

'Section 251' Support – Annual Review

It is a standard condition of support that an annual review is supplied every 12 months, from date of the final support letter, for the duration of the support to process confidential patient information without consent. Applicants should submit this 4 weeks in advance of their annual review due date. The annual review due date is specified under the 'Next Review Date' field for each application entry in the [Register of Approved Applications](#). Please ensure all sections are fully completed to avoid invalidation.

Notification of changes through this Annual Review submission are not permitted and will not be processed nor receive support; changes are managed via a formal separate amendment process.

PIAG/ECC/CAG reference number:	22AG0051
Full application title:	Our Future Health
Application type: research or non-research	Research
Date annual review was due: (If the annual review has been submitted after its due date, please include an explanation)	29 th March 2023 Late application due to confusion associated with multiple amendments to original application also submitted during March.

Information sharing:

Applicants should be aware that data controllers, such as NHS England (previously NHS Digital), may wish to check whether an applicant has provided an annual review to the CAG, to ensure the applicant support to process information without consent remains active before the controller can process a request for data access. We will share confirmation with data controllers whether an annual review has been submitted or not, and whether it is valid, in order to facilitate local disclosure decisions.

1. Security arrangements

All applicants processing confidential patient information under the Regulations are required to provide evidence of suitable security arrangements via agreed routes. This must be in place before any support can come into effect, must be maintained for the duration of the support and is expected to be up to date and (in England) reviewed by NHS England at each annual review. Security assurance is required in relation to ALL organisations involved in processing confidential patient information. Please carefully assess where the processing is taking place, and provide security assurance based upon the jurisdiction and organisation where the information is being processed. Applicants may need to provide more than one security assurance depending on the jurisdiction information is processed, or if processing of identifiable information is taking place in more than one organisation.

Processing takes place in:	England	Wales	Scotland
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Security assurance provided by:	Data Security and Protection Toolkit (DSPT) – by organisation or specific function	Caldicott Principles into Practice (CPIP) report/or Welsh Information Governance Toolkit – by organisation	Review by the Public Benefit and Privacy Panel for Health & Social Care
Applicant should contact:	Exeter.Helpdesk@nhs.net	The Confidentiality Advice Team (CAT) cag@hra.nhs.uk	Public Benefit and Privacy Panel (PBPP) for Health & Social Care
How assurance is provided to CAG	<ol style="list-style-type: none"> 1. Organisational self-assessed completion of relevant DSPT. 2. Applicant contacts Exeter Helpdesk to request NHS England to review the relevant DSPT self-assessed submissions 3. NHS England review the DSPT submission and confirm to CAG when 'Standards Met' 	Relevant CPIP out-turn report/Welsh IG toolkit provided directly by DHCW to CAG	An approval letter from PBPP, where processing is taking place in Scotland, is accepted as evidence of adequate security assurance.

For applicant completion:

Please list all organisations physically processing relevant information without consent for which security assurance is required. Security assurance is provided through NHS England DSPT team reviewing the self-assessed submission. Please ensure you have contacted NHS England and asked them to review your submission. The annual review will not be valid until NHS England has reviewed the submission and confirmed its status as 'standards met'.

If confidential patient information is being processed by NHS England (previously NHS Digital), please select this box: OBJ:OBJ

Security assurance has already been provided for NHS England (previously NHS Digital) so please do not complete any details below for NHS England (previously Digital).

Organisation (Full name)	ODS Code	Date self-assessment submitted to NHS England	Date NHS England confirmed assessment reached 'Standards Met'
APS Group	8K333		03/10/2022

Is any processing of identifiable information taking place in Wales? No

Is there any processing of identifiable information taking place in Scotland? No
If processing of confidential patient information is taking place in Wales or Scotland, please contact the Confidentiality Advice Team for advice on next steps.

2. Study progress

i. Conditions of support (if applicable)

Supported applications often have specific conditions of support, in addition to standard conditions of support. Applicants are expected to comply with all standard conditions of support by default to ensure the support remains active.

Please set out how you have met the conditions of support (expand box as required). This should include any difficulties experienced and mitigating action taken. Specific conditions of support are located in your conditional or final outcome letter

Please answer the following three questions and ensure you check the correct boxes for each question (double click on each box and select 'checked' where relevant).

1. **The application has no assigned specific conditions of support.**

Please note that if there are specific conditions of support (as per the outcome letters) that have not been reported against, this will invalidate the annual review and a new annual review will need to be submitted; this may jeopardise the status of support for those relying upon this lawful basis.

2. **The following provides an update against existing specific conditions of support.**

List each specific condition (expand as necessary) and explain how it has been met

Condition 1: Favourable Opinion from Research Ethics Committee. **Confirmed March 29th 2021**

Condition 2: Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. Our Future Health does not have any access to the confidential information associated with this release. NHS England and APS Group act as Data Processors. APS Group compliance with DSPT was confirmed on **October 3rd 2022 as Standards Exceeded.**

3. **I can confirm the application adheres to all the standard conditions of support.**

ii. Steps taken to anonymise the information or obtain consent from individuals

What steps have been taken to reduce the identifiability of the information or seek consent from the patients? If this has not been done yet, please confirm at what stage you intend to or the reasons why you are not going to.

Our Future Health is partnered with NHS Digitrials service to issue personal invitations to members of the public inviting them to participate in the Our Future Health Programme. The programme seeks to recruit up to 5 million individuals in total, with personal invitations, sent in partnership with the NHS, as a key channel for initial identification/contact.

Issuing Our Future Health invitations through NHS Digitrials is a key plank in the recruitment strategy for England in that it enables the programme:

1. to recruit in a geographic and demographically specific manner
2. to collaborate with NHS Digitrials to test and deploy behaviourally informed messaging improving the service and the response rates
3. to quickly recruit participants to Our Future Health which will facilitate a large amount of future research
4. to build trust with potential participants by respecting the wishes of those who have opted out, by only sending an invitation once to each potential participant, and by demonstrating collaborative links through government supported organisations and the NHS.
5. to promote equity by ensuring all England resident adults, particularly those of historically under-represented groups in health research, can receive a personalised invitation.

The identifiable information comprises name, address, postcode. It is not shared with Our Future Health and is only provided to the 3rd party mailing house for the purpose of mailing an invitation. The file is deleted within 2 weeks of the letters being posted.

As per the original application, there is no feasible way to gain patient consent to issue the invitation letter, prior to the letter being sent.

Alternative sources of name and address data that are not part of the confidential health record, such as the electoral role, were explored prior to the original application and considered again as part of subsequent amendment requests. However, alternative options do not provide the same, or even similar, equity in opportunity in that the base populations are less representative of the UK population, they cost more leaving less resources available for community-based recruitment of seldom heard populations, are less adaptable and personalised, and do not provide a test and deploy framework—a workflow we have optimised in collaboration with NHS Digitrials.

iii. Projected end date

What is the expected end date for your study; **this is the date by which all confidential patient information is no longer identifiable and support is no longer required.**

Since beginning to use patient confidential data to issue NHS Digital's letter invitations in July 2022, Our Future Health has sent 10,347,615 invitations through April 5th 2023. This is supported by the original application (3 million) and an approved amendment in November 2022 (additional 9 million). An interim amendment was approved on 30th March 2023, which enables this total to further extend to a total of 16 million invitations.

A further amendment is due for Full CAG review on April 27th 2023 and seeks permission to issue an additional 16m invitation in the year 2023/24.

It is likely that Our Future Health will seek to issue invitations to the remainder of the England adult population in 2024/25

iv. Project changes

Please provide a summary of any formal amendments made to the CAG that have been supported.

It is important to note that only those details specified in the original application (and any formal amendments) have been supported. For applications supported over 5 years ago, or where the application detail no longer reflects current activity, a new application may be required.

Approved Amendment dated 17th November 2023 – no changes to any of the details or the process set out in the original application. Amendment requested ability to extend the number of invites issued from 3 million to 12 million.

Approved Interim Amendment dated 30th March 2023 – no changes to any of the details or the process set out in the original application. Amendment requested ability to extend the number of invitations issued from 12 million to 16 million.

3. Justification for ongoing support

i. Practicable alternatives/exit strategy

It is a requirement of the Regulations that applicants review the requirement to continue processing confidential patient information without consent on an annual basis. Please provide an overview of alternatives being considered or taken to remove the need for ongoing support, such as the receipt of anonymised data only or the movement towards a pseudonymised approach.

Our Future Health has considered the following alternatives:

- Use of anonymised data – this is not practicable as a means of issuing invitation letters to members of the public.
- Use of pseudonymised data – work with focus and other groups identified that receipt of a named letter, bearing the NHS logo and addressed to the individual would offer greater levels of trust and increased likelihood of the letter being opened. Sending letter to The Householder is problematic for households of multiple occupancy, likelihood of the letter being seen/read by more than one person, cultural variation in roles within a household, and inability to adjust the letter style and content to reflect generational or other differences.
- Use of non-confidential sources of name and address data. Exploration of these options showed them to be prohibitively expensive as it required development of a process and infrastructure to select appropriate recipients, print and post the letters. Economies of scale between NHS Digitrials and their 3rd party mailing house mean that it costs circa 40p per invitation. This includes the cost of envelopes, printing, packing and also the valuable flexibility to vary letter template by area, or by age group or gender to test the efficacy of approaches (processes that we have developed in collaboration with NHS Digitrials). Privately established routes do not offer the cost effectiveness or the flexibility of this approach.
- In addition, use of the NHS-provides opportunity to account for a range of specific groups
 - those who have opted out of receiving an invitation as a result of opt-out campaigns Our Future Health has previously run in any area prior to issue of invitations. Any alternative approach adopted not will not be able to account for these as the data is held by NHS England for specific application to the NHS Digitrials process.
 - Those who have already received an invitation. Our Future Health does not receive information on those who have received a letter, thus a change to an alternative process risks sending repeat letters to some participants, risking confusion and negative reactions. NHS Digitrials holds the record and actively excludes those who have already been sent a letter.
 - Those who have recently died but whose official records are yet to be updated (e.g., electoral role). The NHS Digitrials pipeline reviews all records to remove anyone with an interim death notice or any entry in the date of death field. This means we can correctly exclude a greater proportion of individuals who have likely recently died, reducing distress for their families.

4. Patient and public feedback

Please provide details of any complaints, queries or objections that you have received from patients (which specifically relate to this application to process confidential patient information without consent) and the steps you have taken to resolve them. Have any patients requested that their data is not processed and how has it been ensured that this has been respected?

Participants who do not wish to receive a letter are able to register this opt-out via both telephone or online contact. An opt-out web page is available in the NHS England public facing website, while an 0300 telephone number connects to the NHS England call centre which facilitates opt-outs.

Before any letters are issued in a new area, a 4-week campaign conducted by Our Future Health advertises the programme and how to opt-out of receiving a letter. The campaigns include half page press adverts in local or regional new publications, radio adverts on local or regional level radio stations, and repeat adverts on Twitter, Instagram, and Facebook. To date, just under 250 people have taken up the option to opt-out, from advertising and recruitment areas that have a population total of more than 12 million.

The vast majority of contact with Our Future Health (following any media or receipt of a letter) by the general public takes place via the Study Support Team in the form of emails and telephone calls.

As shown in Figure 1, of the 14,085 calls and emails received by our Study Support Centre during Q4 of 2022, when the main bulk of letters began to be issued, only a very small proportion of queries related to non-formal complaints (those where the caller wished to record the issue but did not wish to instigate a formal complaint with investigation or response) (N=56) or privacy concerns (n=3).

The three calls relating to privacy concerns covered:

- Participant called Study Support about changing their password due to privacy concerns. Apparently, Safari had indicated that their password (not specifically for Our Future Health) had been found in a data leak (not from Our Future Health).
- Participant concerned about their DNA getting into the wrong hands and possible cloning. Wanted to know whether the DNA left the UK and, if so, what security protocols were in place.
- Member of public outlined concerns about their personal DNA results becoming available to outside commercial bodies.

Calls to Study Support are categorised to enable tracking of themes. Inevitably there is sometimes cross over between categories, so in the interests of transparency and completeness we have reviewed and provide information on any category that may involve feedback about receipt of invitations.

The “Complaint” category (n=56) covers any complaint including issues when they attended the site (appointment was late, clinic was hard to locate, issue with staff) and, within that, review shows that no complaints were about receiving a letter/use of their address to send the letter.

The “Data Protection and Privacy Queries” (n=54) category covers queries about how data is protected, how privacy is respected and where/how data may be shared or used. Review of this category identified that the topics

covered the same main themes around security provisions, storage and data sharing queries of which the following are provided as real examples:

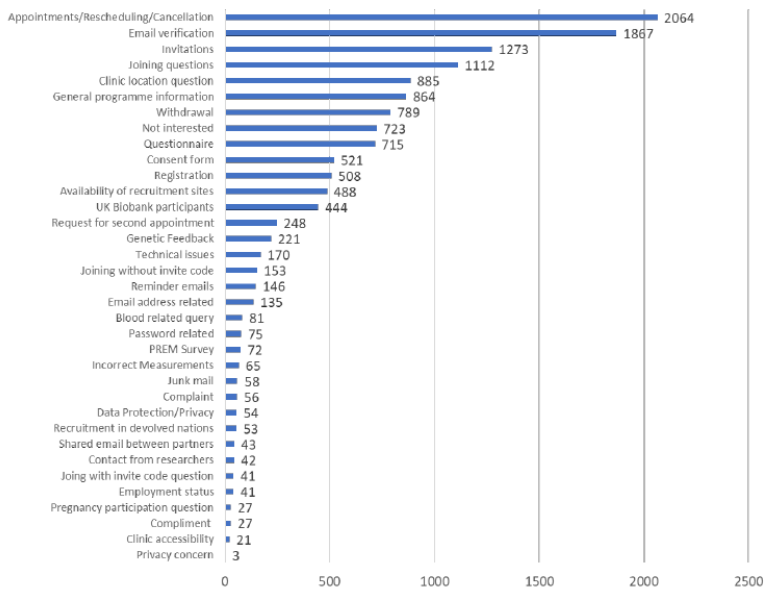
- A) Participant concerned about the intention to replace GDPR in the UK and the scrapping of EU laws. If there is any possible impact, will they be informed?
- B) Potential participant concerned about future privacy of the data collected and is their guidance on how personal data (particularly genetic) will be used?
- C) Potential participant questioning the questionnaire and whether this information will be available to any Government bodies like DWP and Benefits. Can these offices ask to see the data and will you provide it to them if asked?
- D) Potential participant wishes to clarify whether any government agencies or law enforcement officers would be able to apply to court to gain access to any DNA information held by Our Future Health?
- E) Potential participant had an issue when typing in ourfuturehealth.org [not our web address] and Asian Beauty Dating Site came up. Worried about the security of signing up for program and giving personal data.

The “Invitations” category (n=1,273) is primarily used for people who call or email requesting further information about the programme after receiving an invitation. In the most recent full quarter (Q4 2022), the “Invitations” category comprised a total of 110 calls, a subset of which included individuals who wished to inform us that they were declining to participate (for a variety of reasons) and requesting that we do not write to them again. The following selection is representative of these kinds of feedback. All of the following were acted upon as per request:

- 1) *I would in no way wish to participate in your health survey. I do not give permission for any of my medical records to be shared. Please remove me from any databases or records in connection with this programme.*
- 2) *Has been asked to take part in this study. Unfortunately, he will have to decline as he has a condition and would not be up to attending extra clinics or filling out questionnaires.*
- 3) *Unfortunately, I am not interested so therefore please could you remove my details from your service including any further marketing about Our Future Health so I am not contacted in the future.*
- 4) *Please could you kindly remove the above name and address from your surveys permanently.*
- 5) *I am writing to inform you that my husband passed away last week so cannot be part of your health programme.*
- 6) *We no longer live in England so can you please remove me from your database –*
- 7) *I recently received a request to join this survey. I have decided not to take part for 2 reasons. I have concerns over whether the data may be processed by a company based off shore. I have had problems previously. in this respect. Secondly, having taken part in a lesser survey some years ago I found it very time consuming and somewhat intrusive.*
- 8) *I have received your letter dated 2 November on my return to the UK on family matters. I am normally based in France and so do not think that I can take part in your research as I may well be out of the country when you want to do tests or obtain information.*
- 9) *Can you please delete from your list please as he has a learning disability and cannot answer the questions about his health and it would cause him anxiety to try and think of answers that you want to hear.*
- 10) *The person on the below letter has no connection to me or my flat. Can you make sure that the lady on the attached letter is taken off of my address as she is no connection to me or my home.*

Finally, the “Not Interested” category (n=723) represents a cohort of people who contact Our Future Health to confirm they are not interested and do not want to accept the invitation.

Figure 1. Numbers of calls and emails received by Our Future Health Study Support Centre (Q4 2022)



Occasionally, Our Future Health is contacted by post or, in one specific case, by unusual alternative routes. Of these, 2 contacts have raised specific complaints about receiving a letter.

The first case contacted us by post, identifying that he had asked the NHS not to use his details for invitations to research studies and setting out the fine he intended to leverage for breach of this. He did not include his full name or address thus it was not possible to check this assertion.

The second case was referred to us via the Cambridgeshire REC Chair, who was contacted on his personal mobile by an individual who declined to give his name but wanted to complain that he had opted out but still received a letter. He alleges that he spoke to CAG and to NHS Digital (as was). As he declined to give his name and address, it was not possible to verify the assertion or investigate the claims in any way.

In summary, Our Future Health has received 2 formal complaints from the mailing of over 10 million letters. In addition, 57 calls were categorised as privacy concerns or data protection concerns. None were formal complaints about receiving a letter, and in total such queries represent 0.0006% of letters issued.

In addition, we maintain close links with NHS Digital Contact Centre, who receive calls from individuals wishing to opt-out of receipt of an invitation. They have confirmed that 8 calls related to complaints that NHS Digital would use their address in this way.

5. Public benefits

To support the need for continued support, applicants should set out what public benefits have arisen since support has been in place, and from time of last annual review. Support to process confidential patient information without consent is based upon there being a public interest in the activity proceeding so applicants should consider this section carefully. Applicants should set out what public benefit has been achieved, or whether a public benefit is still anticipated.

Immediate benefits to Individuals – the ability to process higher volumes of participants is already delivering a significant benefit as the clinic visit includes:

- Blood pressure check
- Cholesterol check
- Height, weight and waist measurement

These results are provided at the appointment using a REC-approved proforma that aids interpretation of the results and indicates when an individual may wish to attain a follow-up test. High blood pressure and high cholesterol are two of the biggest predictors of an early death. In the UK, it is suspected that millions of people live with undiagnosed high blood pressure and/or cholesterol – leaving them at an increased risk of various serious health conditions, such as heart attack and stroke.

Our Future Health is offering every adult in the country the chance to learn their blood pressure and cholesterol levels for free. If a person is found to have a dangerously high reading, they can then take steps with the help of healthcare professionals to lower their chances of suffering from life-threatening health complications.

Data is now being collated on the specific numbers but, having processed over 100,000 participants through the clinics, it is clear that a significant number are receiving information which enables them to act to improve their health. Anecdotal examples include:

[REDACTED] is a retired post office manager who joined Our Future Health in Leeds: *“When I had my appointment at Our Future Health, my blood pressure reading was sky-high. It was quite a shock. I always thought I was quite fit – I haven’t needed to go to the doctors since 2013 and I’ve never had a health issue. The healthcare assistant advised me to see my GP, and my GP sent me to Bradford Royal Infirmary to have more checks done. I’m now on blood pressure medication, to manage the issue.”*

[REDACTED], joined Our Future Health in Manchester: *“Before my appointment, I’d never had my cholesterol checked. I’m a fit person, I run and go to the gym a lot. But even then, the phlebotomist told me that my healthy cholesterol isn’t as good as it should be. So coming away knowing that was absolutely worth it. It means I can make some changes to my diet.”*

Medium-term Benefits to Individuals – Our Future Health has a stated aim to provide Integrated Risk Scores to all participants who wish to receive this information. Combining lifestyle factors—based on analysis of questionnaire responses—with genetic risk analysis, integrated risk scores provide opportunities for individuals to make decisions about lifestyle, potential investigations or interventions or actions that could help them live healthier lives for longer.

Short- to Medium-term Benefits to Researchers – the more rapidly a cohort of significant size can be created, the sooner researchers can begin to use the resource to discover, test, validate and implement new ways of detecting, intervening and treating common chronic diseases.

Longer-term Benefits to Public/Health and Social Care System – as the number of episodes of improvement, earlier detection, and earlier treatment of disease begin to accrue, there is an overall benefit to both individuals, society, and the health system from reduced co-morbidity and impact of disease.

5. Confirmation of contact details

Please confirm contact details for the publicly available register of approved applications.

The contact details below are the same as those currently published in the Register of Approved Applications.

The contact details below are NOT the same as those in the Register of Approved Applications. In order for this change to be processed the reason for this change must be specified here.

The reason for the change to contact details is as follows:

Name of controller for application: [REDACTED]

Contact Name and role: [REDACTED], Lead for NHS and Data

Full address: Our Future Health, New Bailey, 4 Stanley Street, Manchester M3 5GS

Telephone: [REDACTED]

Email: [REDACTED]

Named applicant Name: [REDACTED]

Signed: [REDACTED]

Date: 13th April 2023

Please return this completed form to cag@hra.nhs.uk. Questions over completion should be directed to cag@hra.nhs.uk or contact the CAG general advice line on 0207 104 8100 between 9-5.

Please note this document will be assessed by the Confidentiality Advice Team in the first instance. Depending upon the content, the team might request further information, arrange a subsequent meeting to discuss the content of the annual review, or escalate to the Chair or to CAG.