

PHE EBOLA GOVERNANCE GROUP

TERMS OF REFERENCE

1. Purpose of the ToR

These ToR aim to set out the understanding between the members of the PHE Ebola Biobank Governance Group which has come together to ensure appropriate use of clinical samples collected during the Ebola virus disease outbreak in Sierra Leone and that have been entrusted to PHE.

These ToR outline certain roles and responsibilities between the Parties, and serve to clarify aspects relating to the release of samples from the PHE Ebola Biobank. The terms within these ToRs are not legally binding.

2. Responsibilities

The Parties shall perform the responsibilities set forth in Exhibit A.

3. Definitions

“**CMO**” shall mean Chief Medical Officer

“**Group**” shall mean the PHE Ebola Biobank Governance Group

“**Party**” shall mean any of PHE, SL, LSHTM, Wellcome and WHO.

“**Parties**” shall mean all of PHE, SL, LSHTM, Wellcome and WHO.

4. Term

The ToR are effective from 22nd June 2016 and will be ongoing until terminated by agreement between the Parties.

5. Membership

The Group will comprise of the following regular members:

External members:

- xxx, London School of Hygiene and Tropical Medicine (Chair)
- xxx Wellcome Trust
- xxx DFID and Wellcome
- xxx, WHO.

PHE members:

- Professor Derrick Crook, National Infections Service
Dr xxxx, Scientific Leader Research Services (alternate)

- Professor xxx, Research Translation and Innovation (deputy chair)
- xxx
xxx, International Office (alternate)
- xxx Head of High Containment Microbiology
xxx Operations Manager (alternate)
- xxx (secretariat)

Sierra Leone members:

- xxx, University of Sierra Leone, Ministry Of Health and Sanitation
- xxx, University of Sierra Leone, 34th Military Hospital, Sierra Leone
- xxx, Sierra Leonean Director of Hospitals & Laboratories.

6. Accountability

The EBGG is accountable to the PHE Management Group and the Government of Sierra Leone.

7. Withdrawal of Membership and Resignation

There is no requirement for membership to be drawn from across the organisation for this group.

The Group may, at its discretion, withdraw the membership of any member who does not attend three successive regular meetings.

In addition, any member may have their membership withdrawn if (i) they cease to fulfil the requirements of membership of the Group, (ii) they become incapable of continuing as a member whether due to illness, infirmity or incompetence, or (iii) there are serious concerns as to how the member is discharging their role under these ToRs.

Members wishing to resign from the Group must do so formally in writing (for which purpose email will be acceptable) to the Secretariat, and may nominate a replacement.

8. Meetings

All meetings will be chaired by xxx, LSHTM. The Chair will act to resolve disputes over a decision on a study in exceptional circumstances.

A meeting quorum will be a majority of members of the Group, which must include a majority of Sierra Leone members.

Decisions will be made by consensus (i.e. members are satisfied with the decision even though it may not be their first choice).

Decisions made about access to samples must receive approval from the majority of members before being accepted. This must include a majority from Sierra Leone.

The Group may make a decision outside a formal meeting by the circulation of a paper in correspondence. Decisions made in correspondence will be reported to the next meeting of the Group. The Secretary shall circulate any such papers with a deadline for the date by which the decision and any comments are to be received. Members who do not respond to

papers circulated in correspondence will be deemed to have agreed to the recommendations.

Applications may be scrutinised by an independent scientific reviewer, selected by the EBGG, in order to ensure independence, competence and rigour of peer review.

Meeting agendas and minutes will be provided by xxx, PHE. This includes: preparing agendas and supporting papers, preparing meeting notes and information. Meeting papers will be circulated to Group members at least 7 days before a meeting.

Meetings will be held 4 times during year 1 and not less than twice annually thereafter until the biobank is exhausted. Meetings will be held in London and Sierra Leone with IT arrangements appropriate to the resources available to all Parties.

The Group will provide reports twice annually to PHE Management Group and to the Government of Sierra Leone.

With prior approval of the Chair members may co-opt any other official of their organisation to attend Group meetings on their behalf to assist it in fulfilling the organisation's role.

9. Conflicts of Interest

Members of the EBGG are expected to respect the confidentiality of issues discussed if any such items are identified. In addition, those members who hold part time or honorary contract roles with other organisations are asked to clearly indicate any conflicts of interest which may arise. In such circumstances, the Chair of the EBGG may request that a member is not present during the discussion of a particular agenda item.

The PHE [Conflict of Interest Policy](#) aims to ensure that PHE's decision-making processes for access to the biobank are conducted in accordance with the highest standards of integrity. This policy must be read and understood by the members of the EBGG and each person covered by this policy has a responsibility to comply with its terms.

10. Review, Amendment, Modification or Variation

The ToR will be reviewed annually by the members of the Group and may be amended, varied or modified in writing after consultation and agreement by the Parties.

EXHIBIT A – PHE EBOLA BIOBANK

Section 1	Responsibility: Release of Samples	PHE	SL	Other EBGG members
1.1	During and before the meetings, establish and keep under review criteria for the release of samples for: ethics; quantity of sample requested and the likely value of proposed research; arrangements to maintain data security and confidentiality (such as issuing Material Transfer Agreements and Confidential Disclosure Agreements) and proposed dissemination of results.	X	X	X
1.2	Review and consider all applications to the PHE Ebola Biobank that fulfil the above criteria	X	X	X
1.3	Ensure effective communication with nominated representatives of the Government of Sierra Leone so that those nominees have appropriate opportunities to influence the work of the Group	X		X
1.4	Each Party will agree during a meeting how they will work together to secure funding from sources (such as the Wellcome Trust).	X	X	X
1.5	Receive and consider reports of all publications and other outputs leading from the use of samples released from the PHE Ebola Biobank.	X	X	X
1.6	Consider reports on the operation of PHE Ebola Biobank. Where any such report raises concern, to provide advice on possible remedial actions.	X	X	X
1.7	Communicate with the international research community, including research funders, to highlight progress achieved through research involving the PHE Ebola Biobank.	X	X	X
1.8	Discuss concerns raised by any member of the Group, ensure that PHE senior management and the Sierra Leone Government are made aware of unresolved issues and provide advice on possible remedial actions.			X
1.9	Provide reports twice annually to the PHE Management Group and to the Government of Sierra Leone.			X