

Accreditation of a trusted research environment standard operating procedure

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Document version history

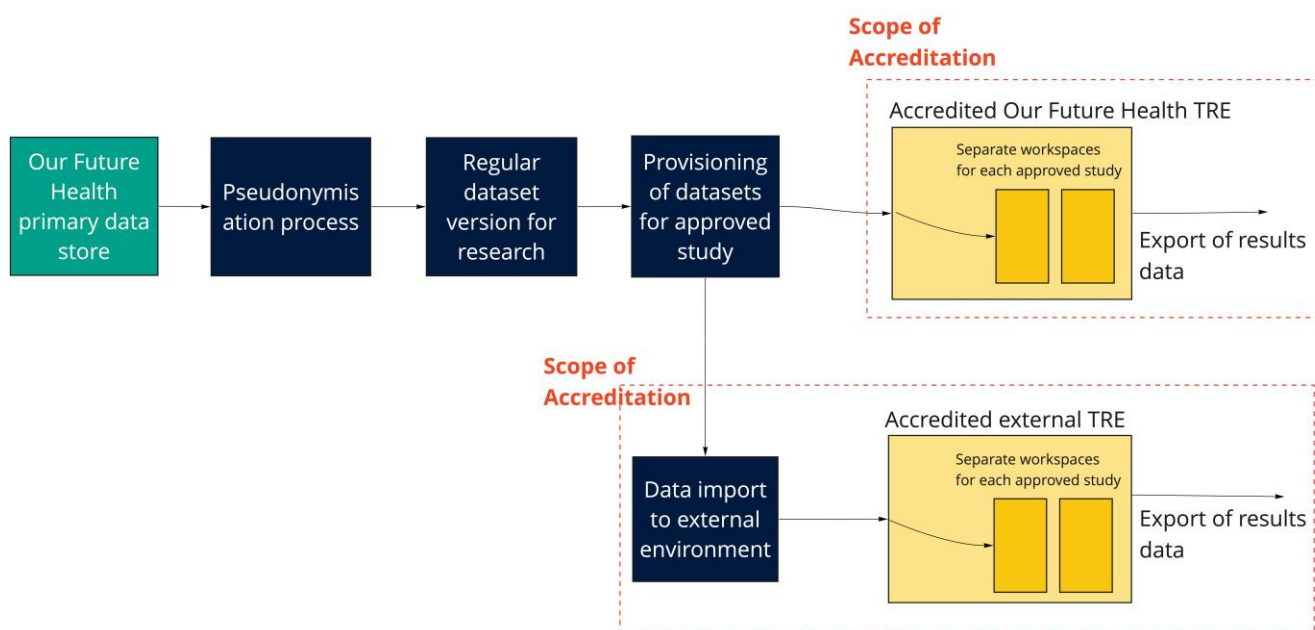
Version number	Date	Significant changes from previous version	Author signature
1.1	26 th May 2022	n/a	Emily Binning
1.2	30 th June 2022	Minor (formatting)	Emily Binning
1.3	30 th September 2022	Minor (4 and 5 updated for brevity and clarity)	Emily Binning
1.4	15 th November 2022	Minor (5.1.1, 5.1.2, 5.2)	Emily Binning

1. Purpose

An organisation may apply to host Our Future Health data within a trusted research environment (TRE), in order to allow registered researchers to conduct an approved study. The purpose of the Our Future Health TRE accreditation process is to allow Our Future Health to ensure the prospective TRE has robust enough organisational, technical, security and administrative processes to allow Our Future Health to uphold its obligations to its participants and to relevant regulation such as the UK General Data Protection Regulation (UK GDPR).

2. Scope

This standard operating procedure (SOP) describes the process by which organisations may apply to achieve accreditation of a specific trusted research environment. Accreditation includes all associated processes, for example, data import, data export, and human resource processes.



The researcher registration process, study approval process, and data transfer process are out of scope of this SOP.

3. Definitions

Access Board: an Our Future Health board responsible for developing and implementing the access process, 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.

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 language 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.

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

Organisation	Responsible for
Our Future Health	<ul style="list-style-type: none"> • Accreditation process, content and materials, including document control • Administration of accreditation fee and contract • Signatory to contract with successful applicant
Applicant	<ul style="list-style-type: none"> • Application: <ul style="list-style-type: none"> • Self-assessment questionnaire • Preparation of necessary evidence • Attendance of interviews • Payment of fee • Timely responses to queries and requests for further information to complete application process within specified timeframe • If successful, signatory to contract with Our Future Health
Assessor	<ul style="list-style-type: none"> • Assessment of applications • Scheduling examination interviews and remediation • Briefing of applicant on content of examination interviews • Leading examination interviews • Review of evidence • Calculation of risk scores • Reporting

5. Accreditation procedure

5.1 Procedure steps

5.1.1 TRE Owner completes declaration of interest form and submits form to Our Future Health. Our Future Health confirms a) eligibility to apply for accreditation, b) whether a Transfer Impact Assessment is required as per the UK GDPR, and c) access to the correct version of the accreditation documents via email.

5.1.2 Our Future Health provides applicant via email with a) confirmation of eligibility, b) application documentation, and c) introduction to assessor, including confirmation of how to submit application. Applicant reviews documents and completes self-assessment questionnaire. One application must be completed per TRE instance. If more than one TRE exists, each must be accredited via this process separately.

5.1.3 Assessor and applicant sign NDA. Once NDA complete, applicant submits questionnaire and evidence documents via mechanism confirmed in 5.1.2.

5.1.4 Our Future Health issues invoice for application fee; applicant pays as per payment terms.

5.1.5 Assessor completes initial review. Further information requested from applicant as required. Applicant expediently provides information via secure file transfer.

5.1.6 Assessor calculates initial risk score using scoring matrix.

5.1.7 Assessor schedules 1 day of examination interviews with applicant, for the purpose of assessing, clarifying, reviewing, and demonstrating evidence to support self-assessment answers. Assessor confirms the specific agenda and expectations for the examination interview.

5.1.8 Applicant and assessor attend examination interviews.

5.1.9 Assessor calculates final risk score.

5.1.10 Risk score meets threshold for accreditation: accreditation granted (proceed to 5.1.11) OR Risk score does not meet threshold for accreditation: remediation (proceed to 5.1.14)

5.1.11 Assessor informs applicant of successful accreditation application.

5.1.12 Successful applicant and Our Future Health sign accreditation deed.

5.1.13 If required, Our Future Health issue invoice for application fee. Our Future Health and successful applicant agree cadence for account management meetings at point of contract signature (at a minimum every 12 months).

5.1.14 If final risk score does not meet threshold for accreditation to be granted as per 5.1.10, enter remediation (5.1.15).

5.1.15 Remediation. Assessor informs applicant of specific self-assessment criteria and evidence which are not sufficient. Applicant addresses the points, and updates and re-submits self-assessment questionnaire. Assessor schedules further sampling review of evidence with applicant, as 5.1.7.

5.1.16 Using re-submitted self-assessment questionnaire and evidence interview results, assessor calculates final risk score. For the avoidance of doubt, this means one round of remediation has been completed. If risk score meets threshold for accreditation, move to step 5.1.10. If not, remediation steps (5.1.15 and 5.1.16) may be completed up to two times.

5.1.17 If risk score does not meet threshold for accreditation after two rounds of remediation, the assessor informs the applicant that accreditation is not achieved. Applicant may not re-apply to the accreditation process for 12 months.

5.1.18 If required, Our Future Health issue invoice for application fee.

5.2 Timeframe

It is expected that the accreditation process will take up to a maximum of 90 days from when an application is received (5.1.3), including remediation activities 5.1.15 and 5.1.16.

It is the responsibility of the applicant to ensure the additional information requested in 5.1.5 and 5.1.15 is provided in a timely manner. In the case of delays, the assessor will notify Our Future Health and the applicant.

Our Future Health will provide 6 months' notice if it intends to close the TRE accreditation process to applications, i.e. at the end-of-life of the process.

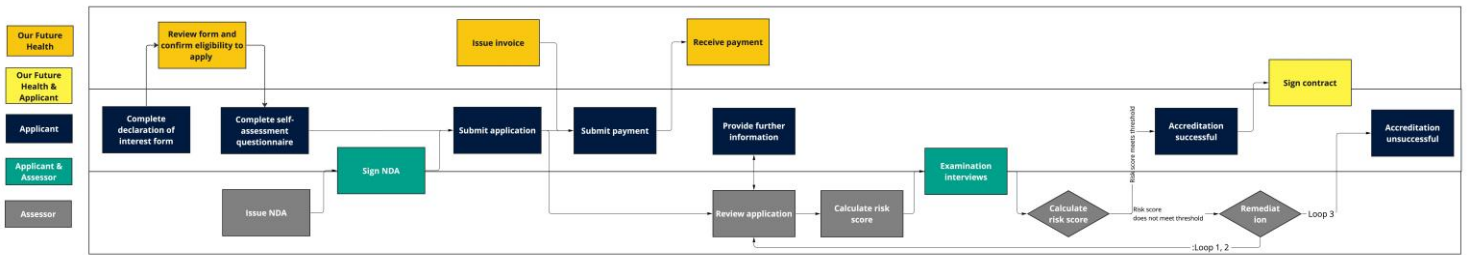
5.3 Data transfer

Once accreditation is granted, data may not be transferred to the accredited TRE until:

- Contract between successful applicant and Our Future Health is signed;
- secure transfer scheme agreed and tested, including any required security review;
- researcher has been registered; and
- study approved by via the Our Future Health access process.

5.4 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
- TRE accreditation change control standard operating procedure
- Account management of an accredited TRE standard operating procedure
- Invalidation of accreditation standard operating procedure