

North West - Haydock Research Ethics Committee

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Manchester
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Telephone: 02071048103

18 June 2021

Professor Naomi Allen
UK Biobank Limited
Clinical Trial Service Unit and Epidemiological Studies Unit
Nuffield Department of Population Health, The Big Data Institute
University of Oxford, Oxford
OX3 7LF

Dear Professor Allen,

Title of the Research Tissue Bank: UK Biobank: a large scale prospective
epidemiological resource
REC reference: 21/NW/0157
Designated Individual: Mrs Samantha Welsh
IRAS project ID: 299116

The Research Ethics Committee reviewed the above application at the meeting held on 08 June 2021. 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.

This application was for the renewal of a Research Tissue Bank application. The previous REC Reference number for this application was **16/NW/0274**.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the Research Tissue Bank.

Number	Condition
1)	Please include a sentence in the withdrawal form to make it clear that providing a reason for withdrawal is entirely optional.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the Research Tissue Bank, which can be made available to host organisations to facilitate their permission for the Research Tissue Bank. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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 13/05/2016 to 13/05/2021.

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Human Tissue Authority licence [HTA Licences]	26 Feb 2020	26 February 2020
IRAS Checklist XML [Checklist_30042021]		30 April 2021
Other [EGF]	3.0	29 October 2007
Other [Participant Withdrawal Form]	2.0	23 March 2017
Other [Data Dictionary Showcase]	1	29 April 2021

Other [Annual Progress Report Form]	1.0	29 April 2021
Other [UK Biobank Protocol]	21 March 2007	21 March 2007
Other [Protocol Addendum 1]	09 April 2009	09 April 2009
Other [Protocol Addendum 2]	2 July 2009	02 July 2009
Other [Table 1 Samples Collected and Stored at UKB]	1.0	29 April 2021
Other [CV NAllen]	April 2021	29 April 2021
Other [BGMini]	1.0	17 July 2019
Other [Participant Feedback Survey (Cardiac Monitoring)]	1.0	06 November 2020
Other [In Clinic Application PIL FAQ (Cardiac Monitoring)]	2.3	12 January 2021
Other [Self Application PIL & FAQ (Cardiac Monitoring)]	3.1	06 November 2020
Other [Reminder to Return UKB Heart Monitor 30 days]	2.1	26 April 2021
Other [Reminder to Return UKB Heart Monitor 58 days]	1.1	26 April 2021
Other [Reminder to start wearing the UKB heart monitor]	1.1	26 April 2021
Other [Thank you for participating in UKB Heart Monitor]	1.1	26 April 2021
Other [Thank you for returning your UKB Heart Monitor]	1.1	26 April 2021
Other [Cog Funct invitation email]	1.1	12 February 2021
Other [Cog Funct non responders reminder email]	1.1	27 April 2021
Other [Cog Funct reminder partial responders email]	1.1	27 April 2021
Other [Cog Funct Last Chance reminder email]	1.2	27 April 2021
Other [Pre_Imaging Visit Questionnaire]	2.4	27 November 2020
Other [Cheadle COVID-19 Repeat Imaging Invite]	1.1	01 December 2020
Other [COVID-19 Info Leaflet Second Assessment]	1.5	17 December 2020
Other [Stockport COVID-19 Repeat Imaging Postal Appt Confirmation]	1.4	27 November 2020
Other [Cheadle COVID-19 Repeat Imaging Email Appt Confirmation]	1.1	01 December 2020
Other [Cheadle COVID-19 Repeat Imaging appointment reminder SMS]	1.0	20 October 2020
Other [Cheadle COVID-19 Repeat Imaging 1st Reminder]	1.1	01 December 2020
Other [Cheadle COVID-19 Rpt Imaging 2nd Reminder]	1.0	20 October 2020
Other [Cheadle Repeat Imaging 2nd Invite]	1.2	17 December 2020
Other [COVID Secure Measures for Participants]	1.3	17 December 2020
Other [DFP UKB Invitation email]	1.1	13 June 2019
Other [Website content UKB (DFP)]	1.1	13 June 2019
Other [DFP UKB Participant Study Summary]	1.0	01 April 2019
Other [food pref invitation email]	1.1	27 April 2021
Other [food pref reminder non responder reminder email]	1.1	27 April 2021
Other [food pref reminder partial responders email]	1.1	17 April 2021
Other [food pref last chance reminder email]	1.1	27 April 2021
Other [Food preferences Metadata]	1.1	20 May 2019
Other [Email Appt Confirmation]	1.1	28 April 2021
Other [IF Letter to GP and Specialist Report]	3.0	29 April 2021
Other [IF Letter to Participant]	3.0	29 April 2021

Other [Imaging Appointment Confirmation Letter]	4.0	28 April 2021
Other [Imaging Invitation Stockport]	3.0	26 April 2021
Other [Imaging Invitation Postal]	2.0	23 January 2020
Other [Info Leaflet]	11	29 September 2019
Other [Second, Third & Fourth Invitation to attend Imaging]	0.2	26 April 2021
Other [Imaging 2nd reminder]	1.0	27 April 2021
Other [Imaging SMS Appointment Reminder]	1.0	26 April 2021
Other [Reminder postal invitation (Imaging)]	1.0	17 January 2020
Other [Pain Invitation email]	1.1	27 April 2021
Other [Pain non responders reminder email]	1.1	27 April 2021
Other [Pain partial responders reminder]	1.1	27 April 2021
Other [Pain Last Chance reminder email]	1.1	27 April 2021
Other [Pain questionnaire Metadata]	2.4	07 November 2018
Other [First reminder Repeat Imaging Stockport]	22 April 2021	22 April 2021
Other [IF Letter to GP and Specialist Report]	3.0	29 April 2021
Other [IF Letter to Participant]	3.0	29 April 2021
Other [Imaging Appointment Confirmation Letter]	4.0	28 April 2021
Other [Invitation Repeat Imaging Invite]	22 April 2021	22 April 2021
Other [Repeat Imaging appointment confirmation email]	22 April 2021	22 April 2021
Other [Second Reminder Repeat Imaging Stockport]	22 April 2021	22 April 2021
Other [Invitation Postal (Repeat Imaging)]	05 Feb 2019	05 February 2019
Other [2nd Invitation Repeat Imaging Stockport]	28 April 2021	28 April 2021
Other [Imaging SMS Appointment Reminder]	1.0	26 April 2021
Other [Sleep Metadata Questionnaire]	2.0	12 March 2020
Other [Sleep Questionnaire Invitation Email]	0.1	26 July 2019
Other [Sleep Questionnaire Non Responders]	0.1	26 July 2019
Other [Sleep Questionnaire Partial Responders]	0.1	26 July 2019
Other [Sleep Questionnaire Final Reminder]	0.1	26 July 2019
Other [SMS Contact Details Update]	29 April 2021	29 April 2021
Other [Touch Screen Questionnaire]	29 April 2021	29 April 2021
Other [Annual Participant Newsletter]	27 November 2020	27 November 2020
Other [Document 1 Protocol Extract]	21 Sept 2006	21 September 2006
Other [Table 2 Longitudinal Health Outcomes Data]	30 April 2021	30 April 2021
Other [Table 3 Future Plans]	30 April 2021	30 April 2021
Other [Touch Screen Questionnaire Reaction Time Test (Snap)]	1.3	05 April 2018
Other [Touch Screen Questionnaire Picture Vocabulary Test]	0.1	09 November 2017
Other [Touch Screen Questionnaire Fluid Intelligence Test]	1.3	09 November 2017
Other [Touch Screen Questionnaire Pairs Test]	1.3	09 November 2017
Other [Touch Screen Questionnaire Numeric Memory Test]	1.2	09 November 2017
Other [Touch Screen Questionnaire Trail Making Test]	0.1	09 November 2017
Other [Touch Screen Questionnaire Matrix Pattern Completion]	0.1	09 November 2017

Other [Touch Screen Questionnaire Prospective Memory Test]	1.2	09 November 2017
Participant consent form [20061124 Consent form]	20061124	24 November 2006
Participant consent form [Consent Form Imaging]	29 Jan 2014	29 January 2014
Participant consent form [DFP Informed Consent Form]	4.0	01 April 2019
Participant consent form [DFP Study Partner Informed Consent Form]	2.0	01 April 2019
Participant consent form [DFP Informed Consent Form Mezurio]	4.0	01 April 2019
Participant information sheet (PIS) [Participant Information Leaflet]	21 April 2010	21 April 2010
Participant information sheet (PIS) [Repeat Imaging Info Leaflet]	Sept 2019	29 September 2019
Participant information sheet (PIS) [DFP UKB Participant Information Sheet]	1.2	21 June 2019
Participant information sheet (PIS) [DFP Study Partner Information Sheet]	2.0	01 April 2019
Participant information sheet (PIS) [DFP Participant Information Sheet Mezurio]	4.1	21 June 2019
Participant information sheet (PIS) [COVID-19 Info Leaflet Second Assessment]	1.4	09 December 2020
Protocol for management of the tissue bank [Access procedures]	1.0	29 November 2011
REC Application Form [RTB_Form_30042021]		30 April 2021

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

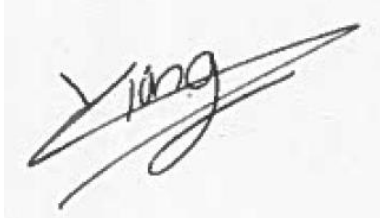
We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:

<https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS project ID: 299116

Please quote this number on all correspondence

Yours sincerely,

A handwritten signature in black ink, appearing to read 'S. Edgar', with a long horizontal stroke extending to the right.

Mr Stephen Edgar
Chair

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

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

(RTB) Conditions of Approval

Copy to: Mrs Samantha Welsh, UK Biobank Limited

North West - Haydock Research Ethics Committee

Attendance at Committee meeting on 08 June 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr John Bridson	Clinical Ethicist	Yes	
Mr Stephen Edgar (Chair)	Designer	Yes	
Mrs Sue Fitzpatrick	Director	Yes	
Mrs Lesley France	Statistician	Yes	
Miss Lyndsey Hill	LECTURER IN MENTAL HEALTH NURSING	Yes	
Dr Ezzat Kozman	Consultant Gynaecologist	Yes	
Ms Jill Lucock	Registered Nurse	Yes	
Mr Charles Otim	Research Support Officer	No	
Miss Annya Sekula	Nurse	Yes	
Dr Peter Walton	Retired Clinical Scientist	No	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Andrea Bell	Approvals Specialist
Ms Lucy Holt Garner	Observer
Mrs Elaine Hutchings	REC Manager