



## READ BEFORE COMPLETION

**NOTICE:** The EBiSC Access & Use Agreement (EAUA) is a **LEGALLY BINDING CONTRACT** between the European Bank for induced pluripotent Stem Cells (EBiSC) and the User.

1. The person who signs this contract represents and warrants to EBiSC that s/he is an **AUTHORISED SIGNATORY OF THE USER**, who has formal authority to undertake legal obligations on behalf of the User. **If you are not certain whether you have such authority, please do not sign.**
  - Examples of people who the User MAY have authorised to sign include: Directors, Head of Legal, Head of Finance, and Technology Transfer Associates.
  - Examples of people who typically do NOT have such authority include: Head of Laboratory, Principal Investigators, post doc researchers, students or technicians.
2. Before signing, the User must be aware of the contents of the relevant Cell Line Information Pack (CLIP), which may set out **limitations on cell use**. These obligations have been imposed on the Depositor by third parties, and under the EAUA are **passed on** to the User.
3. Under the EAUA, EBiSC cells are accessible solely for '**research use**', as broadly defined. For any **other type of use**, including their commercial resale, or use in the conduct of research activities on a fee-for-service basis, the User must make separate arrangements directly with the Depositor.

Signature of the EAUA by an unauthorised person, or failure of the authorised signatory to tick the box below, may result in a significant delay in processing the request of the User for material.

**The signatory of the User should tick this box to indicate that s/he has read this notice.**

# EBiSC ACCESS & USE AGREEMENT

THIS EBiSC ACCESS & USE AGREEMENT (“EAUA”) is made on .....

## BETWEEN:

(1)

.....

of .....

..... (“User”); and

(2) **The UK Health Security Agency (“UKHSA”), an executive agency of the Department of Health, acting through its European Collection of Cell Cultures (“ECACC”) with an address, at Porton Down, Salisbury, Wiltshire SP4 0JG, UK (“EBE”)**

## BACKGROUND:

A The Innovative Medicines Initiative (“IMI”) is a public-private partnership between the pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations, and the European Union, represented by the European Commission.

B The EBiSC consortium was formed to undertake the IMI project called “European Bank for Induced Pluripotent Stem Cells” (IMI Grant Agreement No. 115582) (the “**EBiSC Project**”), pursuant to which the EBiSC Bank has been established for the Banking of induced pluripotent stem cell (“iPSC”) lines for Research Use.

C The Participants in the EBiSC Project entered into an agreement effective 1 January 2014, as amended from time to time (the “**EBiSC Project Agreement**”) to govern their collaboration in the EBiSC Project.

D It is the express intention of the Participants, under the terms of the Project Agreement, that the EBE should, during the EBiSC Project, assign its legal interest in the EBiSC Project, including its rights and obligations under this EAUA, to a successor EBiSC Bank Entity.

E The Depositor owns the Original Material and the Original Data, which have been deposited with the EBiSC Bank in accordance with the terms of an EMDA.

F The EBE may hold Additional Data, which is not Managed Data, in relation to the Original Material or the Banked Material.

G The Depositor has granted to the EBE, under said EMDA, rights to conduct or procure the conduct of Banking through the EBiSC Bank, and to grant Access Rights to users.

H The User, who is not a Participant, wishes to obtain Access Rights.

I This Agreement sets out the terms and conditions upon which the EBE provides Access Rights to the User and any Affiliated Entity.

J This Agreement does not cover access to any Managed Data.

# EBiSC ACCESS & USE AGREEMENT

## IT IS AGREED:

### 1. DEFINITIONS

“**Access Rights**” means the non-exclusive rights granted by the EBE to a User, and any Affiliated Entity, to provide them with access to Banked Material, Original Data and Additional Data for Research Use;

“**Additional Data**” means any data or information associated with the Original Material or Banked Material, which has been generated within the EBiSC Project or reported or disclosed by any party to the EBE or the EBiSC Bank, and which is neither Original Data nor Managed Data;

“**Affiliated Entity**” means any legal entity that is under the direct or indirect control of the User, under the same direct or indirect control as the User, or is directly or indirectly controlling the User, control taking any of the following forms: (a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity; (b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned;

“**Banked Material**” means the iPSC lines descended from Original Material that are identified at Appendix 1 to this EAUA, and Replicates thereof;

“**Banking**” means: (i) developing, acquiring, importing, exporting, proliferating, maintaining, storing and distributing Original Material and Replicates on an international basis; and (ii) providing value-add services using Original Material and Replicates, in each case for a reasonable fee sufficient to cover costs of operations; provided however, that in no event does “Banking” include the use of Original Material and Replicates in human clinical testing or as human therapeutics;

“**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 EBiSC catalogue;

“**Depositor**” means the owner of the Original Material and the Original Data;

“**Derivatives**” means substances, other than Banked Material, which: 1) are derived from Banked Material; 2) are modifications of Banked Material; 3) are products of the use of Banked Material, including cells differentiated from it; or 4) wholly or partially incorporate Banked Material;

“**EBE**” means the EBiSC Bank Entity, which is ECACC, the not-for-profit corporate vehicle that controls the operations of the EBiSC Bank, and shall include its assignee, successor in title, or such other person as may be notified in accordance with clause 7.2;

“**EBiSC Bank**” means the iPSC biorepository created in the framework of the EBiSC Project, comprising a main facility and a secure backup or ‘mirror’ facility, which facilities will be located at Porton Down, Salisbury, UK and Sulzbach, Germany, respectively, or such other locations as may be determined in the future;

“**EBiSC Pricing Policy**” means the EBiSC schedule of prices, as amended from time to time, which reflects the not-for-profit nature of EBiSC operations;

## EBiSC ACCESS & USE AGREEMENT

“**EMDA**” means EBiSC Material Deposit Agreement, which is an agreement between EBE and Depositor substantially in the standard EBiSC MDA template appended to the EBiSC Project Agreement;

“**Intellectual Property**” means patents, trademarks, service marks, registered designs, copyrights, database rights, design rights, confidential information, applications for any of the above, and any similar right recognised from time to time in any jurisdiction, together with all rights of action in relation to the infringement of any of the above;

“**Managed Data**” means data or information, associated with the Original Material or Banked Material, which, for the purposes of donor protection, is held by the EBE, Depositor or other third party in a secure data management system, access to which will be detailed in a specific data access agreement, outside of the terms of this EAUA, with the relevant holder;

“**Original Data**” means the data or information pertaining to the Original Material provided by the Depositor to the EBE upon deposition of the Original Material, and which is not Managed Data;

“**Original Material**” means the samples of iPSC lines transferred by the Depositor to the EBiSC Bank in accordance with an EMDA;

“**Participant**” means a party to the EBiSC Project Agreement, and ‘Participants’ shall be interpreted accordingly;

“**Replicates**” means unmodified iPSC lines descended from Banked Material which retain the ability to replicate and differentiate;

“**Research Use**” means the use by the User, or Affiliated Entity, of Banked Material, Original Data and Additional Data for all research purposes. For clarity, ‘research purposes’;

- a) includes all pre-clinical research and development activities, all activities relating to developing the ability to commercialise any drug substance or drug product (including process development work) and all activities relating to seeking, obtaining and/or maintaining any regulatory approvals from a regulatory authority;
- b) does not extend to the foregoing research and development activities, or any other activity, provided as a service for a fee; and
- c) excludes the use of Banked Material in human clinical testing and as therapeutics.

“**Third Party Obligations**” means the obligations to third parties, in relation to the use of the Banked Material, which are specified in the Cell Line Information Pack. 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;

“**User**” means the natural or legal person who is party, with the EBE, to this EAUA; for avoidance of doubt, the User is not a Participant.

# EBiSC ACCESS & USE AGREEMENT

## 2. ACCESS AND USE

### 2.1 The EBE:

2.1.1 agrees that, upon execution of this Agreement, or as soon as reasonably possible thereafter, it will provide the User with:

- i. samples of Banked Material; and
- ii. access to Original Data and Additional Data;

2.1.2 hereby grants to the User and any Affiliated Entity, subject to Third Party Obligations, a non-exclusive, royalty-free, worldwide licence to use the Banked Material, Original Data and Additional Data for Research Use during the term of this Agreement;

2.1.3 will invoice the User at prevailing EBiSC tariff rates, in accordance with the EBiSC Pricing Policy.

2.2 The User acknowledges prior receipt of a specific Cell Line Information Pack in relation to each iPSC line identified as Banked Material in Appendix 1.

2.3 The User acknowledges prior receipt of the EBiSC Pricing Policy and agrees that it will:

2.3.1 make full payment of invoices, in British pounds sterling (or other currency by arrangement with EBE upon submission of the order) within 30 days of the date of invoice;

2.3.2 prior to any use, obtain all necessary permits to use the Banked Material for Research Use;

2.3.3 make no attempt, at any time, to establish the personal identity of the individual donor of the primary tissue from which the Banked Material was derived;

2.3.4 use the Banked Material, Original Data and Additional Data:

- i. solely for Research Use,
- ii. in compliance with all applicable laws, government regulations and codes, and
- iii. in compliance with any Third Party Obligations;

2.3.5 ensure that any third party, other than an Affiliated Entity, to whom the User subcontracts research involving the Banked Material, or otherwise permits access to the Banked Material, has undertaken in writing to comply with all relevant restrictions and obligations imposed by this EAUA on the User;

2.3.6 include, in any written application for patent or submission for publication, appropriate acknowledgement of the EBiSC Bank, Depositor and any funders identified with the Banked Material.

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2.4 The EBE and the User agree that nothing in this EAUA shall operate to alter any Third Party Obligations.

2.5 For avoidance of doubt, no access to Managed Data is provided by this EAUA.

### 3. PROPERTY

3.1 Subject to Third Party Obligations, the User shall retain ownership of:

3.1.1 Intellectual Property arising out of the Research Use of the Banked Material, Original Data or Additional Data; and

3.1.2 Derivatives.

### 4. LIABILITY

4.1 Each party represents that it has the requisite power and authority to enter into this EAUA and to perform according to its terms, and that the official of each party executing this EAUA has authority to do so.

4.2 Any Banked Material delivered pursuant to this EAUA is understood to be experimental in nature and may have hazardous properties. The EBE makes no express or implied warranty, condition or representation whatsoever regarding the Banked Material, Original Data or Additional Data. In particular, the EBE:

4.2.1 provides no warranty in regard to the sufficiency, adequacy or fitness of the Banked Material, Original Data and Additional Data for any particular purpose, and

4.2.2 does not represent or warrant that the use of the Banked Material, Original Data and Additional Data will not infringe or violate any patent, copyright, trademark or proprietary right of any third party.

4.3 Nothing in this EAUA shall operate to limit or exclude the liability of either party for death or personal injury caused by the gross negligence or wilful misconduct of that party or any other liability which may not lawfully be excluded.

4.4 The User shall indemnify and, subject to clause 4.6, hold harmless the EBE and the Depositor for any damages or loss incurred in the event of failure of the User, any Affiliated Entity, or a subcontractor of any of them, to comply with the requirements imposed on such entity by this EAUA.

4.5 In the event of any noncompliance referred to in clause 4.4, the User will promptly, and in writing, notify the EBE, who will take and continue to take all reasonable steps to mitigate its loss arising from the event.

4.6 Without prejudice to clause 4.3, the liability incurred by the User, as a result of a single event giving rise to a claim pursuant to clause 4.4, shall not exceed €250,000.

4.7 The User acknowledges and agrees that the Depositor, although a non-signatory to this EAUA, shall have the right to recover damages and any other remedies provided by applicable law directly from the User, without intervention of any nature from the EBE. For the avoidance of doubt, the Depositor has given no express or implied warranty, condition or representation regarding the Banked Material, Original Data or

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Additional Data, neither with regard to its sufficiency, adequacy or fitness for any particular purpose, nor to assert that it will not infringe or violate any patent, copyright, trademark or proprietary right of any third party.

- 4.8 The User acknowledges that the role of the EBE, in undertaking Banking through the EBiSC Bank, is solely to facilitate Research Use; without prejudice to clause 4.3, but subject to clauses 4.4, 4.5 and 4.6, neither the EBE, nor the EBiSC Bank, nor the Depositor shall have any liability for loss, costs, claims, damages or expenses arising out of or in connection with the use of any Banked Material, Derivatives, Original Data or Additional Data under this EAUA.

### **5. CONFIDENTIALITY**

- 5.1 Each party agrees not to (i) disclose any confidential information provided to it by the other pursuant to this EAUA or (ii) use the names or marks of the other without express written permission;
- 5.2 The obligations of confidence referred to in this clause 5 shall not extend to:
- 5.2.1 the contact details of the User, which it agrees may be made publicly available by the EBE by means including the website of the EBiSC Bank;
  - 5.2.2 other information which is, or becomes, generally available to the public, other than by reason of a breach by the EBE of any provision of this clause 5;
  - 5.2.3 information that the EBE is required to disclose to Depositors or potential Depositors pursuant to an MDA, including, but not limited to Additional Data, and as may be required in accordance with Third Party Obligations;
  - 5.2.4 information that the EBE is required to disclose to the organisation(s) appointed to conduct the Banking activities of the EBiSC Bank, subject to suitable undertakings of confidentiality given by such organisations;
  - 5.2.5 information which is known to the EBE prior to its receipt from the User and the EBE is free to disclose it;
  - 5.2.6 information that is subsequently disclosed to the EBE without obligations of confidence by a third party owing no such obligations to the disclosing party in respect thereof; or
  - 5.2.7 information that is required to be disclosed in accordance with applicable law or by appropriate regulatory authorities.

### **6. TERM AND TERMINATION**

- 6.1 This EAUA shall come into effect on the date of its execution by both parties and, subject to clause 6.2, shall remain in force for as long as the Banked Material is held and used by the User.
- 6.2 This Agreement may be terminated on thirty (30) days written notice by either party to the other.

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- 6.3 Upon termination or expiry of this Agreement for any reason, and subject to the provisions of the EBiSC Project Agreement if and as they apply to the User and any Affiliated Entity:
- 6.3.1 the Access Rights granted to the User and any Affiliated Entity pursuant to this Agreement will cease to have effect; and
- 6.3.2 the User shall:
- i. discontinue its use of the Banked Material,
  - ii. upon direction of the EBE, return or destroy any remaining Banked Material, and
  - iii. notify each Affiliated Entity and subcontractor to whom it has given access to the Banked Material of the termination or expiry of this Agreement.

The provisions of clauses 2.2, 4, 5 6, 7, 8, 9, 10, 11 and 13 shall survive expiry or termination of this EAUA.

### **7. ASSIGNMENT**

- 7.1 If the User transfers any rights in the Banked Material or the part of its business controlling the same to a third party, the rights of the User under this EAUA will, subject to its obligations hereunder, be deemed to be assigned to the transferee. The User undertakes to ensure that the transferee is notified of the existence of this EAUA and to notify the EBiSC Bank in writing of the transfer.
- 7.2 The EBE may, without the consent of the User, as part of an assignment of its legal interest in the EBiSC Project, assign its rights, subject to its obligations, under this EAUA, to another not-for-profit corporate entity, and shall notify the User promptly following any such assignment. Alternatively, the User undertakes to novate this EAUA to such assignee, upon the reasonable request of the EBE.
- 7.3 This EAUA shall be binding upon and inure to the benefit of the respective successors and permitted assigns of the parties hereto.

### **8. RELATIONSHIP**

The relationship of the parties is that of independent contractors and not agents of each other or joint venturers or partners. Each party shall maintain sole and exclusive control over its personnel and operations.

### **9. AMENDMENT**

Except as expressly provided in this EAUA, no amendment or waiver will be binding unless executed in writing by both parties. If any provision of this EAUA is for any reason found to be unenforceable, the remainder of this EAUA will continue in full force and effect.

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## 10. NOTICES

Any notice given under this EAUA shall be in writing and signed by or on behalf of the party giving it and shall be served by delivering it personally, or sending it by pre-paid recorded delivery or registered post to the relevant party at the following address:

*For the User:* .....

.....

*For the EBE:* Bryan Bolton, ECACC, UKHSA, Porton Down, Salisbury, Wiltshire SP4 0JG, UK

## 11. ENTIRE AGREEMENT

This Agreement, including any and all appendices and referenced documents, constitutes the entire agreement between the parties regarding the use of the Banked Material, Original Data and Additional Data, superseding all other representations, understandings or agreements, whether oral or written.

## 12. COUNTERPARTS

This EAUA may be executed in counterparts, each of which when so executed shall constitute an original copy hereof, but all of which together shall constitute one agreement.

## 13. GOVERNING LAW AND JURISDICTION

13.1 This EAUA and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of Belgium.

13.2 All disputes or differences arising in connection with this EAUA which cannot initially be settled amicably shall be finally settled by arbitration in Brussels under the rules of arbitration of the International Chamber of Commerce, by three arbitrators to be appointed under the terms of those rules. The chairman shall be of juridical education and the arbitration proceedings shall be conducted in English. The award of the arbitration will be final and binding upon the parties concerned.

13.3 The parties concerned may, rather than arbitrate under clause 13.2, instead elect to resolve by mediation a dispute or difference arising in connection with this EAUA which cannot be settled amicably. Such election shall be by unanimous written consent of the parties involved in the dispute. Notwithstanding the foregoing, any party may seek immediate injunctive or other interim relief from any court of competent jurisdiction with respect to any matter for which monetary damages would not adequately protect such party's interests or otherwise to enforce and protect intellectual property rights owned or licensed to such parties.

# EBiSC ACCESS & USE AGREEMENT

**AS WITNESS the parties have caused this EAUA to be duly signed by the undersigned authorised representatives as follows:**

**User**

Authorised to sign on behalf of:

Signature: .....

Name: .....

Title: .....

Date: .....

Stamp (if applicable)

**EBiSC Bank Entity**

Authorised to sign on behalf of: **ECACC**

Signature: .....

Name: .....

Title: .....

Date: .....

Stamp (if applicable)

# EBiSC ACCESS & USE AGREEMENT

## APPENDIX 1: BANKED MATERIAL

Cell Line Name ..... Cell Line Name .....

Cell Line Name ..... Cell Line Name .....