

# Data Deletion, Back-up and Archiving Principles for Accredited TREs

## Version 1.1 December 2022

### Document version history

Version number	Date	Significant changes from previous version	Author signature
1.1	December 2022	4.4, 5.2, 5.3, 5.4	Emily Binning
1.0	November 2022	n/a	Emily Binning

### 1. Background and Context

- 1.1. Core Cohort Data will be made available to accredited TREs via periodic data releases.
- 1.2. Registered researchers will be able to access Core Cohort Data within accredited TREs for the purposes of carrying out Approved Studies.
- 1.3. New Approved Studies must use the latest data release.
- 1.4. Registered researchers may be given access to, and choose to update to, any subsequent data releases for the duration of their Approved Study.

### 2. Scope of the Principles

- 2.1. The data deletion, back-up and archiving principles apply to Core Cohort Data, Results Data and Findings held in accredited TREs.

### 3. Definitions

Archive: data no longer in active use kept for long-term retention purposes, such as compliance.

Backup: a duplicate or copy of current data. The duplicate is used to restore data in the case of a disaster, loss, damage, accident or malicious action.

Core Cohort Data: all data collected by and under the possession or control of Our Future Health that is derived from Cohort Participants including Baseline Data, Baseline Genetic Data, and Linked Data that is contained in the Resource. Core Cohort Data does not include Results Data.

Findings: any Intellectual Property, Know-How or other information arising out of or in connection with any Stage 1 Study and/or Stage 2 Study 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 using other data;

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), represented in textual or graphical form.

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.

TRE Owner: organisation accountable for a trusted research environment.

#### 4. Data Backup Principles

- 4.1. Our Future Health is responsible for keeping and making available a backup of all Core Cohort Data, including the storage and maintenance of all data releases, in line with applicable law.
- 4.2. TRE Owners (excluding Our Future Health) may never keep a backup of Core Cohort Data.
- 4.3. TRE Owners are responsible for keeping backups of Results Data and Findings, in line with applicable law, regulation, and relevant contracts.
- 4.4. TRE Owners must have a data backup policy for all TRE data including Results Data and Findings.

#### 5. Data Deletion Principles

- 5.1. All data held in accredited TREs must be deleted by TRE Owners in line with applicable law, regulation, and relevant contracts.
- 5.2. TRE Owners must have a data deletion policy for all TRE data including Results Data and Findings.
- 5.3. At the end of an Approved Study, Core Cohort Data must be made inaccessible to Registered Researchers of that Approved Study or deleted from the accredited TRE.
- 5.4. Upon termination of the Resource T&Cs, and/or invalidation of TRE accreditation, Core Cohort Data must be deleted from an accredited TRE.

- 5.5. Data sent to an accredited TRE in error from the Our Future Health primary data store, for example data which lacks access board approval or relevant data sharing agreements, must be deleted from the accredited TRE.
- 5.6. Data deletion processes must consider all instances of data including archives, backup copies in rotation to other storage media or services, and snapshots of data to ensure consistent data handling.

## 6. Data Archiving Principles

- 6.1. Our Future Health recognise the requirement for researchers to provide archived datasets to regulators.
- 6.2. Data archiving principles will be addressed in a separate document.