



Health Research  
Authority

**North West - Haydock Research Ethics Committee**

3rd Floor - Barlow House  
4 Minshull Street  
Manchester  
M1 3DZ

20 February 2020

Dr Jane C Steele  
University of Birmingham  
College of Medical and Dental Sciences  
Edgbaston  
Birmingham  
B15 2TT

Dear Dr Steele

**Title of the Research Tissue Bank:** Human Biomaterials Resource Centre  
**REC reference:** 20/NW/0001  
**Designated Individual:** Professor Stefan Hubscher  
**IRAS project ID:** 276525

The Research Ethics Committee reviewed the above application at the meeting held on 11 February 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.

This application was for the renewal of a Research Tissue Bank application. The previous REC Reference number for this application was 15/NW/0079.

**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 27 February 2015 to 27 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Human Tissue Authority licence [HTA research licence 12358]	N/A	29 March 2016
Other [Curriculum Vitae]	N/A	24 November 2019
Other [Healthy Volunteer screening questionnaire]	1.0	25 November 2019
Other [DVT patients questionnaire]	N/A	25 November 2019
Other [Annual progress report inc. sample requests, collection and release]		20 December 2019
Participant consent form [Adult Patient consent form]	1.0	25 November 2019
Participant consent form [Healthy Volunteer consent form]	1.0	25 November 2019
Participant consent form [Neurodegenerative Disorders consent form]	1.0	25 November 2019
Participant consent form [Nominated Consultee declaration]	1.0	25 November 2019
Participant consent form [Parent Child consent form]	1.0	25 November 2019
Participant consent form [Personal Consultee consent form]	1.0	25 November 2019
Participant consent form [Placenta, Cord and Cord Blood consent form]	1.0	25 November 2019
Participant consent form [UHBFT Consent Form for Investigation or Treatment]	1.0	25 November 2019
Participant information sheet (PIS) [Adult Patient information sheet]	1.0	25 November 2019
Participant information sheet (PIS) [Children under 8 years old information sheet]	1.0	25 November 2019
Participant information sheet (PIS) [Children 8-12 years information sheet]	1.0	25 November 2019
Participant information sheet (PIS) [Children over 13 years information sheet]	1.0	25 November 2019
Participant information sheet (PIS) [Healthy Volunteer information sheet]	1.0	25 November 2019
Participant information sheet (PIS) [Neurodegenerative disorders information sheet]	1.0	25 November 2019
Participant information sheet (PIS) [Nominated Consultee information sheet]	1.0	25 November 2019
Participant information sheet (PIS) [Parent information sheet]	1.0	25 November 2019

Participant information sheet (PIS) [Personal Consultee information sheet]	1.0	25 November 2019
Participant information sheet (PIS) [Placenta, Cord and Cord Blood information sheet]	1.0	25 November 2019
Protocol for management of the tissue bank [HBRC Protocol]	1.0	25 November 2019
REC Application Form [RTB_Form_26112019]		26 November 2019
Relative information sheet [Donor Family information sheet]	1.0	25 November 2019

## 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:

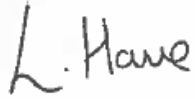
<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

## 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/>

Yours sincerely

A handwritten signature in black ink that reads "L. Howe". The signature is written in a cursive style with a large initial "L" and a smaller "H" and "O" following.

Laura Howe  
Approvals Officer

On behalf of

**Dr Tim S Sprosen**  
**Chair**

E-mail: [haydock.rec@hra.nhs.uk](mailto:haydock.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

Copy to: Professor Stefan Hubscher, University of Birmingham

## North West - Haydock Research Ethics Committee

Attendance at Committee meeting on 11 February 2020

### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>
Mr John Bridson	Clinical Ethicist	Yes
Miss Isabelle Butcher	PhD Researcher	Yes
Mr Stephen Edgar	Designer	Yes
Mrs Lesley France	Statistician	Yes
Mrs Susan Graves	Quality Complaints Co-ordinator	Yes
Mr Simon Hill	Pharmacist	No
Dr Ezzat Kozman	Consultant Gynaecologist	Yes
Mr Charles Otim	Research Support Officer	Yes
Dr David Pilling	Consultant Radiologist	Yes
Miss Anna Sekula - BREAK IN SERVICE	Nurse	No
Dr Tim S Sprosen	REC Chair - Epidemiologist	Yes