



Health Research
Authority

North East - Newcastle & North Tyneside 2 Research Ethics Committee

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24 April 2019

Professor Matthew Collin
Newcastle University
Human Dendritic Cell Laboratory
Institute of Cellular Medicine
Newcastle University
NE2 4HH

Dear Professor Collin

Title of the Research Tissue Bank: UKHR
REC reference: 18/NE/0374
Designated Individual: Dr Christopher Morris
IRAS project ID: 238319

Thank you for your letter of 15 April 2019, 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.

We plan to publish your research summary wording for the Research Tissue Bank 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 Research Tissue Banks 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 hra.studyregistration@nhs.net outlining the reasons for your request. 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 Research Tissue Bank.

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].

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		28 August 2018
Covering letter on headed paper		
Human Tissue Authority licence [12534 Licence Substantive]	July 2016	06 July 2016
IRAS Checklist XML [Checklist_15042019]		15 April 2019
Other [CI CV - Matthew Collins]		21 November 2018
Other [PIS 11-15]	1.2	19 February 2019
Other [PIS 6-10]	1.2	19 February 2019
Other [PIS 0-6]	1.2	19 February 2019
Other [Assent child]	1.2	19 February 2019
Other [ECDGAR info]	1.2	01 March 2019
Other [IRHDR info]	1.2	01 March 2019
Other [RHD]	1.2	01 March 2019
Other [Access Committee Terms]	1.2	01 March 2019
Other [Letter of invitation - adult]	1.2	01 March 2019
Other [Letter of invitation - parent]	1.2	01 March 2019
Other [Reply slip]	1.2	19 February 2019
Other [Withdrawal form]	1.2	01 March 2019
Other [Application for data or samples]	1.2	01 March 2019
Other [PIS Relative]	1.2	19 February 2019
Other [Consent Relative]	1.2	19 February 2019
Other [Invitation Relative]	1.2	19 February 2019
Participant consent form [consent adult]	1.2	19 February 2019
Participant information sheet (PIS) [PIS adult]	1.2	19 February 2019
Protocol for management of the tissue bank	1.2	19 February 2019
REC Application Form [RTB_Form_14112018]		14 November 2018
Relative consent form [Consent parent]	1.2	19 February 2019
Relative information sheet [PIS parent]	1.2	19 February 2019
Summary of research programme(s)	1.1	28 August 2018

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.

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/>

18/NE/0374

Please quote this number on all correspondence

Yours sincerely



pp

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Chair

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Enclosures: *Standard approval conditions*

Copy to: Dr Christopher Morris, Newcastle University