

Amendment request form

Use this template to submit an amendment to an approved application. The completed template will be reviewed by the Confidentiality Advice Team who will then confirm the appropriate action. The Confidentiality Advice Team can be contacted prior to completion to advise on whether the nature of the change requires a formal amendment. Supporting documentation can be used in conjunction with this form.

Please note that support for amendments will not come into effect until a final approval letter is provided.

PIAG/ECC/CAG reference number: 22AG0051

Application title: Our Future Health

Amendment date: March 2023

Research / Non-research

1. Please indicate the nature of the change below.

- Data flows
- Data items
- Data sources (see question 4)
- Purposes of application
- Data controller (please note that an amended application form and supporting documents setting out the new data controller arrangements will be required, you are advised to contact the Confidentiality Advice Team prior to submission)
- Data processor (required to have a satisfactory Information Governance Toolkit submission in place - see question 6)
- Duration amendment
- Other (please specify): Our original application anticipated up to 3 million invitation letters being issued as part of pilot with NHS Digitrials.

A subsequent amendment requested an increase in this limit to 12 million, to test scale up and broaden access to Our Future Health in specific geographic areas.

Due to the success of the current activities we are preparing a revision to our original application (to be submitted in April) to enable a steady scale up of invitations aligned to the needs of the programme. However in the interim, this amendment requests

permission to increase the total number of invitations issued to 16 million to enable continuation of operational delivery of our established clinics ahead of CAG consideration of the wider application.

2. Please summarise the change to the application, specifying how the amendment differs from the detail of the original application:

The original application anticipated 3 million invitations being issued over the course of around 1 year.

At that point Our Future Health had no mechanisms for collecting blood directly from those who responded positively to the invitation letter, and anticipated blood collection to be carried out in partnership with other organisations.

Since then:

- A) Experience has shown very minimal opt out or negative feedback from recipients of letters. Based on 8 million invitations issued, 234 opt outs were recorded between July 1st 2022 and March 20th 2023, 2 formal complaints were received and circa 200 calls were taken, requesting to not receive another letter.
- B) Our Future Health has established a contract for creation of pop-up clinics and mobile units to enable volunteer's physical measurements (height, weight, BP) and blood sample to be completed. A rolling programme of clinic opening and closing in specific regions across the country is in operation.
- C) Our Future Health has developed a well-integrated operational process which combines forward planning to run opt out campaigns for 1 month, parallel operational set up of new clinics and an overt check point to confirm all elements are complete prior to the issue of invitations. The wider geographic coverage has enabled the opt out campaign to move to advertising on a regional basis, using larger publications and radio stations covering much bigger regional areas and therefore enabling a wider readership/listener audience and bigger reach on social media channels.

Taken together, this enables Our Future Health to invite individuals at a higher rate than initially anticipated (moving from sending around 50-100k invitations per week in September, to sending up to 500k invitations a week) and greater scale (developing the clinic process to enable between 10-12k appointment slots per week) to support achieving recruitment targets and enable the objectives of the research programme to be delivered.

While NHS Digital is the primary recruitment route, the overall recruitment approach for England has developed to include:

- A) NHS Blood and Transplant (successful pilot has been shaped into a full service starting with invitation issue at end of May and first appointments to collect a blood sample in early July, with around 1k appointments due to be available in that first month)
- B) Pilot partnership with iPLATO and GP surgeries – so far the pilot has seen the issue of 325,182 first messages and 41,465 reminder/second messages over the last 5 months, with plans for further issue of texts in partnership with GP surgeries in coming months.

Other channels postulated and scoped but not yet implemented include partnership with Secondary Care providers and also the NHS Health Check programme.

These additional channels will support both achieving the volume of participants and facilitate the ability to ensure the cohort composition reflects the population to the greatest extent possible based on the most recent census.

Recruitment paths in Scotland and Wales are also being established, with planning in 2023 to enable recruitment to begin in early 2024 providing a further opportunity to both increase the volume and to bring additional geographic and other variation in cohort characteristics.

NHS Digitrials is a crucial plank of the recruitment from England, as it offers the ability to target by postcode, age and sex at birth.

This interim application requests permission to extend the current number of invitations issued via NHS Digital from 12m to 16m, with invitation mailings taking place over the next 2 months (circa 500k/week). In parallel, Our Future Health will submit a second proposal requesting permission to extend the total number of invites further, with deeper information covering:

- benefits of the programme
- PPIE focused on view regarding the extension to cover issue of invitations to a larger population of England
- implementation planning, the approach other recruitment channels and explanation covering why other sources of name and address data are not a suitable alternative for the purpose.

No other aspect of the process is changing. Our Future Health simply requests approval to issue 4 million additional invitations using the approved process.

3. Please confirm the justification for the amendment. This should explicitly include the following:

- the reason why it is in the public interest for the amendment to proceed
- the benefits that the amendment will, or is expected to, provide
- The time period for which the amendment is expected to be required
- The consequences if the amendment did not go ahead

As set out in the approved application, Our Future Health seeks to recruit 5 million volunteers over the next 4 years, creating the largest ever research resource to support development of investigations and treatments for earlier stage disease. The focus is on improving quality of life and reducing the burden of late-stage disease on individuals, families, social care and the NHS.

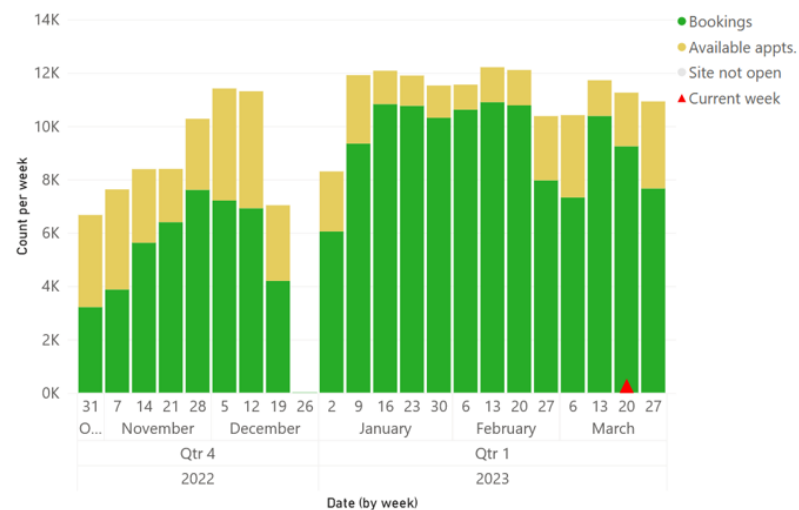
The first step in achieving this ambitious goal is to fulfill our targets of recruiting to the programme.

The recruitment process includes consent, provision of personal details, completion of a questionnaire and provision of body measurements and blood sample. To enable this, Our Future Health has invested in a number of pop up and mobile clinics, offering appointment slots to enable health-related measurements and blood samples to take place.

The NHS Digital trials invitation route has proved to be successful in driving up attendance at the pop-up clinics and has enabled 10-12k appointments per week to be made available.

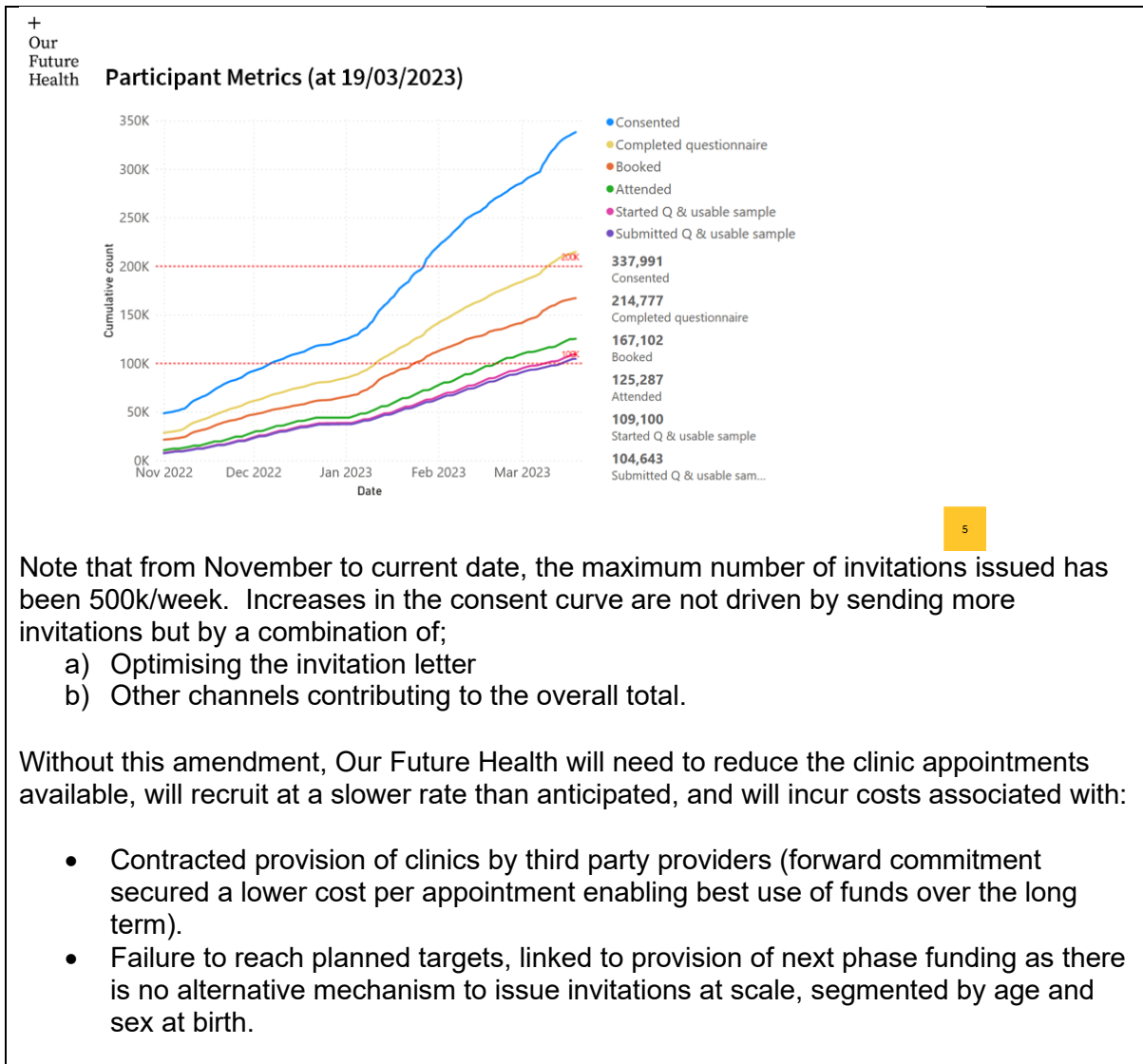
+
Our
Future
Health

Numbers of booked, available & planned appointments per week (at 19/03/2023)



The initial approval covered the issue of invitations to 3 million individuals over a one year period from July 2022. A second amendment sought approval to increase the total to 12 million individuals, over the same time period, enabling Our Future Health to fill clinics, use available appointments and recruit 250k volunteers by March 2023 and more between April and July.

To date, this approach has enabled the following numbers to be recruited, consented, Questionnaire completed and appointments booked/blood sample obtained:



4. If amending the data sources, has the data controller for this agreed in principle for this access to be provided? Please provide evidence of any authorization.

Not Applicable – no change to data source is requested.

5. It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA

requires that reasonable efforts are made to inform data subjects of the use of their data. The nature of the change may mean that there is a need to update the current information provided to patients. Please confirm whether patient information materials (websites, leaflets, posters etc.) have been updated to reflect the change and detail the changes below.

If no change is intended to be made, please specify the reasons for this decision.

Not Applicable – the nature of the change does not generate any need to update the information provided to patients. As per the original approved application, a full opt out campaign is run in all areas for 1 month prior to the issue of invitation letters in that area. Patient information materials are as per those approved by REC. The amendment simply requests approval to use this entire approach to issue a further 4 million invitations in addition to the currently approved 12 million.

6. All applicants processing confidential patient information under the Regulations are required to demonstrate that appropriate technical and organisational measures are taken to prevent unauthorised processing of that information.

This evidence is demonstrated through maintaining a satisfactory Information Governance Toolkit (IGT) submission for the length of time approval is in place. Please complete the following details:

Is a current IGT in place? Yes / No

If 'no', please explain current status, and predicted timescale to reach a satisfactory IG Toolkit score:

If 'Yes':

IGT Organisation code:

Current percentage score: %

IG Toolkit version:

Improvement plan in place?

Has the HSCIC IG Toolkit Team provided confirmation directly to the CAG that a satisfactory IGT submission is in place? (If not known please contact the HSCIC IGT Team (exeter.helpdesk@hscic.gov.uk) to ensure they send this information to cag@hra.nhs.uk)

As per original application, Our Future Health does not see, handle or process any confidential data from NHS Digital. NHS Digital acts as Data Processor on our behalf and has all appropriate certifications.

7. If a research application, has an amendment to a Research Ethics Committee been submitted? Please provide supporting documentation/date to be reviewed/favourable ethical opinion.

REC approval was provided on 29th March 2021

REC have confirmed to CAG support that no change is needed to the REC submission to account for this amendment.

8. Confirmation of contact details

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

Applying organisation: Our Future Health

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

Full address: New Bailey, 4 Stanley Street, Manchester M3 5JL

Telephone: [REDACTED]

Email: [REDACTED]

Information Guardian/Chief Investigator Name:

Signed: [REDACTED]

Date: 23rd March 2023

This form should be submitted, in conjunction with any relevant supporting documentation, to cag@hra.nhs.uk. If you require any assistance in completing this form you are advised to contact the Confidentiality Advice Team on cag@hra.nhs.uk or on 0207 104 8100.



Health Research Authority

Once submitted the form will be reviewed by the Confidentiality Advice Team in the first instance who will confirm whether the amendment is valid or if further information is required.

