

Account management of an accredited TRE standard operating procedure

Version 1.3 September 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 appendix updated for brevity and clarity)	Emily Binning

1. Purpose

Once accreditation is granted, it is ongoing. It is recognised that elements of the systems and processes related to the accredited TRE will change or mature over time. The accreditation will be upheld via:

- i. The account management meeting described in this standard operating procedure;
- ii. The TRE accreditation change control procedure; and
- iii. Audit in specified circumstances.

2. Scope

This standard operating procedure describes the account management meeting, 1.i, and applies to all accredited TREs.

The change control process and audit process are out of scope of this document.

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 trusted research environment that has achieved accreditation via the Our Future Health accreditation process.

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.

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">Meeting administration
TRE Owner	<ul style="list-style-type: none">Completion of pre-meeting checklistCompletion of meeting actions

5. Procedure

5.1 Upon grant of accreditation, Our Future Health and accredited TRE Owner agree cadence for account management meetings (at a minimum every 12 months).

5.2 Our Future Health is responsible for scheduling meeting, setting agenda (see appendix), and providing accredited TRE Owner ample time for preparation and completion of pre-meeting checklist (see appendix).

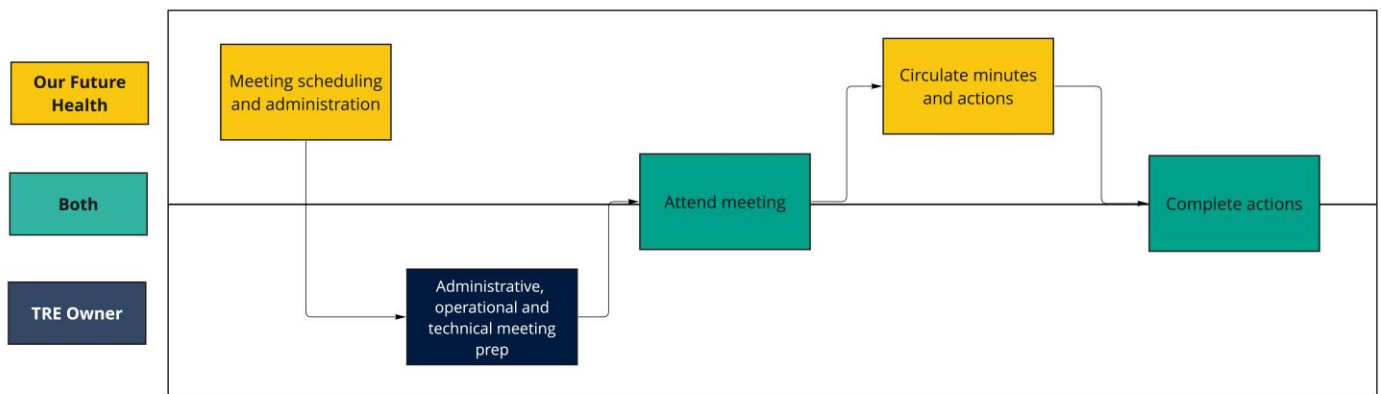
5.3 Pre-meeting, accredited TRE Owner completes required actions and submits relevant information to Our Future Health.

5.4 Our Future Health and accredited TRE Owner attend meeting.

5.5 Our Future Health circulates minutes and actions.

5.6 Accredited TRE Owner completes actions.

5.7 Procedure diagram



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
- TRE accreditation change control standard operating procedure
- Invalidation of accreditation standard operating procedure

Appendix – meeting agenda checklist

Our Future Health will use the below checklist to compile the agenda for each account management meeting.

	Item	Detail
1	Change control notices	Review of change control notices, actions and outcomes since the last account management meeting
2	Security events, issues, breaches	Review of the security events, issues and breaches related to Our Future Health data since the last account management meeting. For the avoidance of doubt, this is intended as a summary review and is not to be used in place of timely incident management.
3	Threat assessment	Review of an updated threat assessment, including commentary on threats since the last account management meeting.
4	Technical assurance	Penetration test or security assessment results review
5	Registered researchers and technical staff onboarding / offboarding	Review of the current lists of: <ul style="list-style-type: none"> • Registered researchers and technical staff with current access to the accredited TRE • Registered researchers and technical staff offboarded from the accredited TRE since the last account management meeting
6	Approved / ongoing studies	Review of studies using Our Future Health data currently ongoing within accredited TRE.
7	Data exports	Review of the data exports from the accredited TRE since the last account management meeting.
8	Data deletion	Review of the data deletion actions from the accredited TRE since the last account management meeting.
9	Our Future Health roadmap plans	Relevant updates on the Our Future Health roadmap, including for the Our Future Health TRE, TRE accreditation process, and related processes, plus feedback from the accredited TRE Owner.
10	Process assessment	Feedback on what is working and what is not working, e.g. communication, transparency, ways of working.
11	Accreditation fee	Accreditation maintenance fee.