

## The European Bank for induced pluripotent Stem Cells (EBiSC)

### DATA ACCESS AGREEMENT

This agreement governs the terms on which access will be granted through the EBiSC Data Access Committee (DAC) to Personal Data associated with EBiSC lines. Personal Data may include, for example, genetic data or clinical data. Personal Data associated with EBiSC lines are stored in the human pluripotent stem cell registry (hPSCreg, hosted by Fraunhofer-IBMT, Berlin, Germany) or in the European Genome-phenome Archive (EGA), hosted by the European Bioinformatics Institute (Hinxton, UK) at the UK Outstation of the European Molecular Biology Laboratory.

In signing this agreement, You are agreeing to be bound by the terms and conditions of access set out in this agreement.

For the sake of clarity, the terms of access set out in this agreement apply both to the User and the User Institution (as defined below). User Institution and User are referred to within the agreement as “You”, and “Your” shall be construed accordingly.

#### Definitions:

**Cell Line Information Pack** means the package of cell line specific information for the user, including Third Party Obligations, which accompanies each cell line in the EBiSC2 catalogue.

**EBiSC DAC** means the EBiSC Data Access Committee appointed by EBiSC to manage access to Personal Data associated with EBiSC lines. This may include, for example, genetic sequencing data stored at the EGA and STR and HLA data stored in hPSCreg.

**EBiSC** means the European Bank for induced Pluripotent Stem Cells, referring to established infrastructure, banking operations, cell line collection and distribution. The EBiSC – European Bank for induced pluripotent Stem Cells project has received support from the Innovative Medicines Initiative Joint Undertaking under grant agreements n° 115582 and 821362, resources of which are composed of financial contribution from the European Union and EFPIA companies’ in kind contribution ([www.imi.europa.eu](http://www.imi.europa.eu)).

**EBe** means the EBiSC2 Bank Entity which is Fraunhofer UK Research Limited, a not-for-profit company incorporated in Scotland under Company number: SC419797 and having its registered office at Technology and Innovation Centre, Level 5, 99 George Street, Glasgow, Scotland, G1 1RD

**EGA** means the European Genome-phenome Archive, a permanent archive of controlled access data generated for biomedical research and deposited to enable data sharing. The EGA is described on the website <https://www.ebi.ac.uk/ega/home>.

**Data** means Personal Data that is associated with EBiSC lines and is subject to managed access control through the EBiSC Data Access Committee.

**Data Subject** means an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. The Data Subject has been informed of the purpose for which the Data is held and has given his/her informed consent thereto.

**hPSCreg** means the human pluripotent stem cell registry, an on-line resource of human pluripotent stem cell line data. hPSCreg is described at the website <https://hpscereg.eu>.

**User** means a researcher whose User Institution has previously completed this Data Access Agreement and has received acknowledgement of its acceptance.

**Personal Data** means any information relating to a Data Subject. This includes, but is not limited to, sequencing data (whole genome, exome, transcriptome), HLA data, STR data and clinical data.

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

**Third Party Obligations (TPO)** means the obligations of the original cell line depositor to third parties, in relation to the use of the Material, which are specified in the EMDA. For avoidance of doubt, such obligations may include, but are not limited to, reach-through intellectual property rights including royalty obligations to third parties, existing distribution arrangements with third parties, and specific terms of donor consent. The TPO should be specified in the Cell Line Information Pack.

**User Institution** means the organisation at which the User is employed, affiliated or enrolled.

## Terms and Conditions:

In signing this Agreement:

1. You agree to use the Data only for the advancement of medical research, according to the consent obtained from sample donors and in accordance with any TPO, as described in Appendix 2.
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 link the data provided under this agreement to other information or archive data available for the data sets provided, 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 access committees.
4. You agree not to transfer or disclose the Data, in whole or part, or any identifiable material derived from the Data, to others, except as necessary for data/safety monitoring or programme management. Should You wish to share the Data with a collaborator outwith the same Institution, the third party must make a separate application for access to the Data.
5. You agree to use the Data for the approved purpose and project described in your application; use of the Data for a new purpose or project will require a new application and approval.
6. You accept that Data will be updated from time to time, with suitable versioning. If the reissue is at the request of sample donors and/or other ethical scrutiny, You will destroy earlier versions of the Data.
7. You accept that EBiSC, the EBE, the EBiSC DAC, and the funders of the Data or any part of the Data supplied:
  - a. bear no legal responsibility for the accuracy or comprehensiveness of the Data; and
  - b. accept no liability for indirect, consequential, or incidental, damages or losses arising from use of the Data, or from the unavailability of, or break in access to, the Data for whatever reason.
8. You understand and acknowledge that the Data may be protected by copyright and other intellectual property rights, and that duplication, except as reasonably required to carry out Your research with the Data, or sale of all or part of the Data on any media may not be permitted. Users of the data are solely responsible for establishing the nature of and complying with any such intellectual property restrictions.
9. You recognise that nothing in this agreement shall operate to transfer to the User Institution any intellectual property rights relating to the Data. The User Institution has the right to develop intellectual property based on comparisons with their own data.

10. You accept that this agreement will terminate immediately upon any breach of this agreement by You and You will be required to destroy any Data held.
11. You accept that it may be necessary for the EBE or its appointed agent to alter the terms of this agreement from time to time in order to address new concerns. In this event, EBiSC or its appointed agent will contact You to inform You of any changes and You agree that Your continued use of the Data shall be dependent on the parties entering into a new version of the Agreement.
12. You agree that you will submit a report to the EBiSC DAC, if requested, on completion of the agreed purpose. The EBiSC DAC agrees to treat the report and all information, data, results, and conclusions contained within such report as confidential information belonging to the User Institution.
13. You accept that the Data may be protected by and subject to international laws, including but not limited to applicable laws on the protection of Personal Data, and that You are responsible for ensuring compliance with any such applicable law. You undertake to implement or have implemented adequate technical and organisational security measures to protect Data. The EBiSC DAC reserves the right to request and inspect data security and management documentation to ensure the adequacy of data protection measures, particularly in countries that have no national laws comparable to those which pertain in the EEA.

**For and on behalf of User:**

**Name of Applicant(s):** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Signature of Applicant(s):** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Date:** \_\_\_\_\_

**For and on behalf of User Institution:**

**Signature of Institutional or Administrative Authority:** \_\_\_\_\_

**Print name:** \_\_\_\_\_

**User Institution:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**EBiSC2 Bank Entity**

**[Fraunhofer UK Research Ltd, Technology and Innovation Centre Level 5, 99 George Street, Glasgow, G1 1RD]**

Authorised to sign on behalf of:

Signature .....

Name .....

Title .....

Date .....

Stamp (if applicable)

WHEN SUBMITTING THIS DOCUMENT, PLEASE INCLUDE ALL PAGES OF THE AGREEMENT WITH THIS SIGNATURE PAGE

## APPENDIX 1

### EBiSC Publications Policy

You should inform EBiSC when the Data has been used in a Publication. You should include the EBiSC cell line name, the BioSample ID and the EGA data identifiers in any publication resulting from use of the data. These identifiers should be present in the main text of your Publication.

## APPENDIX 2

### Data Usage According to Consent and TPO

[Attach signed CLIPs, which contain information on data usage for each EBiSC line]