H3Africa Biorepository

Biological Material Transfer Agreement

(For Materials Distributed from an H3Africa Biorepository to a Recipient Investigator)

The purpose of this agreement is to provide a record of the biological material transfer and to memorialize the agreement between the DISTRIBUTOR, PROVIDER, RECIPIENT INSTITUTION and the RECIPIENT SCIENTIST (all of which are identified below) to abide by all terms and conditions of the attached H3Africa Consortium Biological Material Transfer Agreement ("H3Africa BMTA"). The RECIPIENT SCIENTIST and an authorized official of RECIPIENT INSTITUTION should sign one copy of this agreement and return a copy to the DISTRIBUTOR. Upon receipt of a fully signed agreement, the DISTRIBUTOR will forward the ORIGINAL MATERIAL to the RECIPIENT SCIENTIST.

1. **ORIGINAL MATERIAL** (data requested may be attached as an Excel document)

   List of sample identifiers _____
   Sample type (DNA, cell line, serum, etc) _____
   Sample origin (human, animal species) _____
   Sample diagnosis (apparently healthy, diabetes, Parkinson Disease, etc) _____
   SPREC Code (if known) _____

2. **PROVIDER** (Scientist depositing the MATERIAL in the Biorepository; to be completed by the Distributing Biorepository)

   Name_____
   Title_____
   Name of Institution_____
   Institution Address _____
   Country_____Postal Code_____
   Name of Legal Representative of Institution_____
   Title of Legal Representative of Institution_____

3. **DISTRIBUTOR** (to be completed by the Distributing Biorepository before sending H3A BMTA to the potential recipient)

   Name of Biorepository_____
   Address Line 1_____
   Address Line 2_____
   Country _____Postal Code_____
   Contact Name_____
   Contact Telephone_____Contact Email_____

4. **RECIPIENT INSTITUTION** (An institutional official authorized to make legal commitments on behalf of the institution should sign this Agreement.)
   Name of Organization_____
   Address Street_____
   City/State_____
   Country/Post Code_____
   Official's Name_____
   Official's Title_____
   Phone Number_____
   Fax Number_____
   Email Address_____

   ►*Signature/Date*_____

5. **RECIPIENT SCIENTIST**
   Name_____
   Title_____
   Organization_____
   Address Street_____
   City/State_____
   Country/Post Code_____
   Phone Number_____
   Fax Number_____
   Email Address_____

   ►*Signature/Date*_____

6. Termination date for this agreement (optional):_____.

7. Fee to reimburse DISTRIBUTOR for preparation and distribution costs: $_____.
(The fee will depend on the Biorepository, sample type, shipping conditions and courier)

Include paragraph on transport conditions, chain of custody and expected time of arrival of sample?

8. THE PARTIES EXECUTING THIS AGREEMENT AGREE TO BE BOUND BY THE TERMS OF THE H3Africa BMTA, THE TEXT OF WHICH FOLLOWS AND IS MADE PART OF THIS AGREEMENT, FOR THE TRANSFER SPECIFIED HEREIN.

9. RECIPIENT INSTITUTION ACKNOWLEDGES THAT NEITHER THE DISTRIBUTOR NOR THE PROVIDER ARE RESPONSIBLE FOR ANY LOSS OF OR DAMAGE TO THE ORIGINAL MATERIAL AS THE RESULT OF AN ACT OF GOD OR ANY EVENT THAT IS OUTSIDE THE CONTROL OF THE DISTRIBUTOR OR THE PROVIDER.

10. THIS AGREEMENT IS EFFECTIVE WHEN SIGNED BY THE RECIPIENT INSTITUTION AND THE RECIPIENT SCIENTIST.

H3Africa Biological Material Transfer Agreement

I. Definitions.

1. PROVIDER: Organization which provided the DISTRIBUTOR with the ORIGINAL MATERIAL as specified above.

2. DISTRIBUTOR: Organization authorized by the PROVIDER to distribute the ORIGINAL MATERIAL on its behalf as specified above.

3. RECIPIENT INSTITUTION: Organization receiving the ORIGINAL MATERIAL from the DISTRIBUTOR as specified above.

4. RECIPIENT SCIENTIST: The party using the ORIGINAL MATERIAL as specified above.

5. ORIGINAL MATERIAL: The description of the material(s) being transferred as specified above.

6. MATERIAL: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not include: (a) MODIFICATIONS, or (b) other substances created by the RECIPIENT SCIENTIST through the use of the MATERIAL which are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES.

7. PROGENY: Unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism.

8. UNMODIFIED DERIVATIVES: Substances created by the RECIPIENT SCIENTIST which constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by the DISTRIBUTOR, or monoclonal antibodies secreted by a hybridoma cell line.

9. MODIFICATIONS: Substances created by the RECIPIENT SCIENTIST which contain/incorporate the MATERIAL.

10. COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organization, including RECIPIENTINSTITUTION OR SCIENTIST, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.

11. NONPROFIT ORGANIZATION(S): A university or other institution of higher education or an organization that does not pay dividends to shareholders and whose purpose is to provide for education or scientific research or any nonprofit scientific or educational organization qualified under a government nonprofit organization statute. Such an organization would be exempt from taxation under the local and national laws of the recipient organizations home country.. As used herein, the term also includes government agencies.

II. Terms and Conditions of this Agreement.

1. The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.

2. The RECIPIENT Institution retains ownership of: (a) MODIFICATIONS (except that, the PROVIDER retains ownership rights to the MATERIAL included therein), and (b) those substances created through the use of the MATERIAL or MODIFICATIONS, but which are not PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES). If either 2 (a)or 2 (b) results from the collaborative efforts of the PROVIDER and the RECIPIENT INSTITUTION, joint ownership may be negotiated.

3. The RECIPIENT INSTITUTION and the RECIPIENT SCIENTIST agree that the MATERIAL:

(a) is to be used solely for teaching and academic research purposes; unless written consent is obtained from the PROVIDER.

(b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the PROVIDER;

(c) is to be used only at the RECIPIENT INSTITUTION'S physical facility and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision; and

(d) will not be transferred to anyone else within the RECIPIENT organization without the prior written consent of the PROVIDER and DISTRIBUTOR.

4. The RECIPIENT INSTITUTION and the RECIPIENT SCIENTIST agree to refer to the DISTRIBUTOR any request for the ORIGINAL MATERIAL from anyone other than those persons working under the RECIPIENT SCIENTIST's direct supervision. To the extent supplies are available the DISTRIBUTOR agrees to make the ORIGINAL MATERIAL available, under a separate H3Africa BMTA, to other scientists (at least those at NONPROFIT ORGANIZATION(S)) who wish to replicate the RECIPIENT SCIENTIST's research; provided that such other scientists reimburse the DISTRIBUTOR for any costs relating to the preparation and distribution of the ORIGINAL MATERIAL.

5. (a) The RECIPIENT INSTITUTION and/or the RECIPIENT SCIENTIST shall have the right, without restriction, to distribute substances created by the RECIPIENT SCIENTIST through the use of the ORIGINAL MATERIAL only if those substances are not the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS.

(b) Under a separate implementing letter to this agreement (or an agreement at least as protective of the PROVIDER's rights), the RECIPIENT INSTITUTION and SCIENTIST may distribute MODIFICATIONS to NONPROFIT ORGANIZATION(S) for research and teaching purposes only.

- Without prior written consent from the PROVIDER, the RECIPIENT INSTITUTION and/or the RECIPIENT SCIENTIST may NOT provide MODIFICATIONS for COMMERCIAL PURPOSES. It is recognized by the RECIPIENT INSTITUTION and SCIENTIST that such COMMERCIAL PURPOSES may require a commercial license from the PROVIDER and the PROVIDER has no obligation to grant a commercial license to its ownership interest in the MATERIAL incorporated in the

MODIFICATIONS. Nothing in this paragraph, however, shall prevent the RECIPIENT INSTITUTION from granting commercial licenses under the RECIPIENT INSTITUTION'S intellectual property rights claiming such MODIFICATIONS, or methods of their manufacture or their use.

6. The RECIPIENT INSTITUTION acknowledges that the MATERIAL is or may be the subject of a patent application. Except as provided in this agreement, no express or implied licenses or other rights are provided to the RECIPIENT INSTITUTION under any patents, patent applications, trade secrets or other proprietary rights of the PROVIDER, including any altered forms of the MATERIAL made by the PROVIDER. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS or any related patents of the PROVIDER for COMMERCIAL PURPOSES.

7. If the RECIPIENT INSTITUTION and SCIENTISTS desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial license. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such a license to the RECIPIENT INSTITUTION/SCIENTIST, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any third party(ies), subject to any pre-existing rights held by others and obligations to the local and national government of the PROVIDER'S home country.

8. The RECIPIENT INSTITUTION is free to file patent application(s) claiming inventions made by the RECIPIENT SCIENTIST through the use of the MATERIAL but agrees to notify the PROVIDER upon filing a patent application claiming MODIFICATIONS or method(s) of manufacture or use(s) of the MATERIAL.

9. Any MATERIAL delivered pursuant to this agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER AND THE DISTRIBUTOR MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

10. Except to the extent prohibited by law, the RECIPIENT INSTITUTION assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL and MODIFICATIONS. The PROVIDER and the DISTRIBUTOR will not be liable to the RECIPIENT INSTITUTION or SCIENTIST for any loss, claim or demand made by the RECIPIENT INSTITUTION/SCIENTIST, or made against the RECIPIENT INSTITUTION/SCIENTIST by any other party, due to or arising from the use of the MATERIAL or MODIFICATIONS by the RECIPIENT SCIENTIST, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the PROVIDER or the DISTRIBUTOR.

11. The H3Africa Biorepository, acting under authorization of the H3Africa Consortium, reserves the right to audit any RECIPIENT SCIENTIST/INSTITUTION to ensure compliance with the terms of this Agreement.

12. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the ORIGINAL MATERIAL in all publications.

13. The RECIPIENT INSTITUTION agrees to use the MATERIAL in compliance with all applicable

statutes and regulations of local and national governments and the H3Africa Consortium; such as, for example, those relating to research involving the use of animals, recombinant DNA, release of personally identifiable genomic information, or stem or induced pluripotent cell research.

14. The RECIPIENT SCIENTIST AND INSTITUTION agree that they will not attempt to individually identify or contact any H3Africa participant who donates materials to be distributed by the H3Africa Biorepositories.

15. In the event of disputes regarding injury due to the RECIPIENT'S use of the MATERIAL, misuse of the MATERIAL by the RECIPIENT, issues relating to Intellectual Property rights, or other disagreements, the dispute shall me mediated or adjudicated…….

16. This agreement will terminate on the earliest of the following dates: (a) when the ORIGINAL MATERIAL becomes generally available from third parties without the requirement of a material transfer agreement, or (b) on completion of the RECIPIENT SCIENTIST's current research with the MATERIAL, or (c) on thirty (30) days prior written notice by either party to the other, or (d) on the date specified above, provided that:

(i) if termination should occur under 13(a), the RECIPIENT INSTITUTION shall be bound to the PROVIDER by the least restrictive terms applicable to the MATERIAL obtained from the then-available resources; and

(ii) if termination should occur under 13(b) or (d) above, the RECIPIENT INSTITUTION/SCIENTIST will discontinue its use of the MATERIAL and will destroy any remaining MATERIAL. The RECIPIENT SCIENTIST, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS; and

(iii) in the event the PROVIDER terminates this agreement under 13(c) other than for breach of this agreement or for cause such as an imminent health risk or patent infringement, the PROVIDER will defer the effective date of termination for a period of up to one (1) year, upon request from the RECIPIENT INSTITUTION, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT SCIENTIST will discontinue its use of the MATERIAL and will destroy any remaining MATERIAL. The RECIPIENTSCIENTIST, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS.

17. Paragraphs 1, 6, 9, 10 and 14 shall survive termination.

18. The ORIGINAL MATERIAL is provided with a transmittal fee solely to reimburse the DISTRIBUTOR for its preparation and distribution costs as specified above.