

North West 5 Research Ethics Committee - Haydock Park

North West Centre for Research Ethics Committees
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28 April 2010

Dr Jane C Steele
Director, Human Biomaterials Resource Centre
College Medical & Dental Sciences
University of Birmingham
Edgbaston
Birmingham B15 2TT

Dear Dr Steele

Title of the Research Tissue Bank: **University of Birmingham Human Biomaterials Resource Centre**
REC reference: **09/H1010/75**
Designated Individual: **Professor Lawrence S Young**

Thank you for your letter of 19 April 2010, 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 (Dr Donal Manning – Consultant Paediatrician).

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.

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 conditions 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: From Dr Jane C Steele		02 November 2009
REC application	IRAS Version 2.5	02 November 2009
Human Tissue Authority Licence: Licensing Number: 12358		11 June 2008
Response to Request for Further Information: From: Dr Jane C Steele		03 March 2010
Protocol for Management of the Tissue Bank	2	03 March 2010
Participant Information Sheet: Taking part in research at University Hospitals Birmingham	2	03 March 2010
Participant Information Sheet: Donation of Human Tissue for Research	2	03 March 2010
Participant Consent Form: Donation of Human Tissue for Research	2	03 March 2010
Participant Information Sheet: Donation of Placenta, Umbilical Cord and Cord Blood for Research	2	03 March 2010
Participant Consent Form: Donation of Placenta, Umbilical Cord and Cord Blood for Research	2	03 March 2010
Response to Request for Further Information: From Dr Jane C Steele		19 April 2010
Participant Consent Form: CF#1; Participant Consent Form: Patient Agreement to Investigation or Treatment	3	19 April 2010
Letter to Dr Jane C Steele from Mr Bob Hibberd, Head of Governance, University Hospitals Birmingham NHS Foundation Trust		14 April 2010

Licence from the Human Tissue Authority

Thank you for providing a copy of the above licence.

Research governance

A copy of this letter is being sent to the R&D office responsible for for University Hospital Birmingham NHS Foundation Trust. You are advised to check their requirements for approval of the research tissue bank.

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. There is no need to inform Local Research Ethics Committees.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

Here you will find links to the following:

- a) Providing feedback. You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
- b) Annual Reports. Please refer to the attached conditions of approval.
- c) Amendments. Please refer to the attached conditions of approval.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email:

referencegroup@nres.npsa.nhs.uk

09/H1010/75

Please quote this number on all correspondence

Yours sincerely

Dr Donal Manning
Chair

E-mail: noel.graham@northwest.nhs.uk

Enclosures: Standard approval conditions

Copy to: R&D office for NHS care organisation: -

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