Our Future Health

# Change to an accredited TRE standard operating procedure

## 1. Purpose

It is recognised that elements of the systems and processes related to the cTRE will change or mature over time. Therefore, at any point during the accreditation period, any material change may require an element of review and/or reaccreditation.

## 2. Scope

This process applies to all material changes occurring to a cTRE or related processes during the accreditation period.

A material change is defined as a change relating to a function or process that invalidates a mandatory answer within the accreditation self-assessment questionnaire or evidence submitted during the accreditation process.

Examples of material changes include:

a.  Update to the data export process
b.  New statutory / legal / regulatory requirements the organisation must adhere to which may affect the accreditation
c.  Changes to supplier systems impacting on cyber security or data policies

Examples of out-of-scope items (these are part of the account management of a TRE process):

a.  Issues, breaches
b.  Actual data exports
c.  New / changes to studies
d.  Changes to personnel
e.  Threats

If the accredited organisation merges or is acquired by another organisation, any "material changes" to the self-assessment questionnaire or evidence must be submitted as per this procedure.

## 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. Studies are approved for a fixed period of time.

**Applicant:** an organisation with a TRE that applies for accreditation of that TRE via the Our Future Health accreditation process.

**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.

**Material change:** a change relating to a function or process that invalidates a mandatory answer within the accreditation self-assessment questionnaire or evidence submitted during the accreditation process.

**Trusted Research Environment:** 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.

**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.

**Trusted Research Environment:** 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 |
|------|--------------|-----------------|
| Chief Technology Officer | Our Future Health | • Request of change certification if necessary |
| Administrator | Our Future Health | • Request of change certification<br>• Processing change forms<br>• Scheduling audit<br>• Updating Our Future Health logs |
| Responsible person | Organisation with cTRE | • Monitoring cTRE and related processes to identify material changes |

| | | |
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| | | • Reporting of material changes via this process; submitting change form, self-assessment questionnaire, and evidence where required<br>• Co-operation with audit |
| Lead assessor | Independent third party assessor | • Assessment of change documentation and evidence via audit<br>• Revising risk score if required<br>• Informing Our Future Health and organisation with cTRE of process outcome |

## 5. Procedure

**5.1 Process steps (refer to 5.2)**
**5.1.1 Material change identified**

A) The organisation with the cTRE submits change form as part of the account management review, either to confirm there has been no material change or to submit details of a material change (see "account management of an accredited TRE SOP"); OR
B) If Our Future Health has reasonable cause to think there has been a material change to a cTRE since it received accreditation from Our Future Health, Our Future Health may request details from the organisation with the cTRE; OR
C) Organisation with the cTRE identifies a material change and submits details to Our Future Health within 3 months.

In all cases, the organisation with the cTRE should submit the change form.

If there has been no material change, the Our Future Health administrator updates the logs and there is no further action.

If there has been a material change, new/updated answers to the self-assessment questionnaire should be submitted along with the change form, and the following process steps should be completed. Note that only answers to self-assessment questions which have changed should be submitted, and only these will be assessed.

**5.1.2 Audit**

Assessor reviews the change form and self-assessment questionnaire.  Assessor identifies whether an audit is required. If not, proceed to 5.1.4.

If an audit is required, the Our Future Health administrator co-ordinates an audit with the organisation with cTRE and the assessor. The scope and timelines of the audit are agreed in advance.

The assessor and organisation with the cTRE attend the audit.

**5.1.3 Risk score re-calculated**

Using self-assessment questionnaire and evidence interview results, assessor re-calculates risk score.

### 5.1.4 Risk score meets threshold for accreditation

If the risk score meets the threshold for accreditation, the assessor informs organisation with the cTRE and Our Future Health that the material change is acceptable.

Our Future Health administrator updates logs.

### 5.1.5 Risk score does not meet threshold for accreditation: remediation

If risk score does not meet threshold for the change to be accepted, enter remediation: step 5.1.6.

### 5.1.6 Remediation

Assessor informs applicant of specific self-assessment criteria and evidence which are not sufficient. Applicant make changes to the TRE or processes as required. Applicant updates and submits self-assessment questionnaire. Our Future Health schedules further sampling review of evidence, to be attended by assessor and applicant.
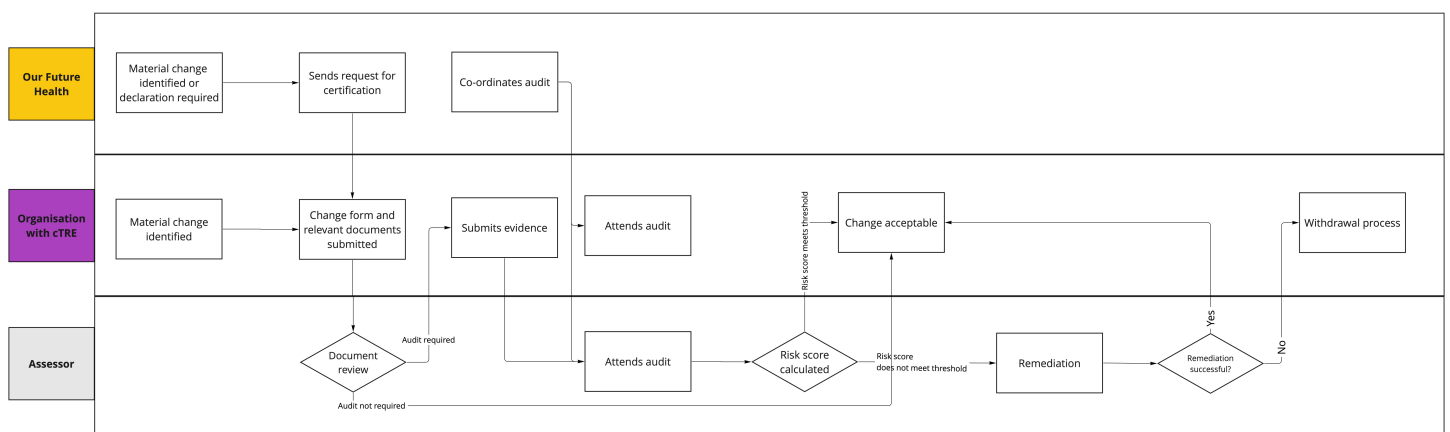
Using self-assessment questionnaire and evidence interview results, assessor calculates final risk score.

If risk score meets threshold for accreditation, move to step 5.1.4.

If not, remediation step may be completed up to two times.

If risk score does not meet threshold for accreditation after two rounds of remediation, enter withdrawal of accreditation process.

**5.2 Process Flow**



# 6.   Related documents, templates and further reading

    a.      Accreditation self-assessment questionnaire
    b.      Accreditation of a TRE SOP
    c.      Updating accreditation SOP
    d.      Account management of an accredited TRE SOP
    e.      Withdrawal of accreditation SOP

# Appendix: Change form

**Instructions**

1. Fill in change form
2. If section 2 was used, update relevant self-assessment questionnaire answers
3. Submit change form and (if relevant) self-assessment questionnaire to Our Future Health
4. If section 1 was submitted, no further action
5. If section 2 was submitted, Our Future Health will be in touch to arrange audit (if required)

| Background information | |
|---|---|
| **Organisation name** | Confidential – do not distribute |
| **Contact name** | |
| **Contact details** | |
| **Name of accredited TRE** | |
| **Change request source** | *Select one*<br>❑ Account management review<br>❑ Our Future Health has requested certification in writing<br>❑ Our Future Health has not requested certification; organisation wishes to declare a material change |
| **Declaration of material change**<br>*Complete EITHER section 1 OR section 2* | |
| **Section 1: No material change** | There has been no material change to the *insert name* cTRE since:<br>*Select one*<br>❑ Accreditation was achieved on *date*<br>❑ The last change form was submitted to Our Future Health on *date*<br><br>I confirm this declaration is complete and correct.<br><br>Signature:<br><br>Role:<br><br>Date: _/_/_ |
| **Section 2.1: Material change** | There has been a material change to the *insert name* cTRE since:<br>*Select one*<br>❑ Accreditation was achieved on *date*<br>❑ The last change form was submitted to Our Future Health on *date*<br><br>*If an answer in 2.1 has been selected, an updated self-assessment questionnaire must be submitted along with this form.* |

|  | I confirm this declaration is complete and correct. I confirm the self-assessment questionnaire has been updated to reflect the material change.

Signature:

Role:

Date: _/_/_ |
|---|---|
| **Section 2.2** | Material change 1 summary: _*description of the material change*_

Updated criteria reference number(s): _*reference numbers of the criteria which have been updated in the self-assessment questionnaire*_

Material change 2 summary:

Updated criteria reference number(s):

*Etc.* |