

Lothian NHS Board

**South East Scotland Research
Ethics Committee 02**

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Date 1 June 2020
Your Ref
Our Ref

Enquiries to :
Extension:
Direct Line:
Email:

29 April 2020

Professor
University of Dundee
Laboratory Block, Level 5
Ninewells Hospital
Dundee, Scotland
DD1 9SY

Dear Professor

Title of the Research Tissue Bank: SHARE: Scottish Health Research Register and Biobank

REC reference: 20/SS/0048

Designated Individual:

IRAS project ID: 278610

The Research Ethics Committee reviewed the above application at the meeting held on 22 April 2020. Thank you for attending 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.

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 is given for a period of five years from the date of this letter 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 [SHARE and Biobank Covering Letter]		06 April 2020
Participant consent form [SHARE Adult Consent Form]	1	06 April 2020
Participant consent form [SHARE Young Persons Consent Form]	1	06 April 2020
Participant information sheet (PIS) [SHARE PIL]	1	06 April 2020
Protocol for management of the tissue bank [SHARE and Biobank Protocol]	1	06 April 2020
REC Application Form [RTB_Form_07042020]		07 April 2020
Summary of research programme(s) [SHARE and Biobank Summary]	1	06 April 2020

Licence from the Human Tissue Authority (not applicable for this study)

If appropriate tissue banks must obtain a licence from the Human Tissue Authority for the storage and use of human tissue for research purposes.

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: 278610

Please quote this number on all correspondence

Yours sincerely

Mr Chair

E-mail:

Enclosures:

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

(RTB) Conditions of Approval

Copy to:

