

## MATERIAL TRANSFER AGREEMENT

This Agreement dated 15<sup>TH</sup> May 2015 is made between

- (1) **Ministry for Health and Sanitation of Sierra Leone**, whose principal place of business is at \_\_\_\_\_, Sierra Leone which expression shall include its successors in title (the "MOHS"); and
- (2) **Public Health England, an executive agency of the Department of Health, UK**, whose principle place of business is at \_\_\_\_\_, UK ("PHE")

Each a "Party" and collectively "Parties"

### RECITALS

- (A) Residual clinical specimens from routine diagnostic screening in the PHE-led laboratories in Sierra Leone which were obtained during the 2014-2015 Ebola outbreak ("Materials") are currently stored in the PHE-led laboratories in Sierra Leone, following routine diagnostic testing for Ebola.
- (B) PHE is in the process of obtaining ethical approval from the Sierra Leone ethics and scientific committee permitting PHE to transfer the Materials \_\_\_\_\_ UK for further diagnostic testing and analysis on the terms and conditions of this agreement.

IT IS AGREED as follows:

1. This Agreement shall commence on the date when it has been signed by both the Parties and shall continue, unless terminated earlier by either Party giving the other Party thirty (30) days' prior written notice.
2. In collaboration with Sierra Leonean scientific investigators, PHE shall use the Materials only for the purpose of further diagnostic and research studies as described in Schedule 1 (the "Collaborative Research Programme"). MOHS acknowledges that as a result of the further diagnostic and research work undertaken, PHE may obtain, from or as a result of the use of, the Materials constructs, strains, derivatives, portions or progeny ("Derivatives"). MOHS agrees that PHE may store the Derivatives \_\_\_\_\_ for future diagnostic and analysis work to potentially inform future public health strategy relating to Ebola and/or similar illnesses in Sierra Leone and elsewhere.
3. In the event that a third party requests the Materials and/or Derivatives for the purposes of further testing and analysis to be carried out by that third party, PHE shall be free to transfer:

- (a) the Materials and/or Derivatives provided that the third party has received ethical approval from the Sierra Leone ethics and scientific committee and that such transfer is conditional upon the third party only using the Materials and/or Derivatives for its internal and academic research; and
- (b) Materials and/or Derivatives provided that, if the third party wishes to use the Materials and/or Derivatives for any commercial purpose or commercially-sponsored research, PHE, prior to such transfer, negotiates suitable terms in good faith with MOHS reflecting its technical contribution to the Collaborative Research Programme. The condition in this clause 2(b) shall also apply in the event that PHE wishes to use the Materials and/or Derivatives for any commercial purpose or commercially-sponsored research.
4. PHE shall keep the Materials secure [REDACTED]. PHE undertakes to ensure that the Materials and/or Derivatives are appropriately safeguarded to prevent theft or unauthorised access.
  5. PHE 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.
  6. Within a reasonable period of time (such period to be agreed between the Parties) from completion of the Collaborative Research Programme, PHE shall provide MOHS in writing with the results of all evaluations and tests, including any raw data, carried out using the Materials and any Derivatives obtained from, or as a result of the use of the Materials.
  7. PHE shall not disclose any results of any evaluations and tests carried out using the Materials to any third party without MOHS's prior written consent which shall not be unreasonably withheld or delayed.
  8. The Materials and any copies thereof made by or in the possession of or under the control of PHE pursuant to this Agreement shall remain the property of MOHS and shall be immediately destroyed (i) on termination of this Agreement, or (ii) in the event that PHE is in breach of any of the conditions of this Agreement, and (iii) at any other time on request of MOHS. If MOHS so dictates the Materials should be destroyed under the circumstances that might arise under this Clause 8 and authenticated certificates of destruction shall be provided to MOHS.
  9. PHE shall not acquire any proprietary rights in the Materials therein.
  10. In the event that PHE makes or observes any new discovery, improvement or invention (an "Invention") relating to the Materials or as a direct result of the Collaborative Research Programme then PHE will promptly bring this to the attention of MOHS. PHE 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 MOHS. In any event, prior to any commercial exploitation of such Inventions, PHE agrees to enter into good faith negotiations with MOHS to negotiate

terms properly reflecting the technical contribution of the Materials. **MOHS will, at all times, retain the right to use any Inventions for non-commercial research purposes.**

11. Subject to the terms of this agreement, in accordance with normal academic practice, all employees, students, agents or appointees of the Parties (including those who work on the Collaborative Research Programme) shall be permitted:
  - (a) following the procedures laid down in clause 12 to publish results obtained during the course of work undertaken as part of the Collaborative Research Programme in any scientific publications including in open access databases for genomic or similar data ("Publications"); and
  - (b) in pursuance of the Parties' public health functions, to discuss work undertaken as part of the Collaborative Research Programme in internal seminars and to give instruction within their organisation on questions related to such work.
  
12. Each Party shall be a named co-author to any Publications and MOHS shall also be acknowledged as the source of the Materials. Each Party will use all reasonable endeavours to submit material intended for publication to the other Party in writing not less than sixty (60) days in advance of the submission for publication. The publishing Party may be required to delay submission for publication if in any other Party's opinion such delay is necessary in order for that other party to seek patent or similar protection for material in respect of which it is entitled to seek protection, or to modify the publication in order to protect confidential information. A delay imposed on submission for publication as a result of a requirement made by the other Party shall not last longer than is absolutely necessary to seek the required protection; and therefore shall not exceed three (3) months from the date of receipt of the material by such Party, although the publishing Party will not unreasonably refuse a request from the other party for additional delay in the event that property rights would otherwise be lost. Notification of the requirement for delay in submission for publication must be received by the publishing party within thirty (30) days after the receipt of the material by the other Party, failing which the publishing party shall be free to assume that the other Party has no objection to the proposed publication.
  
13. Each Party shall be free to make a public statement, in particular press releases, display or by putting on any website ("Announcement"), concerning this agreement and the conduct of the Collaborative Research Programme provided that the Party wishing to make the Announcement promptly notifies the other Party in advance and that such Announcements do not disclose the results of the Collaborative Research Programme (in which case the procedure in clause 12 should be followed) or any confidential information belonging to the other Party. In any Announcements, each Party shall acknowledge the contribution of the other Party, in particular, MOHS shall be acknowledged as the source of the Materials.

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14. The Materials are supplied at PHE's risk. PHE shall be responsible for handling, transport and any other related costs that may be incurred when preparing and sending the Materials to the \_\_\_\_\_ in the UK.
15. The Materials are experimental in nature and MOHS makes no representation and gives no warranty or undertaking, in relation to them. As examples, but without limiting the foregoing, MOHS 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.
16. MOHS shall have no liability to PHE, whether in contract, tort or otherwise, in relation to the supply of the Materials to PHE or their use or keeping by PHE or by any other person, or the consequences of their use, to the maximum extent permitted under applicable law.
17. This Agreement does not create any right enforceable by any person not a party to it.
18. All communication concerning this agreement and the Collaborative Research Programme shall be sent for the attention of the contact and to the Party's address (or to such other person or address as that Party may notify to the other Party in accordance with this agreement) as follows:

(a) PHE

for the attention of: Duncan Selbie, Chief Executive

Public Health England, Wellington House, 133-155 Waterloo Road, London, SE1 8UG, United Kingdom

Email: \_\_\_\_\_

Tel: \_\_\_\_\_

(b) The MOHS

for the attention of: \_\_\_\_\_, Chief Medical Officer

\_\_\_\_\_, Sierra Leone

Email: \_\_\_\_\_

Tel: \_\_\_\_\_

19. A notice given to a Party under or in connection with this Agreement shall be in writing and shall be delivered by hand or sent by pre-paid first class post, recorded delivery or special delivery or sent by airmail or by reputable international overnight

courier, in each case for the attention of the contact and to the party's address specified in clause 18. Delivery of a notice is deemed to have taken place (provided that all other requirements in this clause 19 have been satisfied) if delivered by hand, or by reputable international overnight courier to an address outside the country from which it is sent, at the time the notice is left at the address, or if sent by pre-paid first class post, recorded delivery or special delivery, on the second business day after posting, or if sent by pre-paid airmail to an address outside the country from which it is sent, on the fifth business day after posting, unless such deemed receipt would occur outside business hours (meaning 9.00 am to 5.30 pm Monday to Friday on a day that is not a public holiday in the place of deemed receipt), in which case deemed receipt will occur when business next starts in the place of receipt (and all references to time are to local time in the place of receipt). This clause 19 does not apply to the service of any proceedings or other documents in any legal action.

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.
21. Nothing in this Agreement is intended to, or shall be deemed to, establish any partnership or joint venture 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. 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. Transmission of an executed counterpart of this Agreement (but for the avoidance of doubt not just a signature page) by fax or email (in PDF, JPEG or other agreed format) shall take effect as delivery of an executed counterpart of this Agreement. If either method of delivery is adopted, without prejudice to the validity of the agreement thus made, each party shall provide the other with the original of such counterpart as soon as reasonably possible thereafter.
23. If either Party has any issues, concerns or complaints about the Collaborative Research Programme or this agreement, that Party shall notify the other Party's representative as set out in clause 18 and the parties shall then seek to resolve the issue in good faith. If the issue cannot be resolved within a reasonable period of time, the matter shall be escalated to each party's senior officers, which shall decide on the appropriate course of action to take. If the matter cannot be resolved by the senior officers within thirty (30) days of the matter being referred to them, the Parties

will attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution ("CEDR") Model Mediation Procedure. Unless otherwise agreed between the Parties, the mediator will be nominated by CEDR. No party may commence any court or arbitration proceedings under clause 24 unless the CEDR mediation procedure fails to resolve the issue provided that the right to issue proceedings is not prejudiced by a delay.

24. Each Party irrevocably agrees that any proceedings relating to any dispute or claim, arising out of or in connection with this agreement or its subject matter or formation (including non-contractual disputes or claims) instituted:
- (a) against PHE by MOHS shall be brought in the courts of England and Wales and such disputes shall be governed, and construed in accordance with, the laws of England and Wales; and
  - (b) against MOHS by PHE shall be brought in the courts of Sierra Leone and such disputes shall be governed, and construed in accordance with, the laws of Sierra Leone.

AGREED by the parties through their authorised signatories.

Signed by:

For and on behalf of **Ministry for Health and Sanitation of Sierra Leone**

Name:

Dr

Position:

Chief Medical Officer

Signed by: \_\_\_\_\_

For and on behalf of **Public Health England, an executive agency of the Department of Health, UK**

Name:

Duncan Selbie

Title/Position:

Chief Executive

## **SCHEDULE 1**

### **Aim**

The Collaborative Research Programme detailed within this Agreement will contribute to the wider Ebola recovery efforts, the rebuilding of the diagnostic and public health capability in Sierra Leone, and informing worldwide public health strategy to prepare nations for future Ebola epidemics.

PHE proposes the following research to be undertaken utilising the Materials:

- Genetic sequencing of a range of Ebola virus isolates to aid analysis of the epidemiological spread of the virus throughout the outbreak.
- Studies of antibody responses in both survivors and fatal cases to better understand patient recovery and define future treatment strategies.
- The creation of a panel of viral isolates for screening diagnostic tests and potential therapeutics.
- Targeted PCR tests and next generation sequencing on Ebola negative samples to enable PHE to determine the major causes of similar illnesses, which could be used to improve both diagnostic capability in Sierra Leone and inform future worldwide public health strategy.

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**PHE Material Transfer Agreement**

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