Data retention, storage, archiving and disposal guide for Research and Quality Assurance (QA) projects

A Data Management Plan (DMP) should be developed as part of the project and included in the research protocol or QA project plan. The DMP should addresses collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information, the risks associated with these activities and any strategies for minimising those risks. Further information on Data Management can be found at the section 3.1.43 of the National Statement on Ethical Conduct in Human Research 2023.

Data retention

Research/QA records and data should be securely retained for a specified period following **completion of a project or final publication, whichever is the later**. The **minimum** period for which records/data is maintained is determined by the type of research or QA activity conducted.

For:

- Short-term research projects for assessment purposes only (such as student projects) – 12 months.
- Quality Activity (QA) – 5 years.
- Case Study – 5 years.
- Clinical Research and Clinical Trials – 15 years.
- Genetic research or gene therapy – permanently.
- Data from research work which has heritage value – permanently, preferably within a national collection.
- Research data from participant under 18 years of age – for 15 years after the last participant turns 18.

The following considerations be noted when retaining data:

- Researchers should retain research/QA project data and primary materials (i.e. source documents) for sufficient time to allow reference to them by other researchers and interested parties. For published research/QA project data, this may be for as long as interest and discussion persist following publication.
- Research/QA project data should be made available for use by other researchers unless this is prevented by ethical, privacy or confidentiality matters.
- Research/QA data retention must be in accordance with the institutional policy and Health Sector (Clinical Records) Retention and Disposal Schedule.

If the results from research are challenged, all relevant data and materials must be retained until the matter is resolved. Research records that may be relevant to allegations of research misconduct must not be destroyed.

Storage and archiving of data

Researchers are to retain clear, accurate, secure and complete records of all research including research/QA project data and primary materials. Where possible and appropriate, allow access and reference to these by interested parties.

- Research/QA project data and primary materials must be kept in safe and secure storage during the project and for the appropriate time after completion. They must only be accessible by the project team.
- Paper-based research/QA project data and primary materials should be digitised, and originals archived.

- Electronic research/QA data should be stored on a password protected drive (such as Queensland Health OneDrive), backed up and accessible only to the project team.
    - All records relating to the research/QA project should be stored in the same drive.
    - Identifiable data and de-identified data must be kept in separate, password protected files.
    - Re-identification keys must be kept separately from data.
    - Research/QA project data **must not** be stored on personal computers or portable storage devices.
- A list of the contents of each archive box should be placed on the outside of the boxes (which should be numbered for easy identification). This list should be duplicated and stored separately where it is easily accessible if needed (e.g. QH network drive).
- For sponsored clinical trials, where data is to be stored for 15 years, the site investigator should liaise with the trial sponsor to discuss arrangements for the off-site storage of research records.

Data destruction

Research/QA project data and records must be disposed of in a confidential manner. Shredding is optional, and paper shredders are located throughout the hospital.

Where possible, de-identify all study materials and place in blue bins which are located within lockable areas of the hospital.

Additional information

- Chapter 3.1, Element 4: Collection, Use and Management of Data and Information in the National Statement on Ethical Conduct in Human Research 2023.
- Australian Code for the Responsible Conduct of Research 2018.
- Health Sector (Clinical Records) Retention and Disposal Schedule.
- NHMRC's Management of Data and Information in Research (2019).

For further information please contact the Research Ethics and Governance Unit on 07 4226 3007 or via email at CHHHS_Research_Business@health.qld.gov.au.