

# CARTaGENE ACCESS POLICY

## CARTaGENE

(hereinafter known as "CARTaGENE")

### Access and Use Policy for Data and Biosamples

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#### 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/](http://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. Fees**

**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*.