North West - Haydock Research Ethics Committee
3rd Floor - Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 02071048103

29 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 Database: **UK Biobank: a large scale prospective epidemiological resource**
Designated Individual: **Mrs Samantha Welsh**
REC reference: **21/NW/0157**
IRAS project ID: **299116**

Thank you for responding to the Favourable Opinion with Condition. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our correspondence dated 18 June 2021.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Other [Participant Withdrawal Form]	3.0	25 June 2021

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Human Tissue Authority licence [HTA Licences]	26 Feb 2020	26 February 2020
IRAS Checklist XML [Checklist_30042021]		30 April 2021
IRAS Checklist XML [Checklist_29062021]		29 June 2021
Other [EGF]	3.0	29 October 2007

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
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Other [Self Application PIL & FAQ (Cardiac Monitoring)]	3.1	06 November 2020
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Other [Reminder to Return UKB Heart Monitor 58 days]	1.1	26 April 2021
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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
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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
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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
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Other [Info Leaflet]	11	29 September 2019
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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
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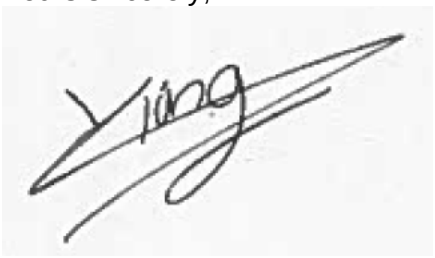
Other [Touch Screen Questionnaire]	29 April 2021	29 April 2021
Other [Annual Participant Newsletter]	27 November 2020	27 November 2020
Other [Document 1 Protocol Extract]	21 Sept 2006	21 September 2006
Other [Table 2 Longitudinal Health Outcomes Data]	30 April 2021	30 April 2021
Other [Table 3 Future 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
Other [Participant Withdrawal Form]	3.0	25 June 2021
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
Response to Additional Conditions Met		29 June 2021

IRAS project ID299116	**Please quote this number on all correspondence**

Yours sincerely,



Miss Yasmin King (ANutr)
Approvals Officer

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

Copy to: *Mrs Samantha Welsh, UK Biobank Limited*

North West - Haydock Research Ethics Committee
3rd Floor - Barlow House
4 Minshull Street
Manchester
M1 3DZ

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:

Document	*Version*	*Date*
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
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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

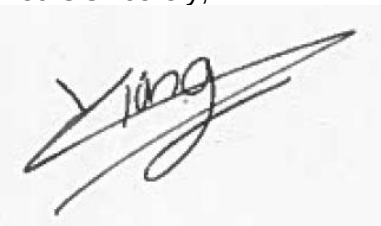
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the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



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:

Name	*Profession*	*Present*	*Notes*
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:

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

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
UK Biobank: a large scale prospective epidemiological resource

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

(●) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the bank be established within a NHS / HSC diagnostic archive?

( ) Yes (●) No

2b. As well as biological samples and data, will the bank also collect and store radiological images from sample donors?

(●) Yes ( ) No

Will donors be invited to undertake any ionising radiation exposures (e.g. X-Rays, CT scans) additional to those authorised as part of normal clinical management?

(●) Yes ( ) No

3. In which country of the United Kingdom is the bank established?

- (●) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland

3a. In which countries of the United Kingdom will centres collecting and/or supplying tissue and data to the bank be located? *(tick all that apply)*

- [x] England
- [x] Wales
- [x] Scotland
- [ ] Northern Ireland

4. Which applications do you require?

- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)

6. Do you plan to include any participants who are children?

( ) Yes (●) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (●) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

( ) Yes (●) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (●) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (●) No

RESEARCH TISSUE BANK / BIOBANK

NHS Health Research Authority

Application to NHS / HSC Research Ethics Committee

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
UK Biobank: a large scale prospective epidemiological resource

Please complete these details after you have booked the REC application for review.

REC Name:
North West - Haydock Research Ethics Committee

REC Reference Number:
21/NW/0157

Submission date:
30/04/2021

Preliminary checklist:

Please tick all activities to be undertaken by or within the establishment *(i.e. the legal entity with control of the tissue/data):*

- [x] Existing holding of stored tissue (any "relevant material" as defined by the Human Tissue Act and held prior to 1 September 2006)
- [x] Removal, collection and storage of new tissue from the living for research
- [x] Collection and storage of existing/residual tissue from the living (includes samples held in diagnostic archives)
- [ ] Removal of organs or tissue from the deceased
- [ ] Collection and storage of organs or tissue from the deceased
- [x] Collection and storage of DNA
- [x] Collection and storage of other biological material
- [x] Arranging the collection of new tissue samples or other biological material by collaborator(s)
- [x] Collection of new data from the living
- [x] Collection of clinical data from patient records
- [x] Other research procedures involving contact with participants (e.g. questionnaires, imaging)
- [x] Conducting research projects using the samples or data
- [x] Releasing samples or data to other researchers with no involvement of the establishment in conducting the research
- [x] Releasing samples or data to commercial suppliers
- [x] Export of samples or data outside the UK
- [ ] Collection and storage of identifiable samples or data relating to adults unable to consent for themselves due to physical or mental incapacity

Part A: Core Information

Administrative information

1. Title of the bank.

UK Biobank: a large scale prospective epidemiological resource of 500,000 people aged 40-69 from around the UK.

2. Name and address of the establishment responsible for management of the bank.

Organisation	UK Biobank Limited
Address	1-4 Spectrum Way
	Adswood
	Stockport
PostCode	SK3 0SA
Telephone	01614755360
Fax	01614755361

Please give details of the locations at which tissue will be stored:
NIHR National Biosample Centre, Units 2-3 Java Park, Bradbourne Drive, Tilbrook, Milton Keynes MK7 8AT;
NIHR National Biosample Centre, Ferry Hinksey Road, Osney Mead Industrial Estate, Oxfordshire OX2 0AP;
UK Biobank, 1-4 Spectrum Way, Adswood, Stockport SK3 0SA;
UK Biobank Reading Imaging Centre, Unit 3B, Pincents Kiln Industrial Park, Pincents Kiln, Calcot, Theale, Reading RG31 7SD; and
UK Biobank Newcastle Imaging Centre, Unit 2, Hawick Crescent Industrial Estate, Newcastle upon Tyne NE6 1AS
UK Biobank Bristol Imaging Centre, Unit G4b, Bolingbroke Way, Patchway, Bristol, BS34 6FE

3. Name of the tissue bank manager within this organisation.
This person will be the main contact point with the REC for purposes of the application.

	Title	Forename/Initials	Surname
	Professor	Naomi	Allen
Address	Clinical Trial Service Unit and Epidemiological Studies Unit		
	Nuffield Department of Population Health, The Big Data Institute		
	University of Oxford, Oxford		
PostCode	OX3 7LF		
E-mail	naomi.allen@ndph.ox.ac.uk		
Telephone	01865743805		
Mobile			
Fax			

A copy of a current CV (maximum two pages of A4) must be submitted with the application.

Questions 4-6 should be answered in relation to each establishment. Please open a separate set of the questions for each establishment.

Storage establishment 1

Name and address of the establishment responsible for storage of any relevant material under the Human Tissue Act.
Where relevant material will be held in more than one establishment, please give details of each establishment.

Organisation	NIHR National Biosample Centre
Address	Units 2-3 Java Park
	Bradbourne Drive
	Tilbrook, Milton Keynes
PostCode	MK7 8AT
Telephone	01908870800

Fax	01908870801

Does this establishment hold a licence from the Human Tissue Authority to store tissue for use for a scheduled purpose? *Please enclose copy of licence if available.*

◉ Yes ○ No ○ Licence application pending

Licence No.: 12002

Please give the name of the "designated individual" for purposes of licensing by the Human Tissue Authority:

	Title	Forename/Initials	Surname
	Dr	Sandhya	Anantharaman
Address	Units 2-3 Java Park		
	Bradbourne Drive, Tilbrook		
	Milton Keynes		
PostCode	MK7 8AT		
E-mail	Sandhya.Anantharaman@ukbiocentre.com		
Telephone	01908870800		
Mobile			
Fax			

Storage establishment 2

Name and address of the establishment responsible for storage of any relevant material under the Human Tissue Act. *Where relevant material will be held in more than one establishment, please give details of each establishment.*

Organisation	NIHR National Biosample Centre
Address	Ferry Hinksey Road
	Osney Mead Industrial Estate
	Oxfordshire
PostCode	OX2 0AP
Telephone	
Fax	

Does this establishment hold a licence from the Human Tissue Authority to store tissue for use for a scheduled purpose? *Please enclose copy of licence if available.*

◉ Yes ○ No ○ Licence application pending

Licence No.: 12624

Please give the name of the "designated individual" for purposes of licensing by the Human Tissue Authority:

	Title	Forename/Initials	Surname
	Dr	Sandhya	Anantharaman
Address	Units 2-3 Java Park		
	Bradbourne Drive, Tilbrook		
	Milton Keynes		

PostCode	MK7 8AT
E-mail	Sandhya.Anantharaman@ukbiocentre.com
Telephone	01908870800
Mobile	
Fax	

Storage establishment 3

Name and address of the establishment responsible for storage of any relevant material under the Human Tissue Act.
Where relevant material will be held in more than one establishment, please give details of each establishment.

Organisation	UK Biobank Limited
Address	1-2 Spectrum Way
	Adswood
	Stockport
PostCode	SK3 0SA
Telephone	01614755360
Fax	01614755361

Does this establishment hold a licence from the Human Tissue Authority to store tissue for use for a scheduled purpose? *Please enclose copy of licence if available.*

(●) Yes ( ) No ( ) Licence application pending

Licence No.: 12002

Please give the name of the "designated individual" for purposes of licensing by the Human Tissue Authority:

Title	Forename/Initials	Surname
Mrs	Samantha	Welsh

Address	UK Biobank, 1-2 Spectrum Way
	Adswood
	Stockport
PostCode	SK3 0SA
E-mail	samantha.welsh@ukbiobank.ac.uk
Telephone	01614755360
Mobile	
Fax	

Storage establishment 4

Name and address of the establishment responsible for storage of any relevant material under the Human Tissue Act.
Where relevant material will be held in more than one establishment, please give details of each establishment.

Organisation	UK Biobank Imaging Centre (Reading)
Address	Unit 3b Pincents Kiln Industrial Park
	Pincents Kiln, Calcot
	Theale, Reading
PostCode	RG31 7SD

Telephone
Fax

Does this establishment hold a licence from the Human Tissue Authority to store tissue for use for a scheduled purpose? *Please enclose copy of licence if available.*

◉ Yes ○ No ○ Licence application pending

Licence No.: 12002

Please give the name of the "designated individual" for purposes of licensing by the Human Tissue Authority:

	Title	Forename/Initials	Surname
	Mrs	Samantha	Welsh
Address	UK Biobank, 1-2 Spectrum Way		
	Adswood		
	Stockport		
PostCode	SK3 0SA		
E-mail	samantha.welsh@ukbiobank.ac.uk		
Telephone			
Mobile			
Fax			

Storage establishment 5

Name and address of the establishment responsible for storage of any relevant material under the Human Tissue Act. *Where relevant material will be held in more than one establishment, please give details of each establishment.*

Organisation	UK Biobank Imaging Centre (Newcastle)
Address	Unit 2 Hawick Crescent Industrial Estate
	Newcastle upon Tyne
PostCode	NE6 1AS
Telephone	
Fax	

Does this establishment hold a licence from the Human Tissue Authority to store tissue for use for a scheduled purpose? *Please enclose copy of licence if available.*

◉ Yes ○ No ○ Licence application pending

Licence No.: 12002

Please give the name of the "designated individual" for purposes of licensing by the Human Tissue Authority:

	Title	Forename/Initials	Surname
	Mrs	Samantha	Welsh
Address	UK Biobank, 1-2 Spectrum Way		
	Adswood		

	Stockport
PostCode	SK3 0SA
E-mail	samantha.welsh@ukbiobank.ac.uk
Telephone	
Mobile	
Fax	

7. Has this bank (or any part of the bank) previously been the subject of an application for ethical review?

(●) Yes ( ) No

If Yes, was the application approved?

(●) Yes ( ) No

Name of Research Ethics Committee:	NRES Committee North West - Haydock
Date of decision:	13/05/2016
REC reference number:	16/NW/0274

Purpose of the Bank

8. Please summarise the types of tissue sample or other biological material to be collected/stored from the living.
Please state the selection criteria for inclusion of samples in the bank. Indicate what samples are already held and summarise plans for further collection.

UK Biobank is a large-scale biomedical database and research resource that is enabling new scientific discoveries to be made that improve public health.

Since 2006, UK Biobank has collected an unprecedented amount of biological and medical data on half a million people, aged between 40 and 69 years old and living in the UK, as part of a large-scale prospective study. With their consent they regularly provide blood, urine and saliva samples, as well as detailed information about their lifestyle which is then linked to their health-related records to provide a deeper understanding of why some people develop certain diseases and others do not.

Table 1 summarises the samples collected and stored at UK Biobank.

In response to the SARS-CoV-2 global pandemic, UK Biobank commenced a major study in 2020 to determine the extent of previous infection to SARS-CoV-2 across the UK population and antibody persistence over time by measuring blood antibody levels. 20,000 individuals (including 10,000 UK Biobank participants and 10,000 of their children and grandchildren (aged over 18)) took part.

Each participant was asked to provide each month (for 6 months in total) 0.5ml sample of blood from their fingertip. The sample was returned to UK Biobank and underwent validated antibody analysis performed by the Target Discovery Institute based at the University of Oxford.

In 2021, UK Biobank began to invite participants to take part in a repeat imaging study with the aim of recruiting up to 3,000 participants, half of whom have been previously infected with SARS-CoV-2 and half have not (identified through linkage to electronic health records and a home-based lateral flow device that measures antibodies to the virus).

The existing repeat imaging protocol included the collection of 26.5ml whole blood in three tubes:
• EDTA tube (10ml whole blood)
• Serum separator tube (8.5ml whole blood)
• Plasma separator tube (8ml whole blood)

As part of the covid repeat imaging study, an additional Lithium Heparin Plasma (LHP) (8ml whole blood) tube will be collected for the purposes of this study, taking the total volume to 34.5ml (which remains significantly less than the volume collected in the 7 tubes used at the baseline UK Biobank assessment visit). This is for the purpose of performing a range of assays to assess immune function.

Sample analysis will assess:
i) Antibody response to SARS-CoV-2, across the full spectrum of antigen diversity and titre;
ii) Cellular immune response to SARS-CoV-2, using intracellular cytokine analysis to determine profile of cytokine responses to individual antigens;
iii) Previous infection history of a range of other pathogens using multiplex technology;
iv) Autoantibody profile;

Samples to be collected going forward:
UK Biobank will continue to collect 26.5ml of blood from participants attending the Imaging visit (EDTA, PST, SST tubes). In addition, the 8ml LHP tube will be collected until the end of the COVID repeat Imaging project (due to end Q3 2021).
Once the COVID Imaging study finishes, an additional fresh EDTA tube (10ml whole blood) will be collected as part of the on-going Imaging project to perform haematological assays and for single-cell RNA sequencing.

9. Please summarise the types of organ, tissue sample or other biological material to be collected from the deceased.
Please state the selection criteria for inclusion of samples. Indicate what samples are already held and summarise plans for further collection. If the establishment will be removing organs or tissues from the deceased in England, Wales or Northern Ireland, please provide a copy of the pathology licence.

None

10. Please summarise the types of data to be collected and linked with the samples.
Indicate whether any personal identifiers will be held and explain why this is necessary. Say whether any particularly sensitive data will be held.

During 2006-2010, UK Biobank recruited 500,000 men and women from the UK population, who were aged 40-69 at the date of their baseline assessment visit. Personal identifiers are held as they were required to enable UK Biobank to recruit the cohort and are necessary to enable re-contact of participants on an on-going basis. Direct identifiers (i.e. NHS numbers, sex, DoB, address, name) are also held as they are required for record linkage to a wide range of electronic medical records across different service providers (each of which may use different identifiers) - further detail of linkage to health-related records is provided below. Address data are also required to re-contact participants via post, and to provide suitable geographical units for spatial analyses (e.g., grid co-ordinates).

Below is a summary of the types of data and samples that have been collected as part of the baseline assessment and enhancement assessments.

Baseline data
Extensive data was collected at baseline from all participants on their lifestyle, environment, personal and family medical history. Participants also underwent a wide range of physical measures, and provided samples of blood, urine and saliva.
• Touch-screen questionnaire data included lifestyle, environment, personal and family medical history.
• Physical measurement data included blood pressure and heart rate; hand grip; standing and sitting height; weight and bio-impedance; hip and waist circumference; spirometry; bone density; arterial stiffness; eye examination (refractive index, intraocular pressure, acuity, retinal photograph and optical coherence tomography) and fitness test.
• Biological sample data included numbers and types of aliquots collected from participants.

With regards to sensitive data, UK Biobank collected data on ethnicity, sexual partners and orientation, health-related data and extracted genomic data from the biological samples.

Enhanced phenotyping data
•Repeat assessment data. The baseline visit was repeated in a sub-set of 20,000 participants in 2012-2013 and has been repeated as part of the imaging assessment visit.
•Physical activity data. Activity over a 7-day period was collected in 2014-2015 via a wrist-worn activity monitor for 100,000 participants. A seasonal repeat in 2,500 participants on 4 occasions was collected in 2018.
•Multi-modal imaging data. Brain, heart and full body MR imaging, plus full body DEXA scan of the bones and joints and an ultrasound of the carotid arteries. The goal is to invite 100,000 participants and to invite up to 70,000 participants back for a repeat scan.
•Online questionnaire data. Data on a range of exposures and health outcomes that are difficult to assess via routine health records, including diet, food preferences, work history, pain, cognitive function, digestive health and mental health. This can include sensitive data as, for example, the mental health questionnaire included questions on substance and childhood abuse.
•Home-based antibody Lateral Flow Test study. To obtain data on previous infection with coronavirus to enable research in to Long-Covid.

Health data linkage
Follow-up of health outcomes occurring in participants is being achieved through linkage to their medical records as well as directly with participants using web-based questionnaires for health outcomes that are less completely recorded in health care records. Table 2 summarises the types of health data outcomes available within UK Biobank. During the next 5 years, we intend to extend linkages to other types of health-related records (e.g. those in the Department for Work and Pensions, and the Meteorological Office) that are likely to be relevant to assessing socio-economic and environmental exposures plus other medical health record datasets. Potential linked datasets under consideration which we might wish to link to in the future are listed in Table 3.

Assay data
Assay data generated from the samples collected and stored by UK Biobank.

• Genome-wide genotyping data measured by Affymetrix (now Thermo Fisher Scientific) on DNA extracted from buffy coat - >800k directly measured genotypes plus 90+M imputed genotypes (~500k participants)
• Biochemical assay data measured in-house – 36 biomarkers measured across serum, urine and red blood cells (~500k participants)
• Telomere data measured by University of Leicester on DNA extracted from buffy coat (~500k participants)
• Infectious disease data measured by German Cancer Research Center on serum – 20 infectious pathogens (~10k participants)
• SARS-CoV-2 antibody status/titre levels measured by Target Discovery Institute, Oxford on EDTA plasma (~10k participants and ~10k children/grandchildren of participants)

There are several projects using samples that are in progress or approved and about to start that will generate more data;
• Whole exome sequencing data measured by Regeneron on DNA extracted from buffy coat (~500k participants)
• Whole genome sequencing data measured by Wellcome Sanger Institute and deCODE genetics on DNA extracted from buffy coat (~500k participants)
• Metabolomics - ~250 metabolites measured by Nightingale Health on EDTA plasma (~500k participants)
• Proteomics - ~1,500 circulating proteins measured by Olink on EDTA plasma (~53k participants)
• Immunology data from Lithium Heparin whole blood samples collected from participants during Imaging COVID study (~3k participants)
Haematology and single cell RNA profiling measured by Wellcome Sanger Institute (~5k participants) this fresh EDTA blood sample will be collected as part of the on-going Imaging project.

Please enclose a list of all data items to be stored.

11. How is it intended to make beneficial use of the samples or data in research?
Please summarise the overall policy of the bank/establishment for use of the samples or data, including release to other researchers or research organisations

UK Biobank's overriding objective is to ensure that the UK Biobank Resource is used extensively and appropriately for health-related research that is in the public interest by academic or commercial researchers (with no exclusive or preferential access), while at the same time maintaining the underlying agreement made with the participants regarding the confidentiality and use of their data and samples.

UK Biobank's access policy is set out in its Ethics and Governance Framework (https://www.ukbiobank.ac.uk/media/0xsbmfmw/egf.pdf). Its Access Procedures (https://www.ukbiobank.ac.uk/enableyour-research) were initially prepared during 2010 to 2011 and were the subject of extensive discussion and dialogue with its funders, the North West (Haydock) REC and the UK Biobank Ethics and Governance Council. The Access Procedures were also put out to public consultation, including consultation with UK Biobank participants. The Access Procedures have been refreshed (with revised procedures being published in Q2 2021) to reflect both the changes in application processes and procedures that UK Biobank has put in place to facilitate use of the data by researchers and the changes in prevailing legislation and regulatory guidance.

Access to the UK Biobank Resource continues to be governed by the Access Procedures.

Access key points:
• The Resource is open access, although researchers have to register to use it. Approved academic or commercial researchers from around the world are able to apply to use it for health-related research that is in the public good.
• UK Biobank has built and owns the Resource, but there is no preferential access and no requirement for researchers to collaborate with the scientific team that has developed it.
• Stringent measures are in place to ensure that UK Biobank participants are not identified.
• When approved researchers are ready to publish results based on the Resource, they are obliged to share their results with UK Biobank so that advances can be built on by others.

There are 5 stages to the Access process:
• Registration: To confirm the identity of each researcher intending to use the Resource, to check their bona fides before registering them as a potential user.
• Application: To allow UK Biobank to assess: (i) whether the proposed research is health-related and in the public good; (ii) whether the proposed research meets the required criteria for access (including legal and ethics standards); (iii) whether the Resource contains the data and/or samples required for the proposed research; (iv) whether the amount of depletable sample required is scientifically justified; (vi) the cost of providing such data and/or samples;
• Access Sub-Committee (ASC) review: The ASC is a sub-committee of the UK Biobank Board, and is responsible for making key access decisions, notably those regarding the use of depletable samples, recontact or potentially contentious research. The ASC meets on a quarterly basis.

• Material Transfer Agreement (MTA): For approved applications, the MTA needs to be executed and access charges paid before release of data and/or samples to the Applicant Principal Investigator (PI).

• Sample / Data Release: Materials will only be released after payment and execution of the MTA. Data is released on a daily basis, whereas samples are released to an agreed timetable.

12-1. How have you actively involved, or will you involve, patients, service users, or members of the public in establishing the bank and its policies?

There has been consultation with stakeholders, members of the public and the scientific community throughout the life of UK Biobank.

From 1 June 2011 to the 6 July 2011, UK Biobank completed a public consultation on its Access procedures. Its purpose was to obtain the views of participants, scientists, members of the public and other interested parties on the draft procedures for allowing access to the UK Biobank Resource. Input from the consultation was used to refine and finalise the Access Procedures in November 2011.

UK Biobank is committed to ensuring that its participants are informed of progress and developments in UK Biobank, to obtaining participants' opinions on proposed enhancements to the study, and to providing them with information on how to contact UK Biobank should they have any questions. UK Biobank does this in part through its annual newsletter, sent via e-mail and/or postal mail to its half a million participants. A copy of the 2020 participant newsletter is enclosed.

UK Biobank holds regular face-to-face meetings in towns and cities across the UK with our participants and these remain extremely popular. This forum enables us to answer any questions our participants have as well as obtain their feedback on the study and its future direction. Due to the coronavirus pandemic it has not been possible to hold such meetings over the past 12 months. We have instead held virtual participant events and, for example, held one such event in February 2021 for participants of our Coronavirus Serology Study. This was an interactive evening, attended by 1,200 participants and which enabled them to engage with our Principal Investigator, Professor Sir Rory Collins, our Chief Scientist, Professor Naomi Allen, and one of UK Biobank's core funders, Professor Sir Jeremy Farrar (Wellcome Trust). A further 450 participants watched the on-demand content available from our website. Due to the success of the virtual format and the fact that it enables us to reach a far greater number of participants in one sitting than ever before, we intend to continue to hold virtual meetings with our participants on a more frequent basis.

UK Biobank's biomedical resource became available for researchers to access in 2012 and contains a wide range of genetic and phenotypic data. Since that date, the number of researchers accessing this biomedical resource to conduct a wide range of health-related research has increased dramatically and UK Biobank now has 20,000 researchers registered to use the resource from over 70 countries, with 2,000 projects currently underway. UK Biobank issues regular communications to registered researchers to notify them of new data releases. We also host a scientific conference each year to update the research community on recent developments and future plans, as well as showcase research findings derived from UK Biobank. On-demand content is also made available via the UK Biobank website (www.ukbiobank.ac.uk) for anyone unable to attend. In addition, at the end of 2020 we issued a survey to all active registered researchers (20,000) to gain their insight in to the value and impact of UK Biobank to date. The results of this survey will be used to inform our future direction.

An independent Ethics and Governance Council (EGC) was established by UK Biobank's funders when UK Biobank began the recruitment of its 500,000 participants in 2006. It became apparent over time that UK Biobank had developed at a considerable pace and, as a consequence, the EGC recommended that its oversight role would be more effectively discharged by better integration within UK Biobank as an advisory committee of the UK Biobank Board. This recommendation was accepted by the UK Biobank funders and by the UK Biobank Board and led to the establishment of the UK Biobank Ethics Advisory Committee (EAC) in 2018.

The UK Biobank Ethics Advisory Committee (EAC) is a Committee of the UK Biobank Board, chaired by Professor

Anneke Lucassen. Its remit is to provide advice to the Board on ethical issues that arise during the maintenance, development and use of UK Biobank, including:
• Identifying, defining and examining relevant ethical issues
• Providing advice, guidance and recommendations on relevant ethical issues
• Reviewing and advising on policies which have an ethical dimension that are relevant to UK Biobank
• Conducting detailed conceptual and empirical ethics research to ensure that advice is evidence-based, and that UK Biobank maintains its robust ethical justification for current and future activity.

In tandem, and to ensure that UK Biobank is ethically equipped to anticipate relevant ethical issues and respond to them in an agile way, an ethics/social science researcher will undertake detailed empirical and conceptual research as part of a research-led arm of the EAC.

13. How will you inform donors and other patients, service users and members of the public of the results of research?

Summaries of research projects that have been approved and are currently underway can be found at https://www.ukbiobank.ac.uk/approved-research/ and UK Biobank reminds its participants in communications to visit the website to receive regular updates. A research update is also included in the Participant Newsletter, which is sent annually to all participants.

14. How will the bank be managed and financed?

It is managed by an executive team of experienced scientists and managers. They are supported by operational, administrative, IT, finance and legal staff. The CEO/PI and deputy CEO report to a quarterly board meeting with associated audit and risk committees.

It is funded through core funding from its major funders (MRC and Wellcome Trust) and with additional support from BHF and CRUK.

Information governance

15. What personal identifiers will be held with the data records? *Please tick all that apply.*

- [x] Initials
- [x] Full name
- [x] Address
- [x] NHS or CHI number
- [x] Hospital ID no.
- [x] GP registration
- [x] Date of birth
- [x] Year of birth
- [x] Date of death
- [x] Postcode
  - ( ) District level
  - ( ) Sector level
  - ( ) Sub-sector level
  - (•) Unit level
- [x] Other geographical identifiers

please specify

Address data has been converted to grid co-ordinates (Northing and Easting), which have been rounded up to a 1km distance, and are available for research use. More detailed data (up to 100m granularity) is also available but only upon special request.
Postcode data is held, but is converted into grid co-ordinates for data release.

Purpose for which postcode/geographical identifiers required:

- [x] Deprivation scoring
- [x] Lifestyle analysis
- [x] Geographical analysis

- [x] Gender
- [x] Occupation
- [x] Ethnicity
- [ ] Other identifiers

16-1. What systems will be in place to ensure the confidentiality of personal data? *What will be your policy for limiting access to identifiable data within the establishment. Say who will have access and for what purposes, what training they will have and how the confidentiality policy will be monitored and enforced.*

UK Biobank is the data controller of the personal data which relates to the UK Biobank participants and which forms the UK Biobank resource. This data is stored by the Clinical Trials Service Unit (CTSU), which is part of Nuffield Department of Population Health (NDPH) at the University of Oxford. UK Biobank has a contract with the University of Oxford appointing it as a data processor and which contains robust UK GDPR compliant data processing clauses. NDPH can only act on the instructions of UK Biobank and NDPH has no ability to process the data for any other purpose save for those purposes which UK Biobank (alone) determines.

The architecture of the NDPH data storage systems is discrete in that identifiable data (participant's name, adddress and other identifiers) is held separately to the clinical and health data (which is stored with the identifiers removed).

Access to identifiable data
Access to any identifiable information in the UK Biobank resource is strictly limited to a small number of UK Biobank staff and its appointed processors who are (1) UK Biobank's Participant Resource Centre (PRC) at the University of Cardiff, and (2) NDPH at the University of Oxford (as described above).
- The PRC is UK Biobank's primary contact point for participants. UK Biobank has a contract with the University of Cardiff appointing the PRC as a data processor and which contains robust UK GDPR compliant data processing clauses. The PRC acts as a call centre, handling inbound and outbound phone calls and participant email queries; it deals with queries from participants about participation in new studies and participation in UKB more generally. The PRC use the identifiable data in the database to contact participants, to verify the identity of a participant who gets in contact with them and to record any interaction they have with a participant. The PRC do not have access to the clinical database.
- A limited and controlled number of administrative staff at UK Biobank and NDPH have access to the database which stores participant identifiable information to enable the continued maintenance and growth of the UKB resource. This includes inviting participants to join new studies and to be provided with information such as newsletters. These staff also undertake administrative processes such as withdrawals.

No other parties have access to the identifiable data UK Biobank holds. This includes UK Biobank's funders (which include the Wellcome Trust and UKRI Medical Research Council).

Access to de-identified data
UK Biobank permits access to the de-identified data from the UK Biobank resource to approved researchers. The access criteria is that a researcher must be a bona-fide researcher conducting health-related research in the public interest. All access applications are treated equivalently and subject to the same access criteria.
Access applications are subject to the provisions of the Access Procedures, available at:
https://www.ukbiobank.ac.uk/media/omtl1ie4/access-procedures-2011 -1.pdf and each approved researcher must enter into a Material Transfer Agreement (an MTA) with UK Biobank which (amongst other things) requires the researcher to:
- conduct the research in accordance with the approved research project;
- publish the findings and to return the results to UK Biobank;
- use appropriate security measures when processing the data;
- comply with applicable data protection laws.

The researcher is expressly prohibited from identifying or attempting to identify any individual participant.

The de-identified data are either made available directly to the researcher (for them to download and use in their own environment) or the researcher is granted access to use the data through UK Biobank's Research Analysis Platform

(RAP).

Security / confidentiality measures
UK Biobank takes the security of the UK Biobank resource extremely seriously. It has in place, and it ensures it appointed processors, linkage bodies and researchers have in place necessary technical security controls, organisation controls and physical security.

UK Biobank is ISO27001 certified such that UK Biobank's Information Security Management System is audited regularly by independent external auditors to ensure that UK Biobank has the policies and procedures needed to maintain that certification along with the risk controls (legal, physical and technical) necessary for robust IT security management.

The UK Biobank resource also has the following technical and organisational security measures in place:
- Physical security – physical systems which contain participant data are encrypted and stored in secure locations. Such locations are subject to access control systems (including external and internal fob/swipe card access), are protected by external controls such as CCTV and additional electronic and physical controls are in place to protect servers from physical and environmental threats.
- System access controls – access to files or systems containing participant data is controlled by using a default "deny-all" policy. This means that only staff with explicit authorisation can access UK Biobank systems. Authorisation controls are in place to ensure access to systems containing participant data is restricted to a "need-to-know basis". All devices used to access the UK Biobank systems require username and password protection.
- System security – electronic transmission of participant data is encrypted. Appropriate firewall, anti-virus/anti-malware provisions are also in place and updated regularly. To mitigate a loss of data, back-up copies of personal data are stored in a protected environment. Disaster recovery, research continuity plans and incident management policies and procedures are also in place.
- De-identification / pseudonymisation –UK Biobank goes to significant lengths to de-identify/pseudonymise all data it releases to approved researchers.
- Sample security –samples are stored by UK Biobank with a unique identifier.
The samples are predominately stored at UK Biobank's premises in Stockport. Only a limited number of approved staff at NDPH can link the sample identifier to a participant. This measure means the samples are stored in a de-identified way. .
- Monitoring and testing – the UK Biobank resource is subject to regular extensive penetration testing against its systems, including internal and external networks to ensure they are hardened against attack. Third parties are appointed to audit UK Biobank's systems from time to time to ensure that they remain secure and to provide best practice security advice. Audits are undertaken to ensure staff with authorisation to access any personal data are complying with UK Biobank's instructions.
- Audits/inspections – UK Biobank works in collaboration with its processors but reserves the right to conduct audits/inspections where necessary. In addition, UK Biobank conducts annual on-site audits at the PRC to check compliance with UK Biobank's technical and organisational measures. Audits are specifically conducted in relation to security measures, internal processes and policies as well as staff awareness and training. No participant data is stored on the PRC's own systems.
- Staff awareness and training – all staff involved in the UK Biobank resource are required to complete mandatory data protection and information security training on a regular basis. All staff are also subject to confidentiality provisions within their contracts of employment. UK Biobank also conducts regular simulated phishing attacks to increase staff vigilance and UKB also adopts a 'clear-desk' policy which all staff are required to comply with.
- Data Security and Protection Toolkit (DSPT) - NDPH has completed the Data Security and Protection Toolkit https://www.dsptoolkit.nhs.uk/. All organisations that have access to NHS patient data and systems must use this toolkit to provide assurance that they are practicing good data security and that personal information is handled correctly.
- Researchers – UK Biobank requires researchers to enter into a MTA which sets out minimum security measures which must be in place for the protection of the UK Biobank resource data. UK Biobank also has specific security audit rights under the MTA and researchers are required to annually self-certify their MTA compliance.

17. What security and audit measures will be in place to secure access to identifiable data held by the bank?

Please refer to the response given to Question 16-1.

Use of samples or data in future research

Questions 18 - 27 apply where the bank/establishment will be conducting its own research using the samples or data. Answer in relation to this research programme.

Questions 28 - 39 apply where the bank will be releasing its own samples and data to other researchers.)

18. Do you wish to seek generic ethical approval for research projects conducted by the bank/establishment using the stored samples/data, under conditions agreed with the REC, without requirement for the researchers to apply individually to the REC for approval?

○ Yes ◉ No

If Yes, questions 19 - 27 will be enabled.
If No, questions 19 - 27 will be disabled. Researchers will be required to apply individually to obtain ethical approval using the project-based application form.

Questions 28 - 39 apply where the bank will be releasing samples and data to other researchers.

28. Do you wish to seek generic ethical approval on behalf of external researchers who will be using samples or data supplied by the bank, under conditions agreed with the REC, without requirement for researchers to apply individually to the REC for approval?

◉ Yes ○ No

If Yes, questions 29 - 39 will be enabled
If No, questions 29 - 39 will be disabled. Researchers receiving tissue or data will be required to apply individually to the REC to obtain ethical approval using the REC project-based application form.

29. What types of research will be undertaken by other individuals/organisations using the samples or data and in what field(s) of biomedicine? *Name any research organisations or units you plan to collaborate with at this stage.*

UK Biobank aims to encourage the widest possible use of the Resource to help develop improvements in the treatment and prevention of many different diseases. Bona fide researches working in countries around the world are able to apply to use the Resource for all types of health-related research that is in the public interest.

Due to UK Biobank being a prospective study and available to any bona fide researcher worldwide, the types of research use are wide-ranging and hard to predict. To date, interest has ranged from investigating the cross-sectional determinants of factors assessed at baseline, through to genome-wide association scans of particular phenotypes, through to machine-learning approaches to identify novel patterns between a wide range of genetic and environmental exposures and a wide range of health outcomes.

Summaries of research projects that have been approved and are currently underway can be found at https://www.ukbiobank.ac.uk/enable-your-research/approved-researc h. The nature of the research that is currently being conducted reflects the increasing breadth and depth of data that are now available, with 77% of applications requesting genotype data, 60% requesting imaging data, and 92% requesting health outcome data. Of note, over 700 research groups have accessed the health record data for the purposes of performing COVID-19 research in the last 12 months.

Approved research is also included in the annual RTB report. Current approved projects include whole exome sequencing, whole genome sequencing, large-scale proteomics, metabolomics and single cell sequencing.

As the biological samples collected are a finite resource, UK Biobank's policy for the assay of depletable biological samples is that sample should be efficiently turned into non-depletable data. Any application to request biological samples must meet UK Biobank's Sample release policy. This policy requires that the proposed assay satisfies the following criteria as far as possible:
• Complete coverage, or a large subset of the cohort
• Validated assay methodology
• Minimal depletion
• Maximal output
• Data usability

30. Will any types of research or research organisation be excluded from receiving samples or data?

◉ Yes ○ No

If Yes, please give details:
Only health-related research that is in the public interest will be approved by UK Biobank.

31. Will samples be released for use in animal research?

○ Yes ◉ No

32. Will the samples be used in research into termination of pregnancy or reproductive cloning?

○ Yes ◉ No

33. What arrangements will be made to consider applications from researchers for use of the samples or data? How will decisions on access be made and who will be involved?

Please refer to the response given to Question 11 and consult UK Biobank's Access Procedures version 1.0 (November 2011) for further detail.

34. What conditions will apply to the sharing of data with researchers? *Please say how this will be monitored and enforced.*

UK Biobank's Material Transfer Agreement (see MTA) sets out the conditions and obligations which will apply on the Applicant PI, researchers and Institution of any approved research application. The content of UK Biobank's standard MTA, and the conditions contained within it, are non-negotiable.

The MTA includes a provision for UK Biobank to complete an audit of the approved applicant to monitor compliance with the terms of the MTA.

35. Please give details of how data will be effectively anonymised or pseudonymised to protect the confidentiality of subjects. What measures will you take to prevent possible re-identification by linking to other databases?

UK Biobank pseudonymises all data supplied to researchers uniquely on a per project basis. For each project, all participants within a dataset are allocated identifiers from a long-period random number generator and these identifiers are then replaced by a ranking score according to their magnitude, effectively removing any residual information from the random number generator.

Projects receiving identifiable samples or data should apply separately for ethical review using the project-based application form and give details of the consent arrangements.

36. Will samples or data be released to individuals/organisations conducting research outside the UK?

◉ Yes ○ No

If Yes, please give details and describe any additional safeguards you will put in place:
We will apply the same standards to security and feedback of data as we do to applicants conducting research within the UK.

37. What will your policy be for requiring feedback of research findings specific to the donor to be linked with the stored samples/data?

It is a requirement of the Material Transfer Agreement ("MTA") that research findings from users of the resource are returned – these can be linked with the original donor through the unique identifying code that is unique to each research project and incorporated back into the central data repository so that they can be used by other researchers.

38. Where research findings are clinically significant for individuals, will arrangements be made to notify the individuals concerned?*If Yes, please say what arrangements will be made and give details of the support or counselling service. If No, please explain the reasons why the findings will not be notified to subjects or other healthcare professionals.*

○ Yes ◉ No

There is no routine reporting or feedback of findings from subsequent research (i.e. either findings from sample assays, or from data analysis) because participants consented to a no feedback policy when they joined the study (and the value of such feedback is questionable). Please refer to UK Biobank's Ethics and Governance Framework (EGF) for further justification. In conjunction with the consent form (see attached) and the information materials, the EGF formed the basis on which the 500,000 participants were enrolled in the study.

However, for participants of the UK Biobank Imaging studies (Imaging, Repeat Imaging and COVID-19 repeat imaging) the position is slightly different. This is because abnormalities can show up on scans taken for research. If the radiographer does happen to notice a potentially serious abnormality while taking the scan, they will refer the scans to a specialist doctor (radiologist) for review. If the radiologist agrees that the abnormality is potentially serious (regardless of whether or not it might be treatable), UK Biobank will write to the participant and their GP, usually within a few weeks of the imaging visit so that further investigations can take place, if necessary.
For this reason, participants can only take part in the imaging study if they agree that UK Biobank can tell both them and their GP if they notice a potentially serious abnormality on one of their scans i.e. this forms part of the consent. However, UK Biobank would not tell the participant about a potentially serious abnormality if it was identified at a later date by researchers analyzing the scans as part of their research project. Again, each participant of the imaging study is required to consent on this basis.

39. What arrangements will be made with researchers for return, disposal or further storage of samples and data when studies are completed? What mechanisms will be in place for approving further studies?

Because the biological samples are a finite resource, UK Biobank will agree the minimum amount of sample required for their research with approved research applicants.

Approved research applicants are required to sign a Material Transfer Agreement (MTA) which includes the provision that, on the completion of the Research Project, the applicant will return results to UK Biobank and delete any datasets, destroy or return any residual samples, and confirm to UK Biobank (in writing) that this has taken place.

Sample collection and informed consent arrangements

Questions 40 - 41 apply only to the bank's existing collections of stored samples/data:

40. Has informed consent already been given for use of samples/data in research?

◉ Yes ○ No ○ Not applicable

If Yes, for what purposes has consent been given?
Each participant has given permission for long-term storage and use of biological samples for health-related research purposes (even after incapacity or death), and relinquishes all rights to these samples which are donated to UK Biobank.

Please enclose a copy of the information sheet and consent form used (if available).

41. If informed consent has not been given, is it proposed to seek consent for future use of samples/data in research?

○ Yes ○ No ◉ Not applicable

Application should be made to the Confidentiality Advisory Group' (CAG) to process the identifiable data of living donors without consent in England and Wales – see guidance notes.

Question 42 applies to collections from the deceased only:

42. What arrangements will be made to seek appropriate consent (or authorisation in Scotland)? *Please describe the involvement of collaborators.*

Not applicable

Please enclose copy of information sheet(s) and consent form(s).

Questions 43 - 46 apply to prospective collection of samples or data from the living:

43-1. How and by whom will donors be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

In order to help tackle the global coronavirus pandemic, in 2020 UK Biobank completed a Serology study to measure antibodies for the coronavirus which causes COVID-19. 20,000 volunteers, a combination of existing UK Biobank participants and their children and grandchildren aged over 18 years, took part. This was done in order to increase the age range over which we could determine the extent of previous infection and was the first time that UK Biobank had ever asked anyone not already a UK Biobank participant to take part in one of its studies. The approach we took to recruitment was to invite all UK Biobank participants (who were alive and willing to be re-contacted) to sign-up for the Serology study and to consider asking their family members (children and grandchildren) if they would consider joining this study. The children and grandchildren were recruited for the purposes of the Serology study only.

There are, as yet, no plans to recruit new participants to the UK Biobank study.

43-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

44. How and by whom will donors first be approached? *Indicate whether this will be in the course of healthcare provision or whether additional procedures will be involved?*
In the case of additional procedures, what burdens could arise for participants?

No new participants will be recruited to the study.

Please enclose a copy of any questionnaire to collect data from donors which is additional to data collected in the course of normal healthcare provision.

45. Will there be any further contact with donors to collect additional samples or data following the initial donation?

◉ Yes ○ No

If Yes, please give details:
Participants gave permission, in their original consent, for UK Biobank to re-contact them. A number of enhancements to the study have already been completed as listed in Q10.

During the next 5 years we anticipate activities will include:

•Ongoing recruitment to the imaging study (100,000) and repeat imaging (70,000) enhancement

•Continued development and implementation of web-based questionnaires in order to assess other types of health outcome (e.g. cognition, sleep, mental health, autistic traits, quality of life, visual self-recognition, pain (repeat)) directly from participants (see Table 3)

•Invitation to all eligible participants to provide a repeat of the baseline touchscreen questionnaire and remote sample collection (e.g., capillary blood sample).

46. Will you obtain informed consent to use samples and data in research?

◉ Yes ○ No

If you will be obtaining consent from adult donors, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 1, and for children in Part B Section 2. If you plan to seek informed consent from other vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

If you will not be obtaining informed consent, please complete question 47.
Upon joining UK Biobank, participants gave consent for UK Biobank to collect, store and make available a range of data about them, and for UK Biobank to follow their health over time in the interest of health-related research.

We are always seeking opportunities to further enhance the data in UK Biobank and, as a consequence, we invite our participants to take part in enhancement studies. In some cases, for example the Imaging study, this requires the participant to provide their consent to take part. In each case, REC approval for the enhancement study (including review of participant materials and consent process) is sought. This was the case for two recent enhancements:

•SARS-CoV-2 serology study (previously approved by the Haydock REC ref: 16/NW/0274; substantial amendment numbers 14, 15, 16)
•Antibody lateral flow test study (previously approved by the Haydock REC ref: 16/NW/0274; substantial amendment numbers 17,18, 20, 21, 22, 23, 24)

Please enclose a copy of the information sheet(s) and consent form(s).

Questions 48-49 apply in all cases where consent to research is to be sought:

48. Will you record informed consent in writing?

◉ Yes ○ No ○ N/A

49-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information in English, or who have special communication needs? *(e.g. translations, use of interpreters)*

UK Biobank provided interpreting and assistance services for participants with disabilities. For non-English speakers, UK Biobank encouraged participants to be accompanied by a relative or friend to interpret on their behalf.

49-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to data subjects in Wales?

Participant invitation literature, including instructions regarding the consent process, were available in Welsh.

Questions 50 - 51 apply to all applications

50. Will any financial or other incentives be offered to donors?

○ Yes ◉ No

51. What steps will be taken where donors or relatives subsequently withdraw consent to the use of samples/data for research? What information will participants be given about this?

As part of the recruitment process, persons invited to take part in the study were provided with detailed information about UK Biobank, so that they could make an informed decision as to whether or not to take part. However, an equally important part of the information provided was the detail on how a participant might withdraw from the study, should they change their mind at a later date.

UK Biobank defined 3 levels of withdrawal:

No Further Contact ("NFC"): This means that UK Biobank would no longer contact the participant directly, but would still have permission to use information and samples provided previously and to obtain further information from their health-relevant records.

No Further Access ("NFA"): This means that UK Biobank would no longer contact the participant or obtain information from their health-relevant records, but would still have permission to use the information and samples provided previously.

No Further Use ("NFU"): This means that, in addition to no longer contacting the participant or obtaining further information about them, any information and samples collected previously would no longer be available to researchers. UK Biobank would destroy the samples (although it may not be possible to trace all distributed sample remnants) and would only hold information for archival audit purposes. The participant's signed consent and withdrawal would be kept as a record of their wishes. Such a withdrawal would prevent information about the participant from contributing to further analyses, but it would not be possible to remove their data from analyses that had already been done.

Whilst accepting that withdrawals would inevitably occur, UK Biobank sought to minimise the number of withdrawals by providing participants with detailed information at the outset. A dedicated Participant Resource Centre was established and remains in place to handle individual queries and concerns received by telephone or email. Participants who wish to withdraw are required to provide written confirmation of this by completing a withdrawal form (see attached Participant Withdrawal Form).

To date, the total number of withdrawals over the life-time of the study remains extremely low:

No Further Access: 225
No Further Use: 828

Sample collection and informed consent arrangements

Summary of the application

56. Please provide a brief summary of the application in a form suitable for publication, using language easily understood by patients and public. *The summary will be published on the website of the National Research Ethics Service following the ethical review. You may cut and paste from answers to other questions.*

Title of the bank: UK Biobank: a large scale prospective epidemiological resource of 500,000 people aged 40-69 from around the UK.
Human Tissue Authority storage licence no:
12002

Establishment responsible for management of the bank:

Organisation	UK Biobank Limited
Address	1-4 Spectrum Way
	Adswood
	Stockport
PostCode	SK3 0SA
Telephone	01614755360
Fax	01614755361

Please give details of the locations at which tissue will be stored:

Samples/data to be stored and collection/consent arrangements (maximum 200 words):
Since 2006, UK Biobank has collected an unprecedented amount of biological and medical data on half a million people, aged between 40 and 69 years old and living in the UK, as part of a large-scale prospective study. With their consent they regularly provide blood, urine and saliva samples, as well as detailed information about their lifestyle which is then linked to their health-related records to provide a deeper understanding of how individuals experience diseases.

Each participant provided their written consent to confirm their willingness to take part and agreed to the following:

• That they may be re-contacted by UK Biobank (e.g. to answer some more questions and/or attend another assessment visit), but this would be optional.
• To give permission for access to their medical and other health-related records, and for long-term storage and use of this and other information about them, for health-related research purposes (even after incapacity or death).
• To give permission for long-term storage and use of biological samples for health-related research purposes (even after incapacity or death).
• That they understood that none of their results would be given to them (except for some measurements during the visit) and that they would not benefit financially from taking part. Participation in the study was entirely voluntary.

Samples are stored at UK Biobank (in Stockport, Reading, Newcastle and Bristol)and the NIHR National Biosample Centres (in Milton Keynes and Oxfordshire).

Research programme/community supported by the bank (maximum 200 words):
UK Biobank is large-scale biomedical database and research resource, containing in-depth genetic and health information from half a million UK participants. The database, which is regularly augmented with additional data, is globally accessible to approved researchers and scientists undertaking vital research into the most common and life-threatening diseases. UK Biobank's research resource is a major contributor to the advancement of modern medicine and treatment and has enabled several scientific discoveries that improve human health.

The data – the largest and richest dataset of its kind – is anonymised and made widely accessible by UK Biobank to researchers around the world who use it to make new scientific discoveries about common and life-threatening diseases – such as cancer, heart disease and stroke – in order to improve public health.

Part C: Tissue Collection Centres

Please enter details of the organisations (NHS or other) in the UK that will act as tissue collection centres for this research tissue bank.

Tissue collection centre	Local collaborator

Part D: Declarations

D1. Declaration by the applicant:

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. If the application is approved I undertake to adhere to the terms of the application of which the REC has given a favourable opinion and any conditions set out by the REC in giving its opinion.
3. I undertake to seek an ethical opinion before implementing substantial amendments to the terms of the application of which the REC has given a favourable opinion.
4. I undertake to submit annual progress reports to the REC.
5. I understand that the information contained in this application, any supporting documentation and all correspondence with NHS Research Ethics Committees or their operational managers relating to the application:
    - Will be held by the main REC indefinitely (or until 3 years after the closure of the tissue bank).
    - May be disclosed to the operational managers or the appointing body for the REC in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed by the National Research Ethics Service to undertake accreditation of the REC.
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
6. I understand that a summary of this application will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication

NRES would like to include a contact point with the published summary of the application for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- ○ Applicant named at A3
- ○ Designated Individual
- ◉ Other – please give details
- ○ None

	Title	Forename/Initials	Surname
	Ms	Nicola	Doherty
Post	Head of Study Administration, UK Biobank		
Work address	1-4 Spectrum Way Adswood, Stockport SK3 0SA		
Work email	nicola.doherty@ukbiobank.ac.uk		
Work telephone	01614755360		

Access to application for training purposes

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to the establishment and other research units and collaborators would be removed.

This section was signed electronically by Professor Naomi Allen on 30/04/2021 12:15.

Job Title/Post:	Chief Scientist
Organisation:	UK Biobank
Email:	naomi.allen@ndph.ox.ac.uk

D2. Declaration by the Designated Individual

I confirm that the information in this form is true and accurate to the best of my knowledge and I support the application.

This section was signed electronically by Mrs Samantha Welsh on 30/04/2021 13:10.

Job Title/Post:	Laboratory Manager
Organisation:	UK Biobank
Email:	samantha.welsh@ukbiobank.ac.uk