



Application for Access to McGill EMC Controlled Data

This application form is for requests for access to controlled access International Human Epigenome Consortium (IHEC) data stored at the European Genome-phenome Archive (EGA) by the McGill Epigenomics Data Coordination Centre. To receive access, applicants must complete this entire application form. All sections and Appendices are integral components of this application. Your project will be checked for conformity with the goals and policies of the *IHEC Goals, Structure, Policies & Guidelines* document dated January 2013, as amended from time to time and available online at <http://ihec-epigenomes.org/about/policies-and-guidelines/> including, but not limited to, policies concerning the purpose and relevance of the research, the protection of the participants, and the security of the participants' data.

Upon acceptance, access to controlled data will be granted for a one year period (starting from the date of acceptance). An Annual Renewal Application must be completed to access/use controlled data beyond that one-year time period.

The McGill Epigenomics Mapping Centre (EMC) and Data Coordination Centre (EDCC) were established in 2012 at the McGill University and Genome Quebec Innovation Centre (Montreal, Canada) to support large-scale human epigenome mapping for a broad spectrum of cell types and diseases. As a member of IHEC, the EMC aims to share its data with the entire research community to accelerate the translation of new knowledge of health and diseases.

Section I - Contact and Project Information

A. Name of main applicant (principal investigator), including institutional affiliation and contact details.

Please ensure that a full postal address and a valid institutional e-mail address are included.

Name:

Position:

Institution:

Institutional E-mail Address:

Website of the institution:

Mailing Address:

B. Name of the authorized institutional representative, including institutional affiliation and contact details.

Please ensure that a full postal address and a valid institutional e-mail address are included.

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|-------------------------------|
| Name: |
| Position: |
| Institution: |
| Institutional E-mail Address: |
| Mailing Address: |

C. Title of Project

Please provide the address of the project website as well, if available.

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D. Names of authorized personnel (within your institution)

Include the names of all investigators, collaborators, post-doctoral researchers, and research staff who will have access to the controlled data in order to work on the project (see Research Project, section F of this application form). Please ensure that a valid institutional e-mail address for each name is included, along with a proper job title.

**Note that co-investigators or collaborators at other institutions must submit a separate Application for Access to EMC Data.*

Name:
Title:
Position:
Affiliation:
Institutional E-mail Address:

Name:
Title:
Position:
Affiliation:
Institutional E-mail Address:

Name:
Position:
Affiliation:
Institutional E-mail Address:

E. Names of authorized students (within your institution)

Include the names of all students who will have access to the controlled data in order to work on the project (see Research Project, section F of this application form). Please ensure that a valid e-mail address for each name is included.

**Students at other institutions should not be included in this list.*

Name:
Position:
Affiliation:
Institutional E-mail Address:

Name:
Position:
Affiliation:
Institutional E-mail Address:

Name:
Position:
Affiliation:
Institutional E-mail Address:

F. Research Project (scientific abstract)

Please provide a clear description of the project and its specific aims in no more than 500 words.

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G. Research Credentials:

Please provide a list of three relevant publications of which the main applicant (PI) is author or co-author.

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If the main applicant (PI) has not authored or co-authored three relevant publications please describe his/her relevant expertise or experience in no more than 300 words.

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H. Lay summary of the project

Please provide a short, accessible description of the project for the general public in no more than 150 words. This description will be made available on a publicly accessible registry on the EMC website.

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I. Datasets

Please provide a list of the EGA dataset accession numbers for all datasets that you are applying to access.

- EGAD00...
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J. Ethics:

- ☐ My country/region does not require my project to undergo ethics review
- ☐ My country/region requires my project to undergo ethics review. This project has been approved by an IRB/REC formally designated to approve and/or monitor research involving humans. The approval letter(s) is/are attached. An institutional approval number should also be provided, if available.

EMC and the Data Access Committee are not responsible for the ethics approval/monitoring of individual research projects and bear no responsibility for User or User Institution(s)' failure to comply with local/national ethical requirements.

Section II: Information technology (IT) Security Assessment

In order to avoid inadvertent disclosure of the personal information of patients to unauthorized persons, EMC asks that you observe basic information security practices. If you make local copies of EMC data, you must minimize the risk that this information might be disclosed to individuals who have not agreed to EMC's patient privacy protection conditions.

Acceptable practices include:

- *Physical security* – Controlled EMC data will be maintained on physically secure computer systems, such as in a locked office. If the data is stored on a laptop computer, it must be encrypted to avoid its disclosure in case of loss or theft.
- *Access security* – Only individuals who are listed on the data access request should have access to EMC data. If copies of the EMC data are stored locally on a shared computer system or file server, then it should be password or encryption-protected so that only the individuals named in the request have access to it. If the computer that holds EMC data is backed up, the backup media should either be encrypted or stored in a physically secure location.
- *Network security* – If EMC data is stored on a network-accessible computer, there should be controls in place to prevent access by computer "hackers", or contamination by viruses and spyware. Network security is usually implemented by your institution's IT department and will consist of some combination of network firewalls, network intrusion monitoring, and virus scanning software.
- *End of project* – After finishing the project for which you are requesting access, or if your access approval is terminated, you must destroy all local copies, including backups. However, if

necessary, you can still keep the EMC data for archival purpose in conformity with national audits or legal requirements.

- *Training* – Everyone who will use controlled EMC data should be trained in the responsible use of patient confidential information, familiarized with the terms and conditions of the data access agreement, and briefed on the security plans you describe here.
- *Compute Cloud Use* – You may place copies of EMC controlled data on a private or commercial compute cloud for analytical purposes. If you do so, you acknowledge that you maintain responsibility for the data and you agree that: You must take care to apply strong encryption to the data while in motion and at rest; restrict access to stored copies of the data to yourself, authorized personnel, students, and authorized collaborators; use firewall rules to restrict ingress and egress from virtual machines to trusted network address(es); keep virtual machines that host controlled data up to date with security patches; destroy all copies of the data, including snapshots and backups, at the end of the Research Project, if your application is not renewed, or if your application is terminated; and ensure there is an agreement in place with your cloud provider that ensures you can meet these requirements. Any use of a private or commercial cloud is between you and the cloud provider. To the extent permitted by law EMC accepts no responsibility for any interaction between you and the cloud provider and is released from any liability arising out of or in any way connected with such interactions.

Access to EMC data is a procedure that entails legal and ethical obligations. We require that you and your institution have a modern, up-to-date information technology (IT) policy in place that must include, at a minimum, the following items:

- Logging and auditing of access to data and to the computer network;
- Password protection to computer network;
- Virus and malware protection to computers on the computer network;
- Auditable data destruction procedure, when necessary;
- Secure data backup procedure, when necessary;
- Strong encryption on any portable device that may store or provide access to EMC data; and
- Privacy breach notification.

You must agree to the following procedures in order to have access to the controlled data of EMC:

1. I will keep all computer systems on which EMC access data reside, or which provide access to such data, up-to-date with respect to software patches and anti-virus file definitions (if applicable).

☐ YES

2. I will protect EMC Access Data against disclosure to unauthorized individuals.

☐ YES

3. I will monitor and control which individuals have access to EMC Access Data.

☐ YES

4. I will destroy all copies of controlled access data in accordance with the terms and conditions of this data access agreement.

☐ YES

5. I will familiarize all individuals who have access to EMC datasets with the restrictions on its use.

☐ YES

6. I agree to swiftly provide a copy of both my institutional and project related IT policy documents upon request from an EMC representative

☐ YES

7. I will notify the EMC immediately if I become aware or suspect that someone has gained unauthorized access to the EMC Controlled Data.

☐ YES

Section III: Data Access Agreement

This agreement governs the terms of access to the controlled access datasets generated by the Epigenomics Mapping Centre ("EMC Data" as defined below). In signing this agreement, you agree to be bound by the terms and conditions of access set out therein.

For the sake of clarity the terms of access set out in this agreement apply to the User and to the User Institution(s) (as defined below). The current agreement is limited to the EMC Data (as defined below) and does not cover other data generated by the different projects participating in the Consortium)

DEFINITIONS

"Consortium" means the International Human Epigenome Consortium (IHEC), a global consortium with the goal of providing free access to high-resolution reference human epigenome maps for normal and disease cell types to the research community. A list of IHEC members can be found on the Consortium website: <http://IHEC-epigenomes.org/about/IHEC-members/>

"Data Producer" means the Epigenomics Mapping Centre (hereafter referred to as EMC).

"External Collaborator" means a collaborator of the Principal Investigator, working for an institution other than the User Institution.

"EMC Data" mean the Controlled Access Datasets of the Epigenomics Mapping Centre to which this agreement applies.

"Publications" includes, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.

“Research Participant” means an individual person who is the source of any EMC Data or any clinical data or biological sample from which EMC data have been generated.

“User” means an individual researcher (including Investigator(s)) participating in a Project who is enrolled at, affiliated with or employed by the Institution, and only during the term of such person's enrolment, affiliation or employment.

“User Institution(s)” means the institution(s) at which the User is employed, affiliated, or enrolled. A representative of it has co-signed this Data Access Agreement with the User and received acknowledgement of its acceptance.

Terms and Conditions:

In signing this agreement, the Users agree to:

Use of Data

1. The User and User Institution(s) agree to only use the EMC Data for the objectives and analyses outlined in section F *“Research Project”* and as approved by their ethics committee(s) in the letter requested in section J *“Ethics”* of this application form (if so required).
2. EMC Data must only be used and disclosed as expressly provided in this agreement, even in the case of discretionary freedom of information disclosure exceptions outlined in Quebec’s *An act respecting access to documents held by public bodies and the protection of personal information* or documents of similar force and effect.

Confidentiality & Control of Data/Non-Identification

3. The User and User Institution(s) agree to preserve, at all times, the confidentiality of the information and EMC Data. In particular, they undertake not to use, or attempt to use the EMC Data to compromise or otherwise infringe the confidentiality of information on Research Participants.
4. The User and User Institution(s) agree to protect the confidentiality of Research Participants in any research papers or publications that they prepare by taking all reasonable care to limit the possibility of identification.
5. The User and User Institution(s) agree not to link or combine the EMC Data provided under this agreement to other information or archived data available in a way that could re-identify the Research Participants, even if access to that data has been formally granted to the User and User Institution(s), or is freely available without restriction.
6. The User and User Institution(s) agree not to transfer or disclose the EMC Data, in whole or in part, or any material derived from the EMC Data, to anyone not listed in section D *“Names of authorized personnel”* or E *“Names of authorized students”* of this application form, except as necessary for data safety monitoring, national audits or program management. Should the User and User Institution(s) wish to share the EMC Data with an External Collaborator, the External Collaborator must complete a separate Application for Access to EMC Controlled Data form.

7. The User and User Institution(s) understand and acknowledge that EMC Data is protected by and subject to applicable laws and ethical guidelines, which may include without limitation the Tri-Council Policy Statement (TCPS 2), Quebec's *An act respecting access to documents held by public bodies and the protection of personal information*, and Quebec's *An act respecting protection of personal information in the private sector*.
8. The User and User Institution(s) agree that except as expressly provided in section F "*Research Project*", or with the express authorization of EMC, no identifiable data may be sent outside the User Institution(s) by the User and User Institution(s) for any reason. The User and User Institution(s) agree to immediately report to EMC any demand for disclosure.

Liability

9. The User and User Institution(s) accept that the IHEC Consortium, the EMC, McGill University, the original EMC Data producers, depositors or copyright holders, and the funders of the EMC Data or any part of the EMC Data supplied: a) bear no legal responsibility for the accuracy or comprehensiveness of the EMC Data; b) accept no liability for indirect, consequential, or incidental damages or losses arising from use of the EMC Data, or from the unavailability of, interruption in EMC Data access for whatever reason; c) bear no responsibility for the further analysis or interpretation of these EMC Data, over and above that published by the Consortium; and d) make no representations or warranties of any kind that the use of the EMC controlled data will not infringe on any patent, copyright, or trademark.
10. The User and User Institution(s) agree to hold the IHEC Consortium, the EMC, McGill University, the original EMC Data producers, depositors or copyright holders, and the funders of the EMC Data harmless, and to defend and indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of User and User Institution(s)'s use for any purpose of Data.
11. The User and User Institution(s) agree not to claim, infer, or imply endorsement of the Research Project by the IHEC Consortium, McGill University or EMC, except as described in paragraph 15.

Standards (Including Publication and Acknowledgements)

12. The User and User Institution(s) agree to follow the *Fort Lauderdale Guidelines*, the *Toronto Statement*, and the *GA4GH Framework for Responsible Sharing of Genomic and Health-Related Data* included as Appendices I, II, and III of this Data Access Agreement. This includes but is not limited to recognizing the contribution of EMC and IHEC and including a proper acknowledgement in all reports or publications resulting from the User and User Institution(s)' use of the EMC Data (see 14. below).
13. The User and User Institution(s) agree to follow the policies laid out in E.4. "*IHEC Data Release Policies*", E.5. "*IHEC Publication Policy*" and E.6. "*IHEC Intellectual Property Policy*" of the *IHEC Goals, Structure, Policies & Guidelines* document dated January 2013, as amended from time to time and available online at <http://ihec-epigenomes.org/about/policies-and-guidelines/> in addition to the conditions set out in this Data Access Agreement and included as Appendices IV, V, and IV of this document. This includes respecting the nine month-long moratorium period

applicable to global data analysis from the time data are deposited. Additional information on the publication moratorium can be found in section E.5 of the aforementioned document and in Appendix V to this agreement.

14. Prompt publication or any public disclosure of the results of the research project is encouraged.
15. The User and User Institution(s) agree to acknowledge the contribution of the EMC in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of EMC Data.
 - a. Collaborations/Acknowledgements: If the Research Project involves a collaboration with a member of the EMC, then manuscripts will be co-authored and reviewed by the EMC collaborator and the source of the EMC Data will be acknowledged such as follows in the methods sections of the manuscript if possible or elsewhere in the main text of the manuscript: "This research used data shared by the McGill Epigenomics Mapping Centre and it is available from the European Genome-phenome Archive of the European Bioinformatics Institute (accession numbers: study EGAS00001000995 and dataset(s) EGAD00...)". If you used the IHEC Data Portal to identify, download, visualize or analyze data, please cite: Bujold et al. "The International Human Epigenome Consortium Data Portal." *Cell Systems* 3.5 (2016): 496-499. Please also cite: McGill Epigenomics Mapping Centre (2015). Dataset from EGA Study EGAS00001000995 [Data file]. Available from <http://epigenomesportal.ca/edcc>.
 - b. Other Studies/Acknowledgements: If the Research Project does not involve a collaboration with a member of the EMC, then the User and User Institution(s) will acknowledge the source of the EMC Data such as follows in the methods sections of manuscripts if possible or elsewhere in the main text of the manuscript: "This research used data shared by the McGill Epigenomics Mapping Centre and it is available from the European Genome-phenome Archive of the European Bioinformatics Institute (accession numbers: study EGAS00001000995 and dataset(s) EGAD00...)". If you used the IHEC Data Portal to identify, download, visualize or analyze data, please cite: Bujold et al. "The International Human Epigenome Consortium Data Portal." *Cell Systems* 3.5 (2016): 496-499. Please also cite: McGill Epigenomics Mapping Centre (2015). Dataset from EGA Study EGAS00001000995 [Data file]. Available from <http://epigenomesportal.ca/edcc>. The User and User Institution(s) also agree to let EMC know of any publications.
16. The User and User Institution(s) agree not to make intellectual property claims on EMC Data and not to use intellectual property protection in ways that would prevent or block access to, or use of, any element of the EMC Data, or conclusions drawn directly from the EMC Data.
17. The User and User Institution(s) can elect to perform further research that would add intellectual and resource capital to the EMC Data and decide to obtain intellectual property rights on these downstream discoveries. In this case, the User and User Institution(s) agree to implement licensing policies that will not obstruct further research and to follow the U.S. National Institutes of Health's *Best Practices for the Licensing of Genomic Inventions* or a similar national guideline that is in conformity with the OECD *Guidelines for the Licensing of the Genetic*

Inventions. These two policies (NIH and OECD) are included as Appendices VII and VIII of the Application.

Protocols

18. The User and User Institution(s) agree to destroy/discard any EMC data held once it is no longer used for the project described in this Data Access Agreement unless obligated to retain the EMC Data for archival purposes in conformity with national audits or legal requirements.
19. The User and User Institution(s) will update the *List of Authorized Personnel* to reflect any changes or departures in researchers, collaborators, and personnel within 30 days of the changes made. This update can be sent by e-mail to this address: **dac.edcc@mail.mcgill.ca**
20. The User and User Institution(s) must notify the Data Access Compliance Office prior to any significant changes to the research protocol of the User described in F "*Research Project*". This update can be send by email to this address: **dac.edcc@mail.mcgill.ca**.
21. The User and User Institution(s) will notify the Data Access Compliance Office (**dac.edcc@mail.mcgill.ca**) within ten days of becoming aware of a breach of the terms or conditions of this agreement.
22. The User and User Institution(s) accept that this agreement may terminate upon any breach of this agreement from the User, the User Institution(s) or any authorized personnel mentioned in section D "*Names of authorized personnel*" or E "*Names of authorized students*" of this application document. In this case, the User and the User Institution(s) will be required to destroy/discard any EMC Data held, including copies and backup copies. This clause does not prevent the User and the User Institution(s) from retaining the EMC Data for archival purpose in conformity with national audits or legal requirements.
23. The User and User Institution(s) accept that it may be necessary for the Consortium, the EMC or its appointed agent to alter the terms of this agreement from time to time. In this event, the Consortium, the EMC or its appointed agent will notify the User and the User Institution(s) by email.
24. If requested, the User and the User Institution(s) will allow data security and management documentation to be inspected to verify that they are complying with the terms of this Data Access Agreement.
25. The User and User Institution(s) agree to distribute a copy of this agreement and explain its content to every person mentioned in D "*Names of authorized personnel*" or E "*Names of authorized students*" of this application form.

Governing Law and Arbitration

26. This Agreement shall be governed by and construed in accordance with the laws of the Province of Quebec and the laws of Canada in force therein without regard to its conflict of law rules. All parties agree that by executing the Data Access Agreement they have attorned to the jurisdiction of the Superior Court of Quebec. In the event of any dispute arising between the parties concerning this Agreement, its enforceability, or its interpretation, said dispute can be settled by a single arbitrator appointed pursuant to the provisions of the *International*

Commercial Arbitration Act, or any successor legislation then in force. The place of arbitration shall be Montreal, Quebec, Canada and the language to be used in the arbitration proceedings will be English. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for interim protection such as, by way of example, an interim injunction.

I have read, understood and agree to abide by the terms and conditions stipulated in the Data Access Agreement.

☐ YES

I have read and understood all contents of the Appendices listed at the end of this document.

☐ YES

Main Applicant (PI):

Name:

Title and position:

Institution:

Signature: _____ Date: _____

Authorized institutional representative:

(This should be the same person as mentioned under Section I B. "Institutional Representative" of this application form):

Name:

Title and position:

Institution:

Signature: _____ Date: _____

EDCC RESERVED SPACE

Once completed and sent electronically to the EDCC, a paper copy of this application must be faxed to: +1 (514) 398-8954 or mailed to:

**Stephanie Dyke PhD, Data Access Officer
McGill University and Genome Quebec Innovation Centre
740 Dr. Penfield Avenue, Suite 5209
Montreal QC, Canada H3A 1A4**

In case you elect to send the paper copy by courier, you may use the EDCC office phone number: +1 (514) 398-8155. (Only the paper copy needs to be signed.)

Appendices

Appendices do not need to be sent back to EDCC.

**APPENDIX I
FORT LAUDERDALE GUIDELINES (2003)**

**APPENDIX II
TORONTO STATEMENT (2009)**

**APPENDIX III
GA4GH FRAMEWORK FOR RESPONSIBLE SHARING OF GENOMIC AND HEALTH-RELATED DATA (2014)**

**APPENDIX IV
IHEC GOALS, STRUCTURE, POLICIES & GUIDELINES – IHEC DATA RELEASE POLICIES (2013)**

**APPENDIX V
IHEC GOALS, STRUCTURE, POLICIES & GUIDELINES – IHEC PUBLICATION POLICY (2013)**

**APPENDIX VI
IHEC GOALS, STRUCTURE, POLICIES & GUIDELINES – IHEC INTELLECTUAL PROPERTY POLICY (2013)**

**APPENDIX VII
NIH, *BEST PRACTICES FOR THE LICENSING OF GENOMIC INVENTIONS* (2005)**

**APPENDIX VIII
OECD, *GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS* (2006)**