NHS
Health Research Authority

East of England - Cambridge Central Research Ethics Committee
Royal Standard Place
Nottingham
NG1 6FS

23 April 2020

Professor Sir Mark Caulfield
Genomics England
The Heart Centre, William Harvey Research Institute
Queen Mary University of London
Charterhouse Square, London
Charterhouse Square
London
EC1M 6BQ

Dear Professor Sir Caulfield

Title of the Research Tissue Bank:	**National Genomic Research Library - Protocol v5.1**
REC reference:	**20/EE/0035**
Designated Individual:	
IRAS project ID:	**278318**

The Research Ethics Committee reviewed the above application at the meeting held on 17 April 2020. Thank you for attending by telephone with Professor Christine Patch and Ms Fiona Maleady-Crowe to discuss the application.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research tissue bank on the basis described in the application form and supporting documentation, subject to the conditions specified below.

The Committee has also confirmed that the favourable ethical opinion applies to all research projects conducted in the UK using tissue or data supplied by the tissue bank, provided that the release of the tissue or data complies with the attached conditions. It will not be necessary for these researchers to make project-based applications for ethical approval. They will be deemed to have ethical approval from this committee. You should provide the researcher with a copy of this letter as confirmation of this. The Committee should be notified of all projects receiving tissue and data from the tissue bank by means of an annual report.

This application was for the renewal of a Research Tissue Bank application. The previous REC Reference number for this application was 14/EE/1112.

Mental Capacity Act 2005

I confirm that the Committee has approved this research project for the purposes of the Mental Capacity Act 2005. The Committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the Research Tissue Bank.

Research governance

Under the UK Policy Framework for Health and Social Care Research, there is no requirement for NHS research permission for the establishment of research tissue banks in the NHS. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the research tissue bank.

Research permission is also not required by collaborators at tissue collection centres (TCCs) who provide tissue or data under the terms of a supply agreement between the organisation and the research tissue bank. TCCs are not research sites for the purposes of the RGF.

Research tissue bank managers are advised to provide R&D offices at all TCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All TCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using tissue or data supplied by the research tissue bank must apply for permission to R&D offices at all organisations where the research is conducted, whether or not the research tissue bank has ethical approval.

Assessment of site suitability is not a requirement for ethical review of research tissue banks.

Registration of Research Tissue Banks

It is a condition of the ethical approval that all Research Tissue Banks are registered on the UK Clinical Research Collaboration (UKCRC) Tissue Directory. The Research Tissue Bank should be registered no later than 6 weeks after the date of this favourable ethical opinion letter or 6 weeks after the Research Tissue Bank holds tissue with the intention to provide for research purposes. Please use the following link to register the Research Tissue Bank on the UKCRC Directory: https://directory.biobankinguk.org/Register/Biobank Registration is defined as having added details of the types of tissue samples held in the tissue bank.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment or when submitting an annual progress report. We will monitor the registration details as part of the annual progress reporting process.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

Duration of ethical opinion

The favourable opinion has been renewed for five years from the end of the previous five year period provided that you comply with the standard conditions of ethical approval for Research Tissue Banks set out in the attached document. You are advised to study the conditions carefully. The opinion may be renewed for a further period of up to five years on receipt of a

fresh application. It is suggested that the fresh application is made 3-6 months before the 5 years expires, to ensure continuous approval for the research tissue bank.

Research Tissue Bank Renewals

The previous five year period ran from 19 February 2015 to 18 February 2020.

This Research Tissue Bank may be renewed for further periods of five years at a time by following the process described in the above paragraph.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper		
Human Tissue Authority licence	Final 1.4	08 October 2014
Other [Annual Report to Tissue Bank]		
Other [Young Persons Assent Form - v2.0]	2	12 June 2019
Other [Consultee declaration regarding whole genome sequencing v2.0]	2	12 June 2019
Other [Withdrawal from the research library v2.0]	2	12 June 2019
Other [Record of Discussion regarding the inclusion of a deceased person in the National Genomic Research Library v1.0]	1	12 June 2019
Other [Digital application for recording patient choice - screenshots]	1	12 June 2019
Other [Pre-Validation Queries]		
Other [Prof Mark Caulfield short CV]		08 January 2020
Participant consent form [Record of discussion regarding whole genome sequencing - v2.0]	2	12 June 2019
Participant information sheet (PIS) [Research Supporting Information v1.0]	v1.0	12 June 2019
Protocol for management of the tissue bank [National Genomic Research Library - Protocol 5.1]	5.1	09 January 2020
Protocol for management of the tissue bank [National Genomic Research Library - Protocol v5.1 tracked version]	5.1	09 January 2020
REC Application Form [RTB_Form_13022020]		13 February 2020

Licence from the Human Tissue Authority

Thank you for providing a copy of the above licence.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review: Reporting requirements

The attached standard conditions give detailed guidance on reporting requirements for research tissue banks with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 278318	**Please quote this number on all correspondence**

Yours sincerely

pp

Miss Stephanie Ellis BEM
Chair

E-mail: cambridgecentral.rec@hra.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

(RTB) Conditions of Approval

East of England - Cambridge Central Research Ethics Committee

Attendance at Committee meeting on 17 April 2020

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Gusztav Belteki	Consultant Neonatologist	No	
Mr Andrew Bush	Director	Yes	
Dr Joseph Cheriyan	Consultant Physician	No	
Ms Anita Chhabra	Clinical Trials Pharmacist	No	
Miss Stephanie Ellis BEM	n/a (retired civil servant)	Yes	
Revd Dr Derek Fraser	Chaplain	Yes	
Dr James Goodman	Registrar in clinical pharmacology and general medicine	No	
Mr David Lewin	Retired Research Officer	Yes	
Mr Anthony Lockett	Medical Director	Yes	
Miss Katarzyna Madej	Pharmacist Clinical Trials Dispensery	No	
Ms Moira Malfroy	Retired Senior Research Nurse/Clinical Trial Manager	Yes	
Professor John Marriott	Pharmaceutical Chemist/Academic Pharmacist	Yes	
Professor Sumantra Ray	Senior Medical Advisor/Scientist	Yes	
Mrs Caroline Saunders	Nurse	No	
Dr Mary-Beth Sherwood	Research Governance Assistant	Yes	
Dr Traiani Stari	Associate Director - Biostatistics	Yes	
Dr Thomas Edward Woodcock	Retired Consultant - Intensive Care Unit	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Mark Sidaway	Approvals Specialist
Ms Ellen Swainston	Approvals Officer