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)
Our Future Health

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

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

( ) Clinical investigation or other study of a 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
- [x] Northern Ireland

4. Which applications do you require?

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

4a. Will you be seeking data from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS)?

( ) Yes (●) No

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

CAG Application Form

NHS
Health Research Authority

This application is to the Confidentiality Advisory Group (CAG) for Health Research Authority approval to gain access to and process patient identifiable information without consent under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether an application should be approved, and if so, any relevant conditions.

Most of the information required for this form is populated automatically from the Integrated Research Application System once relevant sections and questions are completed. Please check that all answers have been correctly generated and modify if necessary.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Our Future Health

Submission date: 03/03/2022

Will you be applying to a NHS Research Ethics Committee (REC) for ethical review of this tissue bank?

(●) Yes - application submitted

Name of REC: East of England - Cambridge East Research Ethics Committee
REC reference number: 21/EE/0016

( ) Yes – application not yet submitted

( ) No

Part A: Core Information

Administrative information

1. Title of the bank.

Our Future Health

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

Organisation	Our Future Health Ltd
Address	Eversheds House
	70 Great Bridgewater Street
	Manchester
PostCode	M1 5ES
Telephone	07796707401
Fax	

Please give details of the locations at which tissue will be stored:
National Biosample Centre, Units 2 & 3, Java Park, Bradbourne Dr, Tilbrook, Milton Keynes MK7 8AT

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
	[redacted]	[redacted]	[redacted]

Address	Eversheds House
	70 Great Bridgewater Street
	Manchester
PostCode	M1 5ES
E-mail	[redacted]
Telephone	[redacted]
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

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	NIHR - National Biosample Centre
Address	Units 2 & 3, Java Park, Bradbourne Dr
	Tilbrook
	Milton Keynes
PostCode	MK7 8AT
Telephone	01908 870800
Fax	

5. 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

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

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]

Address	Units 2 & 3, Java Park, Bradbourne Dr
	Tilbrook
	Milton Keynes

PostCode	MK7 8AT
E-mail	[redacted]
Telephone	[redacted]
Mobile	
Fax	

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

○ Yes ◉ No

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.

Our Future Health plans to collect a sample of either blood or saliva at recruitment of individuals to the project.

We will either collect:
1. Approximately 14ml of blood which will be collected during a routine venepuncture appointment.
2. A 2ml sample of saliva into a saliva collection tube (Oragene 500) provided to participants to donate at home.

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.

The project will be administering a questionnaire to each participant at recruitment. The questionnaire will cover a range of domains:
1. Socio-demographic Factors (age, sex, height, weight, ethnicity, marital status, employment status, occupational history, education)
2. Lifestyle factors (physical activity, mobile phone use, sleep, smoking, vaping, alcohol)
3. Medical history

In addition to the questionnaire, we will link the participants to the health and social care data organised by NHS Digital. We wish to link to death and cancer registries, hospital records (inpatient and outpatient), primary care records, and other health related datasets that provided individual level health and care data.

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

This tissue bank is being established under the auspices of the Industry Strategy Challenge Fund as a major national resource for future research into early detection of disease. As such the intention is to make this resource widely available to academic, clinical and commercial researchers.

During the development of the project, we have engaged widely with the various communities and will continue to do so during the delivery of the program. This includes close connections to leading medical research charities (Cancer Research UK, BHF, Prostate Cancer UK, Wellcome Trust, LifeArc, Alzheimers Research UK, AMRC among others), the biopharmaceutical industry including (Roche, Merck, GSK, AZ, Regeneron, Amgen, J&J) and the wider academic

community through research funding agencies and UKRI.

Broadly the intent is to ensure that appropriately accredited researchers will be provided access to the resource for research projects that are approved by our access committee and are in line with the participant consent. Researchers from the project team will have to ensure they follow the same access and governance principles as external researchers.

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?

In 2020, we involved members of the public in the design and development of the public-facing materials as well as in other aspects of the project design. Much of this work was carried out with Claremont, a behaviour change communications agency with considerable experience in the health care and health research sectors. To date, the co-design of the participant information sheet and consent form has included:

• 18 focus groups with 82 members of the public;
• 4 meetings with a co-design group comprised of 8 members of the public; and
• 21 user testing interviews with members of the public.

In addition, the co-design group met a further two times in 2020: once to contribute to recruitment methods design, and once to provide input to the terms of reference for industry partners.

We also conducted a further series of four focus groups to inform the recruitment routes:

• 2 focus groups with members of the public who have either recently had an NHS Health Check or who are eligible for one; and
• 2 focus groups with members of the public who have donated blood to the NHS via NHSBT.

Claremont is now supporting Our Future Health in 2020 Q4 to 2021 Q1 to:

• co-design additional public-facing-facing information assets including leaflets, posters and 'explainer' videos with 8 members of the public who are meeting 3 times over a period of 3 months (a new co-design group); and
• conduct interviews with a wide range of additional stakeholders including health charities, NHS healthcare providers, and NHSBT staff.

The members of all of the co-design groups have contributed substantially to the design and content of the public-facing materials.

Going in to 2021 Q1-Q2, Claremont will work with ADD to engage local communities with the project, focusing on groups that are underrepresented in health research: Asian communities, Black communities, and people living in areas of high deprivation.

The Our Future Health behavioural science team, and Claremont, are also working closely with the digital team and Kainos on three rounds of user testing (total n=36) of the participant information sheet and consent form, along with the registration and questionnaire completion, delivered digitally.

Our Future Health is also working with consultant [redacted] (founder of A Vibe Called Tech) who specialises in engaging black communities with technologies to:

• develop a diversity and inclusion policy;
• establish a Diversity and Inclusivity Advisory Group;
• and engage Black communities in the cohort recruitment strategy development.

12-2. Have you consulted patients, service users or members of the public and tested the acceptability of processing identifiable patient data without consent?

Both NHS Digitrials and Our Future Health take patient involvement very seriously and it underpins the design, planning and implementation behind this application. Both parties have carried out extensive engagement and involvement as described below.

1. Patient involvement: NHS DigiTrials

Confidential Patient Information will be used without consent only for invitation purposes.

The public value of clinical research is significant but only if that value can be harnessed appropriately. NHS DigiTrials are invested in using Public and Patient Involvement and Engagement (PPIE) for collaborative co-production to assure the service is acceptable, accessible and inclusive. As such, NHS DigiTrials have, and continue to, take a multifaceted approach to PPIE.

NHS DigiTrials have a dedicated Co-Development Panel that comprises 10 attendees that were recruited via public advertisement and through structured interviews to provide a broad representation of regions of England, age, gender and ethnicity. They have varying degrees of experience and interest in clinical trials.

The panel have been consulted to test the acceptability of NHS Digital using identifiable patient information to identify a cohort and disseminate this to a third-party mail house, for the purpose of inviting an individual to take part in research. They have repeatedly expressed their passion for equality of opportunity which led to NHS DigiTrials pursuing a service model that includes use of Section 251 support to enable patients to make decisions themselves about their involvement in research, and to increase representation of different demographics within clinical trials.

The Co-Development Panel were also involved in the review of the messaging for the first NHS DigiTrials Recruitment pilot (the NHS Galleri trial) before these were published. Feedback from the panel confirming that the information clearly explained an individual's options if they did not want to take part was instrumental in aiding the Go-Live decision, and learnings from this will be carried forward into future pilots.

NHS DigiTrials continue to co-design public facing materials to increase awareness of the service, including animations upon feedback from the Co-Development panel that information such as transparency notices are inaccessible due to the language and volume of text included in them.

To verify findings and further test acceptability of the NHS DigiTrials Recruitment service, a survey is being commissioned to administer to 6,000 members of the public, followed by deeper exploration through focus groups and one-to-one interviews facilitated by a Behavioural Scientist.

2.Patient involvement: Our Future Health

2.1 Public involvement, co-design and behaviourally-informed testing to date

Involving the public in the design and co-design of Our Future Health is one of our core values. Between 2020 and 2021, Our Future Health, with Claremont, a behaviour change communications agency, conducted a series of interviews, focus groups and co-design workshops with over 200 members of the public to inform the design the Our Future Health participant information sheet, consent form and other public-facing videos and materials, and other aspects of the programme design. Individuals were recruited to ensure representation across ethnic and socio-economic diverse groups. Fourteen individuals from this work now comprise our Public Advisory Board, which also has representation on our Technology, and Ethics, Advisory Boards. A full description of our public involvement and engagement activities to date can be found in Part A, question 12-1.

Specific to this application we have obtained feedback and advice from four members of our Public Advisory Board, and conducted one-hour 1:1 interviews with 14 members of the public who were naïve to Our Future Health. Respondents were selected to provide a range of opinions, including in ethnic and socio-economic diversity, as well as those who described themselves as distrustful of research and science. Both groups reviewed the proposed invitation letter, and the proposed approach to the identification and invitation of potential participants. A smaller group have reviewed the copy to be used as part of the communications plan.

Summary of important findings relating to use of data without explicit permission:
• All respondents were happy with their data being used as proposed by NHS Digital.
• Most respondents were unaware that mailing contractors were used by the NHS, but happy with their use. One respondent wanted greater reassurance of the security of the contractor and one recommended using a 'softer' term than 'mailing contractor'.
• Many understood the description of how individuals will be identified and invited (including the role of the HRA and CAG), but many did not. Some found the legal language jarring against the warm tone of the invite section and felt that something was being hidden from readers. One interviewee was concerned that the NHS had paid for the printing and postage.
• Respondents were asked whether they thought that the public should have the ability to opt-out of being identified and invited. Three respondents believed that there should be this requirement because of the way their data would be used. None of the respondents would have used the opt-out.
• All respondents felt fully informed by the copy to be used as part of the communications plan that they could opt-out of receiving the invite letter and understood how they could do this.

Change made in response to the testing:
• Text has been added to reassure readers of the security of the mailing contractor and language has been modified to

describe the contractor.
• The text has been simplified, with formatting used to support ease of reading e.g., using bullet points. We will also consider using illustrations to explain the relationship between the HRA, CAG, NHS Digital and Our Future Health.
• The language of the 'how did you get my name and address' section has been adapted to mirror the invitation section of the letter, to enhance trust.

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

We will be maintaining a public website which will amongst other things contain summaries of the the approved research projects and when complete a lay summary of the findings.

We ask that all researchers publish the results of their research in scientific journals.

We will be providing updates/newsletters to participants summarising progress with the study and highlighting key results.

14. How will the bank be managed and financed?

The bank is managed by Our Future Health who have been setup specifically for this purpose. Our Future Health is a company limited by guarantee which is also registered as a charity.

The project is funded by a £79m grant from UK Research & Innovation through the Industrial Strategy Challenge Fund. It is required that we match this funding 2:1 through support from research charities and the biopharmaceutical industry. Negotiations are ongoing to secure this addition funding.

Additionally we have £55m of funding from NHS-X AI Labs fund to support the work on genetic SNP chip analyses on the whole cohort.

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
- [ ] Hospital ID no.
- [ ] GP registration
- [x] Date of birth
- [ ] Year of birth
- [x] Date of death
- [x] Postcode
  - ( ) District level
  - ( ) Sector level
  - ( ) Sub-sector level
  - (•) Unit level
- [ ] Other geographical identifiers

Purpose for which postcode/geographical identifiers required:

- [x] Deprivation scoring
- [ ] 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.*

Identifiable data will always be held separately to other participant data, in the following systems:
• The primary data store will separately store both identifiable participant data and the participant health data, so that the identity of a participant is not stored together with their health data. In aggregate, this data store is the master copy of the Our Future Health data. There will be no access to this data store other than technical systems administration staff via virtual private networks. Access will be time-limited and audited. All data will be stored encrypted and securely backed up to a secondary data centre, within the UK, using public cloud services. Individual participants, following authentication, will be able to view and update certain fields, only for their own information.
• The Customer Relationship Management (CRM) system will hold identifiable data but not any health data or sensitive data. This system is used to track progress of samples through labs, track progress of participants, and to communicate with participants. Access will be limited to members of the clinical operations staff, and a limited number of technical or administrative accounts to administer the system. Actions in the CRM system will be logged for audit purposes. Two-factor authentication will be in place, and the system will be hosted within the UK.
• Identifiable participant data will be securely transferred to NHS Digital in order to link to NHS records. On entry to NHS Digital systems, once the automated linkage has occurred, the data will be de-identified prior to being made available for analysis and research. NHS Digital will act as a data processor, and this will be covered by a Data Processing Agreement.

Note that identifiable data will not be released to researchers, and indeed researchers will only be able to access de-identified data within a trusted research environment (export will not be permitted).

Our Future Health staff are vetted prior to being hired, and will receive ongoing training that covers information governance, data protection and cybersecurity. Corporate systems are secured with regularly updated antivirus tools, blocking known malware sites, regular patching, single sign-on with two-factor authentication across all key systems. When we return to a physical office space it will include secure entry controls. Office networks and firewalls will be regularly patched.

16-2. Please specify whether identifiers will be held in the same database as the clinical data, or in a separate database and linked through a unique study or case number. *If held separately, please specify how and at what point the separation will occur. If held in the same database, will the identifiers be encrypted? If so, please specify what will be encrypted and who will continue to have access.*

Our Future Health have designed a web-based interface by which respondents can view study documentation (PIS, ICF) and consent to the programme electronically/online. The timing of which can occur at any time after invitation, where online connectivity is available.
Consent, demographics, personal data, health information (via questionnaire) etc. will be provided directly by the respondent into the ‘primary data store’.
The Primary health data store will separately store both identifiable participant data and the participant health data, so that the identity of a participant is not stored together with their health data.
There will be no access to this data store other than technical systems administration staff.
Access will be time-limited and audited. All data will be stored encrypted and securely backed up to a secondary data centre, within the UK, using public cloud services.
The Main health data store is part of the pilot platform operated by our supplier Kainos. Kainos are responsible for the ongoing security of the system, that is hosted within an Our Future Health Microsoft Azure environment in the UK. The Technology Director and Lead Architect for Our Future Health work closely with their counterparts at Kainos to regularly review decisions, processes and results of any testing.
Kainos are ISO27001, Cyber Security Essentials (whole-company), and Cyber Security Essentials Plus (specific projects) accredited; they also deliver and manage digital services that are HIPAA and SOC 2 compliant. They adhere to security industry standards including OWASP Secure Coding Practices, GDPR, SAFECode, and NCSC Cloud Security Principles. Kainos recruitment processes (including contractors) ensure all staff undergo pre-employment BPSS screening and DBS checks before joining, including Security Check eligibility. This is recorded, updated and maintained in a central workforce planning tool, including any certifications.
For live operations, Kainos run a 24/7 secure managed service that is ISO27001 and PSN accredited from their UK

headquarters, with security cleared staff. This includes continuous monitoring of all cloud infrastructure and application levels for the detection of malicious activities, incident management and response protocols, deployment and operation of Security Information and Event Management (SIEM) systems for the detection and retention of logs for forensic analysis.

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

Ensuring the security of participant data is of the utmost importance.

The system we design will use Secure by Design and Privacy by Design principles and will be built according to the Government Digital Service Technology Code of Practice, as well as taking into account the NCSC guidance such as the Cloud Security Guidance and 10 Steps to Cyber Security. Technical requirements will therefore include, regular patching, firewalls and denial-of-service protection, very restricted access to production systems with audit trails, all data will be encrypted in transit and at rest, system monitoring and centralised logging, regular penetration testing and vulnerability scanning.
During 2021 Our Future Health will achieve both CyberEssentials Plus and NHS Data Security Protection Toolkit accreditations. Processes will be further strengthened with ISO27001 accreditation in 2022. Our Future Health will be engaging a security lead, working with a security consultancy for provision of services such as penetration testing, incident management and security review, and working directly with the National Cybersecurity Centre.

As explained in Q6-1, an audit system will be in place for both time-limited systems administrator access to the main data store and use of the CRM system. NHS Digital employ equivalent procedures within their systems for the identifiable data they hold. All accounts will be protected by two-factor authentication and linked to staff on-boarding and off-boarding processes.

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.

19. What types of research will be undertaken and in what field(s) of biomedicine?

It is anticipated that this resource will be valuable across a range of disease areas affecting human health.

The projects could span wide aspects of discovery and translational research from internal Our Future Health researchers as well as external researchers from academia and industry.

20. What types of test or analysis will be carried out on the samples or data?

The only upfront analysis that will be performed is DNA extraction and SNP array quantification on a custom designed array (currently being procured).

No other upfront analyses will be performed - samples will be stored in the tissue bank for future biochemical and other genetic testing.

21. Will the research involve the analysis of human DNA in the samples?

◉ Yes ○ No

22. Is it possible that the research could produce findings of direct clinical significance for individuals? *(This may include relatives as well as donors.)*

(●) Yes ( ) No

23. Where research findings are clinically significant for individuals, will arrangements be made to notify the individuals concerned?

(●) Yes ( ) No

If No, please justify. If Yes, say what arrangements will be made and give details of the support or counselling service.
As explained to patients, we are not intending to return results at the time of recruitment.

The decision to return either clinically significant or personal research results will be made on the basis of advice received from our independent Access Review Committee. That committee will include experts from primary care, risk communication, public health, genetics, participants and ethics. They will consult with us both on whether to return results as well as the process to communicate the information and necessary supporting pathways,

Before returning any results we will contact the participants, provide them with more information about what was being proposed to be returned and allow them the option of saying yes or no to receiving the information.

24. Will the samples be used in animal research?

( ) Yes (●) No

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

( ) Yes (●) No

26. 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?

Applications for access to the samples and data will be reviewed by the Our Future Health Access Review Committee. This committee will be chaired by an independent externally appointed academic and will have at least the following represented disciplines:
Principal Investigator
Academic
Clinical
Data Governance/Privacy
Ethics
Lay

The committee will review each application and decide whether the project complies with the terms of the participants consent, whether the project is ethically sound and scientifically justified and whether the project has a reasonable chance of success. It then then either approve or reject the the release of samples and/or data as appropriate.

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

All applications to use the data will have to sign data transfer agreements which will detail all the terms and conditions of access. In summary this will include:

Organisations conducting research studies will ensure compliance with security and information governance accreditations as determined by Our Future Health over time, such as the NHS Data Security and Protection Toolkit

Researchers must not attempt to re-identify individual participants Trusted Research environments

Research data will be accessible within accredited Trusted Research Environments. A Trusted Research Environment is a secure online environment that allows researchers to access data and perform analysis or computation. No participant-level data can be exported from a Trusted Research Environment.

All data made available will be robustly de-identified to protect the privacy of participants while maintaining its scientific and research value

Trusted Research Environments will be fully auditable and will maintain verifiable logs of researcher access, cloud and data usage and exports.

Accreditation of a Trusted Research Environment will be reviewed and renewed periodically by Our Future Health. The accreditation criteria will apply equally to all research environments, and will include security, confidentiality and access control requirements as well as data licensing provisions from data controllers.

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.*

Our Future Health will support a broad range of project that are in the interest of human health.

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

(●) Yes ( ) No

If Yes, please give details:
Any application not in the interest of human health.

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?

Applications for access to the samples and data will be reviewed by the Our Future Health Access Review Committee. This committee will be chaired by an independent externally appointed academic and will have at least the following represented disciplines:
Principal Investigator
Academic
Clinical

Data Governance/Privacy
Ethics
Lay

The committee will review each application and decide whether the project complies with the terms of the participants consent, whether the project is ethically sound and scientifically justified and whether the project has a reasonable chance of success. It then then either approve or reject the the release of samples and/or data as appropriate.

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

All applications to use the data will have to sign data transfer agreements which will detail all the terms and conditions of access. In summary this will include:

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All data made available will be robustly de-identified to protect the privacy of participants while maintaining its scientific and research value

Trusted Research Environments will be fully auditable and will maintain verifiable logs of researcher access, cloud and data usage and exports.

Accreditation of a Trusted Research Environment will be reviewed and renewed periodically by Our Future Health. The accreditation criteria will apply equally to all research environments, and will include security, confidentiality and access control requirements as well as data licensing provisions from data controllers.

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?

Researchers will only access data within a Trusted Research Environment (TRE). As the data is made available to the TRE it will pass through a number of data processing and cleaning steps. These will include robust de-identification. A freshly generated Research Participant ID will be created for each participant, with the linkage back to the original Participant IDs only stored within the secure Our Future Health data store and only available to secure internal systems. In addition, there will be steps to remove or aggregate certain identifying fields, and deal with small groups within the data. During the pilot phase this de-identification will be performed by NHS Digital using their existing comprehensive toolset (currently provided by Privitar); during subsequent phases the solution will be selected via an open procurement process. Researchers will not be able to export participant-level data from TREs, and this is a key mechanism to further reduce the risks of re-identification. Not attempting re-identification will also form part of their contractual terms when accessing the TRE.

Limited Our Future Health staff will have access to identifiable data for operational reasons, such as communicating with participants. However, these operations teams will not have access to any sensitive or health data for participants, nor will they see Participant IDs or be able to export data. Furthermore, in the primary internal data stores, Our Future Health will keep identifying information separate from the main health information, linked only with the Participant ID. These data stores are not directly accessible to anyone other than technical systems administration staff, whose access will be time-limited and auditable.

The de-identification scheme will be open to audit by independent security consultants and vetted as part of our data governance processes reported to the Board. Each application to access data will be reviewed by the Data Access Committee who will assess the potential risks based on the selection criteria and extent of linkages being made available to the research team.

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:
Information about this issue will be explained to participants in the PIS.

Given the funding and intent of the resource it is highly likely that we will have applications from researchers, both academic and industry, around the world. The most likely applicants are expected to come from Europe and North America but we would also expect applications from other world territories.

Based on our intended model for data access with accredited Trusted Research Environments we will be ensuring that all data access/analysis conforms to the same requirements no matter where in the world the researchers might be accessing the data.

If samples are shipped overseas, then as part of any material transfer agreement we would ensure that samples are only shipped provided the applicant has the necessary legal, regulatory and ethical approvals in place.

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

Research findings will be under the exclusive use of the researchers initially but will need to be provided back to the tissue bank within 36 months following the end of data collection (database lock). It would be linked with the participant data record in the database.

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

As explained to patients, we are not intending to return results at the time of recruitment.

The decision to return either clinically significant or personal research results will be made on the basis of advice received from our independent Access Review Committee. That committee will include experts from primary care, risk communication, public health, genetics, participants and ethics. They will consult with us both on whether to return results as well as the process to communicate the information and necessary supporting pathways,

Before returning any results we will contact the participants, provide them with more information about what was being proposed to be returned and allow them the option of saying yes or no to receiving the information.

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?

Data will be made available within accredited Trusted Research Environments for research projects that are approved for fixed and agreed periods of time as specified within the material transfer agreement.

Only sample volumes necessary for the analysis and approved by the access committee will be shipped to researchers so there will be no need for return or disposal. In order to preserve the quality and integrity of the samples we will aim to minimise the freeze thaw cycles and the central processing laboratory will prepare any samples for shipment.

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

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

If Yes, please include details of the arrangements for seeking consent in your answer to questions 43-46. If No, please justify:

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).*

The ways in which donors will be identified will differ between the different types of study settings. Each of these is outlined below.

1. NHS Health Check or other routine blood test in primary care: Eligible patients will be identified by staff at GP practices via computerised searches of GP records.

2. Secondary care outpatient appointments: Eligible patients will be identified by hospital staff via computerised searches of medical records.

3. NHS blood donation: Eligible blood donors will be identified by NHSBT staff.

4. Existing study participants: Eligible participants will be identified by the existing study staff, via computerised searches of their participant records.

5. Survey based sampling: Eligible individuals will be identified by staff at the survey company/organisation via computerised searches of their survey respondent records.

6. Direct recruitment (e.g. referral from a family member) or regional/local/community activity: Individuals will not be identified, but rather will self-identify and volunteer to register/consent directly on the Our Future Health website.

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?

Once identified as eligible, individuals will be 'approached', i.e. sent invitations to participate in Our Future Health, via email, text or letter. The way in which this is done, as well as the content, and by whom, will depend on the recruitment route / study setting. As illustrated below, it is our intention to have the partner organisation send the invitation where possible to reduce the amount of personal data travelling outside of their own environments.

1. NHS Health Check or other routine blood test in primary care: Primary care patients will initially be approached to take part via an invitation letter, email or text message from their GP practice (precise method will depend on the preferred means of communication at the practice). As described briefly in the invitation letter (primary care version), patients will be informed that when they attend their NHS GP appointment, a healthcare professional will also (with their consent) collect a blood sample from them, to send to Our Future Health. Only patients who already have an appointment that involves a blood draw will be invited to participate in Our Future Health, and so this will not be an added burden for them. They will also be asked to complete a questionnaire, and this is also described briefly in the invitation letter.

2. NHS secondary care outpatient appointments: Secondary care patients will be initially approached to take part via an invitation letter, email or text message from their hospital healthcare professional. The format will be the same as for primary care (see above, and primary care version of invitation letter).

3. NHS blood donation: NHS blood donors will be initially approached via an invitation email/letter from NHSBT. As described in the invitation letter, blood donors will be asked to register online before attending their next blood donation appointment, and then a blood sample will be taken for Our Future Health in addition to their normal blood donation. This will not constitute an additional burden for them. Also as described in the letter, they will be asked to complete an online questionnaire.

4. Existing study participants: Existing study participants will be initially approached via an invitation email/letter/text message from the staff/PI of the study they are already participating in. Individuals approached via this route might be invited either to donate a blood sample or a saliva sample. Individuals who are invited to donate a saliva sample via this route will be informed that taking part involves answering some questions; they will also be informed that a kit to collect small samples of their saliva will be sent to them. See the 'At home version' of the invitation letter attached. (We are currently developing the blood sample collection plan for this route and so are not attaching this invitation letter version at this time.)

5. Survey based sampling: These individuals will receive an invitation email/letter/text message from the survey company or organisation. At present, we are planning that individuals invited via this route will only be invited to donate saliva: see the 'At home version' of the invitation letter for further details.

6. Direct recruitment (e.g. referral from a family member) or regional/local/community activity: These individuals will not receive an invitation, as they will self-identify and seek out information about the project independently.

Some of the information in the invitation letter/email/text message will be generic, and some will be context specific. The information that will vary between contexts will relate to the mechanics of how a participant is enrolled, for example, we will give more information about how to enter their own information into a device at home versus having that information collected by a health care professional and entered into a shared device in an NHS setting. All invitations will include a link to a landing page on the Our Future Health website (landing page and website are described further below in Section 3.5.1. Information). Three versions of the Participant Invitation Letter are attached: (1) NHS primary care version, (2) NHS blood donors version, and (3) 'at home' version (which covers existing study participants, survey based sampling, and direct recruitment routes).

The current version of the questionnaire to collect additional data from participants is described in the protocol and a copy is attached.

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:
As described in the information sheet, participants may be contacted periodically to collect further data and samples. Such collections will always be optional.

Participants may also be contacted when selected to be invited to take part in future research projects. Such projects would have independent review/approvals.

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.*Initial broad consent will be sought from all participants at the time of recruitment (Phase 1 consent), and further detailed supplementary consent will be sought as required for additional studies (Phase 2 consent). Further specific consent will also be sought for certain types of feedback, such as research-level genetic risk scores. We are currently seeking REC approval for the initial broad consent (Phase 1) only; subsequent project-specific consent materials and processes will be submitted separately as amendments and/or separate REC submissions by Our Future Health and/or external researchers.

As described in the protocol, information will be provided to support the consent process using an information sheet, as well as via other means including explainer videos. Copies of the information sheet, consent form, and draft scripts for explainer videos are attached for review by the REC.

Our goal is that potential participants will complete the e-consent process online wherever possible; this is necessary to enable the scale needed. Many people will complete the consent process at home (i.e. prior to an NHS primary or secondary care appointment involving a blood draw, prior to a blood donation appointment, or where they have been invited to provide a saliva sample at home). In these cases, potential participants will be provided with very clearly stated information about how to contact the project via email, phone, text or messaging to talk to a trained member of the Our Future Health team who can answer any questions they might have. All staff answering questions will be appropriately trained, monitored and supported.

In some cases, individuals attending in-person appointments (e.g. NHS primary care) will not have completed the consent form online in advance of their appointment despite having had this option. All staff involved in the face-to-face appointment will therefore be trained to answer potential participants' questions and support them through the consent process in-person where necessary. This applies to any Our Future Health staff at the site of the appointment, and all other staff (GPs, practice nurses, phlebotomists at hospitals, NHSBT nurses/staff, mobile unit staff etc.). This will be done in accordance with a Standard Operating Procedure (SOP).

We provide more specific details for each study setting below:

1. NHS Health Check or other routine blood test in primary care: Consent will be obtained online prior to the clinical appointment and with the support of trained Our Future Health staff, or at the GP practice by a trained member of the GP practice staff.

2. Secondary care outpatient appointments: Consent will be obtained prior to the clinical appointment online and with the support of trained Our Future Health staff; at the hospital appointment by a trained member of the hospital staff; or by a trained Our Future Health staff member situated at the hospital site.

3. NHS blood donation: Consent will be obtained prior to the blood donation appointment online and with the support of trained Our Future Health staff, or at the blood donation appointment by a trained NHSBT staff member.

4. Existing study participants: Consent will be obtained online and with the support of trained Our Future Health staff over the phone/email/other remote means.

5. Survey based sampling: Consent will be obtained online and with the support of trained Our Future Health staff over the phone/email/other remote means.

6. Direct recruitment (e.g. referral from a family member) or regional/local/community activity: Consent will be obtained online and with the support of trained Our Future Health staff over the phone/email/other remote means.

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

If No, how will it be recorded?
Consent will be recorded electronically.

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)*

It is our intention to recruit a cohort of participants that is as inclusive and diverse as possible, and translating the materials into languages other than English will be an important part of achieving this goal. We will therefore be translating the final patient facing materials and all our digital tools into other languages; these materials will be submitted to the REC for review before use in the field.

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?

We will be translating the final patient facing materials and all our digital tools into Welsh at the time when we commence recruitment in Wales. We are working closely with Health & Social Care Wales and will ensure that all aspects of the Welsh Language Act are complied with.

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 described in the PIS participants are free to withdraw at any time. The withdrawal procedure is described in the protocol and participant information sheet.

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: Our Future Health
Human Tissue Authority storage licence no:
12624

Establishment responsible for management of the bank:

Organisation	Our Future Health Ltd
Address	Eversheds House
	70 Great Bridgewater Street
	Manchester
PostCode	M1 5ES
Telephone	07796707401
Fax	

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

Samples/data to be stored and collection/consent arrangements (maximum 200 words):
Our Future Health plans to collect information and samples from up to 5 million adults across the UK. We aim to

collect either a blood sample or a saliva sample from the participant as well as ask them to complete a questionnaire about their lifestyle and health. In addition to the data we collect from participants we will also ask for permission to link to their health and care records stored by NHS Digital and other UK NHS Bodies.

Participants will be recruited from a range of settings including those attending routine appointments in primary care (e.g. Health Checks, Blood Tests, etc), routine appointments in outpatients, blood donation appointments, and via direct invitation.

Our Future Health obtains generic consent which covers genetic studies, use by researchers locally, elsewhere in the UK and overseas, and by commercial/private companies carrying out biomedical research.

Research programme/community supported by the bank (maximum 200 words):
Our Future Health is the UK's largest ever health research programme. Today, too many people spend many years of their later lives in poor health. The aim of Our Future Health is to help future generations live in good health for longer.

Researchers will be able to apply to study the information and samples to make new discoveries about health and disease. Discoveries made through Our Future Health could lead to new ways to predict, prevent and detect diseases earlier in life when they can be treated more easily, including diseases such as dementia, cancer, diabetes, heart disease and stroke.

We are encouraging people from all backgrounds and ethnicities to take part in Our Future Health. In the past, people from Black, Asian and minority ethnic communities, and people with lower incomes, have not been well represented in research studies. This has meant that new discoveries have not helped everyone equally.

Part B: Additional Information for CAG

Description of identifiable data

1. Do you plan to extract data from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS)?

○ Yes ◉ No

2. Give a brief description of the confidential/sensitive patient information to be used.

Participants will be recruited following a centralised, automated search of NHS nationally-held, coded datasets. Coded queries are run on the data sets based on inclusion and exclusion criteria provided by the research team to NHS DigiTrials. The search result will be a list of coded information denoting individuals who meet the inclusion and exclusion criteria. The coded details are used to source the information required to issue the invitation (name, address) from the Personal Demographic Service (PDS) dataset and re-identified.

Eligible individuals will be sent an invitation letter via NHS Digital (NHS DigiTrials) using a third-party mailing house contractor (the APS Group).

Potential participants will be identified by NHS Digital, not by the direct healthcare team nor by the researchers. The reviewing/screening of identifiable personal information of patients by NHS Digital employees is covered by the Pilot NHS DigiTrials Recruitment Support Services Direction 2021 (https://digital.nhs.uk/about-nhs-digital/corporate-information-a nd-documents/directions-and-data-provision-notices/secretary-of-s tate-directions/pilot-nhs-digitrials-recruitment-support-services -directions-2021). As a result, support is not required for the searches but for the provision of the names and postal addresses of individuals in a distribution list provided to the contracted third-party mailing company.

The defined cohort will be disclosed to the contracted third-party mailing company (the APS Group) for the purposes of mailing invitation letters to eligible participants in order to seek consent to participate in the research. This disclosure is the only element for which Section 251 support is sought.

The potential participants' contact details that will be passed on to the mailing supplier and included on the invitation letter are:

- Forename
- Surname
- Address
- Postcode

Immediately prior to sending the lists to the mailing contractor (the APS Group), final checks will be run to remove any new opt-outs and sensitivity flags, and to remove anyone who has recently died. No other screening will be undertaken before the invitations are sent.

The invitation letter will also include a code to identify the individual as having been invited, via NHS DigiTrials, when they register for an appointment in the programme. Any identifiers related to the individual, e.g., name, DOB etc. will only be provided to the programme team directly by the respondent themselves when they consent and/or schedule an appointment.

For participants who do not wish to participate, there is a clear exit strategy: consent. The Section 251 support is required only for the initial contact to send an invitation. Participants who are interested in taking part in the programme will need to consent before their patient identifiable data can be used for any other purposes related to this research.

For participants who do not respond to the invitation letter and therefore do not consent, their information will be deleted by the mailing company two weeks after the relevant mailout (including full name and address). No further letters or reminders will be sent.

NHS Digital owns the contract with APS Group and requires the highest standards of compliance to be met.

APS Group is registered with Information Commissioners Office (Registration number Z7411287) Information Commissioners - Data protection register - entry details (ico.org.uk).

Please enclose the full dataset with this application.

3. Please list each of the identifiers required for validation or linkage and say why each data item is required (i.e. the justification for this combination of data items).

- ☐ Name
- ☐ NHS number
- ☐ Hospital ID no.
- ☐ GP registration
- ☐ Date of birth
- ☐ Date of death
- ☐ Postcode
  - ○ District level
  - ○ Sector level
  - ○ Sub-sector level
  - ○ Unit level
- ☐ Other geographical identifiers (please specify)
- ☑ Other identifiers (please specify)Not applicable.

All validation and linkage of identifiable personal information of patients is covered by the Pilot NHS DigiTrials Recruitment Support Services Direction 2021 (https://digital.nhs.uk/about-nhs-digital/corporate-information-a nd-documents/directions-and-data-provision-notices/secretary-of-s tate-directions/pilot-nhs-digitrials-recruitment-support-services -directions-2021). The Support under Regulation 5 of The Health Service (Control of Patient Information) Regulations 2002 is only sought for NHS Digital to disseminate the identified cohort to NHS Digital's contracted mailing supplier to issue the invitations on behalf of the programme.

4. Which identifiers will be retained for analysis purposes?

- ☐ Name
- ☐ Date of birth
- ☐ Date of death
- ☐ Postcode
  - ○ District level
  - ○ Sector level
  - ○ Sub-sector level
  - ○ Unit level
- ☐ Other geographical identifiers (please specify)
- ☐ Purpose for which postcode/geographical identifiers required
  - ○ Deprivation scoring
  - ○ Lifestyle analysis
  - ○ Geographical analysis
- ☐ Gender

- [ ] Occupation
- [ ] Ethnicity
- [ ] Other identifiers (please specify)
- [x] n\a

5. If you need access to sensitive data items, please list them here and give a reason for requesting access to each item.

Not applicable as all processing of sensitive/special category data is covered by the Pilot NHS DigiTrials Recruitment Support Services Direction 2021.

6. What is the justification for using patient identifiable data and/or HES restricted fields? *Say why anonymised/pseudonymised data would not be fit for purpose.*

Please refer to the answers for question 15 (below) for justification for the centralised recruitment method of using the NHS DigiTrials Recruitment Service and the need to send invitation letters via a third-party mail company.

Patient identifiable data is required in order to mail letters to invite potential participants to give their consent to participate in the programme. It is not possible to undertake this task with anonymised or pseudonymised data.

Processing of identifiable data

7. What are the sources of data?

Personal Demographics Service (PDS) is the source for names and addresses that are used to generate the mailing list(s).

8. Please provide an overview of the data flows. *You may use or enclose a diagram to explain this if it is helpful. Stages of identifiability/de-identification should be specified and use of encryption for transfer or storage where applicable.*

Please refer to the data flow diagram uploaded as part of the supporting documents with the IRAS application.

As part of this research programme, the processing of confidential patient information by NHS Digital to generate the cohort to be invited to join the programme is covered by the Pilot NHS DigiTrials Recruitment Support Services Direction 2021 (https://digital.nhs.uk/about-nhs-digital/corporate-information-a nd-documents/directions-and-data-provision-notices/secretary-of-s tate-directions/pilot-nhs-digitrials-recruitment-support-services -directions-2021).

The defined cohort will be disclosed to a contracted third-party mailing company for the purposes of mailing invitation letters to eligible potential participants in order to seek consent to participate to the research. This disclosure is the only element for which Section 251 support is sought. Once the cohort has been generated, the mailing list will be created using identifiable data and disseminated to the third-party Mail House (APS Group https://www.theapsgroup.com/en-gb/). The mailing list is transferred via Secure Electronic File Transfer (SEFT) or Message Exchange for Social Care and Health (MESH). The mailing company will provide a list of names and addresses of any returned letters to NHS Digital.

APS Group, https://www.theapsgroup.com/en-gb/ (third-party Mail House) is a sub-processor responsible for physically producing and sending out the invitation letters and participant information leaflet. They will be named in the Data Sharing Agreement and Data Processing Agreement and will be providing the relevant security assurances.

The detailed data production flow is attached as Appendix 7.

9. What is the frequency of the required extract?

- ○ Monthly
- ○ Quarterly
- ○ Annual
- ◉ Not applicable

10. Describe what other data are held by the organisation, which might interact with the data requested to allow person identification. Will you be linking this data with data obtained with HRA approval or HES data? If so for what purpose?

Not applicable as a Section 251 is sought only for the purpose of sending out the initial invitation letter; there is no further linkage and once mailing is completed the data is securely destroyed.

Data protection principles and standards

11. Which class(es) of section 251 support are you applying for? *Tick all that apply:*

- ☐ Specific support required (requires Regulations to be laid before Parliament)
- ☐ Support required under the Health Service (Control of Patient Information) Regulations 2002 for public health or cancer registry purposes
- ☐ Class 1 support: the process of extracting and anonymising the information
- ☐ Class 2 support: to obtain and use information about past or present geographical location
- ☑ Class 3 support: to select and contact patients to seek their consent
- ☐ Class 4 support: to link patient identifiable information obtained from more than one source
- ☐ Class 5 support: for auditing, monitoring and analysing patient care and treatment
- ☐ Class 6 support: to allow access to an authorised user for one or more of the above purposes
- ☐ Not applicable – only using HES/SUS data extract which is not identifiable

12. Please provide details of how you comply with each of the principles outlined in the Data Protection Act 2018.

1	Fair processing	The lawful basis for processing this data is the Legitimate Interest of the researcher GDPR Article 6(1)(f) and for scientific research GDPR Article 9(2)(j). Material is available on the NHS Digital website providing specific information about the transparency notices. https://digital.nhs.uk/services/nhs-digitrials/nhs-digitrials-ser vice-transparency-notice.
2	Used for specified purposes	
3	Minimum necessary for the purpose	Every effort has been made to minimise the flows of identifiable information; the minimum number of data fields required for the purposes of contacting participants will be accessed and data transferred to a third-party mailing company by NHS Digital based on formal contracts and data sharing/processing agreements. Data sharing agreements will be in place with the programme to ensure that only the data required for participant identification and contact is used and applications to use the service are subject to independent scrutiny by Independent Group Advising on the Release of Data (IGARD) (https://digital.nhs.uk/about-nhs-digital/corporate-information-a nd-documents/independent-group-advising-on-the-release-of-data) which reviews all aspects of compliance with data protection and confidentially laws. Frequency of extract will vary, rather than be a fixed monthly or quarterly process to reflect uptake and ensure no more invitations are sent than is necessary.
4	Accuracy	The PDS data used to generate the mailing list is a live database which is updated continuously. The data held on the PDS is collected by NHS care providers from patients or people acting on a patient's behalf. The NHS care providers collecting the data include GP practices and other primary care contractors (such as pharmacies), secondary and tertiary care providers, and child health,

		community, learning disability and mental health services. Within NHS Digital, staff at the PDS National Back Office (NBO) carry out a range of activities to manage and maintain the accuracy and quality of records on the PDS.
5	Kept for minimum time necessary	The minimum number of data fields required for the purposes of contacting participants will be accessed and the minimum amount of data transferred to a third-party mailing company by NHS Digital. Data sharing agreements and data processing agreements will be in place to ensure that only the data required for sending the invitation letters is transferred to the mailing company and these lists are deleted within 2 weeks of the invitation letters having gone out.
6	In accordance with rights of data subject	GDPR information is available via the links below: https://digital.nhs.uk/about-nhs-digital/our-work/keeping-pat ient-data-safe/gdpr/gdpr-register https://digital.nhs.uk/about-nhs-digital/our-work/keeping-pat ient-data-safe/gdpr/gdpr-register/personal-demographics-service-pds In addition, National Data Opt-Out will also be applied (although this is a policy opt-out).
7	Security and confidentiality protection	System level security policies (SLSP) are in place for NHS Digital. Appropriate data security measures are in place to ensure confidentiality and security of the data between NHS Digital and their third-party mailing company.
8	Not disclosed outside the EU	No data relating to the recruitment of participants will leave the UK as part of the use of these data for the specified purpose .

13. Have you undertaken a self-assessment using the NHS Information Governance toolkit?

(●) Yes ( ) No

If Yes, please provide details of your scoring and a summary of the actions to be taken as a result:

NHS Digital is processing the data on behalf of Our Future Health and holds the following assessment scores:

Organisation code: X26 (NHS Digital); 20/21 Standards Met 06/08/2021
Organization code: 8JX11 (AWS); 19/20 Standards Exceeded 31/03/2020
Organization code: 8K333 (APS); 20/21 Standards Exceeded 23/03/2021

14. Who will act as Information Guardian for any health records or other personal information used by the research team during the study?

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]
Post	Head of Clinical Trials		
Qualifications	GDPR Foundation and Practitioner		
Employer	NHS Digital		
Work Address	7-8 Wellington Place Leeds		
Post Code	LS1 4AP		
Work Email	[redacted]		
Work Telephone	[redacted]		

Fax

15. Do you have anything to add in support of the application, which is not included elsewhere on the form?

Yes. Below we provide the following information in support of the application:

1. Background
2. Key issues behind the design of processes covered by this application
3. Overall design
4. Patient involvement
5. Our Future Health pre-invitation communications plan
6. Recruitment related risks
7. Opt-out mechanisms

Attachments:

- Appendices 1-5 (Our Future Health pre-invitation communications plan)
- Appendix 6 (Example invitation letter)
- Appendix 7 (Detailed Data Production Flow)

1. Background

Our Future Health is the UK's largest ever health research programme. It is built on evidence that today, too many people spend many years of their later lives in poor health. The aim of Our Future Health is to help future generations live in good health for longer by supporting research towards the early identification of disease and development of treatments to facilitate earlier treatment.

To achieve these overarching aims, Our Future Health is creating a large biobank of data and samples that researchers around the world can apply to access in order to conduct research on early detection, prevention and treatment of diseases. In addition to facilitating this kind of discovery research by the global research community using the de-identified dataset, Our Future Health will also enable researchers to apply to re-contact participants via Our Future Health to invite them to take part in approved secondary studies, e.g., for deeper phenotyping, to participate in a clinical trial of a new drug treatment, or other kinds of translational research such as novel approaches to screening for early indicators of disease. Initial programmes of work also include developing an approach to offering the participants personal genomic information arising from their data for reasons that include facilitating recall-by-genotype studies at scale.

Our Future Health plans to collect information and samples from up to 5 million adults across the UK. Researchers will be able to apply for approval to study the information and samples to make new discoveries about health and disease. Discoveries made through Our Future Health could lead to new ways to predict, prevent and detect diseases earlier in life when they can be treated more easily, including diseases such as dementia, cancer, diabetes, heart disease and stroke.

Effective delivery of the potential and the aims of the programme requires people from all backgrounds and ethnicities to consent to take part. In the past, people from Black, Asian and minority ethnic communities, and people with lower incomes, have not been well represented in research studies. This has meant that new discoveries have not helped everyone equally.

Utilising the NHS DigiTrials service provides two specific opportunities to support delivery of the aims of the programme.

First, using the NHS DigiTrials service will support recruitment at scale, ultimately enabling the goal of 5 million participants to be achievable without undue burden on face-to-face health services. Participant recruitment requires consent, completion of a health and lifestyle questionnaire, and provision of a blood sample. The letter inviting participation will include information on a mobile service, due to be in the recipient's geographic area, to support the recruitment process including taking the blood sample. The blood samples will be analysed and stored to create a bank of biological information, and associated with the health and lifestyle data to support research into early disease detection.

Second, using the NHS DigiTrials service supports the use of inclusion and exclusion criteria to ensure the invitations can proactively support recruitment from traditionally under-represented geographic regions, ethnic groups etc.

At this time, we are applying for approval to identify and invite approximately 3 million adults in England through DigiTrials, in order to recruit 150,000 adults, assuming a 5% response rate. During and after this initial recruitment

phase (anticipated start and finish dates July 2022 to March 2023), we will conduct a range of activities to optimise the invitation letter content and design (described further below). After this phase, we anticipate that we will initiate a further phase of identification and invitation with DigiTrials to recruit a larger proportion of the total 5 million adults; approval for this next phase will be sought after the first phase is completed.

Careful monitoring of uptake rates and characteristics will be undertaken to ensure the planning of future mailouts is proportionate and supports the creation of a cohort that includes participants from diverse backgrounds. This means that while we anticipate a series of extracts to invite participants from a range of geographic and ethnic populations, the uptake rate will determine if this is at a monthly, quarterly or some other frequency. Our Future Health explicitly wishes to avoid too frequent an extract of data if it is not necessary. This may mean a frequency of, for example, 6 or 8 weeks, rather than monthly, and may result in longer periods between some extracts and shorter periods between others.

Our Future Health, in parallel, is exploring and piloting other approaches to participant recruitment, including in partnership with a range of NHS organisations (e.g. in primary and secondary care). These approaches have both advantages (e.g., obtaining blood samples for research at the same time as clinical blood draws) and limitations (e.g. sending out invitations via hospitals creates burden on NHS services). The NHS DigiTrials service offers scope for invitations at the scale needed to achieve the target recruitment numbers without creating burden on health care services. Other approaches to recruitment are also being explored including via organisations outside of the NHS but will not enable recruitment to meet UKRI required targets in 2022.

2. Key issues behind the design for this application

This research programme is seeking support under Regulation 5 of The Health Service (Control of Patient Information) Regulations 2002 to invite potential participants using the NHS DigiTrials Recruitment service.

NHS DigiTrials is a set of data services provided by NHS Digital as part of the Find, Recruit, Follow-up Programme set-up to improve health data infrastructure to support research in the UK, and consists of a Feasibility, Recruitment, Communication, and Outcomes services. For clarity NHS Digital remains the legal entity and data controller for the provision of the NHS DigiTrials services. Within this application we are using NHS Digital in order to avoid any confusion.

The use of the NHS DigiTrials Recruitment Service has been selected on the basis of a range of factors including the following consistent with HRA CAG / NHS DigiTrials Recruitment specific criteria:

Scale – Our Future Health is tasked with recruiting up to 5 million consented participants in total. The specific target for 2022 is 180,000 participants recruited via NHS Digitrials (of a total of 250,000 within this time period). Recruitment requires provision of a biological sample and other routes in partnership with the NHS are also being piloted. However due to scale other identification and invitation methods are currently limited due to increasing burden on front line health care services.

Logistics – The nature of the research programme means that other identification and invitation methods are currently limited by requiring NHS services to facilitate a blood sample from the patient. By developing mobile blood collection services and using direct invitation Our Future Health can maintain delivery without adding burden to NHS Services at a challenging time.

Data – Locating the cohort, and in particular maximising representation from underrepresented groups, requires a carefully structured criteria based search of large national data sets that NHS Digital holds.

Diversity – The research programme wants to remove bias from the recruitment process and/or requires individuals from under-represented demographics.

Opportunity – Potential research programme benefits mean that the opportunity to take part should be offered equally to the suitable population. Using NHS Digitrials provides scope to support equality of opportunity for participation.

As such, there are no practical alternative options, including seeking consent to contact, in this instance.

The processing of confidential patient information by NHS Digital employees to generate the cohort to be invited into the research programme is covered by the Pilot NHS DigiTrials Recruitment Support Services Direction 2021 (https://digital.nhs.uk/about-nhs-digital/corporate-information-a nd-documents/directions-and-data-provision-notices/secretary-of-s tate-directions/pilot-nhs-digitrials-recruitment-support-services -directions-2021).

Support under Regulation 5 of The Health Service (Control of Patient Information) Regulations 2002 is sought for NHS Digital to cover the “dissemination” of the identified cohort to NHS Digital’s contracted mailing supplier – in order to send the invitations on behalf of the research programme team. NHS Digital will contract the APS Group, as a sub-

processor to physically produce and send invitation letters. The information is identifiable and generated within England (& Wales) and although the dissemination is for the purpose of conducting the Our Future Health research programme, the NHS DigiTrials Recruitment service has the added benefit of no direct disclosure outside the NHS and its trusted, securely contracted service providers.

NHS Digital will disclose name, full postal address, and invitation code to the mailing company in order to send the invitation letters to identified participants. This will be detailed by a Data Sharing Agreement with Our Future Health which names NHS Digital as a data processor to receive the disseminated cohort and produce the invitations on behalf of the research programme. The data flow and data controller/processor arrangements are set out in a supporting document attached.

The central research programme team (Our Future Health) will only have access to confidential information about the invitees when the individual themselves directly provide it to Our Future Health and/or contact the central research programme team to express an interest in participating. The research programme itself will be undertaken on the basis of consent and therefore support is not necessary post-consent.

3. Overall design

The defined cohort generated by NHS Digital will be disclosed to a contracted third-party mailing company for the purposes of mailing invitation letters to eligible potential participants in order to seek consent to participate to the programme. This disclosure is the only element for which Section 251 support is sought. We propose to have a layered approach with the recruitment in this programme. The steps involved in this are as follows.

Firstly, potential participants will receive either: an invitation letter; an invitation letter plus a brief leaflet; or an invitation letter plus the full participant information sheet. Differences in response rates between these three conditions will be evaluated to inform subsequent decision-making about which option to adopt in the longer term. Regardless of what additional material the potential participant receives alongside the invitation letter, all options will include details on where or how further information can be accessed/requested, and details on how to proceed with consent and participation if interested. The participant information sheet and participant leaflet used will be generic, and the same as those used in other recruitment routes.

Secondly, if interested, potential participants will be directed to the Our Future Health web-based system within which they can electronically consent (e-consent) to the research programme. It is only at this point, when the potential participant has provided their information to the research programme team, that the research programme team are made aware of the individual's details.

4. Patient involvement

Both NHS Digitrials and Our Future Health take patient involvement very seriously and it underpins the design, planning and implementation behind this application. Both parties have carried out extensive engagement and involvement as described below.

4.1. Patient involvement: NHS DigiTrials

Confidential Patient Information will be used without consent only for invitation purposes.

The public value of clinical research is significant but only if that value can be harnessed appropriately. NHS DigiTrials are invested in using Public and Patient Involvement and Engagement (PPIE) for collaborative co-production to assure the service is acceptable, accessible and inclusive. As such, NHS DigiTrials have, and continue to, take a multifaceted approach to PPIE.

NHS DigiTrials have a dedicated Co-Development Panel that comprises 10 attendees that were recruited via public advertisement and through structured interviews to provide a broad representation of regions of England, age, gender and ethnicity. They have varying degrees of experience and interest in clinical trials.

The panel have been consulted to test the acceptability of NHS Digital using identifiable patient information to identify a cohort and disseminate this to a third-party mail house, for the purpose of inviting an individual to take part in research. They have repeatedly expressed their passion for equality of opportunity which led to NHS DigiTrials pursuing a service model that includes use of Section 251 support to enable patients to make decisions themselves about their involvement in research, and to increase representation of different demographics within clinical trials.

The Co-Development Panel were also involved in the review of the messaging for the first NHS DigiTrials Recruitment pilot (the NHS Galleri trial) before these were published. Feedback from the panel confirming that the information clearly explained an individual's options if they did not want to take part was instrumental in aiding the Go-Live decision, and learnings from this will be carried forward into future pilots.

NHS DigiTrials continue to co-design public facing materials to increase awareness of the service, including animations upon feedback from the Co-Development panel that information such as transparency notices are inaccessible due to the language and volume of text included in them.

To verify findings and further test acceptability of the NHS DigiTrials Recruitment service, a survey is being commissioned to administer to 6,000 members of the public, followed by deeper exploration through focus groups and one-to-one interviews facilitated by a Behavioural Scientist.

4.2. Patient involvement: Our Future Health

4.2.1. Public involvement, co-design and behaviourally-informed testing to date

Involving the public in the design and co-design of Our Future Health is one of our core values. Between 2020 and 2021, Our Future Health, with Claremont, a behaviour change communications agency, conducted a series of interviews, focus groups and co-design workshops with over 200 members of the public to inform the design the Our Future Health participant information sheet, consent form and other public-facing videos and materials, and other aspects of the programme design. Individuals were recruited to ensure representation across ethnic and socio-economic diverse groups. Fourteen individuals from this work now comprise our Public Advisory Board, which also has representation on our Technology, and Ethics, Advisory Boards. A full description of our public involvement and engagement activities to date can be found in Part A, question 12-1.

Specific to this application we have obtained feedback and advice from four members of our Public Advisory Board, and conducted one-hour 1:1 interviews with 14 members of the public who were naïve to Our Future Health. Respondents were selected to provide a range of opinions, including in ethnic and socio-economic diversity, as well as those who described themselves as distrustful of research and science. Both groups reviewed the proposed invitation letter, and the proposed approach to the identification and invitation of potential participants. A smaller group have reviewed the copy to be used as part of the communications plan.

Summary of important findings relating to use of data without explicit permission:
• All respondents were happy with their data being used as proposed by NHS Digital.
• Most respondents were unaware that mailing contractors were used by the NHS, but happy with their use. One respondent wanted greater reassurance of the security of the contractor and one recommended using a ‘softer’ term than ‘mailing contractor’.
• Many understood the description of how individuals will be identified and invited (including the role of the HRA and CAG), but many did not. Some found the legal language jarring against the warm tone of the invite section and felt that something was being hidden from readers. One interviewee was concerned that the NHS had paid for the printing and postage.
• Respondents were asked whether they thought that the public should have the ability to opt-out of being identified and invited. Three respondents believed that there should be this requirement because of the way their data would be used. None of the respondents would have used the opt-out.
• All respondents felt fully informed by the copy to be used as part of the communications plan that they could opt-out of receiving the invite letter and understood how they could do this.

Change made in response to the testing:
• Text has been added to reassure readers of the security of the mailing contractor and language has been modified to describe the contractor.
• The text has been simplified, with formatting used to support ease of reading e.g., using bullet points. We will also consider using illustrations to explain the relationship between the HRA, CAG, NHS Digital and Our Future Health.
• The language of the ‘how did you get my name and address’ section has been adapted to mirror the invitation section of the letter, to enhance trust.

4.2.2. Approach to the design and optimisation of the invitation letter

The invitation letter was designed based on the work we conducted with over 200 members of the public in 2020-21, as well as feedback from our Public Advisory Board. Specific additions to the original letter included a description of what Our Future Health is and how the research programme is funded.

As part of this earlier co-design work, we explored the barriers and motivators of participation among a range of individuals, allowing us to understand the motivators or drivers of behaviour in this context. Our Behavioural Science team identified evidence-based strategies to target these drivers to make participation more likely and converted these into messages that can be inserted into the invite letter. We have tested these messages for comprehension and acceptability among our Public Advisory Board and the 14 interviews with members of the public, and revised the content accordingly. Revisions included:

• The use of a QR code to accompany the URL

• The description that the NHS is working in partnership with Our Future Health
• Addition of the initial time commitment
• The addition of the eligibility criteria, to reassure recipients that they have not been selected to take part because of a known/unknown condition

Any revisions to the invitation letter are not anticipated to include changes to the text covering the role of the Confidentiality Advisory Group (CAG). However, should changes to that specific text be required, an amendment would be submitted to CAG.

4.2.3. Planned activities

As referred to above, the messages are being tested in an experimental study design with NHS Digital in a sample of 6,000 respondents to identify the messages most likely to result in participation. This work is underway and will be completed by April 2022. The content likely to change in the invitation letter refers to content on page 1; page 2 will remain unchanged.

In addition, we will conduct further qualitative (e.g. interviews) and quantitative (e.g. surveys) testing with members of the public to continue to evaluate, refine and optimise the invitation messages prior to the first invite letters being issued in June/July 2022. The testing and evaluation will continue when we actually invite potential participants, allowing us to further improve our invitation processes once recruitment goes live.

5. Our Future Health pre-invitation communications plan

Our communications plan is designed to align with the Confidentiality Advisory Group's purpose of protecting and promoting the interests of the public and facilitating appropriate use of confidential patient information for purposes beyond direct patient care.

The objectives for the campaign are to raise awareness of the forthcoming Our Future Health invitation, highlight the opportunity to opt-out from receiving an invitation in advance, maximise visibility of the opt-out mechanics and ensure stakeholders and partners are prepared for enquiries and concerns from the public.

We intend to ensure all owned, social media, press and radio channels are updated/populated with campaign content at least one month prior to the invitations being sent.

The full communications plan is attached as Appendix 1 - 5.

6. Recruitment related risks

6.1. Notification of the public prior to the breach in confidentiality taking place

The programme protocol requires a disclosure before any members of the public can be involved to be asked for their consent and to give the opportunity to opt-out. Therefore, considerable efforts will be made to inform the general public about the programme before the breach has occurred, thereby reducing the risk of members of the public being surprised by the invitation to participate. These communications will also be important to avoid causing worry or confusion for the public, which might result in more general opt-outs and therefore undermine the purpose of the programme specifically and health research more widely. The extent of the notification will be proportionate to the scale of disclosure, risk to public confidence and type of activity. For a research programme of this nature, scale and scope, we are planning extensive communication and awareness activities in the regions in which people will be invited e.g. for 2 weeks, 4-6 weeks before invitations are facilitated. This communication strategy in full is described in the attached communications plan (Appendix 1-5).

6.2 Recruitment related burden

Potential participants will receive one invitation letter only which they are free to ignore it. There are no plans to send reminder invitation letters.

7. Opt-out mechanisms

7.1 National data opt-out

Processes will be implemented to ensure that anyone who has registered a national data opt-out will not receive an invitation letter, in accordance with NHS Digital SOPs.

The national data opt-out (information held by NHS Digital) will be applied when running the query to exclude those who have chosen to opt-out of the use of their data for planning and research purposes. These individuals will not be

invited to take part in the programme. The national data opt-out is a live programme and individuals can register at any time, posters and materials were widely distributed when this was launched and continue to be available for download by local health and care settings.

Immediately prior to sending the lists to the mailing contractor (the APS Group) final checks will be run to remove any new opt-outs, sensitivity flags and to remove anyone who has recently died.

7.2 Programme specific opt-out

As set out above, and prior to invitations being issued in a local area, a communications plan will deliver information to the local population about the programme and the planned issue of invitations.

Our Future Health is committed to following the evidence about the best and most appropriate ways to reflect individual wishes and is aware of extensive research by NHS Digitrials into public wishes regarding the ability to opt-out of receiving letters inviting them to participate in research.

Our Future Health has plans to reflect programme level opt-out in whatever way is confirmed most appropriate by HRA and CAG based on the research evidence NHS Digitrials is collating. At present our approach involves providing programme level opt-out routes as set out below. Should new evidence emerge and be accepted that there is a better, more inclusive, and appropriate way to enable the public to consider their option to participate, and decline to participate, then Our Future Health will submit an amendment to CAG to reflect that evidence.

Unless evidence to the contrary is accepted, the following mechanisms will be implemented.

Recognising the importance of approaches that account for digital literacy and access to the internet, Our Future Health is ensuring both on-line and telephone routes to support individuals who wish to opt-out of receiving an invitation letter. The on-line option will be incorporated on the NHS Digital public facing website, and the link will be referenced on the Our Future Health public facing website to maximise the opportunity for those who hear of the programme through local publicity and choose to opt-out. A centralised telephone number will be primed to support calls from members.

The-opt out page will include:
• The explanation of the function of CAG
• Clear data flow e.g., no data transferring from mailing provider to NHS Digital, data destroyed once letters are sent
• Accessible language and clear headings
• links to the opt-out form and phone number for those who wish to complete the opt-out electronically or by phone

NHS Digital has comprehensive arrangements in place to secure and protect the data it holds. This includes full compliance with standards set out in the Data Security and Protection Toolkit (https://www.dsptoolkit.nhs.uk/OrganisationSearch/X26) and contractual requirements on third-party suppliers to provide data security and protection assurances.

Corporate level security policy (CLSP)

Questions 1-7 should be answered in relation to each organisation receiving and processing identifiable data. Please open a separate set of the questions for each organisation.

Organisation 1

1. Please give the name of the organisation.

The Health and Social Care Information Centre (known as NHS Digital)

2. What security and audit measures have been implemented to secure access to, and limit use of, patient identifiable information within this organisation?

ODS X26. NHS Digital have their own Data Security and Protection toolkit. All data is securely stored and only authorized personnel at NHS Digital are able to access patient identifiable data through the relevant Clear Data Access permissions. Data is only transferred through secure routes such as Secure Electronic File Transfer (SEFT) or Message Exchange for Social Care and Health (MESH). Further information can be sourced at:

https://www.gov.uk/government/publications/review-of-data- security-consent-and-opt-outs

https://digital.nhs.uk/services/national-data-opt-out

https://digital.nhs.uk/services/message-exchange-for-social-c are-and-health-mesh

3. Please provide an assessment of how the organisation's CLSP complies with the principles of the management and control guidelines contained in ISO 27002 (formerly ISO 17799:2005) and ISO 27001:2005 (both formerly parts 1 and 2 of BS7799 "Code of practice for information security management"). *Confirm that the policy or policies have been formally adopted by the organisation and are fully implemented.*

Please find a link to a document that describes how the data security and protection toolkit complies with ISO27002 below:

https://www.dsptoolkit.nhs.uk/Help/2

Please provide an electronic reference copy of the CLSP.

4. Who is responsible for the implementation of the CLSP?

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]
Post	Chief Information Security Officer		
Qualifications			
Employer	NHS Digital		
Work Address	The Health and Social Care Information Centre		
	1 Trevelyan Square		
	Leeds		
Post Code	LS1 6AE		
Work Email	[redacted]		
Work Telephone			
Fax			

5. What is the Data Protection Registration Number for this organisation?

ICO Reg number: Z8959110

6. Does the registration specify research as one of the purposes of processing and include confidential patient information in the classes of data processed?

(●) Yes ( ) No

Further details:

Please provide a copy of the Data Protection Registration(s).

7. Please describe the physical security arrangements for the location(s) where patient identifiable data is to be (a) processed and (b) stored (if these are different).

NHS Digital use a combination of Cloud and Physical Data Centres across their architecture, both types of storage are subject to strict governance including audit. Please see links to relevant controls below.

Physical Security of Cloud Data Centres (Links):

AWS: https://aws.amazon.com/compliance/data-center/controls/
Azure: https://docs.microsoft.com/en-us/azure/security/fundamentals/phys ical-security

The policy is to store data in UK Data Centres only.

Please find a link to a document that describes how the data security and protection toolkit complies with ISO27002 here: https://www.dsptoolkit.nhs.uk/Help/2

Each organisation also has a page with their certifications:

AWS: https://aws.amazon.com/compliance/iso-certified/
Azure: https://docs.microsoft.com/en-us/compliance/regulatory/offering-i so-27001

8.

It is a requirement that those organisations seeking to process identifiable patient information as outlined within this application provide a relevant Information Governance Toolkit submission. Please see the IRAS guidance section for further information in relation to this requirement.

PART C: DECLARATION

D3. Declaration by the Information Guardian

1. I have read and approved the CAG application.
2. I undertake to fulfil the responsibilities of Information Guardian in line with guidance provided with this application form in relation to the personal data to be processed in this project.
3. I undertake to monitor the progress of the project to ensure it complies with HRA conditions of approval and advise the applicant of any shortcomings and how these may be remedied.
4. I agree to report any serious failures to comply with conditions of approval to the HRA Confidentiality Advice Team.

Signature: [redacted]

Print Name: [redacted]

Please return completed application to:
CAG, Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH