

Data Export Principles for Accredited TREs

Version 1.0 November 2022

Document version history

Version number	Date	Significant changes from previous version	Author signature
1.0	November 2022	n/a	Emily Binning

1. Background and Context

1.1. In order to maintain obligations to Our Future Health participants, all export of data from any accredited TRE must be tightly controlled.

2. Scope of Principles

2.1. The data export principles apply to all accredited TREs.

2.1.1. Data export from the Our Future Health TRE will also be subject to the Our Future Health Airlock Policy.

2.2. The data export principles apply to Results data and Findings held within an accredited TRE.

2.3. The principles apply across the TRE, including to data downloaded from software packages, e.g. Jupyter, within the accredited TRE.

2.4. The data export principles apply to approved research studies. Data export principles for approved research studies with recontact will be addressed in a separate document.

3. Definitions

Core Cohort Data: all data collected by and under the possession or control of Our Future Health that is derived from Cohort Participants.

Disclosive Data: data that contains personal information of, or can be used to identify, a participant in the Our Future Health resource. This includes data which would become disclosive when combined with other data that is held or is likely to be held with it.

Findings: any Intellectual Property, Know-How or other information arising out of or in connection with any approved research study and/or approved research study with recontact that is not Results Data. Findings includes any data (excluding Results Data) created, generated or derived from any analysis of (i) the Results Data and/or (ii) the Core Cohort Data and/or Samples.

Individual-level Data: Raw or calculated data from the Resource that is on an individual basis (regardless of whether or not it is de-identified or anonymised) in any form (e.g. textual, tabular, graphical).

Non-disclosive Data: data that does not contain personal information of, and cannot be used to identify, a participant in Our Future Health, either due to its own content, or in combination with other data with which it is held or is likely to be held.

Results Data: any primary individual level data created from analysis of Core Cohort Data, Samples, samples collected by a Research Institution and/or data added to the Resource after the applicable Exclusivity Period, in each case for Cohort Participants as part of an Approved Study except any such primary individual level data generated during: (i) any interventional arm of a randomised control/clinical trial (provided that a Research Institution shall always have sole discretion to add such data to the Resource on a study by study basis and if it exercises such discretion, such data shall become Results Data when contributed to the Resource); and (ii) other excluded studies to be agreed with the Access Board.

4. Data Export Principles

- 4.1. All analyses of Core Cohort Data must be carried out within an accredited TRE.
- 4.2. Registered researchers are never allowed to remove data from an accredited TRE except in accordance with the data export principles.
- 4.3. Core Cohort Data may never be exported from an accredited TRE.
- 4.4. Any exported data must have been generated in line with the purposes agreed by the Access Board as part of an Approved Study.
- 4.5. Only non-disclosive Results data or Findings may be exported from an accredited TRE.
- 4.6. No disclosive Results data or Findings may be exported from an accredited TRE.
- 4.7. Any exported data must be in accordance with the Our Future Health Statistical Disclosure Control Principles.
- 4.8. Export of summary and/or aggregated data is highly preferable to export of individual-level data.
- 4.9. Data export must adhere to the UK GDPR.

- 4.9.1. Data to be exported should be as minimal as possible to fulfil the required purpose.
- 4.10. Data exported from an accredited TRE may never be used to reconstruct individual-level datasets external to the accredited TRE. In this event, Our Future Health reserves the right to terminate access to the Our Future Health data from the institution concerned, and all of its researchers.
- 4.11. Data exported from the accredited TRE must be made available for review by Our Future Health as necessary.
- 4.12. Any exported data that is to be published or presented (or for any other purpose covered by the Our Future Health Publication Policy), must be recorded in the Research Registry as a publication record and must be presented in accordance with the requirements of the Our Future Health Publication Policy.