

H3Africa Biorepository

Biological Deposit Material Transfer Agreement (BDMTA)

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 Submission Policy and Procedures [insert link to website].

The PROVIDER, HOST H3A BIOREPOSITORY PRINCIPAL INVESTIGATORS, and the official authorized to make legal commitments on behalf of both institutions (SIGNING OFFICIAL) 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) _____

Diagnosis (controls, disease phenotypes, etc.) _____

Please insert below or attach a complete list of the essential data variables associated with the biospecimens (Sample ID, etc.)

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 to use them for research purposes, in accordance with the H3AFRICA Biospecimen Policy and Procedures [insert link to website].
- 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).
- C. The H3A PROVIDER AND H3A HOST BIOREPOSITORY acknowledge that deposited biospecimens were collected under conditions of ethical review and informed consent. The H3A HOST BIOREPOSITORY 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 HOST BIOREPOSITORY will inform approved recipients of the applicable ethical considerations prior to release of biospecimens.
- 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 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 an approximately 7 persons 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 on the earliest of the following dates: (a) on completion of deposit of the available specimens in the H3A HOST BIOREPOSITORY or (b) closeout of the H3A HOST BIOREPOSITORY or (c) on the date specified above (page 1), provided that:
 - (i) if termination should occur under H(a), the H3A HOST BIOREPOSITORY shall

be bound to the H3A PROVIDER by the least restrictive terms applicable to the MATERIAL obtained from the then-available resources; and

(ii) if termination should occur under H(b) or (d) above, the H3A HOST BIOREPOSITORY will discontinue its storage of the MATERIAL and will give H3A PROVIDER the option of return at the H3A PROVIDER'S EXPENSE or destroy any remaining MATERIAL; and

(iii) in the event the H3A PROVIDER terminates this agreement under H(c) 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.

(iv) Paragraph II.E above shall survive termination.

- 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 (insert website) covering the following:
- K.
 - Responsibilities of the involved parties
 - Compliance with legal and ethical requirements
 - Preparing shipments
 - Sample identification and coding including SPREC coding
 - Labeling procedures
 - Courier arrangements
 - Shipping standards
 - Shipment conditions: preparation and packaging
 - Documentation
 - Forms to be completed
 - Data transfer
 - Quality Control at Sample Submission Site
 - DNA QC requirements

- Communication with the H3A Host Biorepository
- Post-shipment activities
- Tracking of the shipment
- Receipt, QC storage at BR
- Trouble-shooting
- H3 A Biorepository Contacts

to provide:

- (i) IATA certified transport conditions optimized for the type of biospecimen;
 - (ii) Certified chain of custody from the H3A PROVIDER to the H3A HOST BIOREPOSITORY;
 - (iii) notification to the H3A HOST BIOREPOSITORY of the shipment date, courier, tracking number(s), and expected delivery date;
 - (iv) Compliance with the H3A PROVIDER and H3A HOST BIOREPOSITORY country legal requirements for shipping of biological samples (import/export 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.

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. PROVIDER: H3Africa Researcher who provided the HOST BIOREPOSITORY with the ORIGINAL MATERIAL as specified above.
2. PROVIDER INSTITUTION: Organization that provided the ORIGINAL MATERIAL from the H3Africa Researcher as specified above.
3. HOST BIOREPOSITORY : Organization receiving the ORIGINAL MATERIAL from the PROVIDER. This is the Organization authorized by the H3 AFRICA PROGRAM to store and distribute the ORIGINAL MATERIAL on its behalf as specified above.
4. ORIGINAL MATERIAL: The description of the material(s) being transferred as specified above.
5. 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.
6. PROGENY: Unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism.
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, proteins expressed by DNA/RNA supplied by the DISTRIBUTOR, or monoclonal antibodies secreted by a hybridoma cell line.
8. MODIFICATIONS: Substances created which contain/incorporate the MATERIAL.