CARTaGENE

Access and Use Agreement for Data and/or Biosamples

("**Access Agreement**")

Research Project: [insert title]
Research Project number: [insert]

BETWEEN

CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE, a legal person governed by *An Act Respecting Health Services and Social Services*, RLRQ, c.S-4.2, a law of Quebec, Canada, having its head office at 3175 Côte-Sainte-Catherine Road, Montreal, Quebec, H3T 1C5 Canada. (hereinafter referred to "**CHU Sainte-Justine**")

AND

INVESTIGATOR	**INSTITUTION TO WHICH THE INVESTIGATOR IS AFFILIATED**
[insert]	[insert]
Name	*Name*
Investigator	[insert]
Status or occupation	*Address*
[insert]	[insert]
Address	*Authorized Representative (name and function)*
[insert]	[insert]
Email	*Authorized Representative's email address*
[insert]	[insert]
Telephone	*Representative's telephone number*
Hereinafter referred as "**the Investigator**"	Hereinafter referred as "**the Institution**"

This Access Agreement follows the approval of an Access Request filed by the Investigator and the Institution pursuant to the provisions of the *Access Policy for Use of the Data and/or Biosamples* ("**Access Policy**"). The Investigator and Institution shall comply with the provisions of said Access Policy, which is an integral part of this Access Agreement (Schedule 6). The terms or expressions used in this Access Agreement bear the meaning given in the Access Policy unless otherwise defined herein.

In consideration of the above premises and mutual covenants contained herein, the parties hereto agree as follows:

1. The Investigator shall use the Data and/or Biosamples listed in Schedule 1 in accordance with the terms and conditions outlined in the Access Agreement and in the Access Policy (Schedule 6).

2. The terms and conditions for the transfer of Data and/or Biosamples to the Investigator are described in Schedule 2 of the Access Agreement.

3. Access to Data and/or Biosamples will only be granted to the Investigator and persons listed in the Access Request.

4. The Investigator and the Institution agree to comply with the following obligations:

4.1 Use the Data and/or Biosamples exclusively for the conduct of the Research Project: **Project title (**the **"Research Project")** as approved by the Sample and Data Access Committee (**SDAC**).

4.2 Comply with the security measures set out in Schedule 2 and ensure proper storage and use of Data and/or Biosamples at all times.

4.3 Ensure that Data and/or Biosamples is/are solely disclosed to, made available to, used by and/or in possession of the Investigator or individuals listed in the access request, and only insofar as they remain attached to their Institution. The Data and/or Biosamples may not, at any time, be disclosed or made available to any other individual. The Investigator and the Institution are jointly and severally responsible for the compliance with the terms and conditions of the Access Agreement by all the individuals listed in the access request and shall take the appropriate measures to ensure such compliance. Without limiting the generality of the foregoing, Investigator and Institution shall require that all individuals listed in the access request who are not employed by Institution sign a copy of the "Representations and undertakings of the Co-Investigator or Collaborator" herein attached as Schedule 7.

4.4 In the event that personal information or unapproved health information about a participant or health information for which approval was not granted to Institution and Investigator ("unapproved health information") is inadvertently transferred to the Institution, or the Investigator, or their respective employees, collaborators or agents, it/he/she/they shall not use or

disclose such information and shall 1) immediately notify CHU Sainte-Justine and CARTaGENE, of receipt of such personal information or unapproved health information, 2) promptly destroy such personal information or unapproved health information in a secure fashion and 3) promptly certify such destruction in writing to CHU Sainte-Justine and CARTaGENE. The Institution and the Investigator shall take appropriate care in the disposal or destruction of the information to prevent anyone from gaining access to it. The parties shall make their employees, collaborators and agents aware of the importance of maintaining the confidentiality of any transferred personal information or unapproved health information. These obligations of confidentiality shall survive the expiration or earlier termination of this Access Agreement.

4.5 In the case of involuntary identification of a participant, the Institution and the Investigator shall Destroy the identifying information and provide prompt written notice to the CHU Sainte-Justine and CARTaGENE. The Institution and the Investigator shall not collect, use or disclose any identifying information or attempt to contact a participant.

4.6 Return Derived Data generated in the course of the Research Project to CARTaGENE as indicated in Schedule 3 of the Access Agreement, within the timeframe granted by the SDAC.

4.7 At least thirty (30) days prior to publishing the results of the Research Project, submit a copy of the manuscript to be published to CARTaGENE for review for potential risk of identification of a participant.

4.8 Include an acknowledgement in all publications and presentations as follows: "This research/presentation has been conducted using Data and/or Biosamples from CARTaGENE" and include a reference to CARTaGENE's web site (https://cartagene.qc.ca/en).

5. Follow-up and reports

5.1 CHU Sainte-Justine representatives may conduct audits upon reasonable notice to Institution of Institution's site to ensure compliance with this Access Agreement.

5.2 The Investigator and the Institution shall promptly notify CARTaGENE of any situation listed in the paragraph 8.4.2 from the *Follow-up and Reports* section of the Access Policy (Schedule 6).

5.3 The Investigator and the Institution shall submit an annual report to CARTaGENE detailing the progress and execution of the Research Project protocol and, the last year, a final report at the end of the Research Project detailing its conclusions and its results. If the project timeframe is less than one (1) year, this report shall be the final report.

5.4 The Investigator and the Institution shall provide CARTaGENE with a summary of the Research Project (at the beginning) and of the results (at the end), in lay-language, for publication on CARTaGENE's website.

5.5 No party shall use, or authorize others to use, the name, trademark, trade name, logo, symbol, mark or any adaptation thereof, of any other party hereto in any publication, news release, promotional material, promotional activity, advertisement, or other public announcement, whether written or oral, or make any form of representation or statement in relation to the Research Project that would constitute an express or implied endorsement by such other party of any product or service of the first party without the prior written consent of the affected party, subject, however, to the following:

The parties may disclose, without prior consent:

(i) Title and brief summary of the Research Project and the results and benefits for the public and for public health;

(ii) Names of Investigator and collaborators of the Research Project and a brief description of their academic credentials and professional experience;

(iii) Name of employer and/or Institution to which they are affiliated;

(iv) Source of funding for the Research Project;

(v) Scheduled Research Project start date and end date.

6. Fees

The Institution and the Investigator agree to pay CHU Sainte-Justine the fees outlined in Schedule 5, prior to receiving the Data and/or Biosamples. The payment to CHU Sainte-Justine shall be made within thirty (30) days upon reception of the invoice.

7. Absence of a guarantee and release of liability

7.1 The Data and/or Biosamples to be transferred to the Institution and Investigator were gathered, processed and preserved in accordance with the CARTaGENE research protocol, which abides by the usual quality standards in this field and was duly approved by a recognized research ethics committee.

7.2 Warranty

The Biosamples may contain biohazardous infectious agent(s) and must be handled with caution and prudence. The Institution and Investigator acknowledge that the Data and/or Biosamples is/are experimental in nature and that it is/they are provided without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. CHU SAINTE-JUSTINE MAKES NO REPRESENTATION THAT THE USE OF THE DATA AND/OR BIOSAMPLES WILL NOT INFRINGE ANY PROPRIETARY RIGHT.

7.3 Liability

The parties acknowledge that the Data and/or Biosamples may be hazardous, and may possess other characteristics which are unknown or difficult to determine and which may pose potential hazards and risks either in their handling, delivery, use, storage, disposal and overall treatment and possession. To the extent permitted by the laws of the province under which the Institution and Investigator are governed, Institution and Investigator assume all liability for damages they may suffer arising from; (i) the Institution and Investigator's acceptance, use, handling, storage or disposal of the Data and/or Biosamples, and (ii) Institution and Investigator's use of any data generated under the Research Project through the use of the Data and/or Biosamples, except to the extent such damages result directly from CHU Sainte-Justine's negligence or willful misconduct.

Institution and Investigator shall not be liable for the use by the CHU Sainte-Justine of the results or any other materials delivered hereunder.

8. Default and termination

If the Investigator and/or the Institution fail to comply with the terms and conditions outlined in the Access Agreement and/or with the provisions of the Access Policy, CHU Sainte-Justine shall have the right to retrieve the Data and/or Biosamples transferred to the Investigator and the Institution wherever they may be. The authorization for access or use granted by CHU Sainte-Justine will be immediately revoked and CHU Sainte-Justine reserves the right to take any other recourse that it deems relevant regarding the default, including banning future access and use of the CARTaGENE Data and/or Biosamples and making a claim for damages. In addition, the Investigator and the Institution will not be authorized to use any data or any outcome derived from the use of the Data and/or Biosamples delivered to the Investigator and Institution.

9. Effective date and Duration

9.1 The Access Agreement takes effect on the date all parties will have signed the Agreement. Access and use of the Data and/or Biosamples will only be granted after full execution of the Access Agreement and full payment of the fees. **Access and use will terminate on [insert].**

9.2 On the date of termination of the Access Agreement, unless permitted otherwise in writing by the CHU Sainte-Justine, the Investigator and the Institution shall confirm that they have destroyed and have not kept any copies of the Data and/or any Biosamples by completing and signing the document to this effect found in Schedule 4.

9.3 The Investigator and the Institution may request an extension of the duration of the Access Agreement, which may be granted within the scope of the provisions of the Access Policy and upon written agreement by the parties.

10. Transfer of rights

No right or license is granted under this Access Agreement by either Party to the others either expressly or by implication, except those specifically set forth herein. It is understood that absolutely no proprietary rights, in the Data and/or Biosamples are granted to Institution and/or Investigator.

11. Intellectual property

CHU Sainte-Justine does not claim any intellectual property rights on the results, discoveries, inventions or works derived from the use of the Data and/or Biosamples delivered to the Investigator and Institution. Investigator and Institution are free to file patent application(s) claiming inventions made by the Investigator through the use of the Data and/or Biosamples but agree to notify CARTaGENE upon filing any such patent application.

12. Governing Law and Jurisdiction

The Access Agreement shall be interpreted, construed and enforced under the laws of Quebec and the laws of Canada in force in that province, without regard to its conflict of law rules. The parties agree that by executing the Access Agreement, they have attorned to the exclusive jurisdiction of the Quebec courts, in the district of Montreal, province of Québec, Canada.

THE PARTIES HAVE SIGNED on the date indicated under their signature. This Agreement may be executed in counterparts, each of which shall be deemed an original instrument, and all of which shall constitute a single agreement. The parties may execute this Agreement by facsimile or electronically transmitted signature, and such facsimile or electronically transmitted document, including the signatures thereon, shall be treated in all respects as an original instrument bearing an original signature.

INVESTIGATOR	**[INSERT INSTITUTION NAME]**
Signature : _____	Signature : _____
By : **[insert]**	By : **[insert]**
_____	_____
	Authorized representative of the Institution (Name)
	[insert]
	Authorized representative of the Institution (Function)
Date : _____	Date : _____

CENTRE HOSPITALIER UNIVERSITAIRE SAINTE-JUSTINE

Signature : _____

By : **Jacques Michaud**
Director of Research
CHU Sainte-Justine

Date : _____

SCHEDULE 1

LIST OF DATA AND BIOSAMPLES DELIVERED

Data and Biosamples requested and delivered to the researcher.

A. Project Summary (submitted by the investigator, extracted from the SDAC approved application form)

B. Participant Selection

C. List of Datasets

D. Biosamples

SCHEDULE 2

TERMS AND CONDITIONS FOR THE TRANSFER AND SECURITY MEASURES TO BE APPLIED TO DATA AND BIOSAMPLES

1. The Investigator is responsible for ensuring that all other individuals listed in the Access Agreement comply with the security measures outlined in this Access Agreement.
2. All Investigators and users of the CARTaGENE Data and/or Biosamples must:
   a) Ensure Data security with regards to confidentiality and integrity;
   b) Ensure that CARTaGENE Data is used securely and not used on unsafe servers, workstations, laptops, tablets or removable media backup based on criteria defined by CARTaGENE;
   c) Inform CARTaGENE of any security incidents or breach in confidentiality related to the CARTaGENE Data or Biosamples;
   d) Ensure that all members of the research team using the CARTaGENE Data and Biosamples have signed confidentiality agreements;
   e) Safeguard the integrity of the data by using an encryption system on the computer(s) where the Data will be stored and used;
3. The Investigator and his Institution are responsible at all times for ensuring that sharing and transferring the Data and Biosamples is done in a safe and secure manner;
4. Sharing / transferring CARTaGENE Data by email is prohibited, as are passwords and usernames.
5. CARTaGENE reserves the right to conduct, an audit of the security measures of the Investigator's IT infrastructure, either by an internal expert, or by independent consultants appointed by CARTaGENE. Such an audit will then validate the security measures that are declared and implemented by the Investigator. The audit will be conducted by providing adequate advance notice to the Institution.

Transfer modalities from CARTaGENE to the Investigator

- The Data will be made available through secure file storage.
- Procedures and login information will be forwarded by the person in charge of information technology at CARTaGENE.

Transfer modalities from the Investigator to CARTaGENE

- The return of Derived Data will be done through secure file storage.
- Procedures and login information will be forwarded by the person in charge of information technology at CARTaGENE.

Security measures declared by the Investigator

The security measures that the Investigator reported are detailed in the following tables below. These security measures will be in effect to ensure the security of the Data and/or Biosamples transferred to the Investigator.

[copy-paste security measures from Investigator's application here]

SCHEDULE 3

DERIVED DATA TO BE RETURNED TO CARTaGENE

As part of the Access Policy, Data derived from the use of the CARTaGENE Data and/or Biosamples must be returned to CARTaGENE at the end of the Research Project. Such data ("Derived Data") will become an integral part of the CARTaGENE Database and will be made available to other Investigators. Derived Data can be at individual and aggregate levels including, but not limited to blood analytes, risk scores, neighborhood level indicators, etc.

A twelve (12) month moratorium may be granted to the Investigator for the purpose of allowing publishing. During said period, the Derived Data may be used by other approved researchers, but cannot be published. A moratorium may be granted following a request by the Investigator to the access coordinator, in writing. Due to our internal efforts to generate certain types of genetic data and standardize our datasets, genotyping and DNA sequencing data are not subject to moratoria. Specifically, raw genotyping (whole genome or targeted) and raw sequencing data (whole exome, whole genome, or targeted) should be returned as soon as it is generated. If needed, we may grant an 18-month moratorium on RNA-sequencing data.

The following Data (individual) must be returned to CARTaGENE as soon as it is generated and by the latest at the end of this Access Agreement on **[insert date]:**

[insert more details]

SCHEDULE 4

ATTESTATION THAT DATA AND/OR BIOSAMPLES WERE DESTROYED OR DELIVERED

We attest that we have conformed to the terms outlined in the Access Agreement and have destroyed all Data and/or Biosamples transferred by CARTaGENE in the context of the Research Project titled: **[insert].**

We also attest that we have not duplicated nor stored Data, nor transferred it to any person or party other than those mentioned in the access request.

THE PARTIES HAVE SIGNED on the date indicated under their signature.

Investigator	**[NAME OF INSTITUTION]**
By : _____	By : _____
[Name of the Investigator]	**[Name]** **[function]** *(Authorized representative of the Institution)*
Date : _____	Date : _____

SCHEDULE 5

FEES

Administrative Costs		
Description	**Price/unit**	**Total**
Registration fees	$500.00 /registration	$500.00 (paid/not paid in full)
SDAC Meeting	$2,100.00/meeting	$2,100.00
Professional services from the CARTaGENE team (XX hours@$190.00/hour)	[insert #hours] x $190.00/hour	$[insert]
Additional professional services	$[insert]	$[insert]
Data		
[insert description of first Data set]	[insert price/unit]	[$insert]
[insert description of Bulk Data]	[insert price/unit]	[$insert]
Biosamples		
[insert description of Biosamples]	$[insert] /[insert] Biosamples	$[insert]
Total		**[$insert]***

***Taxes are not included**

Note: Additionally, the cost of delivery of biological material to the Investigator will be billed separately to the Investigator by the biobank, if applicable.

Invoices shall be sent to this address:

CARTaGENE ACCESS POLICY

CARTaGENE

(hereinafter known as "**CARTaGENE**")

Access and Use Policy for Data and Biosamples

(hereinafter known as "**Access Policy**")

1. Context

CARTaGENE is a research infrastructure and scientific research project that conducts research in population health and genomics. To reach its objectives, CARTaGENE has collected data and biological samples from participants (the "**Data**") (the "**Biosamples**"), and built a Database (the "**CARTaGENE Database**") and a biobank (the "**CARTaGENE Biobank**") (the "**CARTaGENE Banks**"). In addition, CARTaGENE wishes to allow members of the scientific community to consult and use these Data and Biosamples to carry out research studies.

2. Subject

The purpose of the *Access Policy* is to support requests made by researchers who wish to use the Data and/or Biosamples (the "**Access Requests**"). To authorize these requests, the use must be made in accordance with the commitments taken by the CHU Sainte-Justine towards participants in the context of CARTaGENE, and in compliance with current Policies and Regulations of the CHU Sainte-Justine.

3. Conditions for using Data and Biosamples

3.1. The Data and Biosamples are provided by participants who have entrusted the CHU Sainte-Justine with this information for the purposes of CARTaGENE. Access to the Data or Biosamples and their use must be done in accordance with the following terms and conditions:

a) One of the priorities for CARTaGENE is to ensure respect and to protect participants' rights to dignity, especially with regard to their privacy. The

researchers who consult or use the Data or Biosamples must also make sure participant's privacy and dignity are protected.

b) The Data and Biosamples collection process and the conditions for their storage and use must not allow the researchers who would receive such Data or Biosamples to identify the participant. For additional security, the *Access Agreement* to be signed by the Investigator (see provision 8.1) must mention that the Investigator agrees to keep confidential any personal information acquired about a participant, even if this information was acquired involuntarily.

c) The Data and/or Biosamples may be consulted and used by persons carrying out research activities, either in the academic sector (universities, research institutes), in the public sector (ministries, government agencies, hospital centres), or in the private sector (industrial or commercial businesses). However, the Investigator must ensure that the use of the Data and/or Biosamples is not to be made for the benefit of an insurance company or an employer of a participant.

d) Prior to submitting an Access Request, the Investigator involved must obtain ethical approval from the ethics committee of the academic institution or the organization he or she is attached to, or from the equivalent body appointed by the company that employs the Investigator.

e) Access or use is approved by the Sample and Data Access Committee ("**SDAC**") for a single research project determined at a time.

f) Once the research project is approved, any change to be made by the Investigator must be brought to the attention of the SDAC, which will decide to uphold or withdraw its approval, by assessing the change pursuant to the provisions in provision 7 of the *Access Policy*. The change request, which did not obtain the approval of the SDAC when required, cannot be made to the protocol of the research project involved. If the Investigator still wishes for this change to be made to the protocol, this will have to be discussed with the access officer who will determine, with the SDAC, the terms and conditions for terminating the collaboration between the Investigator and CARTaGENE, and more specifically, the manner in which the Data and/or Biosamples delivered to the Investigator will be handled.

3.2. The information contained in an Access Request communicated by the Investigator to CARTaGENE or the SDAC shall be kept confidential by CARTaGENE's staff members and the members of SDAC. However, once the Access Request has been received favourably by the SDAC, the following information will be distributed to the public via CARTaGENE's website or by any other method of communication deemed relevant by CARTaGENE:

(i) Title and brief lay summary of the research project;
(ii) Names of researchers and a brief description of their academic credentials and professional experience;
(iii) Name of employer and/or institution to which they are attached;
(iv) Source of funding for the research project;
(v) Scheduled project start date and end date;
(vi) Once the research project is completed, a summary of the project's results and potential results benefiting the general population and public health.

4. Data and Biosamples Access Committee ("SDAC")

The SDAC has the mandate to oversee adherence to the *Access Policy* with regard to any request from an Investigator to use the Data and/or Biosamples.

4.1. Composition

4.1.1. The SDAC is composed of nine (9) members, seven (7) of whom are appointed by the Research Director of the CHU Sainte-Justine after consultations with CARTaGENE's Scientific Director(s). The expertise of these seven (7) members must cover at minimum the following fields: population genomics, epidemiology, public health and data processing.

The other two (2) SDAC members are ex-officio members as non-voting observers. These are two CARTaGENE employees, including the access officer of CARTaGENE.

4.1.2. Members of the SDAC cannot be employees or investigators for CARTaGENE, and they cannot sit on other CARTaGENE internal committees, with the exception of the observers.

4.1.3. Members of the SDAC appoint from among themselves the President and Vice-President, the latter assuming the functions of the President in his absence. The President has, among others, the authority to issue approvals for Access Requests in the following cases:

a) The SDAC has already examined the Access Request and has requested that modifications be made to the research project before granting its approval and, in the President's opinion, the modifications required by the SDAC have been made.

b) The research project was approved by the SDAC and minor modifications regarding confidentiality, security, or the integrity of the Data and/or

Biosamples targeted by the Access Request were subsequently made to the research project.

4.1.4. CARTaGENE's access officer, in collaboration with the President of the SDAC, ensures compliance of meetings held, minutes and decisions rendered in accordance with this current Policy.

4.1.5. If deemed appropriate, the SDAC may solicit the advice of an expert who is not a member of the SDAC to provide insight on the assessment of an Access Request. This expert must not be employed by or conduct research for CARTaGENE and cannot be a member of any other CARTaGENE internal committee.

4.1.6. A member of SDAC may resign by providing thirty (30) days' written notice to the President. The executive director of the CHU Sainte-Justine, following consultations with the Scientific Director of CARTaGENE, can terminate a member's mandate especially if the member is in conflict of interest whereby he or she failed to attend more than three (3) meetings to which he or she was duly convened.

4.2. Term

4.2.1. The term for members of the SDAC shall be two (2) years renewable twice for a total of six (6) years unless it, in the interest of CARTaGENE, is extended by the SDAC.

4.2.2. In the event that a member is elected to become President or Vice-President at the end of his/her term limit (6 years), his/her term can be extended to assume such position.

4.2.3. The term of the President and Vice-President is four (4) years with the possibility of a renewal by vote of the SDAC, in the interest of CARTaGENE.

4.3. Meetings of the SDAC

4.3.1. The SDAC meets at least four (4) times per year to examine Access or Use Requests addressed to CARTaGENE. Members may attend meetings in person, by videoconference or by telephone. In addition, if the President deems it appropriate, the discussions (including the vote) may be held in writing.

4.3.2. SDAC members who attend meetings will receive financial compensation and travelling expenses will be reimbursed, if applicable.

4.3.3. To make sure quorum is reached for the proceedings to be valid, 50% of members with voting rights plus one must be present, including the President or, in his/her absence, the Vice-President.

4.3.4. The access officer of CARTaGENE or his/her delegate, convenes meetings via written notice sent mainly by fax or email, at least ten (10) business days in advance before the scheduled meeting date. The meeting notice must include an agenda for the meeting and a copy of all Access Requests to be examined during the meeting and all relevant documents. At the end of the meeting, the access officer drafts the minutes, which must be approved by the SDAC at the next meeting.

4.4. Conflicts of interest and confidentiality

4.4.1. Any member of the SDAC with a personal interest in a research project for which an Access Request has been submitted to the SDAC, especially if the member is the Investigator targeted by the Access Request or due to business or family relationships, must state this interest to the SDAC members present and withdraw from the meeting when this Access Request is examined by the SDAC. More specifically, the members of the SDAC must state all their relationships with persons, academic institutions, organizations or corporations that have contributed to the project and for which Access Requests were submitted for SDAC approval.

4.4.2. In addition, all members of the SDAC, including support staff and any persons convened to attend a meeting, must agree to uphold the confidentiality of information and documents distributed to members or brought to the attention of members during the meeting or relating to his or her participation at the meeting, and the confidentiality of deliberations and the minutes pertaining to a SDAC meeting.

5. CHU Sainte-Justine Research Ethics Committee ("CER")

5.1. The CER was established by the statutes of the Research Ethics Board of the CHU Sainte-Justine; which determines the composition and the working order of this committee.

5.2. The mandate of the CER is to approve, modify, suspend or reject research projects involving human beings submitted by professors, researchers and students jointly with their research directors, whether these activities are carried out within or outside the CHU Sainte-Justine.

5.3. In the context of CARTaGENE, the CER is informed of all the research projects for which researchers have submitted an Access Request through an annual report submitted by CARTAGENE.

6. Processing of Access Requests by the SDAC

6.1. Submitting an Access Request

6.1.1. A researcher who wishes to use Data and/or Biosamples must apply online on CARTaGENE's "Sample and Data Access System" (www.sdas.cartagene.qc.ca/). CARTaGENE conducts a preliminary examination of the Access Request to determine whether the Data and/or Biosamples required by the Investigator exist and are available based on criteria set by CARTaGENE with respect to its objectives.

6.1.2. Where applicable, the Access Request is transmitted to the SDAC for examination and a decision.

6.1.3. For the Investigator to be granted access to use Data and/or Biosamples, the Access Request must be approved by the SDAC.

6.1.4. If the Access Request is submitted by the Scientific Director of CARTaGENE, it must be processed as would any request from any other Investigator and obtain authorization from SDAC.

6.2. SDAC

6.2.1. The SDAC examines Access Requests based on the assessment criteria presented in section 7 of this current Policy.

6.2.2. The decisions of the SDAC are made based on an absolute voting majority. The SDAC must render its decisions in writing, stipulating the reasons for its decision, which must be communicated to the Investigator involved within two (2) weeks of rendering its decision. At the same time, a copy of the decision must be forwarded to the access officer of CARTaGENE.

6.2.3. A decision in favor of the Request must point out to the Investigator (1) the duration of the access or the use granted, (2) the Investigator's obligations regarding the security of access, use, conservation and transfer of Data and/or Biosamples, if applicable, and (3) the Investigator's obligations in terms of how the Data and/or Biosamples must be handled once their use or consultation is complete.

6.2.4. In the event of a conditional approval, the decision must include a detailed description of the conditions imposed by the SDAC on the Investigator involved.

6.2.5. In the event of an unfavourable decision, if deemed appropriate by the SDAC, the SDAC may include in its decision recommendations on how the Investigator involved could modify his or her request for Access or Use, or modify the research project, to obtain a favourable decision.

7. Access Request assessment criteria by the SDAC

The SDAC must assess all Access Requests in light of the following criteria:

a) Compliance to the conditions for use outlined in section 3 of the *Access Policy;*

b) The scientific quality of the research project targeted by the Request, including:

   (i) The merits of the hypothesis;

   (ii) The research project's objectives and methodology;

   (iii) The probability that the research project's outcome will benefit the public and the overall scientific community.

c) The compatibility of the subject matter targeted by the research project and the scheduled related work, the sources of funding and the governance of project-related activities, in line with CARTaGENE's objectives;

d) Reliable security measures established for the conservation and transfer of Data and Biosamples;

e) The existence of material resources, including sufficient financial resources that will allow the research project to be carried out as scheduled and produce concrete and useful results;

f) The qualifications, skills and experience of the Investigators and research staff involved in executing the target research project;

g) The quantity of Biosamples required for the target research project;

h) The fact that other projects on the same subject have already benefited from the Data and/or Biosamples;

i) The likelihood that the project will lead to the acquisition and dissemination of new knowledge in the fields of genomics, biomedical science, clinical medicine, epidemiology, or public health;

j) Any other criterion the executive director of the CHU Sainte-Justine, or his/her delegate or CARTaGENE deems suitable to add to the list.

8. Access and use of Data and/or Biosamples by the Investigator

8.1. Access Agreement

8.1.1. An Investigator whose Access Request has been approved by the SDAC, and the employer, organization, corporation or academic institution to which the Investigator is attached (the "**Institution**"), must complete and sign a standard document that will be adapted to contain the Investigator's rights and obligations with regard to the Data and Biosamples for which authorization for access or use was granted (the "**Access Agreement** ").

8.1.2. The terms and conditions for transferring Data and/or Biosamples to the Investigator whose request was approved will be determined by CARTaGENE and the SDAC, based on the needs expressed by the Investigator that would allow the Investigator to carry out his or her research protocol. These terms and conditions will be appended to the Access Agreement.

8.1.3. CARTaGENE will have the right to conduct an audit to make sure the Investigator is in compliance with the conditions stipulated in paragraph 8.1.2 above. If CARTaGENE deems it appropriate, it will be able to make recommendations to the Investigator and the Institution to improve their compliance with the conditions, and the Investigator and the Institution will be required to implement the recommendations made.

8.2. Transfer and publication of results

8.2.1. In order to improve its Data and/or Biosamples banks, CARTaGENE must be informed of results emerging from research projects involving the access or use of Data and/or Biosamples. When making a decision on an Access Request, the SDAC will indicate to the Investigator concerned the exact nature of the results to be reported to CARTaGENE, the format in which they will be sent, and the deadline given to the Investigator to transmit them. The Investigator concerned, even if he/she is the Scientific Director of CARTaGENE, will have to submit the results to CARTaGENE's data curator. All results will be deposited in the Database or Biobank, whichever the case.

8.2.2. When certain results require other steps to be completed to protect any related intellectual property rights, the Investigator may contact the SDAC to request a deferral of his or her obligation to disclose certain results to CARTaGENE, until such protection has been obtained.

8.2.3. Investigators who have consulted or used the Data and/or Biosamples are encouraged to publish the results of their research project to allow the

scientific community or general population to benefit from the results. Where relevant, the Investigator involved must mention in his or her publications or presentations that the Data and/or Biosamples used originated from the CARTaGENE Database or Biobank, as applicable. Prior to publishing the results, the Investigator involved, even if he/she is the Scientific Director of CARTaGENE, must provide CARTaGENE with the manuscripts he or she intends to publish to ensure that the manuscripts do not allow the identification of a participant or stigmatization of a group of participants. CARTaGENE's response must be communicated to the Investigator involved within fifteen (15) days from the day the publishing project is submitted to CARTaGENE.

8.2.4. Subject to the provisions in paragraph 8.4.4 of this current Policy regarding the summary of results, CARTaGENE will post documents in digital format on the CARTaGENE website. If authorization to do so is required, by a text editor for example, the Investigator involved will have to provide it to CARTaGENE.

8.3. Intellectual property

The CHU Sainte-Justine does not claim any intellectual property rights with regard to the results, discoveries, inventions or works that could stem from a research project where the Data and/or Biosamples were consulted or used.

8.4. Follow-up and reports

8.4.1. An Investigator, whose Access Request was approved, must accept that CARTaGENE may proceed with an inspection of the areas where the Data and Biosamples could be kept and used, more specifically to make sure that the statements made by investigators on the nature and conduct of their research activities comply with it. The Investigator must also allow CARTaGENE to access the books and records kept on the research project involved.

8.4.2. In addition to the Investigator's obligations with regard to approvals from the SDAC, the Investigator must bring the following situations to the attention of CARTaGENE as soon as possible:

(i) Any situation that jeopardizes the confidentiality of a participant's information;

(ii) Any situation that is likely to affect the security or the integrity of Data or Biosamples targeted by the authorization for access or use;

(iii) Any suspension or withdrawal of an authorization granted by a body or organization other than CARTaGENE and that is required to carry out the research project;

(iv) Any significant change made to the research protocol or to the project's development, including the addition of new researchers who join the Investigator who was granted authorization for access or use.

8.4.3. The Investigator must forward an annual report to CARTaGENE on the progress or achievements of the research project involved. If the research project lasts for less than one (1) year, this report will be a final report. CARTaGENE will transmit these reports to SDAC upon request. The SDAC may require the Investigator to submit reports on a more frequent basis.

8.4.4. The Investigator must send to CARTaGENE's Access Coordinator a summary of the Research Project (at the beginning) and the results (at the end), in a language accessible to the general public, for publication on CARTaGENE's website.

8.5. End of access or use

8.5.1. At the end of the period for which Access or Use was granted as provided for in the Access Agreement, or once the Data and/or Biosamples have been consulted and used, the Investigator must inform CARTaGENE and comply with the provisions of the Access Agreement regarding what must be done with the Data and/or Biosamples involved. The Investigator must also attest in writing to CARTaGENE that he or she has complied with the requirements.

8.5.2. At the end of the access or use period stipulated in the Access Agreement, the Investigator may request an extension by proceeding as stipulated in paragraph 3.1 f) of the *Access Policy* to make any significant change in the research protocol.

9. <u>Fees</u>

9.1. The Investigator who submits an Access Request must pay fees. These fees are required once the research project obtains the approval of the SDAC. The amount of fees is indicated in the Access Agreement. These fees are required to reimburse the cost of preparing the extraction of Data and/or Biosamples, and to cover the cost of processing and analyzing the request for access and use.

9.2. Transportation fees for the Biosamples are not included in these fees. The Investigator will have to pay these fees when he or she submits a delivery request to CARTaGENE.

10. Default and termination

If the Investigator and/or the Institution fail to comply with the terms and conditions outlined in the Access Agreement and/or with the provisions of the Access Policy, measures may be taken by the Access Committee and/or the CHU Sainte-Justine to recover the Data and/or the Biological Samples given to the Investigator and/or the Institution, and the access authorization may be revoked immediately. These measures may include the ban of future access to the Data and/or Biological Samples of CARTaGENE as well as the prohibition of using the Data and/or Biological Samples or any outcome derived from research work carried out using these.

11. Recourses of the CHU Sainte-Justine

CHU Sainte-Justine reserves its rights, with regard to any researcher who is the subject of a Request for Access, and his or her institution, if one or the other breaches the provisions of the *Access Policy* or the Access Agreement that they concluded.

12. Amendment to the Access Policy

Any amendment to the *Access Policy* must be made by the CHU Sainte-Justine, based on the recommendation of CARTaGENE and the SDAC. In addition, the amendment must be approved by the CER.

13. Responsible for Access Policy application

The Chief Executive Officer of the **CHU Sainte-Justine** is in charge of enforcing the *Access Policy*.

SCHEDULE 7

Representations and Undertakings of the Co-Investigator or Collaborator

I, the undersigned, researcher at _____ ("Site"), declare:

1- I have read the Access and Use Agreement for Data and/or Biosamples between CHU Sainte-Justine, (*Institution*) and (*Investigator*) herein attached at Schedule A (the "Agreement");

2- I am one of the Co-Investigators or Collaborators designated for Research Project as described in the Access Request herein attached at Schedule B;

3- I shall abide by all provisions contained in the Agreement that concern me, including section 4 (obligations).

4- I shall ensure with Site that all Site research personnel is informed of their obligations under such terms and conditions.

Co-Investigator or Collaborator

By:_____

Name:

Date:

Site

By:_____

Name and title of authorized representative:

Date: