

**North East - Newcastle & North Tyneside 2 Research Ethics Committee**

NHS BT Blood Donor Centre  
Holland Drive  
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Tyne and Wear  
NE2 4NQ

Telephone: 0207 104 8233  
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04 March 2022

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

Dear Prof Collin

**Title of the Research Tissue Bank:** UKHR  
**REC reference:** 18/NE/0374  
**Designated Individual:** Dr Christopher Morris ((Organisation name not set))  
**Amendment number:** UKHR: Adding Adults Lacking Capacity for the first time  
**Amendment date:** N/A  
**IRAS project ID:** 238319

The above amendment was reviewed at the meeting of the Committee held on 16 February 2022.

**Ethical opinion**

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**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.

## **Compliance with the Mental Capacity Act – the Committee agreed the following:**

### **1.1 Relevance of the research to impairing condition**

The Committee was satisfied that the justification for introducing Adults lacking capacity was appropriate and well thought out. Furthermore, the Committee agreed that the research related to an impairing condition affecting persons lacking capacity or with the treatment of the condition.

### **1.2 Justification for including adults lacking capacity to meet the research objectives**

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

### **2.1 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.

After discussion the Committee confirmed that reasonable arrangements were in place for appointing consultees. However, as previously mentioned, the Committee requested for the typographical errors within the Nominated Consultee Form to be amended.

### **3.1 Balance between benefit and risk, burden and intrusion**

The research is of potential benefit to research participants lacking capacity without imposing a disproportionate burden

### **4.1 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.

### **5.1 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.

## **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 [Response to REC Amendment 1]	NA	01 March 2022
Other [UKHR Reply]	1.3	11 January 2022
Other [Notice of Amendment - RTB]	NA	11 January 2022
Other [Jessica Manson CV]	NA	
Other [Updated REC form]	NA	16 February 2022
Participant consent form [UKHR Personal Consultee Declaration]	1.1	11 January 2022
Participant consent form [UKHR Nominated Consultee Declaration ]	1.2	01 March 2022
Participant information sheet (PIS) [UKHR Information for Consultees]	1.1	11 January 2022

Protocol for management of the tissue bank [UKHR Protocol ]	1.6	01 March 2022
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## Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

## Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. 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 have not 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.

## 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.

## 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/>

<b>IRAS Project ID: 238319</b>
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<b>Please quote this number on all correspondence</b>
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Yours sincerely

*William Lyse*

## Approvals Administrator

On behalf of

**Professor Barry Hirst**  
**Chair**

E-mail: [newcastlenorthtyneside2.rec@hra.nhs.uk](mailto:newcastlenorthtyneside2.rec@hra.nhs.uk)

*Enclosures:*

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

## North East - Newcastle & North Tyneside 2 Research Ethics Committee

### Attendance at Committee meeting on 16 February 2022

#### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Liz Baker	Clinical Research Scientist	Yes	
Mrs Ann Boardman	Retired Educationalist	Yes	
Dr Owen Burbidge	CCLG Tissue Bank Manager	Yes	
Dr Raymond Chadwick	Postgraduate Tutor in Clinical Psychology	Yes	
Mr Milan Gopal	Consultant Paediatric Surgeon and Urologist	Yes	
Miss Phillipa Hearty	Post-Doctorate Researcher	Yes	
Professor Barry Hirst	Professor of Cellular Physiology	Yes	(Chair)
Dr Tony Newton	Director	No	
Dr Meiyi Pu	Consultant	No	
Mrs Susan Webster	Head of Psychology	Yes	
Professor Roger Whittaker	Professor of Clinical Neurophysiology	Yes	

#### Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Sarah Francis	Clinical Trials Co-ordinator (Observer)
Mr William Lyse	Approvals Administrator
Christie Ord	Approvals Specialist
Mrs Helen Wilson	Approvals Officer