

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: 9th November 2022.

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): Original application anticipated up to 3 million invitation letters being issued during the one year DSA. Our Future Health would like to amend this to 12 Million during the 1 year DSA.

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 the 1 year Data Sharing Agreement.

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

Since then:

- A) Experience has shown minimal opt outs or negative feedback from recipients of letters
- B) Our Future Health has established a contract for creation of pop-up clinics and mobile units to enable volunteers' measurements and blood sample to be completed.

This means we can invite individuals at a higher rate, and greater scale to support achieving recruitment targets.

The amendment seeks to enable up to 12 million letters to be issued.

No other aspect of the process is changing. Our Future Health simply requests approval to issue 12 million 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.

Success in recruiting to the programme is a key deliverable in meeting this aim.

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 sign up, measurements and blood samples to take place.

Health Research Authority

The NHS Digitrials invitation route has proved to be successful in driving recruitment and has enabled over 50,000 volunteers to be consented to date, and currently running at around 1k consented volunteers per day

The initial approval covered the issue of invitations to 3 million individuals over a one-year period from July 2022. This amendment seeks approval to cover invitation 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.

Without this amendment, Our Future Health will need to reduce the clinic appointments available, will recruit at a slower rate than anticipated, and will struggle to reach the initial milestone of 250,000 volunteers by March 2023.

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 12 million invitations instead of 3 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 covered by this approval. 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], Lead for Data Linkage

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

Telephone: [REDACTED]

Email: [REDACTED]

Information Guardian/Chief Investigator Name: [REDACTED]

Signed: [REDACTED]

Date: 9th November 2022

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.

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.

