

TRE accreditation change control standard operating procedure

Version 2.1 November 2022

Document version history

Version number	Date	Significant changes from previous version	Author signature
1.1	26 th May 2022	n/a	Emily Binning
1.2	30 th June 2022	Minor (formatting)	Emily Binning
2	30 th September 2022	Major (Two SOPs “change to a cTRE” and “updating accreditation process” combined; procedure updated to include change request via change control notice.	Emily Binning
2.1	15 th November 2022	Minor (5.2, 5.3, 5.6)	Emily Binning

1. Purpose

The purpose of this standard operating procedure is to define the change control process for the Our Future Health TRE accreditation and accredited TREs.

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

It is also recognised that Our Future Health may need to update or amend an aspect of the accreditation, for example in response to legal, regulatory or governance changes such as to the UK General Data Protection Regulation (UK GDPR) or ISO 27001 Annex A. It may also be for other justifiable reasons, such as to enhance security requirements in response to: increased security requirements imposed on Our Future Health by funders, regulators or governance structures; or

an unacceptable level of security incidents occurring within accredited TREs. Our Future Health retains the right to update the accreditation materials or processes.

2. Scope

This document defines a change control process for material changes to documents, materials, processes, and systems relating to Our Future Health TRE accreditation process and accredited TREs.

Aside from the change control process, other measures control the ongoing governance and security of accredited TREs. These are out of scope of this document, and include:

- a. Contractual arrangements and responsibilities
- b. Incident management and security reporting procedures and requirements
- c. Data sharing agreements
- d. Annual account management meeting between accredited TRE Owner and Our Future Health
- e. Audit in specified circumstances

3. Definitions

Access Board: an Our Future Health board responsible for the access process and for overseeing 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.

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

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

Applicant: a TRE Owner 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.

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; OR a change to the accreditation materials or processes. Examples include:

- a. Change to data export mechanisms from the TRE
- b. Change to access control policy
- c. Change to supplier systems impacting on cyber security or data policies
- d. Change in scope of external certifications e.g. ISO 27001
- e. Change of premises or working set-up
- f. Changes occurring to the accredited systems or processes as a result of a merger or acquisition of or by the TRE Owner
- g. Addition of a new self-assessment questionnaire control

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.

TRE Owner: organisation accountable for a trusted research environment.

Trusted Research Environment: an environment that allows registered researchers working on an approved study to conduct analysis on the Our Future Health pseudonymised datasets in a secure way.

4. Responsibilities

Organisation	Responsible for
Our Future Health	<ul style="list-style-type: none"> • Reporting of material changes to the accreditation process • Administration of change control process and CCNs
Accredited TRE Owner	<ul style="list-style-type: none"> • Monitoring accredited TREs and related processes to identify material changes • Implementation of approved changes • Reporting of material changes to accredited TREs • Co-operation with assessor review
Assessor	<ul style="list-style-type: none"> • Assessment of change requests, related documentation, and evidence • Revising risk scores and re-issuing accreditation
Adjudication panel	<ul style="list-style-type: none"> • Panel notified at remediation step to be on standby in case change progresses to invalidation of accreditation

5. Change Control Procedure

5.1 Change is initiated via a Change Control Notice (CCN), see appendix.

5.1.1 In the case of a planned material change affecting an accredited TRE, accredited TRE Owner submits a CCN to Our Future Health via the email address treaccreditation@ourfuturehealth.org.uk. The request is reviewed and impacts assessed. Change is agreed or rejected. If the change is agreed, both parties sign the CCN. Accredited TRE Owner then implements the change in accordance with the agreed CCN.

5.1.2 In the case of a planned material change to the accreditation materials or process, Our Future Health will provide 1 months' written notice to relevant parties via a CCN. Relevant parties include (but are not limited to) organisations with existing accreditation, and applicants' part-way through the accreditation process. 1 month following the issue of the CCN, Our Future Health may implement the change and inform all relevant parties. Refer to 5.6 for details of how this may affect existing accreditation.

5.1.3 In the case that Our Future Health has reasonable cause to suspect there has been an undeclared material change to an accredited TRE since it received accreditation, Our Future Health may request details from the accredited TRE Owner. As appropriate, the accredited TRE Owner should either submit a CCN as per 5.1.1, or confirm there has been no material change to Our Future Health in writing.

5.2 Once a CCN has been implemented as per 5.1, accredited TRE Owners may be required to re-submit sections of the self-assessment questionnaire or evidence materials to the assessor.

- For a minor change: accredited TREs will have 3 months to complete actions.
- For a major change: accredited TREs will have 6 months to complete actions.

If these deadlines are likely to be missed, the accredited TRE Owner should seek an extension, to be agreed with Our Future Health or the Assessor or both, depending on the nature of the change. The nominated accountable person(s) (refer to CCN) should be informed.

If the extension deadlines are missed, the accredited TRE Owner meets the threshold for the initiation of the invalidation of accreditation, refer to the invalidation of TRE accreditation standard operating procedure.

5.3 Before re-submission of the questionnaire and/or evidence, NDA between TRE Owner and Assessor should be reviewed and extended if necessary.

5.4 The assessor will review and update the risk score, and notify the accredited TRE Owner if an audit or evidence review is required. The scope and timelines of the audit will be agreed in advance. The audit will be attended by the assessor and accredited TRE Owner.

5.5 Following the review and/or audit, the accredited TRE Owner will receive a notification whether the risk score threshold for accreditation is met. If so, the change is closed. If not, proceed to remediation, 5.6.

5.6 Remediation

If remediation entered there is an increased risk of invalidation of accreditation. Therefore, the nominated accountable person(s) (refer to CCN) and the adjudication panel should be informed.

5.6.1 Assessor and applicant agree remediation plan, which explicitly states the scope of one round of remediation. .

5.6.2 Upon completion of remediation plan and up to two rounds of remediation, assessor calculates final risk score. If risk score meets threshold for accreditation, the change is closed. 5.6.3 If risk score does not meet threshold for accreditation after two rounds of remediation, accreditation is invalidated. Refer to the invalidation of accreditation standard operating procedure.

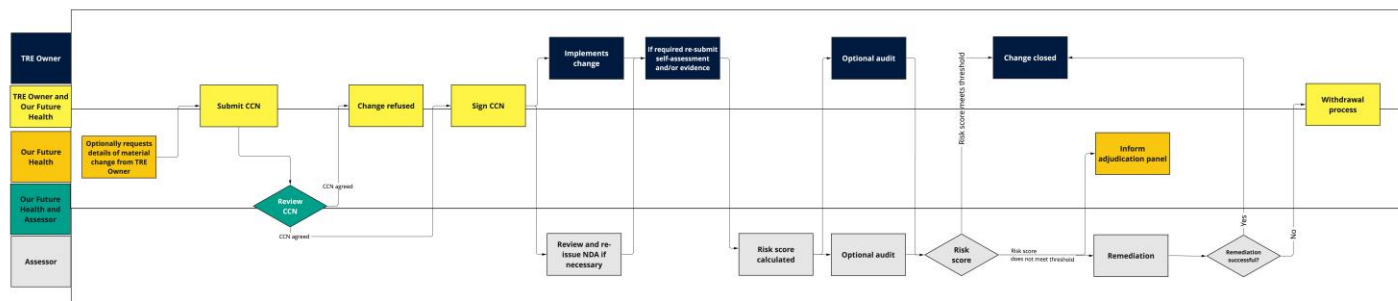
5.7 In the case of a planned material change to the accreditation materials or process:

5.7.1 Existing studies and existing data within an accredited TRE will continue to run under the previous version of the accreditation documents. The change will apply from the first new data ingestion after the change is closed 5.4.

5.7.2 Applicants part-way through completing the accreditation process when a change is implemented, but who have already submitted the self-assessment questionnaire should complete the process under the version as per their submission. They should then submit a CCN once accreditation is granted. No datasets for approved projects can be provided until the change has been closed.

5.8 Procedure diagram

A larger diagram is available separately.



6. Related documents, templates and further reading

- Trusted research environment accreditation policy
- TRE accreditation self-assessment questionnaire
- Accreditation of a trusted research environment standard operating procedure
- Account management of an accredited TRE standard operating procedure
- Invalidation of accreditation standard operating procedure

Appendix: Change Control Notice

Section 1: Background information	
Date of notice	
Title of change	
Organisation name	<i>[Of accredited TRE Owner]</i>
Key contact name	<i>[Person responsible for delivery of change]</i>
Key contact details	
Nominated accountable person(s)	<i>[Person(s) who should be informed if change control deadlines missed or remediation entered and there is a risk of invalidation of accreditation. Likely to be Senior Technical or Governance]</i>
Reference of accredited TRE	<i>[Reference found on certificate of accreditation]</i>
Section 2: Material change	
Proposed change	<i>[Describe change]</i>
Reasons for change	<i>[Describe rationale]</i>
Accreditation process impact	<i>[Describe which documents / subsections of the accreditation application the change affects]</i>
Timetable for implementing change	<i>[Include timetable]</i>
Impact of the implementation of the change	<i>[Describe impact of implementation of the change]</i>
Amendments to agreements	<i>[Confirm whether any amendments are required to any legal terms]</i>
Other	<i>[Include any other necessary information]</i>
Section 3: Confirmation of the change	
Signature of TRE Owner	<i>[Sign when change has been agreed. Include date]</i>
Date	
Signature of Our Future Health	<i>[Sign when change has been agreed. Include date]</i>
Date	