

Guidelines for Data Storage & Archiving



This document is designed to inform researchers of data storage and archiving requirements for research studies undertaken at Barwon Health. These guidelines provide a safeguard for all research data by ensuring adequate storage and disposal and should be followed to comply with good clinical practice and relevant Australian legislative codes.

DATA STORAGE

Who is responsible?

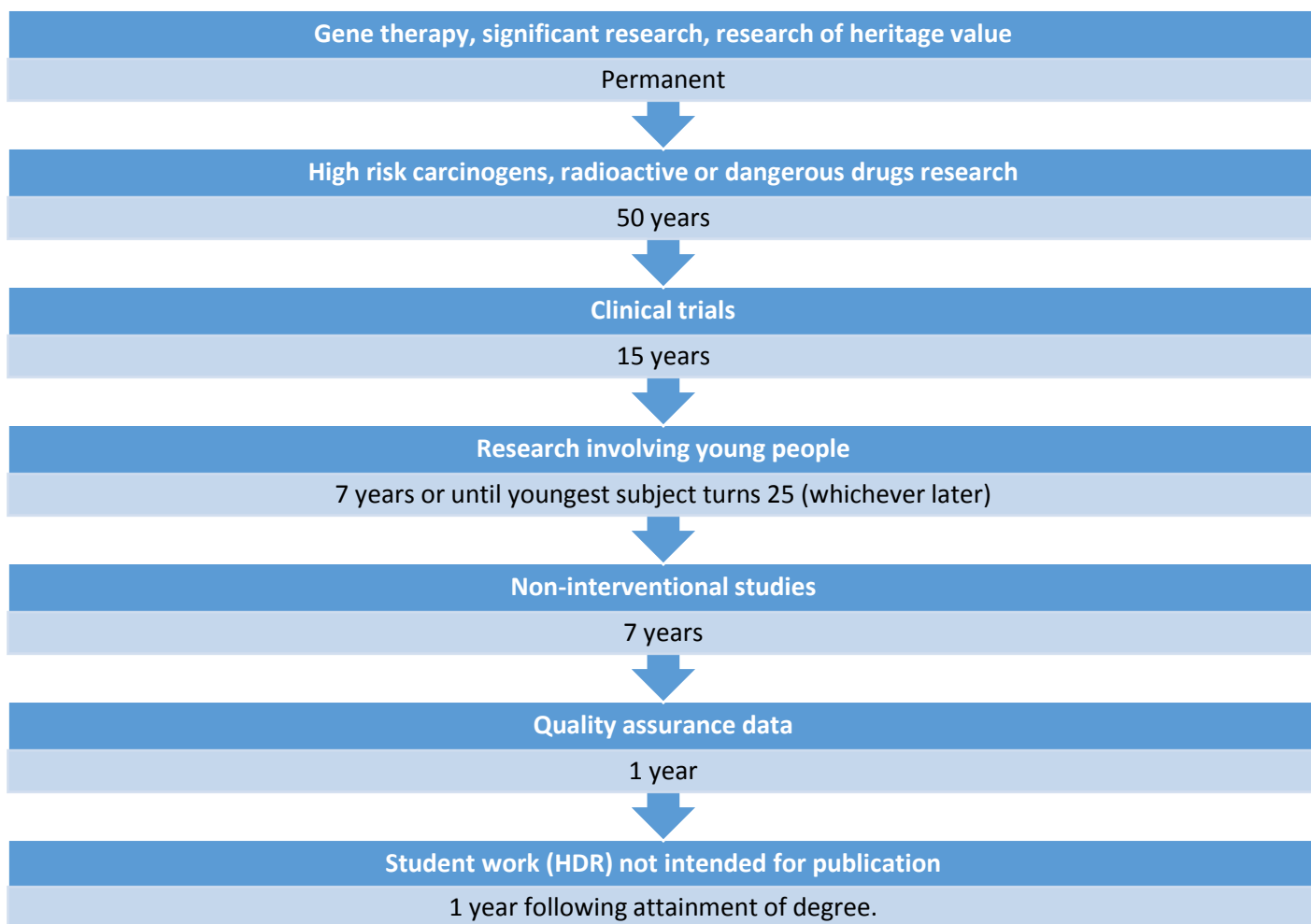
Heads of Department are responsible for providing or arranging data storage that meets security and confidentiality requirements. Researchers are responsible for ensuring this security and confidentiality is upheld in accordance with the principles outlined in the Australian Code, National Statement, and other relevant legislation and guidelines. Researchers should consider the future potential of their research data, taking into account the particular approaches, standards and uses for data that may exist in different institutions, disciplines and research projects.

How long should data be stored?

The minimum recommended period for retention of research data is 5 years from the date of publication. However, Barwon Health generally requires 7 years. The period for which data should be retained is dependent on what type of research is undertaken. Below are some classifications of research and their associated data storage policies.

- Interventional research (drugs, devices or medical interventions) is to be kept indefinitely.
 - Clinical trial data is required to be stored for a minimum of 15 years, or 10 years after the expiry of patent, if applicable.
 - Gene therapy and some medical records are to be stored permanently under the Public Records Act.
- Non-interventional studies i.e. social science research, standalone surveys/questionnaires, etc. are to be kept for 7 years after the date of publication. Unpublished research of this nature should be kept for 7 years post the final report.
- Research data involving young people (< 18 years) should be kept for a minimum of 7 years after date of publication or until the youngest subject turns 25 years of age, whichever is later.
- Research data created in the conduct of research projects that are not clinical trials, but the outcomes of which lead to a patent should be kept for a minimum of 7 years.
- Research data of community or heritage value should be kept permanently and preferably within a national collection.
- Research involving high risk carcinogens, radioactive or dangerous drugs should be kept for a minimum of 50 years.
- Quality assurance activity should be kept for 1 year from the completion of the project.
 - If project results are published, considered controversial or are the basis for a significant change in practice they should be kept for 5 years.
- Student work that is not higher degree by research and not intended for publication should be kept for at least 1 year after the degree is conferred.

Data retention timeframe hierarchy



Are there any exceptions?

Timeframes stated above are the minimal storage requirements. The length of data retention may vary depending upon local jurisdiction, type of research, governing documents and the requirements of funding agencies and commercial sponsors. It is best practice to consult the research ethics and governance office if you are unsure.

Data may need to be held for longer than the minimum periods in any of the following circumstances, and the storage period would re-commence from the date of the last action:

- If there is on-going interest in the data.
- If the research results have been challenged, the data is to be maintained until the matter is resolved.
- Where records are relevant to allegations of research misconduct, those records must be held until allegations have been resolved, including any appeals.
- Where records may be required for possible legal proceedings.
- Where the research would be difficult or impossible to repeat.

What if the owner of the data leaves Barwon Health?

Researchers who leave Barwon Health during the retention period of data for which they are responsible, may transfer a copy of data to a new secure storage location for their own use, unless otherwise specified by contract.

Original data and records are to remain at Barwon Health and any future use of such data in research would still require the approval of the original approving HREC.

How should data be stored?

Data and associated materials are to be kept in safe and secure storage as outlined by the Human Research Ethics Committee (HREC). Data should be accessible, indexed (able to be accessed if required) and retrievable (information contained within a record remains readable for the life of the record).

- Paper records must be stored in an appropriate filing system that is only accessible to authorised staff (e.g. filing cabinets that can be locked when not in use).
- Electronic data (hard drive, mainframe, portable device etc.) must be protected by a password.
- Audio-visual data (e.g. audiotape, audio-visual records, photographs etc.) must be stored in lockable storage facilities in the researchers work area or department in a lockable office.

Taking data off-site

Identifiable data should not be taken off-site. If a researcher wishes to move data from the premises it should be made re-identifiable or non-identifiable prior to leaving the premises. Re-identifiable data may leave the premises, however the key to the code must not leave the premises.

What needs to be kept?

- A research protocol stating a clear and accurate record of the research methods.
- Research data, including electronic data, in a durable, indexed and retrievable form.
- Data sources.
- Approvals (ethics, amendments, reports etc.).
- Signed consent forms.
- Evidence of authorship.

DATA DESTRUCTION

Who is responsible?

The destruction of research data must only be authorised by the Department Head. They should liaise with the coordinator of the department register and the databank custodian to establish that it is appropriate to destroy the documents.

Researchers must establish data ownership and destruction requirements, including methods, timelines and decision-making processes in the planning stage of the project. For example, strategies for individuals or groups to exit the project i.e. who is responsible for the disposal and/or storage of the data in this circumstance?).

Before destroying data and study materials, the reviewer of the data must confirm that the data is not:

- Of archival value and therefore needs to be retained permanently.
- In any way required for the functioning of Barwon Health.
- Currently undergoing legal or ethical review.

How to adequately dispose of data

When data is destroyed, this should be done so in such a way as to ensure complete destruction of the information, for example:

- Data stored in a paper format should be shredded.
- Data stored in an electronic form should be destroyed by rewriting or reformatting – ‘delete’ instructions are not sufficient to ensure that all system pointers to the data incorporated in the system software have also been removed.
- Audio-visual tapes should be destroyed by ‘magnetic field bulk erasers’.