underway cannot be withdrawn.



The death of a participant will not cause their data to be withdrawn from CARTaGENE, unless clear instructions to do so have been made in the participant's will or other legal document.



STORAGE OF DATA

All the data, as well as consent forms, from the participants, will be stored until December 31, 2058, the scheduled end of all CARTaGENE activities, unless CARTaGENE decides otherwise and upon approval of the body responsible for CARTaGENE's ethical evaluation and monitoring.



Regardless of the end date of CARTaGENE's activities, the data and consent forms will be destroyed and no copies will be kept, unless the body responsible for CARTaGENE's ethical evaluation and monitoring decides otherwise.



Consent forms



Participant consent forms will be stored at the RAMQ, or any other entity designated by CARTaGENE, until the end of CARTaGENE's activities. The contents of these documents will never be disclosed to researchers using CARTaGENE.

Data

All data relating to the participants from the questionnaires will be transmitted in a coded format to CARTaGENE database at the Université de Montréal, where they will be stored until the end of CARTaGENE's activities.

ACCESS TO CARTaGENE

Contents of CARTaGENE:

CARTaGENE already contain:

1. The **coded data** of participants collected during the **first phase** from:
 - a. the health questionnaire
 - b. Physical measurements
 - c. biochemical analysis from the blood and urine samples
2. The **coded samples** of blood and urine collected from participants during the **first phase**

After the **Environment** and **Nutrition** component is completed, CARTaGENE will also contain:

3. The **coded data** of the participants collected under the **Environment** and **Nutrition** component from:
 - a) The **Environment** and **Nutrition** questionnaires (this data will exclude addresses indicated in the Environment questionnaire as well as any information participants give relating to employers. This information is required only to validate the postal code and will eventually be destroyed.)

Also, researchers will be able to have access to coded data concerning participants, kept in governmental health databases, subject to approval from the *Commission d'accès à l'information* (CAI).

Access to CARTaGENE

CARTaGENE complies with the Data and Samples Access and Usage Policy adopted by the Université de Montréal, which was duly approved by the required bodies.

Access by researchers

CARTaGENE's data can be used for research in health (ex. biomedical research, epidemiology, and public health), as well as in genomics. It is impossible to predict all studies that could be done on CARTaGENE's data until 2058, but they will serve, among other things, for research on the contribution of environmental and nutritional factors to disease.

E

Only research which has received all the required approvals will be allowed access to the data collected during the Environment and Nutrition component of CARTaGENE. All research projects requesting such access will have to be evaluated by ethics committees and the scientific validity of these studies will be examined, notably, by a Sample and Data Access Committee (SDAC), independent of CARTaGENE.

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CARTaGENE will only allow access to the data to authorized researchers. Neither insurers nor employers of the participants will be granted access to the data.

Internal quality control and production of aggregated data

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CARTaGENE may use the data collected to verify its quality and to produce summary reports based on aggregated data (i.e. general results).

G

The objective of quality control is to ensure the quality of collected data and their future uses in scientific research. The data aggregated is general data which can be used to make a description of database content. As an example, the aggregated data can indicate the number of women/men in CARTaGENE, the number of people who live alone, the number of participants who eat red meat more than three (3) times a week, the number of participants in a given age group, etc.

This is not information that can be used to identify a participant.

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CONFIDENTIALITY AND DATA PROTECTION

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CARTaGENE conforms to policies and security mechanisms that have been approved by the ethics committees as well as the *Commission d'accès à l'information*.

Storage of participants' personal information

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The RAMQ is responsible for the storage of consent forms and the archiving of participants' personal information. It will remain the sole holder of personal information at the end of the Environment and Nutrition component. The RAMQ has the legal obligation to guarantee the confidentiality of the information that it holds and uses. All personal information released to the RAMQ will be handled and protected according to the legislation and standards in force at the *Régie de l'assurance maladie du Québec* and by virtue of the *Act respecting access to documents held by public bodies and the protection of personal information*.

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Separation of personal information and data

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At the end of the Environment and Nutrition component, the Call Center will transfer the participants' personal information and consent forms to the RAMQ for storage. The data contained in the questionnaires will not be transferred to the RAMQ, rather it is coded and transmitted to CARTaGENE.

Personal information is always kept separate from the related data.

In addition, CARTaGENE does not have access to the medical records of participants.

Implementation of security measures

Facilities that contain personal information as well as those which contain data are protected by strict technological and physical security measures. These include strict access controls, encryption of data and codes, implementation of confidentiality agreements and training of employees.

These security measures have been the subject of an evaluation by the *Commission d'accès à l'information*.

Coded data

All data are coded before being transmitted to CARTaGENE. Codes are then modified by CARTaGENE before data is stored. When a request for access to data is made, data is then assigned a new code before being transmitted to the researcher. This way, neither CARTaGENE nor any researcher is able to establish the identity of a participant.

MONITORING AND GOVERNANCE

Ethical oversight for CARTaGENE

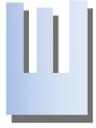
The Ethics Committee designated by Université de Montreal is responsible, on behalf of the University, for the evaluation and ethical monitoring of the **Environment** and **Nutrition** component, and CARTaGENE overall. This Committee is independent of CARTaGENE and its purpose is to protect the interests of participants.

CARTaGENE and the Université de Montréal are both subject to ethical standards that govern research in Québec and Canada.

Commission d'accès à l'information (CAI)

The personal information obtained by CARTaGENE is subject to the Commission d'accès à l'information (CAI) and the *Act respecting the protection of personal information in the private sector*. The CAI is an organization that ensures the protection of personal information held by public or private organizations.

The CAI also has the power to conduct investigations and audits so as to verify that the collection, use, communication and storage of personal information are carried out in accordance with the Act.



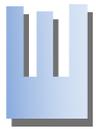
RESEARCH RESULTS

Knowledge transfer

Results obtained by researchers using CARTaGENE will be returned to CARTaGENE, and may be integrated into its database and biobank with a view to enriching them.



The researchers who will have consulted or used data will be asked to publish the results arising from their research project, so that the scientific community and the general population may benefit. However, prior to the publication of results, researchers must provide CARTaGENE with the text they have the intention of publishing, so that CARTaGENE may verify that it does not allow the identification of a participant or to stigmatize a group of participants.



Commercialization



CARTaGENE is not for profit. However, data from the **Environment** and **Nutrition** component of CARTaGENE could, one day, allow research to lead to the development of a product that will be commercialized. CARTaGENE's participants will not receive any financial profit from the **commercialization** of any product.



To obtain additional information:

- ◆ Visit the CARTaGENE website at www.cartagene.qc.ca
- ◆ Contact our toll-free Call Centre (Jolicoeur et Associés):
 - Call 1-800-636-3106 ext. 104
 - E-mail cartagene@etudesondage.com



THE ENVIRONMENT AND NUTRITION COMPONENT TEAM

LEAD INSTITUTION

The [Université de Montréal](#) is the host institution for CARTaGENE and is responsible for CARTaGENE overall.

RESEARCHERS

[Bartha Maria Knoppers](#) (Principal Investigator - CPTP), Ph.D., Professor, Faculty of Law, *Université de Montréal*.

[Philip Awadalla](#) (Co-Principal Investigator) Ph.D., Professor and Researcher in Population Genomics, *Université de Montréal*.

[Claude Laberge](#) (Associate Researcher), M.D., Ph.D., Doctor and Geneticist, Professor, *Université de Montréal*.

[Catherine Boileau](#), (Research Associate), Ph.D., Director of Epidemiology, CARTaGENE.

PARTNERS

The [Canadian Partnership for Tomorrow Project](#) (CPTP), a research project that combines Canadian biobanks, such as CARTaGENE.

The [Régie de l'assurance maladie du Québec](#) (RAMQ), through the CaG-RAMQ Service, is responsible for the retention of consent forms and participants' personal information.

The [Génome Québec - Centre hospitalier affilié universitaire régional de Chicoutimi](#) Biobank in Saguenay stores the CARTaGENE Biobank (blood and urine samples).

FUNDING

The [Environment](#) and [Nutrition](#) component of CARTaGENE is funded by the [Canadian Partnership Against Cancer](#) (CPAC).

Thank you for taking the time to think about CARTaGENE!

Cette brochure est également disponible en français.

CARTaGENE - ENVIRONMENT AND NUTRITION COMPONENT

CONSENT FORM: ENVIRONMENT MODULE

Researchers: Bartha Maria Knoppers (Principal Investigator), Ph.D., Professor, Faculty of Law, *Université de Montréal*. Philip Awadalla (Co-Principal Investigator), Ph.D., Professor and researcher in population genomics, *Université de Montréal*. Claude Laberge (Associate Researcher), M.D., Ph. D., doctor and geneticist, Professor, *Université de Montréal*. Catherine Boileau, (Research Associate), Ph.D., Director of Epidemiology, CARTaGENE.

Collaborators: the questionnaires were developed in collaboration with a group of environmental experts (*CPTP-Environmental Task Force*) under the coordination of Anya Keefe (University of British Columbia).

Source of funding: Canadian Partnership Against Cancer (CPAC).

The aim of CARTaGENE's **Environment** module is to add to its database, data relating to residential and work environmental exposures.

By signing this consent form, I agree to participate in CARTaGENE's **Environment** module and attest the following:

- I have read and understood the **Environment** and **Nutrition** component information brochure. I have been given sufficient time to think and make a decision regarding my participation.
- I agree to complete the questionnaire on residential and work environments.
- I agree that the data gathered from the questionnaire be transmitted in coded form to CARTaGENE.
- I agree that my personal information be stored by the Call Centre until the end of the **Environment** and **Nutrition** component, and then by the RAMQ or any other body designated by CARTaGENE.
- I understand that the addresses supplied as answers for the questionnaire will not be integrated in the CARTaGENE database, and therefore will not be transmitted to

any researcher.

- I understand and agree that the complete postal code constitutes personal information that could, in certain circumstances, lead to identify an individual, a family or a community. Therefore, I have the choice to indicate only the first three (3) characters or all six (6) characters of my postal code. I also understand that my complete postal code will never be given to researchers.
- I understand and agree that I will never have access to the data concerning me, collected for the **Environment** module, and that CARTaGENE will store this data.
- I agree that the data kept by CARTaGENE be destroyed at the planned end of CARTaGENE, on December 31, 2058, unless CARTaGENE decides otherwise and upon approval of the body responsible for CARTaGENE's ethical evaluation and monitoring.
- I agree that all data collected about me, once coded, will be used by researchers in Québec, elsewhere in Canada and in other countries, for research in health and genomics, who have obtained scientific and ethical approvals.
- I understand that I will receive no benefit, financial or otherwise, for my participation in the **Environment** module, even if my data stored in CARTaGENE contributes to the development of a product that is commercialized.
- I understand that after my death, my data cannot be removed from CARTaGENE, unless clear instructions have been given in either my will or other legal document.
- I understand that my participation is completely voluntary and that I can withdraw at any time without giving any reason by calling 1-877-263-2360. I authorize the RAMQ, or any other body acting on behalf of CARTaGENE, to inform CARTaGENE of my decision to withdraw, so that they may destroy all the data that I have given that have not yet been used by researchers.

Contact

To obtain additional information:

- ◆ Visit the CARTaGENE website at www.cartagene.qc.ca
- ◆ Contact our toll-free Call Centre (Jolicoeur et Associés):
 - Call 1-800-636-3106 ext. 104
 - E-mail cartagene@etudesondage.com

To withdraw from CARTaGENE:

- ◆ Contact the RAMQ toll-free at 1- 877-263-2360

Any complaint concerning your participation in this research can be addressed to the Ombudsman at the *Université de Montréal* by calling 514-343-2100 or by e-mailing ombudsman@umontreal.ca (collect calls are accepted).

By agreeing to participate in this component, you do not waive any of your rights nor do you release any researchers or the institution from their civil and professional responsibilities.

Participant's signature: _____ Date : _____

Or contact information (Online Application)

Last name: _____ First name: _____ Date : _____

Address : _____

A copy of this form must be kept by the participant.

CARTaGENE - ENVIRONMENT AND NUTRITION COMPONENT

CONSENT FORM: NUTRITION MODULE

Researchers: Bartha Maria Knoppers (Principal Investigator), Ph.D., Professor, Faculty of Law, *Université de Montréal*. Philip Awadalla (Co-Principal Investigator), Ph.D., Professor and researcher in population genomics, *Université de Montréal*. Claude Laberge (Associate Researcher), M.D., Ph. D., doctor and geneticist, Professor, *Université de Montréal*. Catherine Boileau, (Research Associate), Ph.D., Director of Epidemiology, CARTaGENE.

Collaborators: This questionnaire was developed in collaboration with a group of experts in the field of nutrition under the coordination of Dr. Ilona Csizmadi (Department of Population Health Research - Alberta Health Services) and with the participation of Dr Anita Koushik (*Université de Montréal*).

Source of funding: Canadian Partnership Against Cancer (CPAC).

The aim of CARTaGENE's Nutrition module is to add to its database, data relating to the eating habits of participants.

By signing this consent form, I agree to participate in CARTaGENE's Nutrition module and attest the following:

- I have read and understood the Environment and Nutrition component information brochure. I have been given sufficient time to think and make a decision regarding my involvement.
- I agree to complete the questionnaire regarding eating habits.
- I agree that the data gathered from the questionnaire be transmitted in coded form to CARTaGENE.
- I agree that my personal information will be retained by the Call Centre until the end of the Environment and Nutrition component, and then by the RAMQ or any other body designated by CARTaGENE.
- I understand and agree that I will never have access to the data concerning me, once collected for the Nutrition module, and that CARTaGENE will retain the data.
- I agree that the data kept by CARTaGENE be destroyed at the planned end of

CARTaGENE, on December 31, 2058, unless CARTaGENE decides otherwise and upon approval of the body responsible for CARTaGENE's ethical evaluation and monitoring.

- I agree that all data collected about me, once coded, will be used by researchers in Québec, elsewhere in Canada and in other countries, for research in health and genomics, who have obtained scientific and ethical approvals.
- I understand that I will receive no benefit, financial or otherwise, for my participation in the **Nutrition** module, even if my data stored in CARTaGENE contributes to the development of a product that is commercialized.
- I understand that after my death, my data cannot be removed from CARTaGENE, unless clear instructions have been given in either my will or other legal document.
- I understand that my participation is completely voluntary and that I can withdraw at any time without giving any reason by calling 1 877- 263-2360. I authorize the RAMQ, or any other body acting on behalf of CARTaGENE, to inform CARTaGENE of my decision to withdraw, so that they may destroy all the data that I have given that have not yet been used by researchers.

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By agreeing to participate in this component, you do not waive any of your rights nor do you relieve any researchers or the institution from their civil and professional responsibilities.

Participant's signature: _____ Date : _____

Or contact information (Online Application)

Last name: _____ First name: _____ Date : _____

Address : _____

A copy of this form must be kept by the participant.

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