Health Research Authority

North East - Newcastle & North Tyneside 1 Research Ethics Committee
2nd Floor, 2 Redman Place
Stratford
London
E20 1JQ

Telephone: 0207 104 8241

14 July 2023

Prof Deborah J Henderson
Newcastle University
Newcastle University Biosciences Institute
International Centre for Life
Times Square
NE1 3BZ

Dear Prof Henderson

Title of the Research Tissue Bank:	**The Human Developmental Biology Resource 2023**
REC reference:	**23/NE/0135**
Designated Individual:	**Dr Chris Morris**
IRAS project ID:	**330783**

The Research Ethics Committee reviewed the above application at the meeting held on 11 July 2023. 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 18/NE/0290.

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/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the HRA with the

registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

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 10/12/2018 to 10/12/2023. 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:

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter]	N/A	15 June 2023
Human Tissue Authority licence [HTA licence 12534]	1	06 July 2016
IRAS Checklist XML [Checklist_22062023]		22 June 2023
Other [HDBR Tissue Access Policy]	1	03 August 2018
Other [HDBR Terms of Reference]	1	03 August 2018
Other [SOP - Recruitment of HDBR donors]	4	15 June 2023
Other [SOP - Collection of consented material]	4	15 June 2023
Other [HDBR Sample Sign Out form]	2	01 February 2018
Other [HDBR Participant Data Questionnaire]	1	03 August 2018
Other [RE annual report 2021]	N/A	12 August 2022
Other [Chief Investigator CV]	N/A	14 June 2023
Other [Ethics amendment to PIS]	N/A	30 September 2021
Other [Overview of HDBR PRES survey results April 2021]	1	30 April 2021
Other [BSACP conference abstract]	N/A	07 October 2021
Participant consent form [F18 Consent Form_V5_2707_2018.pdf]	5	27 July 2018
Participant information sheet (PIS) [F16_HDBR_Participant_Information_Sheet_V7.0_300921]	7	03 August 2018
Protocol for management of the tissue bank [Protcol for management of tissue bank]	1	15 June 2023
REC Application Form [RTB_Form_22062023]		22 June 2023

Summary of research programme(s) [Research Summary]	1	15 June 2023

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

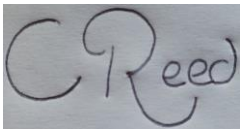
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the 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/

IRAS project ID: 330783	**Please quote this number on all correspondence**

Yours sincerely



PP
Mr Paddy Stevenson
Chair

E-mail: newcastlenorthtyneside1.rec@hra.nhs.uk

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

Research Tissue Bank – Conditions of Approval

Copy to: Dr Chris Morris, Newcastle University

North East - Newcastle & North Tyneside 1 Research Ethics Committee

Attendance at Committee meeting on 11 July 2023

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Chien-Yi Chang	Lecturer	No	
Professor Tim Cheetham	Professor of Clinical Paediatric Endocrinology and Honorary Consultant Paediatrician	No	
Mr Jeremy Dearling	Former Registered Nurse	Yes	
Mrs Emma Ginn	Specialist Pharmacy Officer Quality Assurance	Yes	
Reverend Nigel Goodfellow	Retired Head of Chaplaincy	Yes	
Dr Charles Kelly	Consultant Clinical Oncologist	Yes	
Dr Vrinda Nair	Consultant Neonatologist	Yes	
Mrs Bijal Patel	Research Study Coordinator	No	
Mrs Sue Phillips	Clinical Lead Pharmacist	Yes	
Dr Philip Ryan	Retired Occupational Health Physician	Yes	Chair
Miss Miryam Vermaat	Volunteer	Yes	
Mr Mike Wyatt	Consultant Vascular Surgeon	Yes	

Also in Attendance:

Name	*Position (or reason for attending)*
Ms Nicola Beazley-Long	Approvals Officer
Mr Ali Hussain	Approvals Administrator
Mr z. Mark Sidaway	Approvals Specialist

CONDITIONS OF REC FAVOURABLE OPINION

Research Ethics Committee:	North East - Newcastle & North Tyneside 1 Research Ethics Committee
Research Tissue Bank:	The Human Developmental Biology Resource 2023
REC reference number:	23/NE/0135
Name of applicant:	Prof Deborah J Henderson
Date of approval:	14 July 2023
IRAS project ID:	330783

A REC Favourable Opinion has been given to the Research Tissue Bank ("RTB") by the Research Ethics Committee ("the Committee") subject to the following conditions.

1. <u>Further communications with the Committee</u>

1.1 Further communications with the Committee are the personal responsibility of the applicant.

2. <u>Duration of approval</u>

2.1 Approval is given for a period of 5 years, which may be renewed on consideration of a new application by the Committee, taking account of developments in legislation, policy and guidance in the interim. New applications should include relevant changes of policy or practice made by the RTB, including any substantial amendments approved, since the original approval together with any proposed new developments.

3. <u>Licensing</u>

3.1 A copy of the Licence from the Human Tissue Authority (HTA) should be provided when available (if not already submitted).

3.2 The Committee should be notified if the Authority renews the licence, varies the licensing conditions or revokes the Licence, or of any change of Designated Individual. If the Licence is revoked, the REC favourable opinion would be terminated.

3.3 It is a condition of the REC favourable opinion that all Research Tissue Banks are registered on the UK Clinical Research Collaboration (UKCRC) Tissue Directory

4. Generic ethical approval for projects receiving tissue

4.1 Samples of human tissue or other biological material may be supplied and used in research projects to be conducted in accordance with the following conditions.

4.1.1 The research project should be within the fields of medical or biomedical research described in the approved application form.

4.1.2 The RTB should be satisfied that the research has been subject to scientific critique, is appropriately designed in relation to its objectives and (with the exception of student research below doctoral level) is likely to add something useful to existing knowledge.

4.1.3 Where tissue samples have been donated with informed consent for use in future research ("broad consent"), the RTB should be satisfied that the use of the samples complies with the terms of the donor consent.

4.1.4 All samples and any associated clinical information must be non-identifiable to the researcher at the point of release (i.e. anonymised or linked anonymised).

4.1.5 Samples will not be released to any project requiring further data or tissue from donors or involving any other research procedures. Any contact with donors must be confined to ethically approved arrangements for the feedback of clinically significant information.

4.1.6 A supply agreement must be in place with the researcher to ensure storage, use and disposal of the samples in accordance with the HTA Codes of Practice, the terms of the ethical approval and any other conditions required by the RTB.

4.2 A research project in the UK using tissue provided by a RTB in accordance with these conditions will be considered to have ethical approval from the Committee under the terms of this approval. In England, Wales and Northern Ireland this means that the researcher will not require a licence from the Human Tissue Authority for storage of the tissue for use in relation to this project.

4.3 The RTB may require any researcher to seek specific ethical review for their project. Where this applies an application should be prepared and submitted for ethical review.

4.4 A substantial amendment should be submitted to seek the Committee's agreement to change the conditions of generic approval.

5. Records

5.1 The Bank should maintain a record of all research projects to which tissue has been supplied. The record should contain at least the full title of the project, a summary of its purpose, the name of the Chief Investigator, the sponsor, the location of the research, the date on which the project was approved by the RTB, details of the

tissue released and any relevant reference numbers.

5.2 The Committee may request access to these records at any time.

6. Annual reports

6.1 An annual report should be provided to the Committee listing all projects for which tissue has been released in the previous year. The list should give the full title of each project, the name of the Chief Investigator, the sponsor, the location of the research and the date of approval by the RTB. The report is due on the anniversary of the date on which ethical approval for the RTB was given.

6.2 The Committee may request additional reports on the management of the RTB at any time.

7. Substantial amendments

7.1 Substantial amendments should be notified to the Committee and a favourable ethical opinion obtained before implementing the amendment. A substantial amendment generally means any significant change to the arrangements for the management of the RTB as described in the application to the Committee and supporting documentation.

7.2 A substantial amendment should be generated by accessing the original application form on the Integrated Research Application System (IRAS).

7.3 The following changes should always be notified as substantial amendments:

7.3.1 Any significant change to the policy for use of the tissue in research, including changes to the types of research to be undertaken or supported by the RTB.

7.3.2 Any significant change to the types of biological material to be collected and stored, or the circumstances of collection.

7.3.3 Any significant change to informed consent arrangements, including new/modified information sheets and consent forms.

7.3.4 Request for approval to release tissue to researchers (if not sought as part of the initial application), or changes to the terms of the approval;

7.3.4 A change to the conditions of generic approval

7.3.5 Appointment of a new tissue bank manager (i.e. the person making the application and responsible for further reporting to the REC);

7.3.6 Any other significant change to the governance of the RTB.

8. Serious Adverse Events

8.1 The Committee should be notified as soon as possible of any serious adverse event or

reaction, any serious breach of security or confidentiality, or any other incident that could undermine public confidence in the ethical management of the tissue. The criteria for notifying the Committee will be the same as those for notifying the Human Tissue Authority in the case of research tissue RTBs in England, Wales and Northern Ireland.

9. Other information to be notified

9.1 The Committee should be notified of any change in the contact details for the applicant or where the applicant hands over responsibility for communication with the Committee to another person at the establishment.

10. Closure of the RTB

10.1 Any plans to close the RTB should be notified to the Committee and the HTA as early as possible and at least two months before closure. The Committee should be informed what arrangements are to be made for disposal of the tissue or transfer to another research tissue RTB.

10.2 Where tissue is transferred to another RTB, the ethical approval for the RTB is not transferable. Where the second RTB is ethically approved, it should notify the responsible Research Ethics Committee by submitting an amendment. The terms of its own ethical approval would apply to any tissue it receives.

11. Breaches of approval conditions

11.1 The Committee should be notified as soon as possible of any breach of these approval conditions.

11.2 Where serious breaches occur, the Committee may review its ethical opinion l and may, exceptionally, suspend or terminate the approval.