

H3Africa Biorepository

Biospecimen Deposit Material Transfer Agreement (BDMTA)

Study Name _____

The purpose of this agreement is to provide a record of the transfer of original biological materials (biospecimens) from H3AFRICA (H3A) PRINCIPAL INVESTIGATORS (PROVIDERS) to the HOST H3A BIOREPOSITORY, and to memorialize the agreement between the PROVIDER INSTITUTION and the H3A HOST BIOREPOSITORY to abide in future transfers by all terms and conditions of this Agreement. The BDMTA also covers transfer of minimum essential data associated with the biospecimens, as described in the H3AFRICA Biospecimen Deposit Guidelines.

The PROVIDER, HOST H3A BIOREPOSITORY PRINCIPAL INVESTIGATORS, and the officials authorized to make legal commitments on behalf of both institutions (SIGNING OFFICIALS) should sign the BDMTA and maintain original and/or electronic copies, according to local requirements. Upon receipt of the fully signed agreement, the H3A PROVIDER will forward the biospecimens to the HOST H3A BIOREPOSITORY.

1. DESCRIPTION OF BIOSPECIMENS AND ASSOCIATED DATA

Type (DNA, cell line, serum, etc.) _____

Origin (human, animal species) _____

Shipment Manifest Form: (please tick box to acknowledge inclusion in BDMTA)

Please insert below or attach a complete list of other associated data covered by this BDMTA:

File Name	Description of Variables
_____	_____
_____	_____
_____	_____

Termination Date of Agreement (OPTIONAL) _____

II. TERMS AND CONDITIONS

- A. The biospecimens are being transferred to the HOST H3A BIOREPOSITORY for purposes of future release to qualified researchers who will be pre-approved by the H3AFRICA CONSORTIUM DATA AND BIOSPECIMEN ACCESS COMMITTEE (DBAC) to use them for research purposes, in accordance with DBAC Guidelines (www.h3africa.org).
- B. The H3A PROVIDER and PROVIDER's INSTITUTION retain ownership rights as may exist in relation to such MATERIAL, including any MATERIAL contained or incorporated in progeny or unmodified derivatives (fractions or aliquots). If the PROVIDER changes institutions, the PROVIDER and PROVIDER INSTITUTION will notify the HOST H3A BIOREPOSITORY within 30 days so a determination can be made whether an MTA must be signed by the new institution.
- C. The H3A PROVIDER AND H3A HOST BIOREPOSITORY acknowledge that deposited biospecimens were collected under conditions of ethical review and informed consent (see APPENDIX A). The H3A DBAC has reviewed the ethical review and informed consent documents so that the biospecimens can be released in a manner that honors the intentions of the biospecimen donors. The Informed Consent may restrict the kinds of research that can be conducted, and the H3A DBAC will inform approved recipients of the applicable ethical considerations prior to release of biospecimens as stated in the H3A Data and Biospecimen Access Committee Guidelines.
- D. Any MATERIAL delivered pursuant to this agreement is understood to be experimental in nature and may have hazardous properties. The H3A PROVIDER AND H3A HOST BIOREPOSITORY 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.
- E. The H3A HOST BIOREPOSITORY will not be liable for any loss, claim or demand made by the H3A PROVIDER or other party, due to or arising from the use of the MATERIAL, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the H3A HOST BIOREPOSITORY.
- F. The H3A HOST BIOREPOSITORY agrees that they will not attempt to individually identify or contact any H3Africa participant who donates materials deposited in the H3A HOST BIOREPOSITORY.
- G. In the event of disputes regarding injury due to the use or misuse of the MATERIAL by the H3A HOST BIOREPOSITORY, issues relating to Intellectual Property rights, or other disagreements, the dispute shall be mediated or adjudicated by approximately 7 persons in an ad hoc committee composed of a balanced representation of local and national ethics review boards and the H3AFRICA CONSORTIUM STEERING COMMITTEE, with the H3A PROVIDER and H3A HOST BIOREPOSITORY each naming 2 of the ad hoc committee members.

- H. This Agreement will terminate only upon closeout of the H3A HOST BIOREPOSITORY, as the terms of this agreement shall stand as long as there are samples stored at the H3A HOST BIOREPOSITORY that have been provided by the H3A PROVIDER provided that:
- (i) if termination should occur under H above, the H3A HOST BIOREPOSITORY will discontinue its storage of the MATERIAL and will give the H3A PROVIDER the option of return at the H3A PROVIDER'S EXPENSE or destroy any remaining MATERIAL;
 - (ii) in the event the H3A PROVIDER terminates this agreement for any reason other than for breach of this agreement or for cause such as an imminent health risk or patent infringement, the H3A PROVIDER will defer the effective date of termination for a period of up to one (1) year, upon request from the HOST BIOREPOSITORY, to permit completion of processing in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, HOST BIOREPOSITORY will discontinue its storage of the MATERIAL and will destroy any remaining MATERIAL or give H3A PROVIDER the option of return at the H3A PROVIDER'S EXPENSE.
- I. Courier fees for the shipment of DNA from the H3A PROVIDER to the H3A HOST BIOREPOSITORY at intervals agreed upon by both parties shall be charged to the H3A HOST BIOREPOSITORY. Fees and charges for shipment of biospecimens other than DNA are the responsibility of the H3A PROVIDER.
- J. The H3A PROVIDER will make every reasonable effort to ensure the delivery of biospecimens to the H3A HOST BIOREPOSITORY in the optimal condition using methods defined in the H3AFRICA Biospecimen Deposit Guidelines (www.h3africa.org).

The H3A PROVIDER will provide:

- (i) IATA certified transport conditions optimised for the type of biospecimen;
 - (ii) Certified chain of custody from the H3A PROVIDER to the H3A HOST BIOREPOSITORY; Notification to the H3A HOST BIOREPOSITORY of the shipment date, courier, tracking number(s), and expected delivery date;
- K. The H3A PROVIDER and the H3A HOST BIOREPOSITORY will ensure compliance with national legal requirements for shipping of biological samples (export/import permits).
- L. The H3A PROVIDER acknowledges that the H3A HOST BIOREPOSITORY is not 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 H3A HOST BIOREPOSITORY.
- M. The terms of the BDMTA extend, where applicable, to the transfer of associated data in the Shipping Manifest Form and other biospecimen-related data files.

III. SIGNATURES

The parties executing this agreement agree to be bound by the terms of the H3AFRICA BDMTA. This agreement is effective when signed by the H3A PROVIDER and the H3A HOST BIOREPOSITORY.

1. PROVIDER (H3Africa Principal Investigator depositing the MATERIAL in the Biorepository)

Name _____

Title _____

Name of
Institution _____

Institution Address

Country _____ Postal Code _____

Telephone _____ FaxNumber _____

Email Address _____

► Signature _____ Date _____

2. PROVIDER INSTITUTION SIGNING OFFICIAL

Name _____

Title _____

Name of
Institution _____

Institution Address

Country _____ Postal Code _____

Telephone _____ FaxNumber _____

Email Address _____

► Signature _____ Date _____

3. HOST BIOREPOSITORY RECIPIENT (H3Africa Principal Investigator of HOST BIOREPOSITORY)

Name _____

Title _____

Name of
Institution _____

Institution Address

Country _____ Postal Code _____

Telephone _____ FaxNumber _____

Email Address _____

► Signature _____ Date _____

4. HOST BIOREPOSITORY SIGNING OFFICIAL

Name _____

Title _____

Name of
Institution _____

Institution Address

Country _____ Postal Code _____

Telephone _____ FaxNumber _____

Email Address _____

► Signature _____ Date _____

DEFINITIONS

1. **HOST BIOREPOSITORY:** H3Africa Biorepository authorized by the H3Africa Consortium to store and distribute the ORIGINAL MATERIAL on its behalf.
2. **MATERIAL: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES.** The MATERIAL shall not include: (a) MODIFICATIONS, or (b) other substances created by a recipient through the use of the MATERIAL which are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES.
3. **MODIFICATIONS:** Substances created which contain/incorporate the MATERIAL.
4. **ORIGINAL MATERIAL:** The description of the material(s) being transferred as specified above.
5. **PROGENY:** Unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism, DNA from DNA.
6. **PROVIDER:** H3Africa Principal Investigator from the PROVIDER INSTITUTION who provided the H3A HOST BIOREPOSITORY with the ORIGINAL MATERIAL as specified above.
7. **UNMODIFIED DERIVATIVES:** Substances (fractions or aliquots) created by the H3A HOST BIOREPOSITORY 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, or monoclonal antibodies secreted by a hybridoma cell line, aliquots of DNA, or amplified DNA.

APPENDIX A

Ethics Approval Certificates

Participant Information and Consent Template

Letters Confirming Informed Consent to use and share Biospecimens