

Invalidation of accreditation standard operating procedure Version 1.4 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
1.3	30 th September 2022	Minor (4, 5 and 6 updated for brevity and clarity)	Emily Binning
1.4	15 th November 2022	Minor (5.1, 5.4)	Emily Binning

1. Purpose

This procedure is to define an objective process for the invalidation of accreditation from an accredited TRE in specified circumstances, based on remediation and review by a third-party assessor.

2. Scope

This procedure describes invalidation of accreditation where an accredited TRE no longer meets the accreditation criteria.

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.

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.

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.

TRE Owner: organisation accountable for a trusted research environment.

Trusted Research Environment (TRE): 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">Notifying accredited TRE Owner of process steps and decisions
TRE Owner	<ul style="list-style-type: none">Completion of offboarding processes and providing evidence of suchOptionally initiating decision challenge or appeals process
Assessor	<ul style="list-style-type: none">Confirmation that conditions for invalidation_of accreditation met
Adjudication panel	<ul style="list-style-type: none">Review of invalidation_decision in response to challenge or appeal

5. Procedure

5.1 Assessor confirms that the accredited TRE Owner has completed two rounds of remediation and does not meet the threshold for accreditation, as per the TRE accreditation change control standard operating procedure. The accredited TRE Owner accountable persons (nominated as part of change control procedure) will receive notification in writing from Our Future Health of the decision and the initiation of the invalidation of accreditation.

5.2 The accredited TRE Owner may optionally challenge the decision in writing by contacting Our Future Health at treaccreditation@ourfuturehealth.org.uk. In this case, the adjudication panel conducts a review of the decision and confirms whether the accreditation threshold is met (in which case business as usual resumes), or not (in which case proceed to 5.3). The accredited TRE Owner will receive notification in writing from Our Future Health of the decision.

5.3 Invalidation of accreditation will initiate the following offboarding processes:

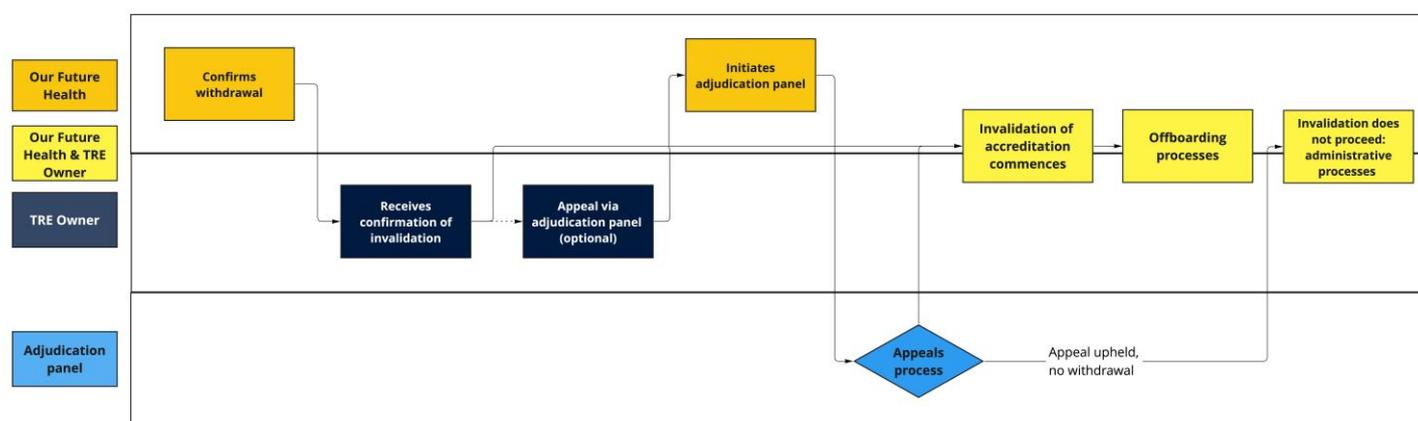
- Accredited TRE Owner must terminate registered researcher access to Our Future Health data.
- Accredited TRE Owner must suspend all access to approved studies. Registered researchers may apply to continue approved studies within the Our Future Health TRE.
- All Our Future Health data must be deleted as per Our Future Health data deletion principles.

The accredited TRE Owner must provide evidence of the above to Our Future Health.

5.4 The TRE Owner may re-apply for accreditation after 12 months by following the accreditation of a trusted research environment standard operating procedure.

5.5 Procedure diagram

A larger diagram is available separately.



6. Adjudication panel

The adjudication panel and appeals process will be formed by the end of Q1 2023. It is likely to include representatives from:

- Chair of the Our Future Health Technical Advisory Board or their nominated delegate
- Chair of the Our Future Health Ethics Advisory Board or their nominated delegate
- Data governance experts
- Data security experts

The adjudication panel will follow English law.

7. Related documents, templates and further reading

- a. Trusted research environment accreditation policy
- b. TRE accreditation self-assessment questionnaire
- c. Accreditation of a trusted research environment standard operating procedure
- d. TRE accreditation change control standard operating procedure
- e. Account management of an accredited TRE standard operating procedure