Public Health England

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Guidelines and application form to access the PHE-MOHS Ebola Biobank

Overview

During the Ebola outbreak in 2014-2015 in Sierra Leone, residual clinical specimens and accompanying data were collected from routine diagnostic testing in Public Health England (PHE) led laboratories. The majority of the samples (about 10,000 of which 1440 are positive for Ebola) and the data have been transferred to the PHE laboratories in the UK for curation by PHE.

The Ministry of Health and Sanitation in Sierra Leone (MOHS) have retained ownership of the data and materials, and they will work with PHE and other collaborators to develop and conduct a series of research projects that will inform future public health strategy relating to Ebola. Researchers from the UK and overseas, from academia, government other research organisations and commercial companies can submit proposals to the Biobank to access and use the samples.

These guidelines are to facilitate access to the materials and data so that they get the widest possible usage while ensuring that such access and usage is for the global public good and is consistent with the undertaking given by PHE to the MOHS. In these guidelines the 'materials' shall include any and all materials, documents, data and information provided to the applicant, and any constructs, strains, derivatives, portions, progeny, improvement and research findings that are obtained from or as a result of the use of the materials.

Applications to the Biobank

The biobank is a limited resource and research projects will be prioritised. The PHE-MOHS Ebola Biobank Governance Group (EBGG) is an independent group that has been established to co-ordinate access to the data and materials for researchers and to ensure the effective use of the resource.

Researchers can apply to the biobank using the application form on page seven. The applicant's attention is also drawn to the following points:

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- the Ebola biobank is for health-related research and researchers applying to use materials/data from the biobank will need to explain explicitly how their research project supports this purpose
- all researchers who wish to access samples for research whether based in the UK or abroad will be subject to the same application process
- the EBGG will carefully control and coordinate access to the materials. The quantity of material approved to be released will be judged against the potential benefits of the research project
- PHE is committed to the fair and lawful processing of personal data in accordance with the UK Data Protection Act. Safeguards must be maintained to ensure the confidentiality of participants' data and materials
- the MOHS will remain the owner of the database and samples, the researcher will not make or seek to make commercial gain from such an invention or 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
- residual materials should either be returned to PHE at Porton or destroyed with authenticated certificates of destruction provided to PHE. Samples, their derivatives and accompanying data must not be shared with a third party

Eligibility criteria

The EBGG will apply a standard set of criteria (subject to ongoing review and amendment) for the assessment of all applications.

1 The proposed research is scientifically sound
2 There is sufficient funding to enable completion of the research
3 The research is designed in such a way that ensures integrity, quality and transparency
4 The research team are suitably qualified by education, training and experience.
5 The research site has adequate capacity and capability to undertake the research
6 The research has all necessary ethical and regulatory permissions
7 The materials will be used to ensure the greatest public health benefit
8 The research has relevance to the people of Sierra Leone, and a likelihood that the people will be able to benefit from it.

In reaching its decision on an application, the EBGG will accept the outcome of peer review that is undertaken by a research funder. Where that is not possible or where there is doubt that an application may not satisfy any of the above criteria, applications may be scrutinised by an independent scientific reviewer selected by the EBGG in order to ensure independence, competence and rigour of peer review.

In addition to the eligibility criteria, the following will also be considered by EBGG:

- importance of the scientific question(s) posed

- quantity of material requested
- arrangements to maintain data security and confidentiality
- proposed dissemination of results

Legal and ethical approval
In line with criterion six in the eligibility criteria, researchers must assure the EBGG that they have obtained Ethical Approval for their research project in the UK and in Sierra Leone prior to the release of materials.

Researchers may have to return any residual materials at the end of the research project or destroy them, with destruction sufficiently documented. This will be clarified in each case through the conditions of a Materials Transfer Agreement (MTA). Applicants must adhere to all conditions of the MTA and are not entitled to transfer the materials to third party premises without specific EBGG approval.

Intellectual property rights
The MOHS is the owner of the materials. Researchers will be able to use the materials to conduct the approved research project, over a particular period of time but will have no ownership rights to the materials or the material derivatives.

Any new discovery made by the researcher must be brought to the attention of PHE who will ensure the MOHS is informed. The researcher will not make or seek to make commercial gain from such an invention or 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 and MOHS.

In any event prior to any commercial exploitation of such inventions, the researcher agrees to enter into good faith negotiations with PHE and MOHS to negotiate terms that reflect the technical contribution of the materials. MOHS will retain the right to use any inventions for non-commercial research purposes.

Researchers will be required to provide to PHE in writing, the results of all evaluations and tests, including any supporting data, carried out using the materials and any derivatives obtained from it. These will be added to the PHE Central Ebola Biobank database and made available to the MOHS. Results cannot be transferred by the researcher to a third party without written permission from the EBGG.

Application review stages
Applicants for materials from the biobank must submit a PHE-MOHS Ebola Biobank Application Form to the PHE HRG (Head of Research Governance). The review of the application will be managed by the EBGG which will conduct a set of standard checks and seek advice on particular applications as required. The level of scrutiny used to assess applications will be proportionate to the nature and scale of the research project, taking into

account (by way of example) whether a significant amount of material is required relative to the project objectives.

When the review is complete and there is consensus the Application will either be:

1 Approved
2 Approved pending receipt of further information (award of funding; obtaining REC approval) within a set period of time.
3 Approved subject to an amendment to the project
4 Declined.

Applicants awaiting the outcome of a funding application will receive ‘approval in principle’, which is conditional on the funding being sufficient to use the Biobank samples for the intended purpose. When funding is in place, a copy of the funding proposal and offer letter must be sent to the EBGG along with any amendments to the original project that have been required by the funder.

The PHE Biobank operates on a cost recovery basis, and does not seek to make an operating profit from the provision of the materials. The applicant shall reimburse PHE for any reasonable handling, transport and any other related costs that may be incurred when preparing and sending the materials.

The applicant will also pay the costs for any subsequent destruction of residual sample and / or its return to PHE. In exceptional cases, eg where an applicant is based in a low or middle income country, or the proposed research does not fall within the funding remit of the principal funder of the study, PHE will consider how such costs might be met from other resources.

Resubmission of declined applications
If a researcher wishes to resubmit an application that has been declined they must submit a written request, giving their reasons why the decision should be revised, within three months of the decision. It will be considered by the EBGG, along with the original application and any other relevant information, and the applicant will be notified of the decision within four - six weeks. If the application is declined the applicant will not be able to submit the same proposal again within a twelve month period

Material Transfer Agreement (MTA)
If the research project is approved then PHE will send an MTA to the applicant for review and completion by the applicant’s institution. Apart from inclusion of the specific details of the approved research project (eg details of the researchers; the required data and/or materials; the completion date for the project), the content of PHE’s MTA, and the conditions contained within it, are non-negotiable. The MTA will be considered to have been executed when PHE has received both the MTA signed by the applicant and their institution.

Provision of materials
Materials will only be released when the EBGG has approved a project biosafety and biosecurity assessment, and a risk management plan.

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.

Publication of findings
If findings have the potential to alter public health practices or interventions they should be shared early with PHE, MOHS and any other relevant public health practitioners in advance of publication. Early release of this information would not prevent later publication.

Researchers granted access to the biobank will be required to submit their research findings for publication within twelve months after the date it was agreed that the research would be completed. PHE will give reasonable consideration to written requests for an extension of these time limits. Researchers must ensure that the published article is available on an open access basis.

If the research findings do not lead to publishable results, results and interpretations must be entered on a publishing platform, such as F1000, FigShare or Dryad for example, so that they can be shared. All results, whether published or unpublished, including raw data, must be provided to PHE to be added to the PHE Central Ebola Biobank database.

The applicant is not required to obtain PHE's approval for any report of its results that derive from use of the biobank but the researcher must provide a copy of any of them to PHE before the date of first public presentation or publication in any format (eg meeting abstract, on-line report, paper journal).
PHE will share these reports with the MOHS. The researcher is also 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.

Publication may also need to be delayed if any party needs to seek patent or similar protection for 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 will 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.

All publications should include the acknowledgement “This research study has been conducted using the Ebola Biobank, which is a partnership between Ministry of Health and Sanitation of Sierra Leone and Public Health England” which is to be linked, when possible, to reference search tools (such as Pubmed and MEDLINE).

Review of the guidelines

It is intended that these guidelines are clear and transparent and are implemented in a manner which is proportionate accountable and fair. The functioning of these guidelines will be reviewed by the EBGG, with views expressed by researchers, funders, and other interested parties being taken into account. The EBGG will amend these guidelines periodically as required.

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PHE-MOHS Ebola Biobank application form

Applicants must refer to the Guidelines whilst completing this form. They must then submit it to the PHE HRG (Head of Research Governance) for review by the PHE-MOHS EBGG, which will take approximately twelve weeks.

CATEGORIES OF SAMPLES AVAILABLE IN THE BIOBANK

Sample types subdivided into categories of test result.

Sample Type	Negative	Positive	Indeterminate	Rejected or pending	Repeat Tests	Total
Blood	4,279	1,236	135	75	248	5,973
Live Swab	65	3	1	1	0.0	70
Dead Swab	1,660	5	0.0	9	0.0	1674
Unknown Swab	2,451	186	44	80	177	2938
Other	126	14	0.0	2	3	145
Total	**8,581**	**1,444**	**180**	**167**	**428**	**10,800**

ASSOCIATED DATA

The following information is associated with some samples in the biobank.

- **Laboratory of origin**
- Laboratory ID number
- Facility from where the patient was referred
- Patient age
- Gender
- Original or follow up sample
- Ebola test result
- **Date of hospitalisation**
- Symptom onset
- Date tested
- Clinical chemistry results
- Viral load
- Malaria test result

The database does not have details of patient outcomes or details of patient contacts, and we cannot guarantee a full data set for all samples. Applicants are advised to contact the PHE HRG to confirm sample availability before their projects are finalised.

1 SAMPLES REQUESTED

Complete the table below with details of the requested samples. Materials will be prepared in accordance with your requirements wherever possible. 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.

Cohort	Type of sample required	Sample volume

2 TITLE OF PROPOSAL **Please give a concise descriptive title for the proposal**
3 STUDY TEAM Please list all collaborators, lead investigator named first, with institute affiliations
4 BACKGROUND Project rationale including a brief review of relevant literature with key references (max 400 words, references additional)
5 SUMMARY OF THE RESEARCH WITH OVERVIEW OF METHODS Include numbers, sample types and volumes required with statistical justification if appropriate. Include methods of analysis distinguishing those requiring containment level 4 (CL4) and those that can take place at lower containment level.
5 DATABASE VARIABLES Please list any metadata associated with the samples required for selection of samples or interpretation of results.

6 RESOURCE REQUIRED AND AVAILABLE Please give details of funding available (or being applied for) to carry out the proposed research. Include any resource available or required for the processing of samples at PHE's CL4 laboratory
7 BIOSAFETY AND BIOSECURITY All applications must be accompanied by a biosafety and biosecurity assessment and risk management plan.

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