

North West - Haydock Research Ethics Committee

2 Redman Place
Stratford
London
E20 1JQ

07 March 2025

Dr Gareth Bicknell
College of Medicine and Health
College of Medicine and Health
University of Birmingham
Edgbaston, Birmingham
B15 2TT

Dear Dr Bicknell

Title of the Research Tissue Bank: Human Biomaterials Resource Centre (Third
Renewal)
REC reference: 25/NW/0013
Designated Individual: Professor Christopher McCabe
IRAS project ID: 351758

Thank you for your letter of 06 March 2025, 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 a member of staff.

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 (England and Wales)

I confirm that the Committee has approved this Research Tissue Bank 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 Research Tissue Bank on, or in relation to, a person who lacks capacity to consent to taking part.

Mental Capacity Act (Northern Ireland) 2016

The Committee approved this research project for the purposes of the Mental Capacity Act (Northern Ireland) 2016. The Committee is satisfied that the requirements of Part 8 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.

Extract from the minutes

'Relevance of the research to the impairing condition

The Committee agreed the research was connected with an impairing condition affecting persons lacking capacity or with the treatment of the condition.

Justification for including adults lacking capacity to meet the research objectives

The Committee agreed the research could not be carried out as effectively if it was confined to participants able to give consent.

Arrangements for appointing consultees

The Committee considered the arrangements set out in the application for appointing consultees under Section 32 of the Mental Capacity Act 2005 (England and Wales) and the equivalent Section 135 of the Mental Capacity Act (Northern Ireland) 2016) to advise on whether participants lacking capacity should take part and on what their wishes and feelings would have likely to have been if they had capacity.

After discussion and revision to the requested documents the Committee agreed that reasonable arrangements were in place for appointing consultees.

Balance between benefit and risk, burden and intrusion

The Committee noted that while the research would not benefit participants lacking capacity it is intended to provide knowledge of the causes, treatment or care of their impairing condition or a condition similar to their impairing condition. The Committee agreed that the risk to participants was likely to be negligible and the research would not significantly interfere with their freedom of action or privacy and would not be unduly invasive or restrictive.

Additional safeguards

The Committee was satisfied that reasonable arrangements would be in place to comply with the additional safeguards set out in Section 33 of the Mental Capacity Act 2005 (England and Wales) and the equivalent Section 137 of the Mental Capacity Act (Northern Ireland) 2016).

Information for consultees

The Committee was satisfied that the information to be provided to consultees about the proposed research was adequate to enable consultees to give informed advice about the participation of persons lacking capacity.'

This application was for the renewal of a Research Tissue Bank application. The previous REC Reference number for this application was **20/NW/0001**.

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 [HBRC Third Renewal - Cover Letter]	12/12/2024	12 December 2024
Covering letter on headed paper [HBRC Third Renewal - Cover Letter]	2.0	06 March 2025
Human Tissue Authority licence [HTA Licence 12358]		01 August 2024
Other [HVQ - Healthy Volunteer Questionnaire]	1.0	03 December 2024
Other [HBRC Protocol - Third Renewal (marked up)]	2.0	04 March 2025
Other [NCIS - Nominated Consultee information sheet]	2.0	21 February 2025
Other [NCIS - Nominated Consultee information sheet (marked up)]	2.0	21 February 2025
Other [NCD - Nominated Consultee declaration]	2.0	21 February 2025
Other [NCD - Nominated Consultee declaration (marked up)]	2.0	21 February 2025
Other [CV for Gareth Bicknell]		04 December 2024
Participant consent form [APCF - Adult Patient consent form]	2.0	21 February 2025
Participant consent form [APCF - Adult Patient consent form (marked up)]	2.0	21 February 2025
Participant consent form [RPCCF - Adult Reduced Physical Capacity consent form]	2.0	21 February 2025
Participant consent form [RPCCF - Adult Patient Reduced Physical	2.0	21 February 2025

Capacity consent form (marked up)]		
Participant consent form [IMCF - Adult Interpreter Mediated consent form]	2.0	21 February 2025
Participant consent form [IMCF - Adult Patient Interpreter-Mediated consent form (marked up)]	2.0	21 February 2025
Participant consent form [HVCF - Healthy Volunteer consent form]	2.0	21 February 2025
Participant consent form [HVCF - Healthy Volunteer consent form (marked up)]	2.0	21 February 2025
Participant consent form [PCCF - Parent Child consent form (side by side)]	2.0	21 February 2025
Participant consent form [PCCF - Parent Child consent form side-by-side (marked up)]	2.0	21 February 2025
Participant consent form [EMCF - Adult Expectant Mothers consent form]	2.0	21 February 2025
Participant consent form [EMCF - Expectant Mothers consent form (marked up)]	2.0	21 February 2025
Participant consent form [NDCF - Neurodegenerative Disorders consent form]	2.0	21 February 2025
Participant consent form [NDCF - Neurodegenerative Disorders consent form (marked up)]	2.0	21 February 2025
Participant information sheet (PIS) [APIS - Adult Patient information sheet]	2.0	21 February 2025
Participant information sheet (PIS) [APIS - Adult Patient information sheet (marked up)]	2.0	21 February 2025
Participant information sheet (PIS) [HVIS - Healthy Volunteer information sheet]	2.0	21 February 2025
Participant information sheet (PIS) [HVIS - Healthy Volunteer information sheet (marked up)]	2.0	21 February 2025
Participant information sheet (PIS) [C1317 Children 13-17yo information sheet]	2.0	21 February 2024
Participant information sheet (PIS) [C1317 - Children 13-17 years information sheet (marked up)]	2.0	21 February 2025
Participant information sheet (PIS) [C812 Children 8-12yo information sheet]	2.0	21 February 2025
Participant information sheet (PIS) [C812 - Children 8-12 years information sheet (marked up)]	2.0	21 February 2025
Participant information sheet (PIS) [CU8 Children under 8yo information sheet]	2.0	21 February 2025
Participant information sheet (PIS) [CU8 - Children Under 8 Years information sheet (marked up)]	2.0	21 February 2025
Participant information sheet (PIS) [EMIS - Adult Expectant Mothers information sheet]	2.0	21 February 2025
Participant information sheet (PIS) [EMIS - Expectant Mothers information sheet (marked up)]	2.0	21 February 2025
Participant information sheet (PIS) [NDIS - Neurodegenerative Disorders information sheet]	2.0	21 February 2025
Participant information sheet (PIS) [NDIS - Neurodegenerative	2.0	21 February 2025

Disorders information sheet (marked up)]		
Protocol for management of the tissue bank [HBRC Protocol - Third Renewal]	2.0	04 March 2025
REC Application Form [RTB_Form_13122024]		13 December 2024
Relative consent form [PCD - Personal Consultee declaration]	2.0	21 February 2025
Relative consent form [PCD - Personal Consultee declaration (marked up)]	2.0	21 February 2025
Relative information sheet [PGIS - Parent Guardian information sheet]	2.0	21 February 2025
Relative information sheet [PGIS - Parent Guardian information sheet (marked up)]	2.0	21 February 2025
Relative information sheet [PCIS - Personal Consultee information sheet]	2.0	21 February 2025
Relative information sheet [PCIS - Personal Consultee information sheet (marked up)]	2.0	21 February 2025
Relative information sheet [DFIS - Donor Family information sheet]	2.0	21 February 2025
Relative information sheet [DFIS - Donor Family information sheet (marked up)]	2.0	21 February 2025
Relative information sheet [PMIS - Post-Mortem information sheet]	2.0	21 February 2025
Relative information sheet [PMIS - Post-Mortem information sheet (marked up)]	2.0	21 February 2025
Summary of research programme(s) [Summary of samples collected and released since Feb 2024]	1.0	10 December 2024
Summary of research programme(s) [New applications received since Feb 2024]	1.0	10 December 2024
Summary of research programme(s) [Summary of sample collection and release Feb23-Feb24]	1.0	27 February 2024
Summary of research programme(s) [New applications received Feb23-Feb24]	1.0	27 February 2024
Summary of research programme(s) [Summary of samples collected and released Feb22-Feb23]	1.0	27 February 2023
Summary of research programme(s) [New applications received Feb22-Feb23]	1.0	27 February 2023
Summary of research programme(s) [Summary of samples collected and released Feb21-Feb22]	1.0	25 February 2022
Summary of research programme(s) [New applications received Feb21-Feb22]	1.0	25 February 2022
Summary of research programme(s) [Summary of samples collected and released Feb20-Feb21]	1.0	25 February 2021
Summary of research programme(s) [New applications received Feb20-Feb21]	1.0	25 February 2021

Licence from the Human Tissue Authority

Thank you for providing a copy of the above licence.

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 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.

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.

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. Where a deferral is agreed, [a minimum research summary](#) will still be published in [the research summaries database](#). At the end of the deferral period, we will publish the [full research summary](#).

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/>

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/>

25/NW/0013

Please quote this number on all correspondence

Yours sincerely

Mr Stephan Edgar
Chair

PP. Dan Pygall
Approvals Specialist

E-mail: haydock.rec@hra.nhs.uk

Enclosures: *Standard approval conditions [\[SL-AC3\]](#)*

[Research Tissue Bank – Conditions of Approval](#)

Copy to: *Professor Christopher McCabe, University of Birmingham*