



# Health Research Authority

## East of England - Essex Research Ethics Committee

The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

28 May 2020

Miss Tolu Osunnuyi  
Cambridge University Hospitals NHS Foundation Trust and the University Of Cambridge  
Biorepository  
MRC Epidemiology Unit  
Level 2, F&G block Addenbrookes Hospital  
CB2 0QQ

Dear Miss Osunnuyi

|   |                                  |
|---|----------------------------------|
| <b>Title of the Research Tissue Bank:</b> | <b>PAH-ICON Consortium</b>       |
| <b>REC reference:</b>                     | <b>20/EE/0087</b>                |
| <b>Designated Individual:</b>             | <b>Dr Mercedes Jimenez-Linan</b> |
| <b>IRAS project ID:</b>                   | <b>269603</b>                    |

Thank you for your correspondence, 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 the Chair.

### **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.

**You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the Research Tissue Bank, which can be made available to host**

**organisations to facilitate their permission for the Research Tissue Bank. Failure to provide the final versions to the REC may cause delay in obtaining permissions.**

## **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 is given for a period of five years from the date of this 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:

| <i>Document</i>                                       | <i>Version</i> | <i>Date</i>      |
|---|----------------|------------------|
| Covering letter on headed paper [REC letter]          |                | 26 February 2020 |
| Other [Tissue Bank Funding]                           |                |                  |
| Other [Insurance Confirmation]                        |                | 23 January 2020  |
| Other [CV ]   |                | 26 February 2020 |
| Other [Provisional Ethical Review Response]           | 1              | 05 May 2020      |
| Participant consent form [Patient consent form]       | 8.1            | 31 July 2019     |
| Participant information sheet (PIS) [Patient PIS]     | 8.1            | 31 July 2019     |
| Protocol for management of the tissue bank [Protocol] | 1              | 23 August 2019   |
| REC Application Form [RTB_Form_26022020]              |                | 26 February 2020 |

## **Licence from the Human Tissue Authority**

Tissue banks must obtain a licence from the Human Tissue Authority for the storage and use of human tissue for research purposes. Please provide the Committee with a copy of the licence once it is available.

## **Research governance**

You are advised to check the requirements for approval of the research tissue bank with your R&D office.

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 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.

## **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 annual progress report form. We will monitor the registration details as part of the annual progress reporting process.

## **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 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 Learning**

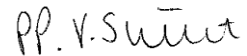
We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:

<https://www.hra.nhs.uk/planning-and-improving-research/learning/>

**IRAS project ID: 269603**

**Please quote this number on all correspondence**

Yours sincerely



**Dr Niki Bannister**  
**Chair**

E-mail: Essex.REC@hra.nhs.uk

Enclosures: (RTB) Conditions of Approval

Copy to: Dr Mercedes Jimenez-Linan, Cambridge University Hospitals NHS  
Foundation Trust