Health Research Authority
NRES Committee East of England - Cambridge South
The Old Chapel
Royal Standard Place
Nottingham
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Telephone: 0115 8839428

19 February 2015

Professor 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 Caulfield

Title of the Research Tissue Bank:	**100,000 Genomes Project Bioresource - main phase Protocol v1.0**
REC reference:	**14/EE/1112**
Applicant	**Professor Mark Caulfield**
IRAS project ID:	**166046**

Thank you for your letter of 9 February 2015 responding to the Committee's request for further information on the above research tissue bank and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Ms Penelope Gregory, nrescommittee.eastofengland-cambridgesouth@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion of the above research tissue bank on the basis described in the application form and supporting documentation as revised.

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 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 this tissue bank by means of an annual report.

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.

Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter and 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.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [Prof M Caulfield Short C.V.]	2014 version	
Covering letter on headed paper [Response to Provisional Opinion from Genomics England]		20 January 2015
IRAS Checklist XML [Checklist_17102014]		17 October 2014
IRAS Checklist XML [Checklist_22012015]		22 January 2015
IRAS Checklist XML [Checklist_13022015]		13 February 2015
IRAS Checklist XML [Checklist_16022015]		16 February 2015
IRAS Checklist XML [Checklist_19022015]		19 February 2015
Other [Peer Review Summary v 1.0]		17 October 2014
Other [Gold et al, Poster for ASHG 21 Oct 2014]		17 October 2014
Other [King et al, JAMA 2014]		17 October 2014
Other [Copy of Conditions listed in the Phenomenizer database featuring intellectual disability]		17 October 2014
Other [Conditions listed in London Dysmorphology database in which intellectual disability/developmental delay is a feature]		17 October 2014
Other [Conditions listed in Baraitser-Winter Neurogenetics database featuring mental retardation]		17 October 2014
Other [HTA and HRA letter re 100,000 Genomes Project- Non Research v 1.4]		17 October 2014

Other [Data Access and Acceptable Uses Policy]		17 October 2014
Other [Letter from Department of Health to Professor Caulfield regarding post-2017 arrangements]		17 October 2014
Other [Professor Mark Caulfield Short C.V.]		17 October 2014
Other [Personal Consultee Information Sheet Cancer v 2.2.]	2.2	11 February 2015
Other [Personal Consultee Information Sheet Rare Diseases v 2.2]	2.2	11 February 2015
Other [4a) Personal Consultee Declaration Form v 2.2]	2.2	11 February 2015
Other [4b) Personal Consultee Declaration Form Rare Diseases v 2.2]	2.2	11 February 2015
Other	n/a but to accompany v2.0 100,000 Genomes Project	11 February 2015
Other [Electronic Signature for Prof Caulfield to accompany REC submission 20 Jan 2015]	n/a	20 January 2015
Participant consent form [3a) CF for Proband Adult with Cancer]	v 2.0	20 January 2015
Participant consent form [For patients with a rare genetic disease and their adult releatives]	v 2.0	20 January 2015
Participant consent form [For parents of patients with rare genetic disease]	v 2.0	20 January 2015
Participant consent form [For parents of a (deceased) child with a rare genetic disease]	v 2.0	20 January 2015
Participant consent form [Nominated respresentatives, relatives or friends of a deceased adult with a rare genetic disease]	v 2.0	20 January 2015
Participant consent form [Assent form for children and young people aged 6 - 15 years]	v 2.0	20 January 2015
Participant consent form [Withdrawal information - for adults or child participants]	v 2.0	20 January 2015
Participant consent form [Consultee declaration of advice regarding adult participant withdrawal information]	v 2.0	20 January 2015
Participant information sheet (PIS) [For adult patients with cancer (or suspected cancer)]	v 2.0	20 January 2015
Participant information sheet (PIS) [For adult patients with rare genetic diseases]	v 2.0	20 January 2015
Participant information sheet (PIS) [PIS for children aged 6 - 10 years]	v 2.0	20 January 2015
Participant information sheet (PIS) [Information for young people aged 11 - 15 years]	v 2.0	20 January 2015
Participant information sheet (PIS) [Index to Participant Literature]	n/a but to accompany v2.0 100,000 Genomes Project	20 January 2015
Participant information sheet (PIS) [For parents of a child with a rare genetic disease]	v 2.0	20 January 2015
Participant information sheet (PIS) [For parents of a (deceased) child with a rare genetic disease]	v 2.0	20 January 2015
Participant information sheet (PIS) [For families of patients with rare genetic diseases]	v 2.0	20 January 2015
Participant information sheet (PIS) [For the nominated	v 2.0	20 January 2015

representatives, relatives or a friends of a deceased adult with a rare genetic disease]		
Protocol for management of the tissue bank [100,000 Genomes Project Protocol FINAL v 2.0]	2.0	20 January 2015
REC Application Form [RTB_Form_22012015]		22 January 2015
Summary of research programme(s) [Prof Caulfield Electronic Signature]	n/a	16 October 2014

Research governance

Under the Research Governance Framework (RGF), 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 a 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.

Site-specific assessment (SSA) is not a requirement for ethical review of research tissue banks.

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

<u>Reporting requirements</u>

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 HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

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 Training

We are pleased to welcome researchers and R&D staff at our training days – see details at
http://www.hra.nhs.uk/hra-training/

14/EE/1112	**Please quote this number on all correspondence**

Yours sincerely

Dr Leslie Gelling
Chair

E-mail: nrescommittee.eastofengland-cambridgesouth@nhs.net

Enclosures: *Standard approval conditions [SL-AC3]*

Copy to: *Laura Riley, Genomics England*