NHS
Health Research Authority

Confidentiality Advice Team (CAT) advice Form

Title and reference number once allocated:	22/CAG/0051 Our Future Health
Organisation:	Our Future Health Ltd
Contact details:	[redacted] (Tissue bank manager) [redacted] ("designated individual" for purposes of licensing by the Human Tissue Authority)
CAT:	[redacted]

Please see advice provided below and use the applicant response column to detail where changes have been made to the application form, extra documents have been submitted or another response. Please specify within section 4 whether you have submitted an application to a Research Ethics Committee and use section 5 to record whether the applicant has contacted the Confidentiality Advice Team within the HRA in relation to an application.

1.	**General advice**		
	Issue identified	**Applicant response**	**Date**
	<u>Scope of support</u> Six 6 ways patients can be selected and contacted are outlined in Q43-1. All appear to require that confidential patient information will be accessed by the direct care team/those with an existing legal basis to access the information. 1. Confirm that these six recruitment pathways are outside the scope of support? Recruitment via NHS DigiTrials is a seventh method of recruitment and does require support. 2. Please confirm the cohort involved, i.e. all adult patients in England may be selected? Is the range from 16 years of age or 18 years of age?	1. Our Future Health can confirm that the other routes do NOT involve use or sharing of confidential data and therefore do NOT require support. NHS DigiTrials is an additional method, which involves NHS DigiTrials sharing the name and address of specific individuals for the purpose of sending an invitation - which DOES require support. 2. NHS DigiTrials will run coded queries, on behalf of Our Future Health, across the national data sets to select at random cohort participants who: A) Are aged 18 or over	

		B) Meet other inclusion or exclusion criteria to enable representative shaping of the overall Our Future Health participant base. This may mean some extracts are sorted for certain geographic locations or ethnic groupings, for example.	
	<u>Identifiers required</u> The identifiers to be disclosed from NHS Digital to APS Group needed to be selected in Part B Q3, although I appreciate the form isn't very clear. 1. Please list the items of confidential patient information that will be disclosed from NHS Digital to APS Group.	Items of confidential data disclosed from NHS Digital to APS Group: • Forename • Surname • Address • Postcode	
	<u>Exit Strategy</u> It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. 1. Clarify when APS Group will delete information for all patients? The text on p31 of the CAG application form explains that the mailing provider will destroy the data once the letters are sent (second bullet point under "The opt-out page will include:"). Does this mean data for all patients will be deleted two weeks after the letters are sent?	Our Future Health can confirm that APS will delete the confidential data (First Name, Surname, Address, Postcode) 2 weeks after the invitations have been sent.	
	<u>Patient Notification and Dissent</u> It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and the Data Protection Act 2018. Although often confused with a requirement to seek consent, patient notification is not the same as seeking consent from individual patients. Patient data is still accessed without consent, however information is provided to patients so they have the option to find out about this use of their	1. The Our Future Health Communications plan V1 for NHS DigiTrials is attached. 2. All patient notification materials are included in the communications plan document 3. In recording dissent it is important to be timely in the enacting of the dissent. Our Future Health offers recording of dissent through mechanisms which respect varying degrees of digital literacy but also utilise technology	

	data and to express an objection if they so wish. The method for respecting any such objections should be described in the application and a copy of the information must be provided as well. The notification should provide a description of the activity, listing the purpose of the study and who is carrying out the study. It should explain how service users can opt out or dissent, where appropriate, to the use of their information for this purpose. 1. The OFH pre-invitation communications plan V1 document was could not be opened. Can you please resend it? 2. Please provide any other patient notification materials, if not already included in the communications plan document. 3. I noted that email and telephone methods of dissent were offered. Can dissent via post also be offered?	to support accurate and timely uploading of the information into an opt out register. The online portal allows real time recording of dissent. The telephone route enables near real time data entry via a central call centre and trained staff who can enter data into the register on behalf of the caller. A postal route is not offered because there will be a potential delay between completing the form (the point at which the individual feels they have opted out), posting, receipt and processing of the paper copy to upload the record of dissent into the electronic register. It is possible that this could involve a delay of up to 5-7 days which is a sub optimal timeframe and could lead to an individual being sent a letter in the intervening time. There are also several points of risk that an application to dissent could be lost/go missing when posted.	
	<u>Patient and Public Involvement and Engagement</u> Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. 1. The answer to Q12-1 refers to Claremont undertaking work to engage local communities, including those underrepresented in health research: Asian communities, Black communities, and people living in areas of high deprivation. This was going to take place in 2021. Has this concluded and can feedback be provided? 2. Please provide written feedback from the patient and public involvement conducted so far.	1. Our Future Health worked with Claremont creative agency to conduct a programme of patient and public involvement work. Over 120 members of the public were involved during 2020-2021 including: • 4 focus groups, 2 co-design meetings, 21 interviews with the public to develop the scientific protocol • 12 interviews with a variety of stakeholders from charities and existing cohort studies • 2 focus groups with 11 NHS primary care staff • 18 focus groups, 10 co-design meetings, 21 interviews with the public to co-develop the participant information sheet, consent form & other public-facing videos & materials • 21 interviews to understand the role of industry in health research • 4 focus groups to explore insights around recruitment methods • 3 focus groups to explore public motivators and feedback preferences	

		• 1 member of the public attended the REC approval meeting with a member of Our Future Health As it was qualitative research, not quantitative, the outputs of the work are summarised as follows: • Co-designed and REC approved PIS and Consent form • 4 co-designed explainer videos for Our Future Health (YouTube) • Public Engagement Strategy (Claremont 2021) • Engaging Black Audiences Report (written by [redacted] – consultant) 30 members of the public were invited to join the Our Future Health Public Advisory Board, and 14 accepted. 6 are affiliate members of the Secondary Care Working Group, Ethics Advisory Board and Technology Advisory Board. **Outputs of these groups since 2021** • Agreed Terms of Reference, working principles, PPIE training pack and evaluation matrix • 3 meetings held in 2021 and 1 ad-hoc consultation. • Topics for consultation and input/approval have included the Founding Industry Member Policy, TREs, amendments to the PIS and consent form	

2.	**Practicable alternatives**		
	Alternative suggested	**Applicant response**	**Date**

3.	**Data Protection Compliance**		
	Assessment	**Applicant response**	**Date**
	<u>Compliance</u>		

The information which has been provided at **Q57 (research) Section** of the application, in relation to compliance with the Data Protection Act 1998 is received; however, the DPA 1998 has now been superseded and has been replaced with the General Data Protection Regulation and Data Protection Act 2018.

Further information can be found on the Information Commissioner's Office (ICO) website around how the principles of the DPA 1998 have been translated into the GDPR 2018, together with the requirements here: https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/principles/

It is recommended that the guidance which is available via the HRA website is reviewed, and any additional information which is required to show compliance against current Data Protection Legislation is provided here to supplement the detail within the application which was provided in relation to the DPA 1998.

Information can be found here: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/

Guidance is also available within the relevant section of the IRAS system, by selecting the green 'I' icon next to the question.

Under each of the principles below, clearly demonstrate how the specific activity is operating in compliance with the principles of the GDPR and Data Protection Act 2018. Please seek specialist advice from your information governance advisors.

1. Principle (b): information is collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes;	Our Future Health confirms the confidential data (First Name, Surname, Address, Postcode) is specifically only extracted for the purpose of issuing a single invitation to a defined cohort of individuals. It is deleted within 2 weeks of the letter being issued and no other further processing of the data take place. Principles (a) and (b): this data processing activity will be "fair" and in accordance with all laws should the CAG grant Our Future Health's application, and lawful as it is within Our Future Health's legitimate interest to initiate this processing. Our Future Health has undertaken a "Legitimate Impact Assessment" and reasonably concluded that the proposed processing is not overridden by the interests, fundamental rights and freedoms of the patients in these circumstances. The Our Future Health Comms Plan details how transparency has been achieved. The individuals who will receive the invitation have: (a) NOT exercised their opt-out right (NHS DigiTrials screens against the National Opt-out Register and any local Opt-out Registers specifically for the Our Future Health invitations, prior to disclosing the data to the mailing house);	

		(b) a reasonable expectation (following public engagement etc. (see Comms Plan) that they may be contacted about taking part in health research. Further, principle 5(1)(b) specifically states: “further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes.” Principle (c): as can be seen from the inclusion criteria given to NHS DigiTrials and the information disclosed to the mailing house, the in-scope data fields are the very minimum required to achieve the legitimate aim of issuing the invitation. The purpose could not be achieved with less data. Principle (d): the accuracy of the personal data in NHS DigiTrial’s dataset is the responsibility of NHS Digital as a data controller in its own right governed by the UK GDPR. Principle (e): as stated above, the mailing house is under a written contract obliging it to delete all the personal information it receives from DigiTrials two weeks after despatch of the invitation. Compliance may be subject to audit, a right which is set out in the contract between NHS DigiTrials and APS Group (the mailing services provider) Principle (f): as stated above, as part of Our Future Health’s approach to data protection by design and default, Our Future Health never actually has access to the patients’ information unless and until they choose to put themselves in contact with Our Future Health following receipt of the invitation. The process for gaining approval; to share the data and the Data Sharing Agreement that Our Future Health signs with NHS Digital is here https://digital.nhs.uk/services/data-access-request-service-dars/data-access-request-service-dars-process: This is in addition to the freestanding obligation all controllers have to ensure appropriate technological and organisational measures Article 32 UK GDPR.	

	2. The controller shall be responsible for, and be able to demonstrate compliance with, paragraph 1 ('accountability'). The accountability principle requires you to take responsibility for what you do with personal data and how you comply with the other principles. You must have appropriate measures and records in place to be able to demonstrate your compliance	Our Future Health as Data Controller has designed this process flow with data minimisation and data protection by design and default at the forefront of its planning and discussions with NHD DigiTrials. For example, the patients' extracted name and address lists will not be shared with Our Future Health at any point. Our Future Health's commitment to complying with the UK GDPR and the DPA 2018 is further evidenced by our live engagement with the ICO's sandbox team considering our written policies, procedures and processes. Our Future Health has undertaken: (a) a Data Protection Impact Assessment (which is reviews annually); (b) a written "Legitimate Impact Assessment;" (c) a written "Public Interest Test" Assessment; and has appointed a "Data Protection Officer." NHS Digital will also process the data on our behalf, under a robust Data Processing Agreement specifying data storage and security requirements. As set out in the CAG Application, showing compliance against each of the principles, NHS Digitrials operates within the NHS Digital infrastructure and is compliant with the highest standards of data governance and data security principles including DSPT. The Data Processing agreement sets high standards for commitments and obligations for the safe and appropriate processing of the data on behalf of Our Future Health and by limiting the sharing of data, establishing a robust data processing agreement and ensuring timely deletion of data after the specific purpose has been discharged, Our Future Health is ensuring full accountability of its responsibilities.	

4.	**Contact with a Research Ethics Committee (Research Applications only)** *If your application is research, please specify whether an application has been or will be made to a REC and if so specify the REC name and REC reference number. If you are unsure whether the application is research you are advised to use the HRA decision tool available here: http://www.hra-decisiontools.org.uk/research/ and contact the queries line (HRA.Queries@nhs.net)with any questions.*	
	REC and IRAS reference number	

IRAS: 293316
East of England - Cambridge East Research Ethics Committee cambridgeeast.rec@hra.nhs.uk
REC reference number: 21/EE/0016

Our approved protocol details (in section 3.3) recruitment via NHS DigiTrials, however it states for saliva, not blood as we intend now. We contacted the REC to inform them a non-substantial amendment would be submitted to update this, but as per their email on 9th March 2022 the REC confirmed "*Non-substantial amendments for RTB and RDB projects do not need to be notified to the REC",* therefore there is no approval letter for the non-substantial amendment as this is not applicable.

A copy of the REC approval letter and approved protocol was supplied to [redacted] by [redacted] on 9/2/2022, along with the aforementioned email from REC.

5. Advice received by applicant

Have you obtained any advice previously from CAT or HRA in relation to the application? If so please provide a short summary of advice provided?

Date and method of contact	What was the nature of advice received? If written advice please provide a copy
Conference calls with NHS Digital and Our Future Health with [redacted] over the month preceding application 16th Feb 28th Feb 2nd March	Our Future Health and NHS DigiTrials had several conversations with [redacted], to establish the following: a) The correct form to complete b) The approach to describing key aspects of the application to ensure the wording is appropriate and easily understood by CAG members c) The best way to handle additional information not covered in the Part B CAG form for Tissue Bank programmes (additional information pertinent to the application is now in Q15). d) Clarification of the extent and format of supporting information in relation to PPIE, PIS and invitation letters required. e) Guidance on the extent of information describing the opt out plans

6. Further documents required for review

Please provide the following documents for review.

	Date

5.	Signature		
	Signature of applicant	**Role (job title)**	**Date**
	[redacted]	CEO, Our Future Health	14th March 2022