Study 4 MTA.

PHE-MOHS EBOLA BIOBANK MATERIAL TRANSFER AGREEMENT

This Agreement is dated 18th April 2018 and is made between

(1) **Public Health England, an Executive Agency of the Department of Health** [redacted]

(2)
Each a "Party" and jointly "Parties"

BACKGROUND

(A) In response to the formal request made to the MOHS-PHE Ebola Biobank Governance Group (EBGG) dated 2nd June 2016, PHE has agreed to supply 80 x 200ul of total DNA extracted from clinical samples (the "Materials") to the Recipient. In this Agreement, the "Materials" shall include, any and all materials, documents, data and information that PHE may provide to the Recipient under or in connection with this Agreement, and any constructs, strains, derivatives, portions, progeny, improvement and research findings obtained from or as a result of the use of the Materials, including, but not limited to, any information as described in Schedule 1 and the "Agreement" shall mean this material transfer agreement and any accompanying schedules.

(B) The Materials are the property of The Ministry of Health and Sanitation of Sierra Leone ("MOHS"). The Materials have been entrusted by MOHS to PHE on condition that they are made available to the research community via the EBGG.

(C) In accordance with the EBGG access guidelines, researchers wishing to access the Materials are required to agree to certain terms and conditions of use as set out in this Agreement.

AGREED TERMS:

1. The Recipient acknowledges that PHE is entering into this Agreement on behalf of the members of the EBGG (including PHE) and MOHS.

2. The Recipient shall keep the Materials secure at the Recipient's laboratory and these shall not be removed from the Recipient's address. The Recipient shall ensure that no-one other than the Recipient and authorised co-workers have access to them. The Recipient undertakes to ensure that the Materials are appropriately safeguarded to prevent theft or unauthorised access.

3. The Recipient shall use the Materials in accordance with good laboratory practice and the highest standards of skill and care and shall ensure compliance with all applicable laws, regulations and administrative guidelines governing the transportation, storage, use or disposal of the Materials. For the avoidance of doubt, the Materials are strictly not for use in humans. In the case where animal studies are to be conducted, the Recipient shall ensure that it considers all in vitro approaches to the research and such studies shall be in compliance with all applicable laws, regulations and administrative guidelines for use of animals in research.

4. The Recipient shall not supply the Materials to any other party. The Recipient shall use the Materials only for the 'Pathogen Identification in Children Attending Ebola Holding Units testing Negative for Ebola Virus Disease in Freetown, Sierra Leone' Research Study and not for any commercial purpose or commercially-sponsored research even if those purposes are being pursued in the Recipient's laboratory without the prior written consent of PHE.

5. Within sixty (60) days from completion of the Research Programme the Recipient shall, in confidence, provide PHE in writing with the results of all evaluations and tests carried out using the Materials. It is the intention of EBGG to ensure that research findings which have potential to have an immediate health impact are published as quickly as possible. To this end PHE will at all times maintain the right to share the results of any and/or all evaluations and tests with MOHS and ensure the publication of the same for the benefit of public health.

6. The Recipient shall not disclose any results of any evaluations and tests carried out using the Materials to any third party without informing PHE.

7. The Recipient will inform PHE of any incidental findings in a timely manner.

8. The Materials and any copies thereof made by or in the possession of or under the control of the Recipient pursuant to this Agreement shall be immediately returned (i) on termination of this Agreement, or (ii) in the event that the Recipient is in breach of any of the conditions of this Agreement, and (iii) at any other time on request of PHE. If PHE so dictates the Materials should be destroyed under the circumstances that might arise under this clause in accordance with the disposal plan detailed in Schedule 2 of this Agreement and authenticated certificates of destruction must be provided to PHE.

9. The Recipient shall not acquire any proprietary rights in the Materials therein and no licence under any MOHS or PHE intellectual property is granted or implied by this Agreement.

10. In the event that the Recipient makes or observes any new discovery, improvement or invention (an "Invention") relating to the Materials or as a direct result of the Research Programme then the Recipient will promptly bring this to the attention of PHE. The Recipient shall not make or seek to make actual commercial gain from such an Invention, nor assign, transfer, licence, make any patent application or secure any other proprietary rights to legally protect any such Invention except with the prior written consent of PHE. In any event, prior to any commercial exploitation of such Inventions, the Recipient agrees to enter into good faith negotiations with the PHE or MOHS, as directed by PHE, to negotiate terms properly reflecting the contribution of the Materials. The Recipient agrees that the MOHS will, at all times, retain the right to use any Inventions for non-commercial research purposes.

11. The Recipient shall use all reasonable endeavours to ensure that the results of the Research Programme are, in accordance with normal academic practice, published in peer reviewed journals, scientific publications and open access databases as promptly as reasonably possible. In the event that the Recipient is unable to publish the results of the Research Programme for whatever reason in a peer reviewed

journal or the results of the Research Programme are unexpected, negative and/or unhelpful, the Recipient shall in addition to complying with clause 6 of this Agreement, make such results available on a publishing platform, such as F1000.com, FigShare or Dryad or equivalent. For the avoidance of doubt, the Recipient shall be permitted to discuss the results of the Research Programme in internal seminars and to give instruction within their organisation on questions related to such work.

12 Notwithstanding clause 11, prior to submitting for publication the results of the Research, the Recipient shall provide PHE with a copy of the final proposed publication in any format, (e.g. meeting abstract, on-line report, paper journal) prior to its submission. PHE will share these reports with the MOHS. The Recipient is not required to obtain PHE's approval for any report that derives from use of the biobank but the researcher is required to advise PHE in advance, in writing, if any report is reasonably likely to provoke media attention or otherwise attract significant public attention. Publication may need to be delayed so that any perceived sensitivities may be managed appropriately.

13 Publication may also need to be delayed if any party needs to seek patent or similar protection for the material, if entitled to do so, or to modify the publication to protect confidential or sensitive information. A delay imposed on publication by either party will last no longer than is necessary to see the required protection or to manage any sensitivities and shall not exceed three months from the date of completion of the research. Notification of the requirement for delay in submission for publication must be received by the publishing party within thirty days after the completion of the research by the other party, failing which the publishing party may assume that the other party does not object to the proposed publication.

14 The Recipient shall acknowledge PHE and MOHS as the source of the Materials in any publication which mentions them. The Recipient shall send the PHE a copy of any reports or publications which describe work carried out using the Materials, as well as any supporting data, and PHE shall be entitled to use all such data, reports and publications and make them available to third parties.

15 The Materials are supplied at the Recipient's risk and without cost but the Recipient shall reimburse PHE for any reasonable handling, transport and any other related costs that may be incurred when preparing and sending the Materials to the Recipient the details of which are set out in Schedule 1. PHE will notify the applicant researcher when the materials will be retrieved from the archive and ready for delivery, and the cost for the sample preparation and delivery. The researcher will then notify PHE of convenient dates and the location for delivery of the materials. PHE will arrange for delivery to be made through an approved third party and the applicant's institution will be liable for delivery payment within 28 days of their receipt. The researcher must confirm to PHE that the materials have arrived.

16 The Materials are experimental and may be hazardous in nature and PHE makes no representation and gives no warranty or undertaking, in relation to them. As examples, but without limiting the foregoing, PHE gives no warranty: (i) that it owns all necessary property and other rights in the Materials and that their use will not infringe any patent, copyright, trade mark or other right owned by any third party; or (ii) that the Materials are of merchantable or satisfactory quality or fit for any particular purpose, have been developed with reasonable care and skill or tested, for

the presence of pathogens or otherwise, or are viable, safe or non-toxic. It will be necessary for the recipient to provide to PHE a biosafety and biosecurity assessment and risk management plan before the samples are dispatched.

17 PHE shall have no liability to the Recipient, whether in contract, tort or otherwise, in relation to the supply of the Materials to the Recipient or their use or keeping by the Recipient or by any other person, or the consequences of their use, to the maximum extent permitted under applicable law. The Recipient shall indemnify and hold harmless the Indemnified Parties from and against all Claims and Losses arising from such supply, use or keeping, including without limitation Claims and Losses arising from:- (i) injury to the Recipient's employees and third parties; (ii) infringement of third party intellectual property rights; and (iii) use of the Materials within or outside the scope of this Agreement.

18 For the purposes of this Agreement: (i) 'Indemnified Parties' shall mean the PHE and its directors, officers, employees, representatives and associated undertakings; (ii) 'Claims' shall mean all demands, claims, proceedings, penalties, fines and liability (whether criminal or civil, in contract, tort or otherwise); and (iii) 'Losses' shall mean all losses including without limitation financial losses, damages, legal costs and other expenses of any nature whatsoever.

19 Except as stated elsewhere in this Agreement, this Agreement does not create any right enforceable by any person not a party to it.

20 Neither Party shall be in breach of this Agreement nor liable for delay in performing, or failure to perform, any of its obligations under this Agreement if such delay or failure result from events, circumstances or causes beyond its reasonable control. In such circumstances the time for performance shall be extended by a period equivalent to the period during which performance of the obligation has been delayed or failed to be performed. If the period of delay or non-performance continues for three months, the Party not affected may terminate this Agreement by giving written notice to the affected Party.

21 Nothing in this Agreement is intended to, or shall be deemed to, establish any partnership between any of the Parties, constitute any Party the agent of another Party, or authorise any Party to make or enter into any commitments for or on behalf of any other Party. Each Party confirms it is acting on its own behalf and not for the benefit of any other person.

22 Any notice or other communication given to a Party under or in connection with this Agreement shall be in writing and shall be:

a. delivered by hand or by pre-paid first-class post or other next working day delivery service at its registered office (if a company) or its principal place of business (in any other case); or

b. sent by email to the address (if to the Recipient) or as notified to the other Party.

23 Any notice or communication shall be deemed to have been received if:

a. delivered by hand, on signature of a delivery receipt;
b. sent by pre-paid first-class post or other next working day delivery service, at 9.00 am on the second business day after posting;
c. sent by email, at 9.00 am on the next business day after transmission.

24 Clauses 22 and 23 do not apply to the service of any proceedings or other documents in any legal action or, where applicable, any arbitration or other method of dispute resolution.

25 This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute a duplicate original, but all the counterparts shall together constitute the one agreement.

26 Without limiting its other rights or remedies, PHE may terminate this Agreement with immediate effect upon thirty (30) days written notice to the Recipient.

27 If any dispute arises out of this Agreement the Parties will first attempt to resolve the matter informally through designated senior representatives of each Party to the dispute, who are not otherwise involved with the Research Programme. If the Parties are not able to resolve the dispute informally within a reasonable time not exceeding two (2) months from the date the informal process is requested by notice in writing they will attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure.

28 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims), shall be governed by, and construed in accordance with, the law of England and Wales.

29 The parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).

AGREED by the parties through their authorised signatories:

Signed by: _____

For and on behalf of **PUBLIC HEALTH ENGLAND.**
Name:
Position:

Signed by: _____

Name: _____

Title/Position: _____

SCHEDULE 1

USE OF THE MATERIALS

80 x 200ul total DNA extracts from clinical samples have been supplied for the 'Pathogen Identification in Children Attending Ebola Holding Units testing Negative for Ebola Virus Disease in Freetown, Sierra Leone' Research Study

The DNA was extracted from a 200ul sample of blood that was taken from patients admitted to Ebola Holding Units in Sierra Leone. The sample was then bead-beated and the Qiagen DNA mini kit was used to extract total DNA.

The recipient will use the total DNA extract to test for infections other than Ebola as the cause of febrile illness and admission to the holding unit.

SCHEDULE 2

MATERIAL DISPOSAL PLAN

Remnant extracted DNA will be stored for the period of one year to allow further testing should queries arise during peer review and immediately post-publication.

Then samples will then be destroyed using the autoclave waste stream as per departmental standard operating procedures. Sample logs will be updated to include the date of disposal.