DATA SHARING AGREEMENT

(PERSONAL DATA)

between

East London NHS Foundation Trust

and

Queen Mary University of London
(for Genes & Health research study, IRAS 146051)

Drafting assumes that:

- *Data which includes personal data is being shared by Provider Institution for a research project designed and conducted by Recipient Institution. Drafting assumes that the Provider Institution and the Recipient Institution are charities (otherwise amend clause 12)*
- *In most cases this will mean that each party is a data controller (i.e. determines the purposes and means of processing the personal data) and each is separately responsible for ensuring that it processes the personal data in compliance with the principles set out in the GDPR.*
- *Provider Institution and Recipient Institution are each based in the UK and consequently subject to GDPR. This template could be adapted for use with organisations based in other EEA countries by amending the definition of Data Protection Laws. This template could also be adapted for personal data transfers to/from organisations based outside the EEA but would require more substantial amendment.*
- *For collaborative research projects designed and conducted jointly by Provider and Recipient, where they jointly determine the purposes and means of how the personal data are processed, Provider and Recipient are likely to be joint data controllers. Consider using a collaboration agreement template as a starting point with joint controller provisions.*
- *For most research projects, personally identifiable data should not need to be shared. Parties have an obligation under data protection law (the principle of data minimisation) to share anonymous or pseudonymised data instead, where possible. Consider using the template data sharing agreement (pseudonymised clinical data).*

DATA SHARING AGREEMENT (PERSONAL DATA)

Between

East London Foundation NHS Trust, having its main administrative offices at 9 Alie Street, London E1 8DE (the "Provider Institution")

and

Queen Mary University of London, a charitable body registered in England and Wales under registration number RC000710, incorporated under Royal Charter and having its main administrative offices at Mile End Road London E1 4NS ("Recipient Institution")

hereinafter referred to as "the Parties" and each of them being "a Party"

BACKGROUND

(A) The Recipient Institution is conducting a research programme entitled "Genes & Health" as described in more detail at Schedule 1 (the "Research") under the direction of Prof David A van Heel ("the Recipient Scientist") and wishes to access and use the data specified in Schedule 2 (the "Data") for the purpose of the Research.

(B) The Provider Institution is willing to supply the Data to the Recipient Institution and the Recipient Institution is willing to receive the Data in accordance with the terms and conditions contained within this agreement (the "Agreement").

TERMS AND CONDITIONS

It is hereby agreed as follows:

1. In this Agreement:

   (a) the term "Data" refers to the NHS health data of Genes & Health volunteers held on and provided from the Provider Institution's record systems, as described in Schedule 2, and in respect of which the Recipient Institution holds individual written consent from each volunteer. It does not extend to any Output Data.;

   (b) the term "Research" includes the generation of a BioResource with Output Data and the publication (if any) of the results of Research in accordance with clause 12;

   (c) the term "Output Data" refers to data sets derived from the Data in the course of the Research which are either anonymised or sufficiently pseudonymised that there is no material prospect of identification of any individual from those data sets. Where such data sets are pseudonymised and in the hands of a party, such as the Recipient Institution, which has the tables of reference which permit re-identification, those data sets are Data and not Output Data;

   (d) the terms "personal data", "personal data breach", "data subject", "controller", "processes", "processing" and "processed" shall have the meanings given in the Data Protection Laws;

   (e) "Data Protection Laws" means the Data Protection Act 2018 as amended from time to time and any successor legislation in the UK, and (for so long as and to the extent that the law of the European Union has legal effect in the UK) the General Data Protection

Regulation (EU) 2016/679 ("GDPR") and any other directly applicable European Union regulation relating to data protection and privacy.

2. In consideration of the obligations accepted by the Recipient Institution under this Agreement, the Provider Institution grants to the Recipient Institution for the duration of this Agreement a non-exclusive, personal and non-transferable licence to use the Data for the Genes and Health BioResource. Nothing in the terms of this licence shall preclude the Recipient Institution from sharing Output Data for the purposes of Research by scientists in academia and industry, subject always to the constraints set out in this Agreement.

3. The Data includes personal data. The Parties acknowledge that the legal basis for the processing of such personal data shall be Article 6(1)(e) of the GDPR (performance of a task in the public interest) and, to the extent that the Data includes any of the special categories of personal data under Article 9 of the GDPR, Article 9(2)(j) of the GDPR (processing in the public interest, scientific or historical research purposes or statistical purposes).

4. The Recipient Institution undertakes to the Provider Institution:

   (a) to use the Data solely for the Research;

   (b) to restrict access to the Data to the Recipient Scientist and those staff comprising the Recipient Scientist's research team, and to ensure that those staff are aware of and comply with the terms of this Agreement;

   (c) to keep the Data confidential and not sub-license, transfer, disclose or otherwise make available the Data in whole or part to any third party except as permitted by this Agreement, without specific prior written consent from the Provider Institution;

   (d) to keep the Data secure by implementing organisational and technological measures to prevent any data breach that are appropriate to the nature and sensitivity of the Data and the harm that may result from a data breach, including (without limitation) the measures set out in clause 5;

   (e) to notify the Provider Institution as soon as reasonably practicable after becoming aware of any unauthorised or accidental access, use or disclosure of the Data, and to co-operate with any investigation made by the Provider Institution in connection with the unauthorised or accidental access, use or disclosure of the Data;

   (f) to process the Data in accordance with all applicable laws and regulations [and any regulator's code(s) of practice applicable to the Data];

   (g) to delete all copies of the Data from its hard drives and movable media and destroy all physical copies of the Data as soon as reasonably practicable on completion of the Research or on termination of this Agreement or once the processing of the Data is no longer necessary for the Research (whichever is earlier), except to the extent the Recipient Institution is required by law to store the Data. This obligation does not extend to automatically generated computer back-up or archival copies generated in the ordinary course of the Recipient Institution's information systems procedures, provided that the Recipient Institution makes no further use of those copies; and

   (h) not to permit the use by any third party of the Output Data for any purpose which gives rise to a material risk of re-identification by that third party of any data subject

5. In particular (and without limiting the generality of the preceding wording) the Recipient Institution shall not make physical or electronic copies of the Data except to the extent

reasonably necessary for the Research and shall ensure that any copy of the Data stored on movable media (including laptops) is password-protected and fully AES-256 encrypted and that any copy of the Data stored on networked or non-networked hard drives is properly protected with firewall and controlled access permissions. The Recipient Institution shall keep a record of where each copy of the Data is stored and shall provide the Provider Institution with a copy of this record on request.

6. The Parties agree that:

   (a) each of them shall be a controller in respect of its own processing of the Data, and shall be solely responsible and liable for its own processing of the Data including (without limitation) the lawful basis for that processing and ensuring that the Data is processed in compliance with the Data Protection Laws; however

   (b) if the Parties are deemed to be joint controllers in relation to the Data, the Parties shall be jointly responsible and liable for the processing of the Data in connection with this Agreement and shall co-operate to determine their respective responsibilities for compliance with their obligations and duties under the Data Protection Laws, including documenting details of this arrangement to demonstrate compliance with Article 26 of the GDPR.

7. Each Party shall assist the other in complying with all applicable requirements of the Data Protection Laws in relation to the processing of the Data for the Research. In particular, each Party shall, in relation to the Data:

   (a) consult with the other Party about any notices given to data subjects;

   (b) promptly inform the other Party about the receipt of any data subject access request, where possible consult with the other Party before releasing any personal data in response to a data subject access request, and provide the other Party with reasonable assistance where required by the other Party to comply with any data subject access request;

   (c) provide any assistance reasonably required by the other Party in responding to any request from a data subject and in ensuring compliance with its obligations under the Data Protection Laws with respect to breach notifications and consultations with supervisory authorities or regulators;

   (d) notify the other Party without undue delay on becoming aware of any breach of the Data Protection Laws or any personal data breach, and co-operate with the other Party in respect of any notification required to be made in respect of the breach, any investigation into the breach and any measures necessary to remedy the breach or mitigate the damage or harm caused by the breach;

   (e) maintain complete and accurate records and information to demonstrate its compliance with the Data Protection Laws; and

   (f) provide the other Party where requested with contact details of at least one employee as point of contact and responsible manager for all issues arising out of the Data Protection Laws in connection with this Agreement.

8. Except to the extent prohibited by law, the Recipient Institution assumes all direct liability for damages which may arise from its receipt, use, storage or disposal of the Data. The Provider Institution will not be liable to the Recipient Institution for any use made of the Data, including any loss, claim or demand made by the Recipient Institution or made against the Recipient Institution by a third party, due to or arising from the use, storage or

disposal of the Data by the Recipient Institution, except to the extent permitted by law when caused by the gross negligence or wilful misconduct of the Provider Institution.

9. The Provider Institution makes no representation and gives no warranty of any kind, either express or implied, including but not limited to warranties of accuracy or fitness for a particular purpose, or that the use of the Data will not infringe any patent, copyright, trademark or other proprietary rights. The Provider Institution will not be liable to the Recipient Institution for any loss arising from any reliance placed on the Data by the Recipient Institution.

10. Nothing in this Agreement limits or excludes either party's liability for (a) death or personal injury resulting from negligence; or (b) any fraud or for any sort of other liability which, by law, cannot be limited or excluded.

11. 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.

12. The Data is provided, and the Research is undertaken in pursuit of public interest, scientific, statistical or historical research purposes. The Provider Institution acknowledges that the results of the Research (including, but not limited to, the Genes and Health BioResource and Output Data) shall belong to the Recipient Institution (except to the extent the results incorporate or include Data), and that the Recipient Institution may seek to publish the results of the Research. The Recipient Institution shall procure that in relation to any publication reporting on the use of the Data, the Recipient Scientist acknowledges the Provider Institution as the source of the Data in the publication and acknowledges the funder that funded the collection and compilation of the Data. . The Recipient Institution shall not publish any confidential or proprietary information belonging to the Provider Institution without its prior written consent, and in no event shall any Data comprising personal data be published. Confidential and proprietary information shall be deemed to include information which was described as such at the point of disclosure and/or was marked as either "confidential" or "proprietary". The confidentiality obligations in this clause shall not apply where the confidential or proprietary information:

    a) has become public knowledge, other than through an unauthorised disclosure by the Recipient Institution;

    b) was already known to the Recipient Institution, prior to disclosure by the Provider Institution;

    c) was disclosed to the Recipient Institution or the Recipient Scientist by a third party, whom to the Recipient Institution's knowledge, was not under any obligation of confidence to the Provider Institution;

    d) was released from confidential status by written authorisation of the Provider Institution; or

    e) is required to be disclosed by law or by requirement of a regulatory body or court order.

13. Save to the extent necessary for the purposes of the Research, nothing in this Agreement grants the Recipient Institution any rights over the Data or under any patents, nor any right to use, or permit the use of, any products or processes containing the Data for any profit-making or commercial purposes ("Commercial Use"). Should the Recipient Institution wish to make Commercial Use of the Data and should the Provider Institution be willing and

able to grant a licence for such purposes, the Parties shall negotiate in good faith to agree an appropriate licence or revenue sharing agreement on fair and reasonable terms.

14. Nothing in this Agreement shall prevent or impede the Provider Institution from being able to use the Data for any purpose, including but not limited to sharing and licensing of the Data to third parties, whether public, private or third sector, for any purpose.

15. 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 assignment that the assignee undertakes to perform all outstanding obligations of the assignor as though the assignee had been an original party hereto.

16. This Agreement shall be effective from the last date of signature and shall continue in force until the conclusion of the Genes and Health Research programme. The term of this Agreement may be extended by the mutual written agreement of both Parties signed by their authorised signatories.

17. The Provider Institution may terminate this Agreement if the Recipient Institution is in breach of any of the terms of this Agreement and, where the breach is capable of remedy, the Recipient Institution has failed to remedy the same within twenty-eight (28) calendar days of service of a written notice from the Provider Institution specifying the breach and requiring it to be remedied.

18. Any provision of this agreement that expressly or by implication is intended to come into or continue in force on or after termination of this Agreement, including the Recipient Institution's obligations under sub-clause 4(g), shall remain in full force and effect.

19. The Data is provided at no cost.

20. The Parties shall procure that in carrying out their obligations under this Agreement, they will comply with all applicable laws, regulations and statutes, including those relating to modern slavery and anti-bribery and the Data Protection Laws. Non-compliance with this clause by a Party shall not be sufficient justification for another Party not to comply with its obligations under this Agreement.

21. A person who is not a party to this Agreement shall not have any rights under or in connection with it.

22. Notices

The Provider Institution's representative for the purpose of receiving notices shall until further notice be:

Karin Albani
Associate Director of Research
East London NHS Foundation Trust
Research Office
Newham Centre for Mental Health
London E13 8SP
Tel: 020 7540 4380 x2318
Email: karin.albani1@nhs.net

The Recipient Institution's representative for the purpose of receiving notices shall until further notice be:

Contracts Manager
Queen Mary University of London
JRMO
5 Walden Street
London E1 2EF

23. This Agreement constitutes the entire agreement between the parties in respect of its subject matter and no statements or representations made by any Party have been relied upon by the other in entering into this Agreement.

24. This Agreement shall be governed and construed in accordance with the laws of England and Wales and the Parties agree to the exclusive jurisdiction of the English Courts.

25. This Agreement may be executed in one (1) 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.

IN WITNESS WHEREOF this Agreement is executed as follows:

for and on behalf of East London NHS Foundation Trust

Signed: CA Kitchener

Name: Chris Kitchener

Title: Data Protection Officer

Dated: 21.11.2019

for and on behalf of Queen Mary, University of London

Signed: C Colechin

Name: Coleen Colechin

Title: Clinical Operations Manager

Dated: 28-11-19

I, the Recipient Scientist, have read and understood the terms of this Agreement:

Signed: David Van Heer

Name: DAVID VAN HEER

Dated: 23 NOV 2019

Schedule 1

The Research

We request access to the Requested Data for biomedical research. All volunteers have given individual written consent for health data access for the duration of the study.

Genes & Health (local name East London Genes & Health) is a long-term population-based study (40,305 volunteers at 22 July 2019)) of British-Bangladeshi and -Pakistani volunteers aged 16+ years in east London with linked genomic and multi-source e-health record data, with ability to invite volunteers for recall for further research. ELGH is currently funded by MRC, NIHR, HEFCE-Catalyst, and Wellcome to recruit 100,000 volunteers by 2023. It is a resource enabling many scientific questions, with priority areas of diabetes, cardiovascular disease and mental health research.

Many volunteers have had contact with East London NHS Foundation Trust services. Mental health (including psychiatry and neurology) is a community prioritized area for Genes & Health research. We have an active collaborative 'Brain Consortium' of academic researchers including senior clinical researchers at East London NHS Foundation Trust.

Our website (www.genesandhealth.org, twitter @eastlondongenes and Cohort Profile (https://www.biorxiv.org/content/10.1101/426163v2) describes the study in much greater depth, and describes our existing health record data linkages using volunteers' NHS numbers. We have valid NHS numbers on >98% of volunteers. We have already accessed primary care NHS data from 4 inner East London CCGs, Bradford (for Bradford Genes & Health) and secondary care NHS data from Barts Health NHS Trust.

Data will be stored and processed at 1. Queen Mary University of London, 2. Data safe haven with export controls (bring researchers to the data model), currently UKSERP (Health Data Research UK Swansea), Data Controlled by Queen Mary University of London.

Schedule 2

The Data

Details of dataset / extracts being shared:	The Recipient Institution will provide the Provider Institution with a list of NHS numbers or pseudonymised NHS numbers of Genes & Health volunteers for which data will be extracted. All available SNOMED codes, ICD codes, or other clinical coding systems, on Genes & Health volunteers, lifelong where available. Radiology, pathology (including blood test) results, to be specified at a later date. E-prescribing information, to be specified at a later date. Sex, date of birth. This data will only be used for checking versus existing Genes & Health data as a data quality control measure.
Format in which Data will be supplied:	By encrypted USB stick; or by direct nhs.net to nhs.net nhsmail transfer of password encrypted files. As comma delimited (.csv) or tab delimited plain text files. Intermittent full datafreezes, not deltas.