



Material Transfer Agreement (for the Supply of Human Tissue Material to LSHTM)

This Agreement is made by and between:

a) *please insert name and address here* (“the Provider Institution”)

and

b) **The London School of Hygiene & Tropical Medicine** whose administrative offices are located at Keppel Street, London WC1E 7HT, United Kingdom, an exempt charity within the meaning of Schedule 3 of the Charities Act 2011, operating through the branch office the **MRC Unit The Gambia at LSHTM**, Atlantic Boulevard, Fajara, PO Box 273 Banjul, The Gambia (“the Provider Institution”)

together known as “the Parties” or individually as the “Party” as appropriate.

BACKGROUND

Provider Institution and Recipient Institution are collaborating in a project “*insert project title here*” (“the Project/Study”) for which they entered into an agreement dated *insert date here* (“the Collaboration/Site Agreement”) and Provider Institution now wishes to transfer certain materials as described herein to the Recipient Institution to perform certain analyses as described in Appendix 1 as part of the Study.

This Agreement records the terms under which the Provider Institution will make available to the Recipient Institution the Material identified in Appendix 2 (the “Material”).

The term “Material” means material, other than human gametes or embryos, which consists of, or includes human cells including but not limited to that which is considered “Relevant Material” for the purposes of the Human Tissue Act 2004¹ together with related data.

The Recipient Institution will hold the Material on the terms of this Agreement and solely for the purpose of the project as described in Appendix 1, within the research group of *insert PI name here* (“the Recipient Scientist”).

The Recipient Institution hereby agrees to comply and procure that the Recipient Scientist and all personnel who work with the Material comply with the following terms and conditions as set out in Schedule 1.

The Schedule and Appendices form part of this Agreement and shall have full force and effect as if set out in full in the body of this Agreement.

Schedule 1	Standard Terms and Conditions
Appendix 1	The Study
Appendix 2	Description of Materials/Quantity of Materials/Description of Packaging
Appendix 3	Material Disposal Plan
Appendix 4	Related collaboration or prime agreements if applicable

¹ The Human Tissue Act 2004 applies to the “authorised activities” principally the removal, storage and use of “Relevant Materials” (as defined under the Act, including human cells, tissue and organs, but not cell lines) which come from a living or deceased person for “Scheduled Purposes” (these are set out in Schedule 1 of the Act, including, but not limited to, “research in connection with disorders, or the function of the human body”, “education or training relating to human health”, and “transplantation”).

In consideration of the mutual benefits to the Parties and the rights and obligations set out in this Agreement the Parties agree to cooperate to transfer the Materials under the terms of this Agreement as set out below.

Accepted and Agreed on behalf of the
Please add the Provider organisation name.

Name:

Position:

Signature

Date:

Accepted and Agreed on behalf of
**London school of Hygiene & Tropical
Medicine**

Name:

Position:

Signature:

Date:

Acknowledged by the Head of Governance and Research Support

Name: ***Farba Faye***

Position: **Head of Governance and Research Support**

Signature:

Date:

SCHEDULE 1

Standard Terms and Conditions

1. The Recipient Institution will not use the Material for administration to human subjects or human application as that term is defined in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (or the equivalent national legislation applicable in the country sending the Material) as may be replaced or amended from time to time, or for clinical or diagnostic purposes.¹
2. The Recipient Institution may use the Material solely for the purposes of the Study and as described in Appendix 1, from the date of receipt of the Material. The Recipient Institution will comply fully with all applicable environmental, health and safety laws, the Human Tissue Act 2004 and other Applicable Laws² with respect to its use (including, but not limited to, storage, transport, disposal or return).
3. The [Recipient/Provider] Institution shall use a courier with suitable skill and experience to safely transport the Material in accordance with all Applicable Laws. The [Recipient/Provider] Institution will bear the cost of carriage and any necessary insurance. The Provider Institution makes no charge for the Material. Risk in and responsibility for the Material shall pass to the Recipient Institution as set out below:
 - (a) Where transport and insurance are paid for by the Provider Institution, upon unloading at the Recipient Institution's designated time and place of delivery as specified and agreed in writing by the Parties; or
 - (b) Where the transport and insurance are paid for by the Recipient Institution, upon loading onto that transport.

If so requested by the Provider Institution the Recipient Institution shall provide it with written confirmation of the safe receipt of the Materials promptly after their delivery to the Recipient Institution's laboratory.

4. The Recipient Institution understands that the Material may have hazardous properties, contain infectious agents or pose other health and safety risks. Subject to clause 9, the Provider Institution makes no representations and gives no warranties either express or implied in relation to it: for example (without limitation), no warranties are given about quality or fitness for a particular purpose, or freedom from infection. The Provider Institution will not be liable for any use made of the Material by the Recipient Institution. The Recipient Institution will use the Material in accordance with good laboratory practice standards, all due skill and care and with dignity, sensitivity and respect. The Recipient Institution will comply with all Applicable Laws, approvals, rules, codes of practice and regulations governing the transportation, storage, use and disposal of the Material. The Recipient Institution warrants that it will only use or permit the use of the Material in work that has ethical approval where such approval is required under Applicable Laws and regulations, as stated in Appendix 1.

¹ The Human Tissue (Quality and Safety for Human Application) Regulations 2007 apply to the procurement, testing, processing, storage, distribution, and import or export of tissues and cells (including cell lines). "Cells" mean human cells (whether individually or in an unbound collection) including cell lines, but not including gametes, embryos outside the body, blood or blood components. "Tissue" for the Regulations, means all constituent parts of the human body formed by cells, but not including gametes and embryos outside the body (which are regulated by the Human Fertilisation and Embryology Authority pursuant to the Human Fertilisation and Embryology Act 1990), or organs.

² Applicable Laws means all laws, rules, regulations, codes of practice, research governance or ethical guidelines, or other requirements of any Regulatory Authority, that may apply to the use of the Material by the Recipient Institution from time to time, including (but not limited) the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006, the Human Tissue (Quality and Safety for Human Application) Regulations 2007, the Human Fertilisation and Embryology Act 1990 (as amended), the EU Tissues and Cells Directive (2004/23/EC) and Commission Directives 2006/17/EC and 2006/86/EC. The Human Tissue Authority Directions and Codes of Practice, and the Medicines for Human Use (Clinical Trials) Regulations 2004, as updated and amended from time to time and, where relevant, the national implementations of the same.

5. Except to the extent prohibited by Law and subject to clause 9, the Recipient Institution assumes all liability for damages which may arise from its receipt, use, storage or disposal of the Material. The Provider Institution will not be liable to the Recipient Institution for any loss, claim or demand made by the Recipient Institution, or made against the Recipient Institution by any other party, due to or arising from its use, storage or disposal of the Material by the Recipient Institution, except to the extent the law otherwise requires.
6. The liability of either party for any breach of this Agreement or arising in any other way out of the subject matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses.
7. The Recipient Institution agrees to obtain the written consent of the Provider Institution if there is any material change to the proposed use of the Material in the Study as described in Appendix 1.
8. **OPTION 1:** Where appropriate, the Parties will aim to co-author any publications arising from this Agreement. For publications arising from use of the Material not authored by the Provider Institution, the Recipient Scientist will acknowledge the Provider Institution as the source of the Material and will provide the Provider Institution with a copy of any publications describing work carried out using the Material. Subject to clause 11, if the Recipient Scientist wishes to include in a publication any information which has been provided by the Provider Institution with the Material and which was clearly identified verbally or marked as “confidential” and “proprietary” at the point of disclosure (“Confidential Information”) or ought reasonably to be considered confidential or proprietary, the Recipient Scientist must obtain written permission from the Provider Institution, providing a copy of the text to allow at least 30 days for review before publication takes place, such permission not to be unreasonably withheld or delayed. The Provider Scientist will provide any comments on the text for publication within 30 days of receipt of the text.

OR

OPTION 2: “Rights and obligations relating to publications, intellectual property, and confidentiality, will be as specified in the Collaboration/Site Agreement. The Recipient Scientist will acknowledge the Provider Institution as the source of the Material in any publication reporting on its use and to provide the Provider Institution with a copy of any publications describing work carried out using the Material.”

OR

OPTION 3: The Recipient Scientist will acknowledge the Provider Institution as the source of the Material in any publication reporting on its use and will provide the Provider Institution with a copy of any publications describing work carried out using the Material. The Provider shall be free to publish the results of the Study provided they acknowledge the Provider Institution as the source of the Material.

If so requested by the Provider Institution, the Recipient Institution shall provide the Provider Institution with a copy of the findings of the Study which may be subject to confidentiality obligations required by the Recipient Institution.

9. The Provider Institution undertakes that where required by Applicable Laws the Material has been obtained from humans with the appropriate consent as required by the Human Tissue Act 2004 and with ethical approval. The Provider Institution retains ownership/custodianship rights in the Materials and hereby grants to the Recipient Institution a non-exclusive research licence to use the Material for the Study only.
10. The Recipient Institution shall keep all information relating to the Material confidential and shall not use it for any purpose other than as provided in this Agreement. This shall not apply to information to the extent it is in the public domain, was or becomes known without any obligation of confidence from a source other than the Provider Institution, was independently developed by the Recipient Institution or is required to be disclosed by law.

11. The Provider Institution agrees that the Material will be anonymised and coded and will not contain any Personal Data as defined by the UK GDPR, i.e. 'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person". or information (and does not intend to provide any information) which has led or may lead to the Recipient Institution being able to identify the person from whom the relevant material came.
12. The Recipient Institution undertakes to store the Material in accordance with all Applicable Laws and not to attempt to identify or contact the donor of the Material or to compromise or otherwise infringe the confidential information of the donors or their right to privacy.
13. Nothing included in this Agreement shall prevent the Provider Institution from being able to distribute the Material to other entities
14. If, as per the details included in Appendix 1, the Material is to be transferred by the Recipient Institution to another institution for the purposes of the Study, the responsibility for compliance with the terms of this Agreement rests with the Recipient Institution.
15. This Agreement will terminate on:
 - (a) completion of the use of the Material in the Study; or
 - (b) forthwith at any time by means of written notice to Recipient Institution if:
 - i) the ethical approval is withdrawn; or
 - ii) the Recipient Institution is in breach of this Agreement.

In the case of any termination, the Recipient Institution shall immediately discontinue all use of the Material and, at the Provider Institution's discretion, promptly return or destroy (at the Recipient Institution's own cost) all unused Material and provide written confirmation that this has been completed. If requested, the Recipient Institution must certify that it has complied in full with any such requirement of the Provider Institution. Should an individual donor or their next of kin rescind their consent, the Provider Institution will require, and the Recipient Institution agrees to discontinue using the appropriately identified sample and return or destroy it in accordance with the Provider Institution's instructions. In the event of any termination the following clauses shall survive termination of this Agreement: 4, 6, 7, 11, 12, 13 and 23.

16. This Agreement shall not be amended except in writing by duly authorised signatories of the Parties.
17. The Parties agree that this Agreement and any subsequent amendments to it shall be binding on their successors in title, and assigns, and undertake to take all necessary steps to ensure that they are so bound.
18. A person who is not a Party to this Agreement shall not have any rights under or in connection with it.
19. **Notices**

All communications and notices from one Party to another shall be in writing to the address or email below.

All notices shall become effective when deposited with reputable overnight courier, or when delivered personally, or, if promptly confirmed by email as provided above when dispatched by email.

The Provider Institutions representative for receiving notices shall until further notice be:

Name:

Title:

Address:

email address:

With a copy to:

Insert details:

Name:

Email address: [please insert]

The Recipients representative for receiving notices shall until further notice be:

Name: **Jamie Whitaker**

Title: **Head of Research Contracts**

Address: The London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT, United Kingdom.

email address: jamie.whitaker@lshtm.ac.uk

With a copy to:

Please include the PI's details.

Name:

Email address: [please insert]

20. This Agreement constitutes the entire agreement between the Parties in relation to its subject matter and no statements or representations made by any Party have been relied upon by the other in entering into this Agreement.
21. The rights and obligations of the Parties are personal and may not be assigned at any time without the prior written consent of the other Party which consent shall not be unreasonably withheld; provided that it shall be a requirement in all cases of assignation that the assignee undertakes to perform all outstanding obligations of the assignor as though the assignee had been an original party.
22. Neither party shall use the names or trademarks of the other party or of any of the other party's affiliated entities in any advertising, publicity, endorsement, or promotion unless the other party has provided prior written consent for the particular use contemplated.
23. This Agreement shall be governed by English Law, and the English Courts shall have exclusive jurisdiction to deal with any dispute which may arise out of or in connection with this Agreement.
24. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. A signed copy of this Agreement delivered by e-mailed portable document format file or other means of electronic

transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

Appendix 1 – The Study

Please provide a brief description of the Study and include the title and the ethics permission number with your description.

Appendix 2 – Materials

Description of Materials	Quantity of Materials	Description of Packaging

Appendix 3 – Material Disposal Plan

Please provide a brief description on how the Materials will be disposed of following the completion of the study or work.

For example, explain what will happen to the samples after the work specified in this MTA?

- 1) Return them to the Provider Institution; or*
- 2) Destroy*

If returned, then to which budget should this be charged?

If they are to be destroyed then who will bear the cost of this, if any?

Appendix 4 – Related Agreements

(Please add any related agreements, if applicable, or delete this page if not.)