

East of England - Cambridge East Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

29 March 2021

████████████████████
Our Future Health Ltd
2 Redman Place
E20 1JQ

Dear ██████████

Title of the Research Tissue Bank:	Our Future Health
REC reference:	21/EE/0016
Designated Individual:	████████████████████
IRAS project ID:	293316

Thank you for your letter of 05 March 2021, responding to the Committee's request for further information on the above research tissue bank and submitting revised documentation.

The further information was considered at the meeting of the Sub-Committee of the REC held on 09 March 2021. A list of the members who were present at the meeting is attached.

We plan to publish your research summary wording for the Research Tissue Bank on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all Research Tissue Banks that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the Research Tissue Bank.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion of the above research tissue bank on the basis described in the application form and supporting documentation as revised.

The Committee has also confirmed that the favourable ethical opinion applies to all research projects conducted in the UK using tissue or data supplied by the tissue bank, provided that the release of tissue or data complies with the attached conditions. It will not be necessary for these researchers to make project-based applications for ethical approval. They will be deemed to have ethical approval from this committee. You should provide the researcher with a copy of this letter as confirmation of this. The Committee should be notified of all projects receiving tissue and data from this tissue bank by means of an annual report.

Mental Capacity Act 2005

I confirm that the Committee has approved this Research Tissue Bank for the purposes of the Mental Capacity Act 2005. The Committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this Research Tissue Bank on, or in relation to, a person who lacks capacity to consent to taking part.

Compliance with the Mental Capacity Act – the Committee agreed the following:

Relevance of the research to the impairing condition

The Committee agreed the research was connected with an impairing condition affecting persons lacking capacity or with the treatment of the condition.

The Committee agreed that, although participants would be confirmed as having capacity when consent was initially sought, the likelihood of a percentage of the five million proposed participants losing capacity at some point was high and that a mechanism for assessing ongoing capacity should be in place in order to satisfy the intent for continued access to medical records.

You noted that there were two bases on which you may become alert to potential changes in capacity:

1. Directly contacted by a representative of the participant – in this case you will establish a process where you verify the identity of the participant and the legal status of the reporting individual. Once verified you will proceed to the loss of capacity process detailed below.
2. From the regular updating of the health information through linkage with NHS Digital - You proposed that before you commence processing of data with NHS Digital (expected end 2021) you will develop an identification algorithm which will refine the broad clinical codes (ICD, Read, SNOMED) for the noted conditions, such that it identifies individuals who have at least a predicted probability of loss of capacity of 50%. This algorithm will be developed using both expert opinions, using data collected from the individuals in Our Future Health, and using data from the General Practice electronic record (e.g. CPRD).

The Committee found the response to be thoughtful and clearly set out. The Committee agreed the research would be connected with impairing conditions affecting persons lacking capacity or with the treatment of the condition.

Justification for including adults lacking capacity to meet the research objectives

The Committee agreed the research could not be carried out as effectively if it was confined to participants able to give consent. It was evident from the longitudinal nature of the project that participants may lose capacity during their time involved in the project and the Committee agreed that this data would be valuable and integral to the tissue bank and linked data.

Arrangements for appointing consultees

The Committee considered the arrangements set out in the application for appointing consultees under Section 32 of the Mental Capacity Act 2005 (England and Wales) and the equivalent Section 135 of the Mental Capacity Act (Northern Ireland) 2016) to advise on whether participants lacking capacity should take part and on what their wishes and feelings would have likely to have been if they had capacity.

The Committee was not entirely satisfied with the arrangements to identify and appoint consultees.

No arrangements were currently in place for identifying or appointing consultees.

You responded that, even the nature of the Our Future Health programme – namely to provide a resource to be used in the early detection and interventions around chronic disease, it would greatly devalue the resource to exclude or completely withdraw participants or remove their data/samples from future research if you become alert to their potential loss of capacity. You will be clear on the participant information sheet that if their capacity changes during the study, you will retain the individuals and ensure that you continue to be compliant with the Mental Capacity Act – essentially by following the below process. Obviously, participants continue to have the option of withdrawing from the study at any time and this is clear on the participant information sheet.

Even with the identification algorithm described above, it would not be appropriate to attempt to follow a process to identify a consultee of the individual. You will have no knowledge of the family/support structure around the individual, nor do you have a clinical relationship with the participant, hence even the process of identifying and assessing the legal authority of a potential consultee is problematic. Additionally, as capacity is a temporal- and decision-specific assessment, the process would require an assessment of capacity at each time you wanted to progress with updating the data via NHS Digital (at least quarterly) since capacity may be declining over time in individuals, this would be unnecessarily burdensome and intrusive for the care providers.

Therefore, in order to continue to update data electronically with NHS Digital (and others) you will move to a fully anonymous data update process for those individuals you have predicted would have lost capacity:

- A new participant ID is created, associated with the health records and linked data of the participant who has lost capacity; this is an anonymous participant with no identifying fields
- The link to the original participant ID is broken
- You will explore if we can directly or via a third-party broker enable the linkage to health records for the anonymous participant, with the goal of ensuring that Our Future Health have no access to identifying information.

The Committee found the response to be thoughtful and clearly set out.

Balance between benefit and risk, burden and intrusion

The Committee noted that while the research would not benefit participants lacking capacity it is intended to provide knowledge of the causes, treatment or care of their impairing condition or a condition similar to their impairing condition. The Committee agreed that the risk to participants was likely to be negligible and the research would not significantly interfere with their freedom of action or privacy and would not be unduly invasive or restrictive.

Additional safeguards

The Committee was satisfied that reasonable arrangements would be in place to comply with the additional safeguards set out in Section 33 of the Mental Capacity Act 2005 (England and Wales) and the equivalent Section 137 of the Mental Capacity Act (Northern Ireland) 2016).

Information for consultees

The Committee considered that the information to be provided to consultees about the proposed research was not adequate for the following reasons:

No information for consultees was provided.

After receiving and discussing the response to the section entitled 'Arrangements for appointing consultees', the Committee was content that no information would be required.

Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter provided that you comply with the standard conditions of ethical approval for Research Tissue Banks set out in the attached document. You are advised to study the conditions carefully. The opinion may be renewed for a further period of up to five years on receipt of a fresh application. It is suggested that the fresh application is made 3-6 months before the 5 years expires, to ensure continuous approval for the research tissue bank.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		
Human Tissue Authority licence		26 October 2020
Other [Questionnaire]	2.3	03 January 2021
Other [CV PI]	1.0	04 January 2021
Other [Introduction Video Script]		
Other [Poster]	1.0	05 January 2021
Other [MCA review]		
Other [Info Leaflet]	1.0	05 January 2021
Other [Invitation Letter]	1.0	05 January 2021
Other [Explainer Video Scripts]	1.0	05 January 2021
Other [CV PI]	2.0	04 March 2021
Other [Introduction Video Script]	1.1	05 March 2021
Other [Poster]	1.1	05 March 2021
Other [Info Leaflet]	1.1	05 March 2021
Other [Invitation Letter]	1.1	05 March 2021
Other [Explainer Video Scripts]	1.1	05 March 2021
Other [Response Letter]	1.0	05 March 2021
Participant consent form	1.1	05 March 2021
Participant information sheet (PIS)	1.1	05 March 2021
Protocol for management of the tissue bank	3.1 Clean	05 March 2021
REC Application Form [RTB_Form_06012021]		06 January 2021
Summary of research programme(s)		05 January 2021

Licence from the Human Tissue Authority

Thank you for providing a copy of the above licence.

Research governance

You are advised to check the requirements for approval of the research tissue bank with your R&D office.

Under the UK Policy Framework for Health and Social Care Research there is no requirement for NHS research permission for the establishment of research tissue banks in the NHS. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the research tissue bank.

Research permission is also not required by collaborators at tissue collection centres (TCCs) who provide tissue or data under the terms of a supply agreement between the organisation and

the research tissue bank. TCCs are not research sites for the purposes of the RGF.

Research tissue bank managers are advised to provide R&D offices at all TCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All TCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using tissue or data supplied by a research tissue bank must apply for permission to R&D offices at all organisations where the research is conducted, whether or not the research tissue bank has ethical approval.

Site-specific assessment (SSA) is not a requirement for ethical review of research tissue banks.

Registration of Research Tissue Banks

It is a condition of the ethical approval that all Research Tissue Banks are registered on the UK Clinical Research Collaboration (UKCRC) Tissue Directory. The Research Tissue Bank should be registered no later than 6 weeks after the date of this favourable ethical opinion letter or 6 weeks after the Research Tissue Bank holds tissue with the intention to provide for research purposes. Please use the following link to register the Research Tissue Bank on the UKCRC Directory: <https://directory.biobankinguk.org/Register/Biobank> Registration is defined as having added details of the types of tissue samples held in the tissue bank.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment or annual progress report form. We will monitor the registration details as part of the annual progress reporting process.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached standard conditions give detailed guidance on reporting requirements for research tissue banks with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form

available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Learning

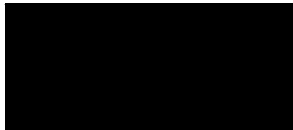
We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:

<https://www.hra.nhs.uk/planning-and-improving-research/learning/>

21/EE/0016

Please quote this number on all correspondence

Yours sincerely



Chair

E-mail:

CambridgeEast.REC@hra.nhs.uk

Enclosures:

List of names and professions of members who were present at the meeting and those who submitted written comments

Standard approval conditions

Copy to:

 NIHR - National Biosample Centre

East of England - Cambridge East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 09 March 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
██████████	Research Governance Advisor	Yes	
██████████ (Chair)	Retired Consultant Oncologist	Yes	
██████████	Pharmacist	Yes	