

# Withdrawal of accreditation standard operating procedure

## 1. Purpose

To define an objective process for withdrawal of accreditation from a cTRE, based on remediation and review by an independent third party.

## 2. Scope

This procedure covers situations where a cTRE no longer meets the accreditation criteria.

## 3. Definitions

**Access Board:** Our Future Health board responsible for developing and implementing the access process, and authorising decisions about research applications to access the Our Future Health resource.

**Access process:** the process by which all research studies using the Our Future Health resource are approved. Includes decisions about access to data and datasets. Our Future Health is responsible for this process, which is overseen by the Access Board.

**Accreditation:** the process developed by Our Future Health to ensure a TRE has demonstrated sufficiently robust organisational, technical, security and administrative processes to be permitted to host a subset of the Our Future Health data to allow registered researchers to conduct an approved study. Accreditation is granted by an independent assessor to a specific TRE.

**Approved study:** a study or research project approved by the access board. The studies are approved for a fixed period of time.

**Assessor:** third party commissioned by Our Future Health to review accreditation applications, including the self-assessment questionnaire and evidence.

**cTRE:** a TRE that has achieved accreditation via the Our Future Health accreditation process.

**Pseudonymised data:** personal data that has been processed in such a way that the personal data can no longer be attributed to a specific person without the use of additional information. Pseudonymisation is a method of data de-identification.

**Registered researcher:** a person who has successfully completed the registration process and had their identity confirmed, including where necessary having had their bona fides (including their affiliation and qualifications) verified.

**Resource:** the Our Future Health data and samples; the Our Future Health TRE; the results data from any approved research project that is added to the Our Future Health TRE; and a register of plain English summaries of each approved study.

**Standard Operating Procedure (SOP):** a set of written instructions that describes the step-by-step process that must be taken to properly perform an activity.

**Trusted Research Environment (TRE):** is an environment that allows registered researchers working on an approved study to conduct analysis on the Our Future Health pseudonymised datasets in a secure manner.

## 4. Responsibilities

Role	Organisation	Responsible for
Administrator	Our Future Health	<ul style="list-style-type: none"> <li>Notifying organisation with cTRE of process steps and decisions</li> </ul>
Responsible person	Organisation with cTRE	<ul style="list-style-type: none"> <li>Complying with process</li> <li>Completion of remediation</li> <li>Completion of offboarding processes</li> <li>Initiating appeals process</li> </ul>
Assessor	Independent third party assessor	<ul style="list-style-type: none"> <li>Reviewing evidence</li> <li>Confirmation as to whether organisation with cTRE meets / does not meet accreditation criteria</li> </ul>
Adjudication panel	Independent	<ul style="list-style-type: none"> <li>Confirming withdrawal decision where contentious</li> <li>Appeals process</li> </ul>

## 5. Procedure

### 5.1 Process steps (refer to 5.3)

#### 5.1.1 cTRE no longer meets accreditation criteria

cTRE has completed remediation as part of the “change to a cTRE SOP (step 5.1.6)” or “updating accreditation SOP (step 5.1.10)”. After two rounds of remediation, the cTRE does not meet the accreditation criteria.

#### 5.1.2 Assessor confirmation

Assessor confirms the accreditation criteria are not met.

If the cTRE agrees, withdrawal of accreditation commences.

If the organisation with the cTRE does not agree, the adjudication panel conducts a review. The adjudication panel makes a decision:

- If accreditation criteria are met, business as usual resumes
- If accreditation criteria are not met, withdrawal commences

#### 5.1.3 Withdrawal of TRE accreditation and offboarding processes

Withdrawal occurs:

- if the assessor has confirmed that accreditation criteria are no longer met, the organisation with the cTRE agrees, and there has been a failure to remediate; OR

- b. if the assessor and the adjudication panel have confirmed that accreditation criteria are no longer met, and there has been a failure to remediate.

Our Future Health confirms withdrawal of TRE accreditation in writing to the organisation with the cTRE. Offboarding processes must commence.

Registered researchers may no longer access workspaces containing Our Future Health data.

All research studies using Our Future Health data must cease. Researchers may apply to continue their studies within the Our Future Health TRE.

All Our Future Health data is deleted as per Our Future Health data deletion standard operating procedure (in draft). Evidence of the above is provided to Our Future Health.

### 5.1.4 Appeals process

Following withdrawal of accreditation, the organisation with the cTRE may appeal for the decision to be re-considered by the adjudication panel.

### 5.2 Adjudication panel

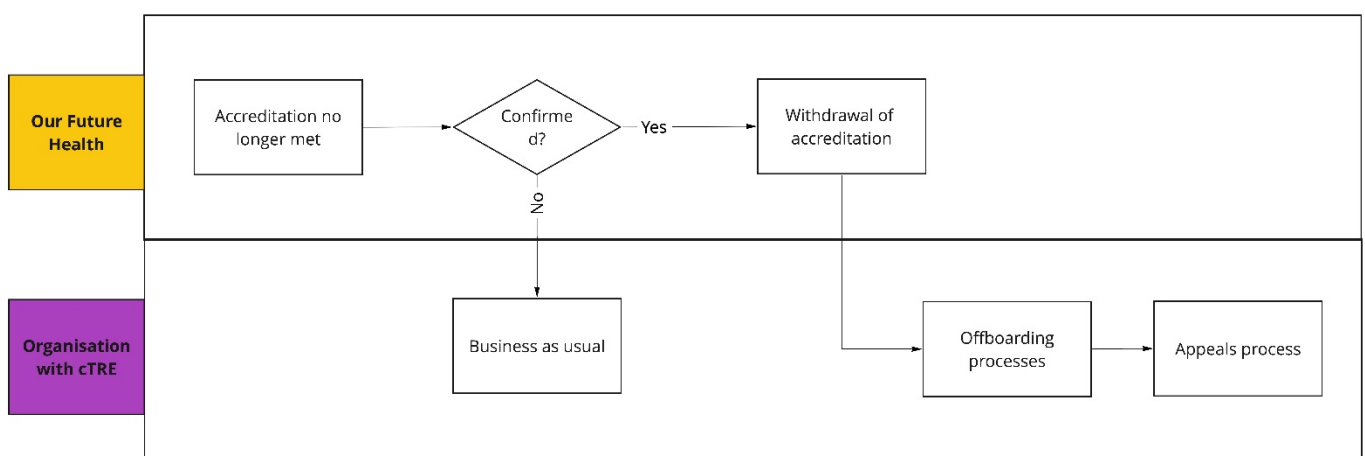
The adjudication panel is yet to be created, and may be made up of the Our Future Health access board plus technical experts.

The adjudication panel will include representatives such as:

- Independent data governance, security, technical and ethics experts
- Participant
- Our Future Health partnerships and executive team representatives

The adjudication panel will follow English law.

### 5.3 Process flow



## **6. Related documents, templates and further reading**

Change to an accredited TRE SOP

Updating accreditation process SOP

Accreditation of a TRE SOP

Account management of an accredited TRE SOP

Data deletion SOP (not yet available)