DATA ACCESS AGREEMENT

between

BioMed X GmbH

and

[User Institution]

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THIS DATA ACCESS AGREEMENT

(the "**Agreement**")

is entered into as of [Date]

BETWEEN:

(1) **BioMed X GmbH**, a company registered in Germany under number HRB 716390 at the Local Court of Mannheim (*Amtsgericht Mannheim*) whose registered address is Im Neuenheimer Feld 515, 69120 Heidelberg, Germany;

– hereinafter referred to as "**BioMed X**" –

(2) [User Institution], [Address]

– hereinafter referred to as "**User Institution**" –

The parties listed in no. (1) to (2) above are also referred to collectively as the "**Parties**" and each as a "**Party**".

NOW IT IS AGREED as follows:

1. DEFINED TERMS

In this Agreement, except where set forth otherwise, the following terms shall have the following meanings:

(a) "**Authorised Personnel**" shall mean the individuals at the User Institution to whom BioMed X grants access to the Data. This includes the Principal Investigator and other Registered Users listed in **Appendix II** and any other individuals for whom the User Institution subsequently requests and BioMed X and/or the DAC agrees to grant access to the Data. Details of the initial Authorised Personnel are set out in **Appendix II**;

(b) "**Data**" shall mean the managed access datasets pursuant to **Appendix I** to which the User Institution has requested access;

(c) "**DAC**" shall mean the Data Access Committee which is a body of one or more named individuals who are responsible for Data release to the User Institution based on consent and/or national research ethics terms.

(d) "**Data Producers**" shall mean BioMed X and, if any, the collaborators listed in **Appendix I** responsible for the development, organisation, and oversight of these Data;

(e) "**Data Subject**" shall mean the person (irrespective of state of health) to whom the Data refers and who has been informed of the purpose for which the Data is held and has given his/her informed consent thereto;

(f) "**EGA**" shall mean the European Genome-phenome Archive;

(g) "**External Collaborator**" shall mean a collaborator of the Principal Investigator or the Registered User, working for an institution other than the User Institution;

(h) "**Intellectual Property**" means (i) patents, designs, trademarks and trade names (whether registered or unregistered), copyright and related rights, database rights, know-how and confidential information; (ii) all other intellectual property rights and similar or equivalent rights anywhere in the world which currently exist or are recognised in the future; and (iii) applications, extensions and renewals in relation to any such rights;

(i) "**Principal Investigator**" shall mean the person responsible for the conduct of the research in accordance with the Research Purposes and the Project;

(j) "**Project**" shall mean the project for which the User Institution has requested access to these Data. A description of the Project is set out in **Appendix II**;

(k) "**Provider of Human Samples**" is the person, entity or institution which collected and/ or stored the human sample(s) of the Data Subject analysed by BioMed X and, if any, its collaborators for generation of the Data. The Provider of Human Samples is listed in **Appendix I**;

(l) "**Publications**" shall include, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research;

(m) "**Registered User**" shall mean an individual conducting research ("**Researcher**") (or an individual conducting research under the supervision of a Researcher) granted access to the Data or any other individuals for whom the User Institution subsequently requests and BioMed X and/or the DAC agrees to grant access to the Data that is employed by the User Institution and is bound by confidentiality and non-use obligations in respect of the Data. For avoidance of doubt, the Principal Investigator is a Registered User. Details of the initial Registered User(s) are set out in **Appendix II**;

(n) "**Research Purposes**" shall mean non-commercial biomedical research only.

2. USE OF DATA

2.1 The User Institution has requested access to the Data and agrees to use the Data only in the specific Project for Research Purposes. Should the User Institution intend to use

the Data for any other project or purpose, it must file a new application and pass again the application process. The User Institution acknowledges and accepts that the DAC and/or BioMed X decide in its sole discretion about granting access to the Data for any project and/or purpose and/or to any person and neither the DAC nor BioMed X is obliged to provide a reasoning of its decision.

2.2 The User Institution and its Authorised Personnel further agree that they will only use these Data for Research Purposes which are within the limitations (if any) set out in **Appendix I**.

2.3 The User Institution and its Authorised Personnel shall only use the Data in accordance with a respective ethics vote of the competent ethics committee of the Provider of Human Samples. In case the Project goes beyond reproduction of BioMed X's research results in Publications, the User Institution must obtain a new ethics vote and include it as **Exhibit I** to **Appendix II**.

2.4 The User Institution and its Authorised Personnel shall only use the Data in accordance with this Agreement and all applicable laws.

3. CONFIDENTIALITY

3.1 The User Institution and its Authorised Personnel agree to preserve, at all times, the confidentiality of Data pertaining to identifiable Data Subjects. In particular, the User Institution and its Authorised Personnel undertake not to use or attempt to use the Data to deliberately compromise or otherwise infringe the confidentiality of information on Data Subjects and their right to privacy. Without prejudice to the generality of the foregoing, the User Institution and its Authorised Personnel agree to use at least the measures set out in **Appendix I** to protect these Data. The User Institution and its Authorised Personnel shall particularly store the Data and any copy thereof only in encrypted form at a safe place with limited access and transfer the Data and any copy thereof only in encrypted form and via secured connections/networks.

3.2 The User Institution and its Authorised Personnel agree that they will submit a final report to the DAC and BioMed X within sixty (60) days after completion of the agreed Project and/or Research Purposes. The DAC and BioMed X agree to treat the report and all information, data, results, and conclusions contained within such report as confidential information belonging to the User Institution. Notwithstanding the foregoing, BioMed X shall be entitled to share User Institution's final report with the Provider of Human Samples.

4. DATA PROTECTION

4.1 The User Institution agrees that it, and its Authorised Personnel, are covered by and shall comply with the obligations contained in the EU Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the "**GDPR**"), or equivalent national provisions no less onerous then those contained in the GDPR. In particular, the User Institution and its Authorised Personnel understand their duties under such legislation in relation to the handling of Data and the rights of Data Subjects.

4.2 The User Institution agrees to:

4.2.1 protect the confidentiality of Data Subjects in any Publications that it prepares by taking all reasonable care to limit the possibility of identification;

4.2.2 not to link or combine these Data to other information or archived data available in a way that could re-identify the Data Subjects, even if access to that data has been formally granted to the User Institution or is freely available without restriction;

4.2.3 not to modify, alter or amend the Data; and

4.2.4 only to transfer or disclose these Data, in whole or part, or any material derived from these Data, to the Authorised Personnel. Should the User Institution wish to share these Data with an External Collaborator, the External Collaborator must complete a separate application for access to these Data.

4.3 The User Institution agrees to destroy/discard the Data and any copy thereof held, once it is no longer needed for the Project, unless obliged to retain a copy of the Data for archival purposes in conformity with audit or legal requirements.

5. ACCESS AND GOVERNANCE

5.1 The User Institution agrees that it shall take all reasonable security precautions to keep the Data confidential, such precautions to be no less onerous than those applied in respect of the User Institution's own confidential information.

5.2 The User Institution agrees to distribute a copy of the terms of this Agreement to the Authorised Personnel. The User Institution will procure that the Authorised Personnel comply with the terms of this Agreement.

5.3 If requested by BioMed X, the User Institution will allow data security, management documentation and the results and analyses obtained from the use of the Data together with any records and documents relating thereto to be inspected to verify that it is complying with the terms of this Agreement or to ensure the adequacy of data

protection measures in countries that have no national laws comparable to those applicable to the European Economic Area (EEA). A representative of BioMed X will be permitted access by the User Institution for the purposes of the aforestanding sentence.

6. NOTIFICATION OBLIGATIONS BY THE USER INSTITUTION

6.1 The User Institution shall notify BioMed X immediately of any changes or departures of the Authorised Personnel.

6.2 The User Institution shall notify BioMed X prior to any significant changes to the protocol for the Project.

6.3 The User Institution agrees to notify BioMed X of any errors detected in the Data.

6.4 The User Institution shall notify BioMed X and the DAC as soon as it becomes aware of a breach of the terms and conditions of this Agreement.

7. INTELLECTUAL PROPERTY

7.1 The User Institution recognises that nothing in this Agreement shall operate to transfer to the User Institution or its Authorised Personnel any Intellectual Property in or relating to the Data.

7.2 The User Institution and its Authorised Personnel shall have the right to develop Intellectual Property based on comparisons with their own data. Such Intellectual Property developed by User Institution through the use of the Data shall be and remain the exclusive property of the User Institution.

8. PUBLICATIONS

8.1 The User Institution and its Authorised Personnel agree to acknowledge in any work based in whole or part on the Data, the published paper from which the Data derives, the version of the Data, and the role of the Project and its funders in its distribution. The User Institution and its Authorised Personnel further agree to acknowledge the origin of the biomaterials (i.e., the Provider of Human Samples) and the Data Producers as well as the EGA Study ID and the dataset details as set forth in **Appendix I** of this Agreement.

8.2 The User Institution and its Authorised Personnel agree to use the acknowledgement wording provided for the relevant Data in all reports or publications resulting from the use of these Data. The User Institution and its Authorised Personnel will also declare in any such work that those, who carried out the original analysis and collection of the

Data, bear no responsibility for the further analysis or interpretation of it by the User Institution.

8.3 The User Institution and its Authorised Personnel agree to follow the Publication Policy in **Appendix III**. This includes respecting the moratorium period for the Data Producers to publish the first peer-reviewed report describing and analysing these Data.

9. TERMINATION OF THE AGREEMENT

9.1 The Registered Users and the User Institution accept that this Agreement shall terminate automatically with immediate effect upon breach of any provision of this Agreement by any Registered User and/or the User Institution.

9.2 The User Institution accepts that the changing ethical framework of human genetic research may lead to:

9.2.1 alteration to the provisions of this Agreement, in which case BioMed X shall notify the User Institution in writing of such alterations if they are provided by mandatory law and the User Institution may choose to accept such alterations or to terminate this Agreement; or

9.2.2 in extreme circumstances, the withdrawal of this Agreement if conflict with new mandatory law provisions could not be avoided by other means.

9.3 Either Party shall have the right to terminate this Agreement with effect of thirty (30) days after receipt by the other Party of a written notice of termination.

9.4 In the event that this Agreement is terminated in accordance with this clause 9, the User Institution shall return or destroy all Data at the direction of BioMed X. This shall include the deletion/ destruction of each and every copy and/or backups of the Data in the possession or under control of the User Institution and/or its Authorised Personnel. User Institution is entitled to retain one (1) copy of the Data on a secure place in encrypted form subject to compliance with the further confidentiality obligations provided herein and under applicable laws to the extent this is required for archival purposes in conformity with audit or legal requirements.

10. LEGAL STATEMENT

10.1 The User Institution acknowledges that BioMed X and all other parties involved in the creation, funding or protection of the Data:

10.1.1 make no warranty or representation, express or implied as to the accuracy, quality or comprehensiveness of the Data; and

10.1.2 exclude to the fullest extent permitted by law all liability for actions, claims, proceedings, demands, losses (including but not limited to loss of profit), costs, awards damages and payments made by or incurred by the User Institution and/or its Authorised Personnel that may arise (whether directly or indirectly) in any way whatsoever from the User Institution's and/or Authorised Personnel's use of the Data, or from the unavailability of, or break in access to the Data for whatever reason.

10.2 The User Institution understands that all Data are protected by copyright and other intellectual property rights, such that duplication or sale of all of or part of the Data on any media is not permitted under any circumstances, except with the prior written consent of BioMed X.

11. NO ASSIGNMENT

No Party may assign any rights or claims under this Agreement without the prior consent of the other Party in writing.

12. CHOICE OF LAW; JURISDICTION

This Agreement (and any dispute, controversy, proceedings or claim of whatever nature arising out of this Agreement or its formation) shall be construed, interpreted and governed by the laws Germany and shall be subject to the exclusive jurisdiction of the competent courts of and with place of proceedings in Mannheim.

13. MISCELLANEOUS

13.1 Nothing expressed or implied in this Agreement will constitute either Party as the partner, agent, employee or officer of, or as a joint venturer with, the other Party, and neither Party will make any contrary representation to any other person.

13.2 This Agreement and its Appendices comprise the entire agreement between the Parties concerning its subject matter. It shall supersede all prior agreements and conventions, oral and written declarations of intent and other arrangements or side agreements (whether binding or non-binding) made by the Parties in respect thereof.

13.3 All Appendices to this Agreement shall form an integral part of this Agreement. In case of a conflict between any Appendix and the provisions of this Agreement, the provisions of this Agreement shall prevail.

13.4 The headings in this Agreement are inserted for convenience only and shall not affect the interpretation of this Agreement.

13.5 Amendments and additions to this Agreement shall be valid only if made in writing; the electronic form (§ 126a of the German Civil Code ("BGB")) and the text form (§ 126b BGB) are excluded. This also applies to any amendment to this written form clause.

14. SEVERABILITY

Should one or more provisions of this Agreement be or become invalid or unenforceable in whole or in part, this shall not affect the validity and enforceability of the remaining provisions of this Agreement. In place of any Standard Terms of Business (*Allgemeine Geschäftsbedingungen*) which are invalid or not incorporated in the Agreement the statutory provisions shall apply (§ 306 (2) BGB). In all other cases, the Parties shall agree a valid provision to replace the invalid or unenforceable provision which reflects as closely as possible the original economic purpose, provided a supplementary interpretation of the Agreement (*ergänzende Vertragsauslegung*) does not have precedence or is not possible.

This Agreement has been entered into on the date stated at the beginning of this Agreement.

SIGNATURES

BioMed X GmbH	**[User Institution]**
represented by:	represented by:
_____	_____
Name:	Name:
Title:	Title:

Principal Investigator

I confirm that I have read and understood this Agreement.

_____	_____
Name:	
Title:	

Appendix I - Dataset Details

Dataset reference (EGA Study ID and Dataset Details)

Name of project that created the dataset

Name of Provider of Human Samples

Names of other data producers/collaborators

Specific limitations on areas of research

Minimum protection measures required

Data shall be held only in encrypted files on an institutional computer system (including the institutional computer network) of the User Institution. The User Institution and its Authorised Personnel shall particularly store the Data and any copy thereof only in encrypted form using state of the art encryption and all encryption keys shall be securely stored and maintained.

Only Authorized Personnel shall have access to the Data and any copy thereof. Copies of the Data shall be made only to the limited extent necessary for the Project and the Research Purpose.

The institutional computer system of the User Institution and any component thereof providing a user access to the Data shall be hold at a safe place with limited access. The institutional computer system shall have password protected logins and state of the art firewall protection and any user login shall have enabled automatic screenlocks (set to lock after 5 minutes of inactivity).

Laptops holding the Data, or any copy thereof should have password protected logins, state of the art firewall protection and screenlocks (set to lock after 5 minutes of inactivity). If held on USB keys or other portable hard drives or other storages device, the data must be encrypted using state of the art encryption.

Any transfer of the Data and any copy thereof shall be done in encrypted form and via secured connections/networks only.

Appendix II - Project Details

Details of dataset requested i.e., EGA Study and Dataset Accession Number

Brief abstract of the Project in which the Data will be used (500 words max)

All Individuals who the User Institution to be named as Registered Users

Name of Registered User	Email	Job Title	Supervisor

All Individuals that should have an account created at the EGA

Name of Registered User	Email	Job Title

Ethics vote of the competent ethics committee:

[To be attached as **Exhibit I**]

Appendix III - Publication Policy

BioMed X intends to publish the results of their analysis of this dataset and do not consider its deposition into public databases to be the equivalent of such publications. BioMed X anticipates that the dataset could be useful to other qualified researchers for a variety of purposes. However, some areas of work are subject to a publication moratorium.

The publication moratorium covers any publications (including oral communications) that describe the use of the dataset. For research papers, submission for publication should not occur until three (3) months after these data were first made available on the relevant hosting database, unless BioMed X has provided written consent to earlier submission.

In any publications based on these data, please describe how the data can be accessed, including the name of the hosting database (e.g., The European Genome-phenome Archive at the European Bioinformatics Institute) and its accession numbers (e.g., EGAS00000000029), and acknowledge its use in a form agreed by the User Institution with BioMed X.