**DATA ACCESS AGREEMENT**

This Data Access Agreement (hereinafter referred to as the “Agreement”), effective as of [date] (hereinafter referred to as the “Effective Date”) is made by and between:

[…] (hereinafter “referred to as the “XXX”), a [nationality] company/institution/organization with tax registration number […], based in [city], [country], [address], represented by Ms/Mr. […] that acts in his/her capacity as […].

and,

[…] (hereinafter “referred to as the “User Institution”), a [nationality] company/institution/organization with tax registration number […], based in [city], [country], [address], represented by Ms/Mr. […] that acts in his/her capacity as […].

Dr. […] (hereinafter referred to as the “User”) is employee of the User Institution.

# RECITALS

# Whereas the User Institution and the User are interested in accessing to the managed access datasets, details of which are set out in the corresponding Application form attached as Appendix.

# Whereas XXX has granted the User and User Institution access to the requested datasets

Now therefore, in consideration of the mutual promises, covenants and conditions set forth herein, the parties agree as follows:

# AGREEMENT

# Definitions:

“Authorised User” refers to employees, affiliated or enrolled staff of the User Institution to whom XXX grants access to the Project Data. This includes the individuals listed in the Appendix and any other individuals for whom the User Institution subsequently requests access to the Project Data. Details of the initial Authorised Users are set out in Appendix.

“Data Subject” refers to the person whose sample has been used to generate Project Data.

“Project” refers to the research project for which the User Institution has requested access to the Project Data.

“Project Data” refers to the data generated in the Project.

 “Publications” refers to, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.

“Research Group” refers to the Research Group XXXX from the XXX.

“Research Purposes” refers to research that is seeking to advance the understanding of genetics and genomics, including the treatment of disorders, and work on statistical methods that may be applied to such research.

 “User” refers to the principal investigator who has successfully applied for access to Project Data.

“User Institution” refers to the organization with which the User is employed, affiliated or enrolled.

# Terms and Conditions of the DAA:

This Agreement governs the terms on which access will be granted to the Project Data generated by the Project. By signing this Agreement, User and User Institution agree to be bound by the terms and conditions of access set out in this Agreement, as follows:

1. User and User Institution agree to use Project Data only for Research Purposes.
2. User and User Institution agree not to use, and not to allow use of, Project Data or any part thereof for the creation of products or services for sale or for any commercial purpose, whether sale by User, User Institution or by third parties.
3. User and User Institution acknowledge that the Project Data received is anonymized and that the Research Group will under no circumstances provide User and User Institution with any means to identify any Data Subject. User and User Institution agree not to use Project Data to identify or contact individual Data Subjects. User and User Institution agree to preserve, at all times, the confidentiality of information and Project Data. In particular, User and User Institution undertake not to use, or attempt to use Project Data to compromise or otherwise infringe the confidentiality of information on Data Subjects and their right to privacy.
4. User and User Institution agree to ensure that any Authorized Users who have access to Project Data comply with all obligations of the present Agreement. User agrees to disclose Project Data only to the Authorized Users, who are bound by a duty of confidentiality which is at least as strict as provided for in this Agreement. User and User Institution agree to be responsible for all breaches of confidentiality and of the terms of this Agreement by the Authorized Users. Any change in the User or Authorised Users shall be notified to XXX within 30 days.
5. User and User Institution agree to store Project Data on a computer system with adequate security controls that prevent unauthorized access to or loss of Project Data and to maintain appropriate control over the Project Data. User and User Institution represent and warrant to have in place, and agree that will keep having in place, state of the art technical and organizational security measures preventing unauthorized access and loss of Project Data or other forms of unlawful processing of Project Data, including without limitation, physical security measures, access controls, security and privacy technologies, security checks in relation to personnel, security incident response management and audit arrangements. User and User Institution agree to notify forthwith the administrator of the Project, XXX, of any violations of the foregoing.
6. User and User Institution represent and warrant that all required ethico-legal approvals, restrictions and commitments, without limitation data subject consent and approval of the pertinent ethical review board, for the proposed use of the Project Data have been obtained and adhered to.
7. In the event the Project Data is issued to User and User Institution subject to any Data Subject’s restrictions, User and User Institution hereby assume the obligation to abide by these restrictions as their own obligation towards the Data Subject. User and User Institution agree that a Data Subject who has suffered damage(s) as a result of any violation by User and User Institution of pertinent provisions in this Agreement or of applicable legislation, is entitled to receive compensation from User and User Institution for the damage(s) suffered. In the event of such a violation, the Data Subject is also entitled to bring an action before a court within the Data Subject’s jurisdiction.
8. User and User Institution agree not to attempt to link Project Data to other information or archive data available for the data sets provided under this Agreement, even if access to that data has been formally granted to User and User Institution, or it is freely available without restriction, without the required consents and approvals. User and User Institution agree to retain control over Project Data, and not to distribute Project Data provided under this Agreement, in any form, to any third party.
9. User and User Institution agree not to transfer, share or disclose Project Data, in whole or in part, to or with anybody else, whether or not he or she is affiliated with the User Institution, unless he or she is a named and approved collaborator.
10. User and User Institution agree to use Project Data for the purpose and project described in the application form approved by the Data Access Committee. Use of the data for a new purpose or project or by another researcher will require a new application and approval. Substantive modification of the original application requires submission of an amendment to the original application.
11. User and User Institution agree to, when analyses result in newly estimated variables at an individual level, submit these new variables for archiving with the Research Group. This should be done no later than that the related paper will be submitted for publication.
12. User and User Institution accept that Project Data will be reissued from time to time, with suitable versioning. If the reissue is at the request of sample donors and/or subject to other ethical scrutiny, User and User Institution will destroy earlier versions of the Project Data.
13. User and User Institution understand and acknowledge that Project Data may be protected by copyright, database right and other intellectual property and proprietary rights, and that duplication, sale, licensing or any other form of disposing or distribution or making available, of all or part of the Project Data on any media is not permitted.
14. User and User Institution acknowledge that the Project Data are made available under this Agreement on the title of un-assignable and non-exclusive access. User and User Institution recognize that nothing in this Agreement shall operate to transfer any rights, including but not limited to intellectual property rights and database rights, in or relating to Project Data. If any new intellectual property rights are created through, arising from, or as a result of the use of the Project Data by User and Authorised Users, ownership of these intellectual property shall be determined in good faith depending on each party relative contribution. XXX will be granted a non-exclusive, royalty-free licence to use such new intellectual property rights for research purpose activities.
15. User and Authorised Users agree to acknowledge in any work based in whole or in part on Project Data, the published paper from which the Project Data derives, the version of the data, the role and /or contribution of the Research Group and the relevant primary collectors and their funders. User and Authorised Users agree to respect in any publication the mention of the inventors or authors according to applicable Law and commonly accepted conventions for scientific publications. Notwithstanding the foregoing, prior to any disclosure, User and Authorised Users shall submit to XXX, at least thirty (30) days in advance, all intentions to publish or to otherwise disclose the results. XXX shall report in writing, within those thirty (30) days, if is of the opinion that the protection of the results might be threatened and/or its commercial interests are likely to be prejudiced by the aforementioned publication or disclosure (it shall be understood that the lack of reply in the 30-days period is a tacit approval of the disclosure). In case of prejudice, XXX may request User and Authorised Users to omit confidential information and/or to delay the publication or disclosure to allow proper protection of the results to be disclosed. Such delay shall sufficiently be motivated in writing and shall not exceed sixty (60) additional days, except if otherwise agreed between the parties.
16. User and User Institution agree to destroy the Project Data after the resulting paper has been published. Upon destruction of data a written confirmation will be sent to XXX.
17. User and User Institution accept that the Research Group, the original Project Data generators and the funders of the Project Data:
	1. bear no legal responsibility whatsoever for the accuracy, completeness or comprehensiveness of the Project Data; and
	2. accept no liability for direct, indirect, consequential or incidental, damages or losses arising from any use of Project Data by anyone, including without limitation any clinical use and any commercial use thereof, or arising from the unavailability of, or break in access to, the Project Data for whatever reason.
18. User and User Institution accept that this Agreement will terminate immediately upon any breach of this Agreement by User and User Institution and will be required to destroy any Project Data held.
19. User and User Institution accept that it may be necessary to alter the terms of this Agreement from time to time in order to address new concerns. In this event, XXX will inform of any changes and User and User Institution agree that the continued use of Project Data shall be dependent on the parties entering into a new version of the Agreement.
20. User will submit a report to the Data Access Committee, if requested, on completion of the research study of the Project Data. Such report will include the data resulting from the research study of the Project Data. The Data Access Committee agrees to treat the report and all information, data, results, and conclusions contained within such report as confidential information.
21. User and User Institution accept that Project Data may be protected by and subject to national and international laws. User and User Institution are responsible for ensuring compliance with any such applicable law with respect to the use and processing of the Project Data. The Data Access Committee reserves the right to request and inspect User Institution’s data security and management documentation to ensure the adequacy of data protection measures applied on the Project Data.
22. This Agreement shall be governed by and construed under the laws of Spain. With express waiver to any other jurisdiction that may correspond to the parties, any dispute or controversy in relation to, in connection with or resulting from the interpretation, performance, or execution of this Agreement that cannot be solved amicably between the parties shall be submitted exclusively to the courts of the city of Barcelona (Spain).
23. This Agreement may be executed in two or more counterparts, each of which shall be considered an original instrument. The parties of this Agreement will process personal data of its signatories for the execution of this Agreement until it is in force and after that, until the applicable legal limitation periods. The parties may at any time exercise their rights of access, rectification, erasure, opposition, limitation and portability, through the address of the other party indicated above, as well as submit a claim to the supervisory authority on Data Protection. Each counterpart will be considered a valid and binding original, and all counterparts taken together shall constitute one and the same Agreement.

In witness whereof, the parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Signed by: Name of User Institution:

Name and affiliation of User (Principal Investigator): Legal representative of User Institution:

Date: Date:

(Stamp or seal of User Institution)

Signed by: XXX

Name and affiliation of XXX Research Group Legal representative of XXX:

Principal Investigator:

Date: Date:

(Stamp or seal of XXX)

**APPENDIX – APPLICATION FORM**

**APPLICATION FOR DATA ACCESS (to be completed by the Requester)**

Application for access to data shall be submitted to XXX.

XXX Data Access Committee will consider the application according to the information received.

1. **Name of applicant including affiliation and contact details**

|  |  |
| --- | --- |
| *Name* |  |
| *Institution* |  |
| *Address* |  |
| *Phone number* |  |
| *E-mail address* |  |

1. **Details of dataset requested**

|  |  |
| --- | --- |
| *EGA Study and Dataset Accession Number*  |  |
| *Description of the specific datasets that are being requested* |  |

1. **Purpose and Project**

|  |  |
| --- | --- |
| *Brief abstract of the purpose and the project in which the data will be used. This should include specific details about the use of the data in the Project (500 words max)* |  |

1. **Feasibility**

|  |  |
| --- | --- |
| *Description of your experience and expertise and how this will be applied to the proposed Project. Include up to 3 citations, major funding sources and identify any collaborator in the Project* |  |

1. **Research ethics**

|  |  |
| --- | --- |
| *Information about any ethical issues arising as a result of your research in the Project*  |  |

1. **Users**

List of employees, affiliated or enrolled staff of the user institution interested in accessing to the data:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Name of user* | *Job Title*  | *E-mail address* | *Supervisor* | *EGA Registered User (Yes/No)* |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*The personal data you provide to the XXX will be processed for considering your application of access to an EGA dataset owned by XXX.*

*Legal entity responsible for processing your data: XXX, address
Purpose of the data processing: Management of your application.*

*Legitimation: Activity of public interest.*

*Recipient: Third parties with whom XXX is legally obliged to provide the data.*

*Term: XXX will keep your data until your access to the EGA dataset is in force and, after that, until the applicable legal limitation periods.*

*Rights: You can exercise your rights of access, rectification, erasure, opposition, limitation and portability through the address indicated above or by submitting a claim to the supervisory authority on Data Protection.*

*DPO: e-mail address*

*I authorize the processing of my data for the indicated purpose by signing the present application form:*

*Signature of the principal investigator who applies for access to the data*

*Name:*

*Date:*

*Signature:*