



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 or post-doctoral scholar), including institutional affiliation and contact details.

Please ensure that a full postal address and a valid institutional email address are included.

Name:	
Position:	
Institution:	
Institutional Email Address:	
Website of the Institution:	
Mailing Address:	

B. Title of the Project:

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C. Names of individuals authorized to access the Data (including students and institutional employees)*:

Please include the names of all individuals who will have access to the controlled data in order to work on the project. Please ensure that a valid institutional email address for each name is included, and ensure that each individual has read and understood the access agreement.

Name:	
Position:	
Affiliation:	
Institutional Email Address:	

Name:	
Position:	
Affiliation:	
Institutional Email Address:	

Name:	
Position:	
Affiliation:	
Institutional Email Address:	

***If you require more space to list authorized individuals, please attach a separate file.**

D. Research Project (Scientific Abstract):

Please provide a clear description of the project and its specific aims. Note that any use of the Data, if approved, must fall under the purview of the described project (500 words max):

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E. 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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F. Research Credentials

Please provide a list of three publications, relevant to the Project description outlined in Section D, of which the Main Applicant is author or co-author.

If the Main Applicant 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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G. Datasets

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

<ul style="list-style-type: none">• EGAD00...•

H. 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.
- Ethics review has been waived for this project. Documentation to this effect is attached.

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

Definitions:

Data refers to any and all human genetic, epigenetic or phenotype data obtained from through this Agreement.

Data Provider refers to the Epigenomics Mapping Centre (hereafter referred to as EMC).

Data Subject refers to an individual who is the source of any Data covered by this Agreement.

Project refers to the Research Project to which this Agreement pertains, as described in Section I, Paragraph D of this document.

Publications refers, without limitation, to any and all articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research that have been accepted by peer review.

You refers to any and all individuals or institutions accessing Data through this Agreement.

Terms and Conditions:

In signing this agreement:

1. You agree to only use the Data for the objectives and analyses outlined in Section I, Paragraph D, "Research Project", and as approved by the appropriate ethics committee in the letter requested in Paragraph H, "Ethics" (if applicable).
2. You agree to contact the Data Provider at dac.edcc@mail.mcgill.ca within ten days of any breaches or attempted breaches of this agreement; within thirty days of any updates to the list of authorized personnel described in Section I, Paragraphs A and C; and prior to any changes to Your approved research protocols.
3. You agree to preserve, at all times, the confidentiality of information and Data pertaining to Data Subjects. In particular, You undertake not to use or attempt to use the Data to compromise or otherwise infringe the confidentiality of information on Data Subjects and their right to privacy.
4. You agree not to attempt to re-identify Data Subjects by linking the Data provided under this agreement to other sources of information or available archive data, even if access to that data has been formally granted to you, or it is freely available without restriction, without specific permission being sought from the relevant data access committee.
5. You agree to allow Data Providers to publish the initial analysis of their data in a timely manner before publishing an article using, or analyzing, the Data. For the purpose of this agreement, "timely" refers to within a period of **nine months** after the **release** of the data into public databases.
6. You 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

using the following text (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>.”

You also agree to let EMC know of any publications made using the Data.

7. You recognize that nothing in this agreement shall operate to transfer to You any intellectual property rights to the Data.
8. You acknowledge that access to controlled data is granted for a one year period (starting from the date of acceptance). An Annual Renewal Application must be completed in order to access/use controlled data beyond that one-year time period. You are responsible for submitting Your Renewal Application in a timely manner.
9. Upon termination of the project described in Section 1, Part D, You will destroy the Data in addition to any potentially identifiable downstream analysis files produced using the Data. Any use of the Data for a project other than that described in Section I, Part D will need to be approved under a new Agreement.
10. You accept that it may be necessary for the Data Provider to alter the terms of this agreement from time to time in order to address new concerns. In this event, You will be contacted and informed of any material changes. You agree that Your continued use of the Data shall indicate your acceptance of the new terms of the Agreement.
11. You accept that this agreement will terminate immediately upon any breach by You as determined by the Data Provider and You will be required to destroy any Data held.
12. You agree not to make intellectual property claims on the Data and not to use intellectual property protection in ways that would prevent or block access to, or use of, any element of the Data, or conclusions drawn directly from the Data.
13. You agree that the Project 1) bears no legal responsibility for the accuracy or comprehensiveness of the Data; 2) accepts no liability for indirect, consequential, or incidental damages or losses arising from use of the Data, or from the unavailability of, interruption in Data access for whatever reason; 3) bears no responsibility for the further analysis or interpretation of these Data, over and above that published by the Consortium; and 4) makes no representations or warranties of any kind that the use of the Data will not infringe on any patent, copyright, or trademark.
14. You agree to hold the Data Producers, as well as the Depositors, Copyright holders, Funders, and Data Access Committees of the Data harmless, and to defend and indemnify all such parties against all liabilities, demands, damages, expenses, and losses arising out of Your use for any purpose of the Data.

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

Main Applicant (PI or post-doc):

Name:

Title and position:

Institution:

Signature: _____ Date: _____

Authorized institutional representative of the applicant's institution:

Name:

Title and position:

Institution:

Signature: _____ Date: _____

EDCC RESERVED SPACE