Health Research Authority
National Research Ethics Service

NRES Committee North West - Haydock
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27 February 2015

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:	**15/NW/0079**
Designated Individual:	**Professor Jonathan Frampton**
IRAS project ID:	**171283**

Thank you for your submission 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 and the Second Reviewer.

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 Rachel Katzenellenbogen, nrescommittee.northwest-haydock@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*
Human Tissue Authority licence [HTA research licence 12358]	N/A	19 December 2012
Other [Appendix 1. HTA licence 12358 structure]	1.0	12 January 2015
Other [Appendix 2. ATF governance structure]	1.0	12 January 2015
Other [Health Screening Questionnaire]	1.0	12 January 2015
Other [Appendix 3. ATF Management Committee. Membership and TOR]	1.0	12 January 2015
Other [January 2015. Annual report form]		21 January 2015
Other [January 2015. Summary of sample collection and release]		21 January 2015
Other [Annual Report: Applications for release of samples]		21 January 2015
Other [Appendix 1. HTA licence 12358 structure]	N/A	21 January 2015
Other [Appendix 2. ATF governance structure]	N/A	21 January 2015
Other [Health Screening Questionnaire]	N/A	21 January 2015
Other [Appendix 3. ATF Management Committee. Membership and TOR]	N/A	21 January 2015
Other [January 2015. Annual report form]	N/A	21 January 2015
Other [January 2015. Summary of sample collection and release]	N/A	21 January 2015

Participant consent form [UHBFT Consent For Investigation Or Treatment]	N/A	
Participant consent form [Adult Patient Consent Form with tracked changes]	2.0	20 February 2015
Participant consent form [Adult Patient Consent Form clean]	2.0	20 February 2015
Participant consent form [Healthy Volunteer Consent Form with tracked changes]	2.0	20 February 2015
Participant consent form [Healthy Volunteer Consent Form clean]	2.0	20 February 2015
Participant consent form [Parent/Child Consent Form with tracked changes]	2.0	20 February 2015
Participant consent form [Parent/Child Consent Form clean]	2.0	20 February 2015
Participant consent form [Consent Form for Patients with Neurodegenerative Disorders with tracked changes]	2.0	20 February 2015
Participant consent form [Consent Form for Patients with Neurodegenerative Disorders clean]	2.0	20 February 2015
Participant consent form [Personal Consultee Declaration with tracked changes]	2.0	20 February 2015
Participant consent form [Personal Consultee Declaration clean]	2.0	20 February 2015
Participant consent form [Nominated Consultee Declaration with tracked changes]	2.0	20 February 2015
Participant consent form [Nominated Consultee Declaration clean]	2.0	20 February 2015
Participant consent form [Consent Form for the Donation of Placenta, Umbilical Cord and Umbilical Cord Blood with tracked changes]	2.0	20 February 2015
Participant consent form [Consent Form for the Donation of Placenta, Umbilical Cord and Umbilical Cord Blood clean]	2.0	20 February 2015
Participant information sheet (PIS) [Adult Patient Information Sheet]	1.0	12 January 2015
Participant information sheet (PIS) [Healthy Volunteer Information Sheet]	1.0	12 January 2015
Participant information sheet (PIS) [Parent Information Sheet]	1.0	12 January 2015
Participant information sheet (PIS) [Information Sheet for Patients with Neurodegenerative Disorders]	1.0	12 January 2015
Participant information sheet (PIS) [Personal Consultee Information Sheet]	1.0	12 January 2015
Participant information sheet (PIS) [Nominated Consultee Information Sheet]	1.0	12 January 2015
Participant information sheet (PIS) [Child Information Sheet (under 8 years old) with tracked changes]	2.0	20 February 2015
Participant information sheet (PIS) [Child Information Sheet (under 8 years old) clean]	2.0	20 February 2015
Participant information sheet (PIS) [Child Information Sheet (8 - 12 years old) with tracked changes]	2.0	20 February 2015
Participant information sheet (PIS) [Child Information Sheet (8 - 12 years old) clean]	2.0	20 February 2015
Participant information sheet (PIS) [Child Information Sheet (over 13 years old) with tracked changes]	2.0	20 February 2015
Participant information sheet (PIS) [Child Information Sheet (over 13 years old) clean]	2.0	20 February 2015
Participant information sheet (PIS) [Information Sheet for the Donation of Placenta, Umbilical Cord and Umbilical Cord Blood with tracked changes]	2.0	20 February 2015

Participant information sheet (PIS) [Information Sheet for the Donation of Placenta, Umbilical Cord and Umbilical Cord Blood clean]	2.0	20 February 2015
Protocol for management of the tissue bank [HBRC Protocol]	1.0	12 January 2015
REC Application Form		13 January 2015
Relative information sheet [Donor Family Information Sheet]	1.0	12 January 2015

Licence from the Human Tissue Authority

Thank you for providing a copy of the above licence.

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/

15/NW/0079	**Please quote this number on all correspondence**

Yours sincerely

On behalf of
Dr Tim S Sprosen
Chair

E-mail: nrescommittee.northwest-haydock@nhs.net

Enclosures: Standard approval conditions

Copy to: Professor Jonathan Frampton, University of Birmingham