

## MATERIALS ACCESS AGREEMENT FOR HUMAN EMBRYONIC EUTCD STEM CELL LINES

This Agreement is made on the ..... day of ....., 20..

### BETWEEN

- (1) The **Secretary of State for Health**, acting through the National Institute for Biological Standards and Control as part of the Medicines and Healthcare Products Regulatory Agency with a place of business at UKSCB, NIBSC, Blanche Lane, South Mimms, Potters Bar, Hertfordshire, EN6 3QG, UK (hereinafter called NIBSC);

and

- (2) [*Requestor*] whose principal place of business is situated at [*address*] (hereinafter called "the Requestor"), and whose Principal Investigator is [*name*].

In respect of the following material;

EUTCD-grade [*Name/Number of Cell Line designated by the Depositor*]

### WHEREAS

- (A) NIBSC is responsible for managing the UK Stem Cell Bank (the "Bank") which receives funding from the Medical Research Council and the Biotechnology and Biological Sciences Research Council;
- (B) The Depositor has developed the stem cell lines and has deposited vials in the Bank (the Material);
- (C) The Principal Investigator wishes to obtain vials of the Banked Material to use in the Project and has obtained the necessary permission from the Steering Committee to undertake the Project;
- (D) The Requestor has entered into appropriate agreements with the Depositor to allow the Principal Investigator access to vials of the Banked Material.

This Agreement sets out the terms and conditions under which NIBSC will supply vials of the Banked Material to the Requestor.

### IT IS HEREBY AGREED AS FOLLOWS

#### 1. DEFINITIONS AND INTERPRETATION

- 1.1 In this Agreement the following words and phrases shall have the following meaning unless the context requires otherwise:

- (a) "Application" means the application to the Steering Committee by the Principal Investigator requesting access to vials of the Banked Material for use in the Project.
- (b) "Approval" means the written evidence of Steering Committee approval of the Application which allows the Requestor to access vials of the Banked Material from the Bank, a copy of which is attached to this Agreement at Schedule 1.
- (c) "Banked Material" means cell banks of the EUTCD-grade stem cell lines defined in this Agreement, including any cell line or progeny that NIBSC has established from the Material, vials of which are provided to the Requestor for use in the Project.
- (d) "Code of Practice" shall mean the code of practice for the Use of Human Stem Cell Lines which is published by the Steering Committee and which may be amended from time to time.
- (e) "Competent Authorities" means the Human Tissue Authority (HTA) and the Human Fertilisation and Embryology Authority (HFEA) which expressions shall include their successors in title.
- (f) "Confidential Information" means any information, data and documents that are not in the public domain. For the avoidance of doubt anything marked as "Confidential" is Confidential Information.
- (g) "Depositor" means the party owning the Material.
- (h) "Derivatives" means any materials or products other than Banked Material that are derived from, are produced by the use of or that wholly or partially incorporate the Banked Material.
- (i) "Effective Date" means the date when this Agreement has been signed by all Parties.
- (j) "EUTCD" means the European Tissue and Cell Directives (Directives 2004/23/EC, 2006/17/EC, 2006/86/EC, 2012/39/EU, EU/2015/565 and EU/2015/566).
- (k) "Expiry Date" means five years after the Effective Date.
- (l) "Material" means vials of the EUTCD-grade human embryonic stem cell lines defined in this Agreement, that were provided to NIBSC for deposit in the Bank under a Deposit and Distribution Agreement for human embryonic EUTCD stem cell lines.
- (m) "Licence" means the licence agreement executed between the Requestor and the Depositor for access to and use of the Banked Material, a copy of which is attached to this Agreement as Schedule 1.
- (n) "Principal Investigator" means the individual named in the Application who has received approval from the Steering Committee to undertake the Project.
- (o) "Project" means the programme of work to be undertaken by the Principal Investigator and specified in the Approval.

- (p) "Requestor" means a party to this Agreement requesting access to vials of the Banked Material from the Bank and who has been granted the Approval.
  - (q) "Serious Adverse Event" means any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of tissue or cells intended for human application and which, in relation to a donor of tissue or cells intended for human application or a recipient of tissue or cells, (i) might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions, or (ii) might result in, or prolong, hospitalisation or morbidity. It is a requirement of the HTA, under the Quality and Safety for Human Application Regulations 2007, that a serious adverse event is reported to them within 24 hours of the event being discovered.
  - (r) "Serious Adverse Reaction" means an unintended response, including a communicable disease, in a donor of tissue or cells intended for human application or a recipient of tissue or cells, which may be associated with the procurement or human application of tissue or cells and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity. It is a requirement of the HTA, under the Quality and Safety for Human Application Regulations 2007, that any serious adverse reaction is reported to them within 24 hours of the reaction being discovered.
  - (s) "Steering Committee" means the Steering Committee for the UK Stem Cell Bank and the Use of Human Stem Cell Lines, established to supervise the use of human stem cell lines.
  - (t) "Support Documents" means any documents provided by NIBSC to the Requestor as detailed in Schedule 2 of this Agreement.
- 1.2. Clause, schedule and paragraph headings shall not affect the interpretation of this Agreement.
- 1.3. The schedules form part of this Agreement and shall have effect as if set out in full in the body of this Agreement and any reference to this Agreement includes the schedules.
- 1.4. Words in the singular shall include the plural and vice versa.
- 1.5. A reference to one gender shall include a reference to the other genders.
- 1.6. A reference to a statute, statutory provision or any subordinate legislation made under a statute is to such statute, provision or subordinate legislation as amended or re-enacted from time to time whether before or after the date of this Agreement and, in the case of a statute, includes any subordinate legislation made under that statute whether before or after the date of this Agreement.
- 1.7. A reference to writing or written includes faxes but not e-mail.
- 1.8. A reference to an agreement is a reference to that agreement as varied or novated (in each case, other than in breach of the provisions of this Agreement) at any time.
- 1.9. References to clauses and schedules are to the clauses and schedules of this Agreement; references to Paragraphs are to paragraphs of the relevant Schedule.

- 1.10. Any phrase introduced by the terms including, include, in particular or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding or following those terms.

## **2. ACCESS TO AND USE OF BANKED MATERIAL**

- 2.1 Following the receipt of (i) the Approval and (ii) a signed copy of the Licence, and upon the Effective Date, NIBSC will supply Requestor with vials of the Banked Material and/or the Support Documents.
- 2.2 Requestor shall receive and use the Banked Material in compliance with i) the terms of this Agreement, ii) all applicable laws, governmental regulations, codes and guidelines, including all relevant health and safety and environmental legislation and iii) applicable requirements of Competent Authorities.
- 2.3 The Requestor and the Principal Investigator shall use the Banked Material supplied under this Agreement, solely for the Project specified in the Approval. For the avoidance of doubt, the Requestor and the Principal Investigator undertake not to use the Banked Material for reproductive cloning.
- 2.4 Where the Banked Material is intended to be used in the development of materials that may be used in a clinical trial or work leading to a therapy, the Requestor must put in place procedures to ensure the traceability of cells or tissues containing the Banked Material or Derivatives and to notify NIBSC and the HTA of (i) any Serious Adverse Event that may influence the quality or safety of tissues or cells and (ii) any Serious Adverse Reaction observed during and after clinical application which may be linked to the quality or safety of tissues or cells. Notification to the HTA is required to be within 24 hours of the incident being discovered.
- 2.5 NIBSC will charge a fee for the supply of the Banked Material and the Support Documents. This charge shall be separate from any consideration that the Depositor may seek under the terms of the Licence and/or that the Requestor has agreed with other parties.
- 2.6 The Requestor undertakes not to use the Banked Material or the Confidential Information, whether alone or in conjunction with any other information, in any effort to establish the identity of the donor of the EUTCD-grade human embryonic stem cell lines defined in this Agreement from which the Banked Material was established.
- 2.7 The Requestor undertakes not to, save for the purpose of quality assurance testing only, transfer the Banked Material to any parties other than the parties to this Agreement, unless written approval is first given by the Steering Committee.
- 2.8 The Requestor acknowledges that no right or licence is granted under this Agreement to sell or make any commercial or clinical use of i) the Banked Material and/or any Derivatives and/or ii) the Support Pack. The Requestor is solely responsible for obtaining rights or licences from the Depositor or any third party as required for the use contemplated by it.
- 2.9 The Requestor agrees that from the Effective Date i) the Requestor's contact details, and ii) description of Banked Material provided under this Agreement may be made publicly available by NIBSC, such as in, but not limited to, the Bank's website.

### 3. CONFIDENTIALITY AND PUBLICATION

- 3.1 Each party agrees not to disclose any Confidential Information provided to it by any other party pursuant to this Agreement.
- 3.2 The obligations of confidence referred to in this Clause 3 shall not extend to any information which:
- (i) is or becomes generally available to the public otherwise than by reason of a breach by the recipient party of any provision of this Clause 3; or
  - (ii) is known to the recipient party and is at its free disposal prior to its receipt from the other; or
  - (iii) is subsequently disclosed to the recipient party without obligations of confidence by a third party owing no such obligations to the disclosing party in respect thereof; or
  - (iv) is required to be disclosed in accordance with applicable law or by appropriate regulatory authorities, including but not limited to the Competent Authorities.
- 3.3 The Requestor shall acknowledge NIBSC and the Bank as the source of the Banked Material and the Depositor as the originator of the Material in any publication or public disclosure of the Project and notify the Bank and the Depositor when such a publication or public disclosure is to be made.
- 3.4 The Requestor agrees to provide the Bank with copies of any publication reporting the Project within ninety (90) days of publication
- 3.5 Each party agrees not to use or refer to this Agreement in any promotional activity, or use the names or marks of the other without the express written permission of the other.

### 4. WARRANTIES/LIABILITIES

- 4.1 Nothing in this Agreement shall operate to limit or exclude the liability of either party for death or personal injury caused by the negligence of that party or any other liability which may not lawfully be excluded.
- 4.2 NIBSC warrants that the Banked Material has been processed, tested and stored in compliance with the EUTCD since its receipt of the Material at NIBSC.
- 4.3 The Requestor warrants that (i) all information provided in the Application is accurate and complete, (ii) any declarations and/or information provided to the Steering Committee and/or NIBSC are accurate and complete.
- 4.4 The Banked Material is supplied to the Requestor for the experimental purposes described in the Approval. NIBSC makes no representation and gives no warranty or undertaking whatsoever, either express or implied, in relation to the Banked Material, including but not limited to, merchantability or fitness for a particular purpose or that the use or supply of the Banked Material will not infringe any patent, copyright, trademark or other right of any third party, except as expressly provided for in this Agreement. The Requestor is responsible for assessing suitability of the Banked Material for his intended purpose. For the avoidance of doubt, NIBSC does

not warrant that the Banked Material is free of extraneous agents or biologically active contaminants and the Requestor should treat Banked Material as potentially infectious or hazardous. The Requestor undertakes not to use the Banked Material in its current form in humans.

- 4.5 NIBSC shall, subject to clause 4.1, have no liability for any loss, costs, claims, damages or expenses arising out of or in connexion with this Agreement and/or the Requestor's use of the Banked Material or Derivatives. NIBSC shall under no circumstances be liable to the Requestor whether in contract, tort (including negligence), breach of statutory duty, or otherwise, for any loss of profit, or any indirect or consequential loss or damage sustained by the Requestor in Requestor's use of the Banked Material or Derivatives.
- 4.6 The Requestor shall indemnify and hold harmless NIBSC, its directors, officers, employees and affiliates against any claims, proceedings, demands and liabilities including, without limitation, any claim etc. arising from or connected with the use, handling or storage of the Banked Material or Derivatives or of any products or information resulting from their use, as well as any claim that the use of such materials, products or information infringes the rights of third parties.
- 4.7 NIBSC shall not be liable for any acts or omissions of the Requestor or its affiliates, assignees or collaborators who shall take all reasonable steps to decide or settle any dispute in respect of such acts or omissions among themselves and without involving NIBSC.

## **5. TERM AND TERMINATION**

- 5.1 This Agreement shall commence on the Effective Date and shall (subject to its earlier termination) continue in force until the Expiry Date. Thereafter, the parties may, at their sole discretion, extend this Agreement by mutual agreement in writing.
- 5.2 The provisions of Clauses 1, 2, 3, 4, 5, 6 and 14 shall survive the expiry or termination of this Agreement.
- 5.3 This Agreement may be terminated by either party by giving notice in writing to that effect to the other if the other party is in breach of its obligations under this Agreement and fails to remedy such breach within ninety (90) days of receiving notice from the notifying party that identifies and gives details of the breach.
- 5.4 NIBSC may terminate this Agreement without liability to the Requestor by giving written notice to the Requestor if:
- (i) the Steering Committee withdraws its Approval for the Banked Material's use; or
  - (ii) the Requestor commits a material breach of any term of this Agreement and, where such breach is capable of remedy, it fails to remedy such breach within a period of ninety (90) days of receipt of notice to do so; or
  - (iii) the Requestor ceases to do business, becomes unable to pay its debts as they fall due, becomes or is deemed insolvent, has a receiver, liquidator, manager, administrator, administrative receiver or similar officer appointed in respect of the whole or any part of its assets or business (or is the subject of a filing with any court for the appointment of any such officer), makes any



composition or arrangement with its creditors, takes or suffers any similar action in consequence of debt or an order or resolution is made for its dissolution or liquidation (other than for the purpose of solvent amalgamation or reconstruction), or any equivalent or similar action or proceeding is taken or suffered in any jurisdiction and the same is not dismissed or discharged within ninety (90) days thereafter.

- 5.5 The termination of this Agreement shall be without prejudice to the rights and remedies of either party which may have accrued up to the date of termination.

## **6. CONSEQUENCES OF TERMINATION OR EXPIRY**

- 6.1 Upon termination or expiry of this Agreement for any reason whatsoever:

- (i) any rights or licences granted under or pursuant to this Agreement will cease to have effect;
- (ii) the provisions of any provision which expressly or by implication is intended to come into or remain in force on or after termination shall continue in full force and effect.
- (iii) the Requestor shall immediately return to NIBSC all Support Documents and remaining Banked Material, including all copies of such Support Documents and Banked Material or, if NIBSC so requests, the Banked Material shall be destroyed at the Requestor's expense and authenticated certificates of their destruction shall be provided to NIBSC.
- (iv) the Requestor shall cease using the Derivatives until i) a further agreement is reached with the Depositor and ii) NIBSC is informed that such an agreement is in place.

## **7. ASSIGNMENT**

- 7.1 The Recipient shall not novate, assign or transfer any interest in this Agreement, in whole or in part, without the prior written consent of NIBSC.
- 7.2 In case of the transfer of all or a relevant part of the activities of NIBSC or the Bank to other organisations, NIBSC shall be entitled to transfer its rights and obligations hereunder to such other organisations.

## **8. NOTICES**

- 8.1 Any notice given under this Agreement 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 its registered office for the time being.

## **9. VALIDITY**

- 9.1 If any provision of this Agreement is or becomes for any reason whatsoever invalid, illegal or unenforceable, it shall be divisible from this Agreement and shall be deemed to be deleted from it and the validity of the remaining provisions shall not be affected in any way.

## **10. VARIATION**

- 10.1 No variation of or amendment to this Agreement shall bind any party unless made in writing and signed by all parties.

## **11. WAIVERS**

- 11.1 Failure of either party to enforce or exercise, at any time or for any period, any term of this Agreement does not constitute, and shall not be construed as, a waiver of such term and shall not affect the right to enforce such term, or any other term contained in this Agreement, at a later date.
- 11.2 No delay or failure of any party in exercising or enforcing any of its rights or remedies whatsoever shall operate as a waiver of those rights or remedies or so as to preclude or impair the exercise or enforcement of those rights or remedies. No single or partial exercise or enforcement of any right or remedy by any party shall preclude or impair any other exercise or enforcement of that right or remedy by that party.

## **12. COUNTERPARTS**

- 12.1 This Agreement may be executed in any number of counterparts, each of which when executed shall constitute a duplicate original, but all the counterparts shall together constitute the one Agreement.
- 12.2 No counterpart shall be effective until each party has executed at least one counterpart.

## **13. ENTIRE AGREEMENT**

- 13.1 This Agreement and any documents referred to in it constitutes the sole Agreement between NIBSC and the Requestor and supersedes any previous arrangement, understanding or agreement between the parties relating to the subject matter hereof.
- 13.2 Any breach of any clauses, paragraphs and/or schedules by the Requestor constitutes a material breach of this Agreement.

## **14. GOVERNING LAW AND JURISDICTION**

- 14.1 This Agreement 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 law of England and Wales.



- 14.2 The parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this agreement or its subject matter or formation (including non-contractual disputes or claims).

For Information Only

This Agreement has been duly signed by authorised representatives of the parties:

Signed on behalf of  
**Secretary of State for Health**

Signature:

Name:

Title:

Signed by the Requestor

Signature:

Name:

Title:

Signed and acknowledged by  
the Principal Investigator

Signature:

Name:

Title:

**SCHEDULE 1**

- (i) Copy of the Approval
- (ii) Signed copy of the Licence

For Information Only

**SCHEDULE 2**

**EUTCD-grade cell line Support Documents**

Attach documents as appropriate:

1. EUTCD-grade cell line and limited information
2. EUTCD-grade cell line and full information
3. EUTCD-grade cell line and enhanced information

For Information Only