# H3Africa Biorepository

**Biospecimen Release Material Transfer Agreement (BRMTA)**

The purpose of this agreement is to provide a record of the transfer of original biological materials (biospecimens) from the H3AFRICA (H3A) HOST BIOREPOSITORY identified as a signatory to this Agreement to the RECIPIENT SCIENTIST and his or her INSTITUTION (whether academic, regional, national, or private), and to memorialize the agreement between the RECIPIENT SCIENTIST’S INSTITUTION and the H3A HOST BIOREPOSITORY to abide in future transfers by all terms and conditions of this Agreement. This BRMTA also covers transfer of minimum data associated with the biospecimens, as described in the H3AFRICA Biospecimen Deposit Guidelines ([*http://h3africa.org/consortium/documents*](http://h3africa.org/consortium/documents)). All biospecimens in the H3Africa Biorepository were deposited with appropriate ethical review and any scientific investigations using these biospecimens can only be undertaken with further ethical review as appropriate.

The RECIPIENT SCIENTIST, the official authorized to make legal commitments on behalf of the RECIPIENT SCIENTIST’S INSTITUTION (legal representative/SIGNING OFFICIAL), additional ethical review board if required by any party to this AGREEMENT, and the Principle Investigators of the H3A HOST BIOREPOSITORY(IES) must sign the BRMTA and maintain original and/or electronic copies, according to local requirements. Upon receipt of the fully signed agreement, the HOST H3A BIOREPOSITORY (IES) will begin consultations to distribute the biospecimens to the RECIPIENT SCIENTIST.

Attachment Checklist (copies are acceptable)

□**H3Africa Consortium Data and Biospecimen Access Committee-Approved Biospecimen Access Request**

□H3Africa Data and Biospecimen Access Request Form (with plans for specimen disposal)

□Ethical review approval by an Institutional Review Board or a governmental ethical review board

□Recipient Scientist’s Protocol as approved after ethical review

□Copy of the Consent Form originally used to collect the biospecimens (supplied by Host Biorepositories/DBAC)

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**I. TYPES OF BIOSPECIMENS AND ASSOCIATED DATA**

List the types of Biospecimens requested (DNA, serum, plasma, cell lines, etc.): \_\_\_\_\_\_\_\_\_

List the types of Data Requested: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**II. TERMS AND CONDITIONS**

1. The biospecimens are being transferred to the RECIPIENT SCIENTIST for purposes of biomedical research by qualified investigators who have been pre-approved by the H3AFRICA CONSORTIUM DATA AND BIOSPECIMEN ACCESS COMMITTEE (DBAC: http://h3africa.org/consortium/documents) and by the RECIPIENT SCIENTIST’S institutional and/or ethical review board and the RECIPIENT SCIENTIST’S INSTITUTIONAL LEGAL REPRESENTATIVE.
2. The DBAC will evaluate whether the request conforms to H3Africa policies and procedures including consistency of the proposed research use with data or biospecimen use limitations stipulated by the submitting H3Africa Investigators and his/her institution for each study.”
3. Researchers who have been granted access to H3Africa biospecimens are defined as scientists or medical professionals employed at (or legitimately affiliated with) a registered legal entity such as an academic, non-profit or government institution, or a commercial company.
4. During the first three years of a biospecimen collection’s availability, the DBAC will only grant access to applicants outside the H3Africa Consortium who seek to use the samples in collaboration with African researchers and who aim and are willing to build African research capacity and capabilities.”
5. The H3A PROVIDER (H3Africa Principal Investigator depositing the MATERIAL in the Biorepository) and the 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).
6. To maintain custodial continuity of the biospecimens, the RECIPENT SCIENTIST must notify the biorepository within 30 days if he or she changes institutions. Such a move would invalidate this AGREEMENT and the DBAC approval for distribution of the biospecimens as the RECIPIENT SCIENTIST’S INSTITUTIONAL LEGAL REPRESENTATIVE would no longer be valid. The RECIPIENT SCIENTIST and his/her new INSTITUTION are free to negotiate a new MTA with the DBAC and the HOST BIOREPOSITORY (IES ) With the permission of the original RECIPIENT INSTITUTION the biospecimens can be transferred to the new Recipient Institution once the new MTA is in place. If the original Recipient Institution declines to transfer the biospecimens to the Scientists new institution, the original Recipient Institution must dispose of any residual biospecimens and notify the Host Biorepository(IES) of this action. See Clause L.
7. The H3A PROVIDER and H3A HOST BIOREPOSITORY acknowledge that deposited biospecimens were collected under conditions of ethical review and informed consent. The H3A DBAC has reviewed the ethical review and informed consent documents under which the biospecimens were deposited in the HOST BIOREPOSITORY and also the proposed research and ethical review documents of the RECIPIENT SCIENTIST 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.
8. 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 fitness for a particular purpose, or that the use of the material will not infringe any patent, copyright, trademark, or other proprietary rights.
9. The H3A HOST BIOREPOSITORY will not be liable for any loss, claim or demand made by the RECIPIENT SCIENTIST or his or her INSTITUTE 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.
10. Aggregate results from research involving H3Africa Biospecimens will be disseminated through acceptable academic publications. Return of individual research findings is not possible as the biospecimens were de-identified before submission to the biorepositories.
11. H3Africa biospecimens have the potential to generate data that could be used to identify an individual (whole-genome microarray genotyping data, DNA sequencing data, etc.)The RECIPIENT SCIENTIST and his or her INSTITUTION agree that no attempt to individually identify or contact any H3Africa participant who has donated materials deposited in the H3A HOST BIOREPOSITORY will be made. RECIPIENT SCIENTISTS are further prohibited from making such data that might identify an individual available through open-access websites or genetic databases. Instead such data is to be returned via European Genome-Phenome Archive (see H3Africa Consortium Data Sharing, Access and Release Policy at http://h3africa.org/consortium/documents
12. H3Africa biospecimens can be distributed to commercial institutions under the following conditions:
    1. “Commercialization” of the MATERIAL, including any MATERIAL contained or incorporated in progeny or unmodified derivatives (for example, fractions or aliquots, WGA products), is expressly prohibited. The samples are transferred solely for the purposes of research
    2. to create assays that are customized for testing biospecimen from persons of African descent which will have express benefits for the health of persons of African descent
    3. The commercial entity will have received formal ethical approval from an institutional or regional ethical review board.
    4. The proposed research will be performed as collaboration with an African research institution (academic, medical, governmental or other).
    5. The proposed research will enhance African research capacity.
13. Sharing of the biospecimens with another researcher or collaborator (for validation of results or application of another technology, etc.) is permitted only if described in the Biospecimen Access Request Form and approved by the DBAC. New arrangements to include “sharing” of biospecimens require an appeal to the DBAC.
14. In the event of disputes regarding injury due to the use or misuse of the MATERIAL by the RECIPIENT SCIENTIST or his or her INSTITUTE, issues relating to Intellectual Property rights, or other disagreements, the RECIPIENT SCIENTIST or INSTITUTION may contact the H3Africa DBAC Chair to discuss the issues. The H3Africa DBAC Chair may approach the H3Africa Steering Committee for their advice in problematic cases.
15. This AGREEMENT will remain in effect until the proposed research is concluded or other circumstances invalidate this AGREEMENT (see Clause C). Any residual material must be destroyed or otherwise disposed of as approved in the BAR by the DBAC. A letter certifying completion of the research and disposal of any remaining material according to local safety regulations must be returned to the BIOREPOSITORY. The BIOREPOSITORY cannot accept the return of any residual materials.
16. Special or extraordinary handling and processing fees assessed for the fulfillment of the Biospecimen Access Request are the responsibility of the RECIPIENT SCIENTIST. Courier fees for the shipment of biospecimens from the H3A HOST BIOREPOSITORY shall be paid by the RECIPIENT SCIENTIST.
17. The H3A HOST BIOREPOSITORY will make every reasonable effort to ensure the delivery of biospecimens to the RECIPIENT SCIENTIST in the optimal condition using methods recommended as best practices by the Biorepository Industry and in compliance with IATA regulations. Every effort will be made to provide: (i) IATA certified transport conditions optimized for the type of biospecimen; (ii) certified chain of custody from the H3A HOST BIOREPOSITORY to the RECIPIENT SCIENTIST; (iii) notification to the RECIPIENT SCIENTIST of the shipment date, courier, tracking number(s), and expected delivery date; and (iv) compliance with the H3A HOST BIOREPOSITORY and RECIPIENT SCIENTIST’S country legal requirements for shipping of biological samples (import/export permits). The biospecimens will be labeled with both a barcode and human-readable identification code and will be accompanied by a shipping manifest (available electronically) containing the biospecimen identification code and minimal QC data.
18. The RECIPIENT SCIENTIST and his or her INSTITUTION acknowledge 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.
19. The terms of the BRMTA extend, where applicable, to the transfer of associated data in the Shipping Manifest Form.
20. The recipient scientist agrees to acknowledge the H3Africa Consortium in any publications arising from the acquired biospecimens.
21. **DEFINITIONS**

* HOST BIOREPOSITORY: H3Africa Biorepository authorized by the H3 AFRICA CONSORTIUM to store and distribute the ORIGINAL MATERIAL on its behalf.
* PROVIDER: H3Africa Researcher who provided the HOST BIOREPOSITORY with the ORIGINAL MATERIAL as specified above.
* PROVIDER INSTITUTION: Organization that provided the ORIGINAL MATERIAL from the H3Africa Researcher as specified above.
* RECIPIENT SCIENTIST: the person receiving the H3A biospciemen(s) who is responsible for the conduct of the research approved by the H3A DBAC. The RECIPIENT SCIENTIST must sign the BRMTA agreeing to adhere to the terms and conditions of this MTA. The RECIPIENT SCIENTIST must also ensure that his or her research team has been informed of and agreed to the provisions of this MTA.
* RECIPIENT SCIENTIST’S INSTITUTIONAL LEGAL REPRESENTATIVE: an official having authority to make legal commitments on behalf of the RECIPIENT SCIENTIST’S INSTITUTION must sign this MTA accepting responsibility for the conduct of the research according to the terms and conditions of this MTA and the principles of the H3 Africa Consortium.
* The H3Africa (H3A) Data and Biospecimen Access Committee (DBAC) is a committee that will review requests from researchers for access to data and/or biospecimens collected and generated by the H3Africa consortium. The DBAC will consist of 9 voting members with appropriate scientific, bioethics and data expertise, as well as 4 ex officio members. The DBAC will evaluate whether: (1) A request conforms to the H3A policies and procedures, (2) The proposed use of the data and or biospecimens are in line with the conditions that the data and or biospecimens were originally collected as per the informed consent. DBAC will have the authority to either approve or reject the request
* BAR: Biospecimen Access Request
* ORIGINAL MATERIAL: The description of the material(s) being transferred as specified above.
* 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.
* MODIFICATIONS: Substances created which contain/incorporate the MATERIAL.
* DNA from DNA: for example, DNA prepared by whole genome amplification
* 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.

**IV. SIGNATURES**

The parties executing this agreement agree to be bound by the terms of the H3AFRICA BRMTA. This agreement is effective when signed by the H3A HOST BIOREPOSITORY and the RECIPIENT SCIENTIST and his or her INSTITUTION. Additional signatories can be added, if required.

* + - 1. **RECIPIENT SCIENTIST**

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**2. RECIPIENT SCIENTIST’S INSTITUTION** **SIGNING OFFICIAL**

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**3. HOST BIOREPOSITORY**

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**4. HOST BIOREPOSITORY SIGNING OFFICIAL**

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