CARTaGENE

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

Access and Use Policy for Data and Samples

(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 "**Samples**"), 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 Samples to carry out research studies. The rules that apply to the constitution, management, conservation and elimination of CARTaGENE banks are the subject of the *Policy on CARTaGENE Banks*.

2. Subject

The purpose of the *Access Policy* is to support requests made by researchers who wish to use the Data and Samples (the "**Access Requests**"). To authorize these requests, the use must be made in accordance with the commitments taken by the Sainte-Justine UHC towards participants in the context of CARTaGENE, and in compliance with the Policies and Regulations of the Sainte-Justine UHC, including the *Politique sur la recherche avec des êtres humains (Policy on research involving human beings),* the *Directives d'application concernant certains aspects de la Politique sur la recherche avec des êtres humains du CHU Sainte-Justine (Directives for the application of certain aspects of the Sainte-Justine UHC's Policy on research involving human beings),* and the *Document de la gestion des banques de Données constituées ou utilisées pour des fins de recherche (Document on the management of Databases built or used for research purposes).*

3. Conditions for using of Data and Samples

3.1 The Data and Samples are provided by participants who have entrusted the Sainte-Justine UHC with this information for the purposes of CARTaGENE. Access to the Data or Samples 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 Samples must also make sure participant's privacy and dignity are protected.

b) The Data and Sample collection process and the conditions for their storage and use must not allow the researchers who would receive such Data and Samples 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 Samples may be consulted and used by persons carrying out research activities, either in the academic sector (ex.: universities, research institutes), in the public sector (ex.: ministries, government agencies, hospital centres), or in the private sector (ex.: industrial or commercial businesses). However, the Data or Samples must not be used for the benefit of an insurance company or a participant's employer, and the Investigator has to guarantee this.

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 Research Ethics Committee ("**CER**") appointed at the Sainte-Justine UHC and 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 CER which will decide to uphold or withdraw its approval, by assessing the change pursuant to the provisions in paragraphs 6.1.1., 6.2 and 7.2 of the *Access Policy*. In addition, any significant change made to the research project's protocol 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 paragraphs 6.1.1., 6.3 and 7.1 of the *Access Policy*. The change request, which did not obtain the approval of the CER and 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 Principal Investigator who will determine with the SDAC or Data Curator the terms and conditions for terminating the collaboration between the Investigator and

CARTaGENE, and more specifically, the manner in which the Data or Samples delivered to the Investigator will be handled.

3.2 The information contained in an Access Request communicated by the Investigator to CARTaGENE, the SDAC or CER shall be kept confidential by the CARTaGENE staff members and members of SDAC and CER. However, once the Access Request has been received favourably by the SDAC and CER, the following information will be distributed to the public via the CARTaGENE 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 Sample 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 or Samples. The SDAC does not render any decision on the ethical aspects of the request for use, given that the CER is mandated to do so (*see provision 6.2*).

4.1 Composition

4.1.1. The SDAC is composed of nine (9) members, seven (7) of whom are appointed by the executive director of the Sainte-Justine UHC after consultations with CARTaGENE's Principal Investigator. The expertise of these seven (7) members must cover at minimum the following fields: population genomics, epidemiology, public health and information technology.

The two (2) other SDAC members will be ex officio members: observers, with no voting rights. These persons, or their delegates, will carry out the following functions: Director of Epidemiology for CARTaGENE and Director of Legal Affairs for CARTaGENE.

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

4.1.3. Members of the SDAC appoint from among themselves the President and Vice-President who assumes the functions of President in the President's 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 or Samples targeted by the Access Request were subsequently made to the research project.

4.1.4. The Director of Legal Affairs and Ethics for CARTaGENE, or his or her delegate, is the ex officio Secretary of the SDAC, and in cooperation with the President of SDAC, oversees the compliance of meetings held, the minutes taken and the decisions rendered based on 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 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 Sainte-Justine UHC, following consultations with the Principal Investigator of CARTaGENE, can terminate a member's mandate especially if the member is in conflict of interest whereby he or she failed to attend meetings to which he or she was duly convened more than three (3) times.

4.2 Meetings of the SDAC

4.2.1. The SDAC meets at least four (4) times a year to examine access or use requests addressed to CARTaGENE. Members may attend meetings in person or via telephone. In addition, if the President deems it appropriate, the meeting may be held in writing, and, if applicable, members may forward their votes via email or fax.

4.2.2. SDAC members who attend meetings will receive financial compensation and travelling expenses will be reimbursed, if applicable, based on the table in Schedule 4.2.

4.2.3. 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 his or her Vice-President in the President's absence.

4.2.4. The secretary of the SDAC 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 secretary drafts the minutes which must be approved by the SDAC at the next meeting.

4.3 Conflicts of interest and confidentiality

4.3.1. 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, the member 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.

4.3.2. 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. Sainte-Justine UHC Research Ethics Committee ("CER")

5.1 The CER was established by the statutes of the Research Ethics Board of the Sainte-Justine UHC; which determines the composition and the working order of this committee (see the *Politique sur la recherche avec des êtres humains du Sainte-Justine UHC* on Sainte-Justine UHC's website at: http://www.chu-sainte-justine.org/documents/General/CdeR/C%C3%89R/A2.%20Statuts%2013%20juin%202007.pdf

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

Sainte-Justine UHC, based on the regulations stated in Item 3 of the *Policy on research involving human beings*.

5.3 In the context of CARTaGENE, the CER is entrusted with this mandate for all research projects for which researchers have submitted an Access Request.

6.0 Processing of Access Requests by the CER and SDAC

6.1 Submitting an Access Request

6.1.1 A researcher who wishes to use Data or Samples must submit a request in writing to CARTaGENE using the form provided to the Investigator for this purpose, and based on the conditions that will be communicated to the Investigator. CARTaGENE conducts a preliminary examination of the Access Request to determine whether the Data or Samples required by the Investigator exist and are available based on criteria set by CARTaGENE with respect to its objectives.

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

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

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

6.2 CER

6.2.1. With regard to the applicable legal and ethical standards and internal policies of the Sainte-Justine UHC, the CER examines all Access Requests and renders decisions on all requests. The assessment criteria applied by the CER are defined in section 7 of this Policy.

6.2.2. If the CER deems it appropriate, additional conditions may be added to a decision in favour of the Access Request. These conditions will be specified in detail in its decision.

6.2.3. All decisions must be communicated to the Investigator involved as soon as possible. At the same time, a copy of the decision must also be sent to the person in charge of coordinating access to Data and Samples for CARTaGENE and to the President of SDAC.

6.3 SDAC

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

6.3.2. 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 person in charge of coordinating access to Data and Samples and to the President of the CER.

6.3.3. A decision in favour of the Request must point out to the Investigator (1) the length of time access or use will be granted, (2) the Investigator's obligations regarding the security of access, use, conservation and transfer of Data and Samples, if applicable, and (3) the Investigator's obligations in terms of how the Data or Samples must be handled once the usage or consultation is complete.

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

6.3.4. 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. <u>Access Request assessment criteria</u>

7.1 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 Samples;

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 qualification, skills and experience of the Investigators and research staff involved in executing the target research project;

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

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

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 Sainte-Justine UHC, or his/her delegate or the Principal Investigator of CARTaGENE deems suitable to add to the list.

7.2 By the CER

The CER assesses each Access Request in light of the following criteria:

a) The research project respect the the applicable legal and ethical standards and policies of the Sainte-Justine UHC;
b) The research project is expected to be conducted in accordance with the laws in effect in Quebec with regard to respecting the reputation, privacy and protection of personal information of all individuals, including project participants;
c) The research project is conducted in accordance with the representations and the commitments made to participants by the Sainte-Justine UHC for CARTaGENE, as formulated in the information brochure or on the official CARTaGENE website.

8. <u>Access and use of Data or Samples by the Investigator</u>

8.1 Access Agreement

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

authorization for access or use was granted (the "**Access Agreement** "). This standard document is attached in the *Access Policy*.

8.1.2. The terms and conditions for transferring Data or Samples to the Investigator whose request was approved will be determined by CARTaGENE's IT Director and Data Curator 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 Sample banks, CARTaGENE's Investigators wish to be kept informed of certain results of research projects involving the access or use of Data or Samples. The SDAC, when it renders its decision on an Access Requests, will point out to the Investigator involved, the exact nature of the results he or she must share with the CARTaGENE's Principal Investigator and the format and timeframe for transferring the results. If the investigator involved is the Principal Investigator of CARTaGENE, he or she will have to transfer the results to the Data Curator at CARTaGENE. All results are added to the CARTaGENE 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 or Samples 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 or Samples used originated from the CARTaGENE Database or Biobank, as applicable. Prior to publishing the results, the Investigator involved must provide the CARTaGENE Principal Investigator with the papers he or she intends to publish to allow the Principal Investigator to ensure that the papers does not allow the identification of a participant or stigmatization of a group of participants. The response from the CARTaGENE Principal Investigator must be communicated to the Investigator involved within fifteen (15) days from the day the publishing project is submitted to CARTaGENE. If the Investigator involved is the Principal Investigator of CARTaGENE, he or she must submit his or her publication project to the CARTaGENE Data Curator.

8.2.4. Subject to the provisions in paragraph 8.4.4. of this Policy regarding the summary of results, the Principal Investigator will be able, at his or her discretion, to post documents in digital format on the CARTaGENE website that posts the research results. If authorization to do so is required, by a text editor for example, the researcher involved will have to provide this to the CARTaGENE Principal Investigator.

8.3 Intellectual property

The Sainte-Justine UHC 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 or Samples were consulted or used.

8.4 Follow-up and reports

8.4.1. An Investigator, whose Access Request was approved, must accept that CARTaGENE and the CER may proceed with an inspection of the areas where the Data and Samples 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 and the CER 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 CER and SDAC, the Investigator must bring the following situations to the attention of the Principal Investigator 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 Samples 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

If the Investigator involved is the Principal Investigator of CARTaGENE, he or she must notify the SDAC.

8.4.3. The researcher must forward an annual report to the CARTaGENE Principal Investigator on the progress or achievements of the research project involved. If the researcher involved is the Principal Investigator of CARTaGENE, the annual report must be transmitted to the SDAC. If the research project lasts for less than one year, this report must contain a summary of the research project's results. These reports must be transferred from CARTaGENE to the CER and

SDAC. The CER and SDAC may require the Investigator to submit reports on a more frequent basis.

8.4.4. A summary of results, written in a language that is accessible to the public, will be drafted by the Investigator involved and transferred to the CARTaGENE Principal Investigator for publication on the CARTaGENE 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 Samples have been consulted and used, the investigator must inform the CARTaGENE Principal Investigator and comply with the provisions of the Access Agreement regarding what must be done with the Data or Samples involved. The Investigator must also attest in writing to the Principal Investigator 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 CER and 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 Samples, and to cover the cost of processing and analyzing the request for access and use.

9.2 Transportation fees Samples 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. Recourses of the Sainte-Justine UHC

Sainte-Justine UHC 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.

11. <u>Amendment to the Access Policy</u>

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

12. Responsible for Access Policy application

The executive director of the Sainte-Justine UHC is in charge of applying the *Access Policy*.

CARTaGENE

Access and Use Agreement for Data and/or Samples

("**Access Agreement**")

BETWEEN

Sainte-Justine University Hospital Center, a duly constituted legal entity with its head office at 3175, Chemin de la Côte-Sainte-Catherine, Montréal H3T 1C5, represented by Mr Alain Moreau, director of the research center

(hereinafter known as **"Sainte-Justine UHC")**

AND

Investigator	**Institution, Organization or Corporation to which the Investigator is affiliated**
_____	_____
Name	Name
_____	_____
Status or occupation	Address
_____	_____
Personal address	Representative (name and function)
_____	_____
Email address	Representative's email address
_____	_____
Telephone no.	Representative's telephone no.
Hereinafter known as "**the Investigator**"	Hereinafter known as "**the Institution**"

THE SAINTE-JUSTINE UHC, THE INVESTIGATOR AND THE INSTITUTION AGREE TO THE FOLLOWING:

1. This Access Agreement follows the approval of a request for access filed by the Investigator and the Institution pursuant to the provisions in the *Access and Use Policy for*

Data and Samples ("**Access Policy**") that forms an integral part of the Access Agreement and to which the Investigator and Institution agree to comply. The terms and expressions used in the Access Contact have the meaning given to them in the Access Policy, with the exception of terms and expressions expressly defined in this document.

2. The Sainte-Justine UHC agrees that the Investigator uses the Data and Samples, the list of which is included in Schedule 1 of the Access Agreement as per the conditions outlined in this document and in the Access Policy.

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

4. The Investigator and the Institution agree especially to do the following:

4.1 Use the Data and Samples exclusively for the research project that received prior approval from the SDAC and CER and bearing the following title:

_____

[Title of research project as approved]
(the "**Research Project**")

4.2 Use the Data and Samples exclusively for the purposes described by the Investigator in the access request application submitted to CARTaGENE.

4.3 Abide by the security measures set out in Schedule 2 of the Access Agreement herein, with regard to the Data and Samples, for the period during which the Investigator or the Institution will have the Data or Samples in their hands.

4.4 Where appropriate, submit to IT security audits carried out by CARTaGENE and comply with, as applicable, recommendations issued by CARTaGENE on completion of such audits.

4.5 Ensure, at all times, that only the Investigator or persons appointed in the request, and only insofar as they remain attached to the Institution, can hold, obtain knowledge of, consult or use the Data or Samples received, and as the person responsible for the data and samples received, not to disclose or make the Data or Samples received available to any other person.

4.6 Ensure at all time the proper state and the conditions for maintaining and using the Data and Samples.

4.7 Destroy immediately, make sure no copy is kept and not disclose to anyone, any information that would allow a participant to be identified or linked to the Data or Samples provided by the participant, and to which the Investigator or the Institution could discover, even involuntarily.

4.8 Return the results of the Research Project to the CARTaGENE Principal Investigator as indicated in Schedule 3 of the Access Agreement, within the timeframe granted by the SDAC. If the Investigator is the CARTaGENE Principal Investigator, these results must be submitted to the Data Curator.

4.9 Prior to publishing the results of the Research Project, the Investigator agrees to submit a copy of the paper he or she intends to publish to the CARTaGENE Principal Investigator and make sure this paper is free of any elements likely to identify a participant. If the Investigator is the CARTaGENE Principal Investigator, this text must be submitted to the Data Curator.

4.10 Mention in any publication or presentation, that the Data or Samples used originated, as applicable, from the CARTaGENE Databank or Biobank.

4.11 Before making a change to the protocol of the approved research project, obtain prior approval from the CER and, if the change is significant, obtain approval from the SDAC. If approval is not granted and the Investigator still wishes for this change to be made to the protocol, he or she can no longer continue to use the Data or Samples and the Investigator must comply with the directives given by the Principal Investigator to terminate his or her collaboration with CARTaGENE for this research project, and especially with regard to what he or she will do with the Data or Samples provided.

5. Follow-up and reports

5.1 The Investigator and the Institution agree to let representatives from the Sainte-Justine UHC, including representatives from CARTaGENE and the CER, audit the areas where Data or Samples may be kept or used and to make sure statements made by the Investigator and the Institution on the nature and conduct of Research Project activities comply with what was stated. Representatives from the Sainte-Justine UHC, including representatives from CARTaGENE and the CER, will also be able to look into the Investigator's and the Institution's books and records regarding the Research Project.

5.2 The Researcher and the Institution agree to bring to the attention of the CARTaGENE Principal Investigator, in a timely manner, the situations listed in paragraphs 8.4.2. of

the *Access Policy*. If the Investigator is the CARTaGENE Principal Investigator, he or she must advise the SDAC.

5.3 The Researcher and the Institution must forward to the CARTaGENE Principal Investigator an annual report that presents the status of the progress and execution of the Research Project protocol, and if the project timeframe is less than one year, this report must contain a summary of the Research Project's results. If the Investigator is the CARTaGENE Principal Investigator, he or she must hand this report to the SDAC.

5.4 The Investigator and the Institution must prepare a summary of results for the Research Project, written in a language that is accessible to the public, and transmit this summary to the CARTaGENE Principal Investigator for publication, so that the following information be posted on the CARTaGENE website or distributed by any other method of communication deemed appropriate by CARTaGENE:

(i) Title and brief 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 affiliated
(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 a recall of the resulting benefits for the public and public health.

6. Fees

The Institution and/or the Investigator agree to pay the Sainte-Justine UHC, within 45 days of receiving the invoice to this effect, the sum of _____

7. Absence of a guarantee and release of liability

7.1 The Data and Samples to be transferred to the Investigator or the Institution were gathered, processed and preserved in accordance with the CARTaGENE research protocol which abides by the usual quality standards in this field and was approved by the CER, in compliance with the standardized operating procedures adopted and implemented by CARTaGENE to control the quality of CARTaGENE Banks.

7.2 However, the Sainte-Justine UHC does not in any way whatsoever guarantee the quality of the Data and Samples to be delivered to the Investigator and the Institution and does not guarantee that these Data or Samples will be able to be consulted or used

in any way or for any purpose. The Sainte-Justine UHC does not guarantee the accuracy of the Data and does not guarantee that these Data or Samples, their use or consultation contravenes the rights of third parties, including the rights of participants.

7.3 The Investigator and the Institution acknowledge that the Samples may contain viruses, latent viral genomes and other infectious agents. The Investigator and the Institution agree to treat these Samples as though they were contaminated and to make sure these Samples are manipulated in laboratories only by professionals who have been trained and forewarned, and guarantee that any biological risks will be suitably confined.

7.4 By acknowledging the receipt of Data or Samples, the Investigator and the Institution accept full responsibility for how they will consult, manipulate and use these Data and Samples, and fully release the Sainte-Justine UHC from any liability. Moreover, the Investigator and the Institution agree to defend and hold harmless the Sainte-Justine UHC, its agents and employees, from any claims, damages, requests, expense or loss stemming from the receipt, consultation or use for whichever purpose, from manipulating and storing the Data or Samples, whether these were modified or not by the Investigator, the Institution, its employees and agents and brought against the Institution, its agents or employees.

8. Default and termination

If the Investigator or the Institution fail to comply with the commitments outlined in this Access Agreement and with the provisions of the *Access Policy*, the Sainte-Justine UHC will be able to retrieve the Data and Samples transferred to the Investigator or the Institution wherever they may be. The authorization for access or use granted by the Sainte-Justine UHC will end immediately and the Sainte-Justine UHC reserves the right to take any other recourse that it deems relevant regarding the default, including making a claim for damages. In addition, the Investigator or the Institution will not be able to use any data or any outcome of the research work carried out based on the Data or Samples delivered to the Investigator or Institution.

9. Duration

9.1 The Access Agreement takes effect on the date all parties will have signed the Agreement, and the Investigator or the Institution will not have access or be able to use the Data or Samples prior to this date. Access and use will terminate at the latest on _____.

9.2 By the latest on the scheduled end date for access and use, the Investigator and the Institution must hand over to the CARTaGENE Principal Investigator, the information

described in paragraph 4.4 above as well as the remaining Data and Samples, or they must destroy these by following the instructions in Schedule 4.1 of the Access Agreement. The Investigator and the Institution must also attest, in writing, that they have kept no copies of Data or any Sample, by completing and signing the document to this effect found in Schedule 5 of the Access Agreement.

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

10. <u>Transfer of rights</u>

The Investigator and the Institution will not obtain, with regard to the Data or Samples, any right other than those expressly described in the Access Agreement. More specifically, they will not obtain any property rights or intellectual property rights on the Data or Samples targeted by this Access Agreement.

11. <u>Commitment from the Investigator and the Institution</u>

The Investigator and the Institution declare and agree that none of the Data or Samples targeted by the Access Agreement will (a) be consulted or used by an employer or insurer of the participants associated with the Data and Samples involved; (b) the Data or Samples will not be delivered to such employer or insurer and, (c) the Data or Samples will not be used for the benefit of such employer or insurer.

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

[NAME OF INSTITUTION]

By : _____
[Name of the Investigator]

By : _____
[Name and function]
((Authorized representative of the Institution))

Date : _____

Date : _____

Sainte-Justine University Hospital Center

By: Alain Moreau, PhD_____
Director for Research

Date: _____

SCHEDULE 1

LIST OF DATA AND SAMPLES DELIVERED

SCHEDULE 2

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

SCHEDULE 3

RESULTS TO BE COMMUNICATED TO CARTaGENE

SCHEDULE 4.1

INSTRUCTIONS FOR DATA AND SAMPLES AT THE END OF THE CONSULTATION AND USAGE

SCHEDULE 4.2

FINANCIAL COMPENSATION DISTRIBUTED TO THE SDAC MEMBERS ATTENDING A MEETING

Compensation given to members present in person or by telephone to the entire SDAC meeting.	$300.00
Reimbursement of travel expenses	

SCHEDULE 5

ATTESTATION THAT DATA AND SAMPLES WERE DESTROYED OR DELIVERED