

Model Data Access Agreement for Epigenetic Controlled Data

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:

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:	
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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. 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.

F. 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: 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 an IHEC participating centre, responsible for the development, organization, and oversight of a local database.

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 F, "Ethics" (if applicable).
2. 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.
3. 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.
4. You agree that in handling this data, you and your institution will follow a modern, up-to-date information technology (IT) policy that must include, at a minimum, the following items:
 - a. Logging and auditing of access to data and to the computer network;
 - b. Password protection to computer network;
 - c. Virus and malware protection to computers on the computer network;
 - d. Auditable data destruction procedure, when necessary;
 - e. Secure data backup procedure, when necessary;
 - f. Strong encryption on any portable device that may store or provide access to EMC data; and
 - g. Privacy breach notification.
5. You acknowledge that access to the Data is granted for the duration of the project described in Section I, Part D. Upon termination of the project. 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.

6. 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.
7. 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.
8. 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.
9. You recognize that nothing in this agreement shall operate to transfer to You any intellectual property rights to the Data.
10. You agree not to make intellectual property claims on the Data (including somatic mutations) 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.
11. 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.
12. 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.
13. *You agree to a moratorium on publishing global analyses of the dataset until Data Producers have published their own global analysis or [...] months have passed from the time the data is deposited, whichever occurs first.*¹ You acknowledge that prompt publication or public disclosure of the results of the Research Project is encouraged.
14. You agree to acknowledge the contribution of the Data Provider in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data. You agree to include in Your acknowledgment the IHEC Data Portal session ID associated with [...] corresponding to the data You used (in the methods sections of manuscripts if possible or elsewhere in the main text of the manuscript).

¹The necessity of imposing an embargo period should be carefully considered, as this practice is not conducive to open science. If an embargo is deemed necessary, the above-mentioned formulation proposes a type of clause that could be used.

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:

Name:

Title and position:

Institution:

Signature: _____ Date: _____

July 2018

Yann Joly (Chair)

Stephan Beck (Co-Chair)

Guillaume Bourque

David Bujold

Charles Dupras

Stephanie O.M. Dyke

Katie M. Saulnier

For the IHEC Bioethics and EpiMap Working Groups.