

Updating accreditation process standard operating procedure

1. Purpose

Our Future Health retains the right to update the accreditation materials or processes. This procedure describes the process Our Future Health will follow to make these updates.

2. Scope

This applies to: the Our Future Health self-assessment questionnaire (including accreditation principles, accreditation criteria, reporting and risk assessment); accreditation processes including the application process, change process, account management process, and this process; and any other documented aspect of the Our Future Health accreditation.

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: 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.

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: 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.

UK General Data Protection Regulation (UK GDPR): the UK’s domestic data privacy law, which took effect on 31st January 2020. The UK’s implementation of the EU GDPR.

4. Responsibilities

Role	Organisation	Responsible for
Chief Technology Officer	Our Future Health	<ul style="list-style-type: none"> • Identification of need • Incorporation of update into roadmap • Update of content, documentation and publication
Governance	Our Future Health	<ul style="list-style-type: none"> • Ensuring accreditation process and criteria remain up to date
Administrator	Our Future Health	<ul style="list-style-type: none"> • Administration of notifications and publication • Communication with organisations with cTRES • Scheduling examination interviews • Scheduling remediation • Updating logs
Responsible person	Organisation with cTRE	<ul style="list-style-type: none"> • Submission of self-assessment questionnaire • Attendance at examination interviews
Lead assessor	Independent third party assessor	<ul style="list-style-type: none"> • Assessment of self-assessment questionnaire • Briefing of applicant on content of examination interviews • Leading examination interviews • Review of evidence • Calculation of risk scores • Reporting on process outcome

5. Procedure

5.1 Process steps (refer to 5.2)

5.1.1 Need identified

Our Future Health identifies a need to update or amend an aspect of the accreditation. This is likely to be in response to legal, regulatory or governance changes, for example changes to the UK General Data Protection Regulation (UK GDPR) or ISO 27001 Annex A must be reflected in the accreditation criteria.

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; an unacceptable level of security incidents occurring within accredited TREs.

Required update incorporated into Our Future Health accreditation roadmap.

5.1.2 Notification

Our Future Health informs organisations with cTREs and current applicants of intended update and expected timeframe for 5.1.4 and 5.1.5, at least 1 month before publication.

Organisations note dates into project plans.

5.1.3 Update of documentation

Our Future Health incorporates update into documentation in consultation with, where relevant, the Technology Advisory Board, Ethics Advisory Board, Scientific Advisory Board, Public Advisory Board.

Update signed off by: Founders Board and Our Future Health Executive Team.

5.1.4 Publication of update

Update published. Our Future Health informs organisations with cTREs and current applicants of publication and confirms timeframe for submission of self-assessment questionnaire.

5.1.5 Submission of self-assessment questionnaire

For a minor update: cTREs will have 3 months to submit self-assessment questionnaire.

For a major update: cTREs will have 6 months to submit self-assessment questionnaire.

If these deadlines are missed, withdrawal of accreditation commences as per withdrawal SOP.

5.1.6 Risk score calculated

Using scoring matrix, assessor calculates risk score. Assessor identifies whether examination interview required. If not, proceed to 5.1.9.

5.1.7 Examination interviews

Our Future Health administrator schedules examination interview, for the purpose of assessing, clarifying, reviewing, and demonstrating evidence to support self-assessment answer(s).

Based on risk score, assessor shares 1) list of evidence required from applicant and 2) list of attendees required at examination interview.

Examination interviews occur.

5.1.8 Risk score re-calculated

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

5.1.9. 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 cTRE may be accredited for the update.

Our Future Health administrator updates logs.

5.1.10 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 5.1.9 in the accreditation process.

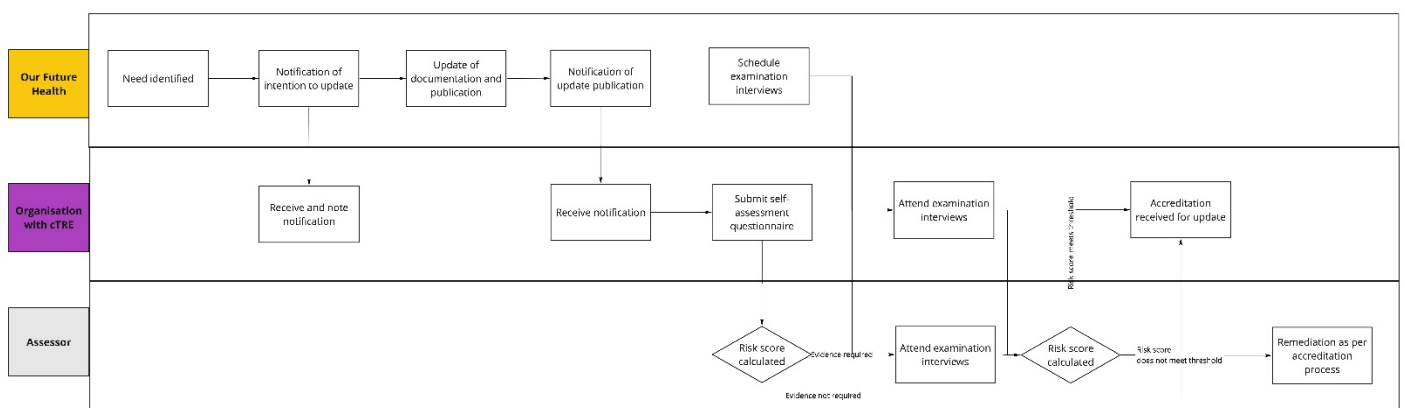
If, following two rounds of remediation, the risk score is not met for the new requirements, accreditation is withdrawn.

5.2 Additional notes

During this process, and until the timeframes specified in 5.1.5 have elapsed, existing studies and existing data with a cTRE will continue to run under the old accreditation. The published update will apply from the first new data ingestion after 5.1.9 is achieved.

Applicants part-way through completing the initial accreditation process, but who have already submitted the self-assessment questionnaire, when an update is published should complete the original accreditation process, and then submit an update once accreditation is granted. No datasets for approved projects can be provided until accreditation for the update has been achieved.

5.3 Process flow



6. Related documents, templates and further reading

- Accreditation self-assessment questionnaire
- Accreditation of a TRE SOP
- Change to an accredited TRE SOP
- Account management of an accredited TRE SOP
- Withdrawal of accreditation SOP