RESPONSIBLE EXECUTIVE	Angela Watt
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IMPLEMENTATION STRATEGY	Email update to all employees and uploaded to the Office for Research website.
EVALUATION STRATEGY	Updated policy to be evaluated by Melbourne Health Office for Research Governance management team.
STANDARD/S (National, Aged Care, Disability Services)	NSQHS Clinical Governance Standard.
VERSION SUMMARY	These guidelines have been developed to set out the requirements for archiving, retention and disposal of research data at Melbourne Health (MH).

EXECUTIVE SUMMARY

1. MH recognises that research Data and associated Metadata, Primary Materials etc. as a valuable product of research that may be irreplaceable and should be appropriately managed.
2. Appropriate archiving and retention of research Data and Metadata should follow good Data management practices and support the audit trail.
3. Archived data and Metadata should always be accessible.
4. Research Data and Metadata should be retained for at least the minimum periods outlined in this guideline.
5. Research Data and Metadata should only be destroyed when appropriate, and in accordance with this guideline.

1. ASSOCIATED MELBOURNE HEALTH POLICY

MH Research Policy MH18.

2. PURPOSE AND SCOPE

To describe requirements for requirements archiving, retention and disposal of research data for research studies conducted at Melbourne Health (MH).

This guideline is applicable to all research data obtained or generated for research projects undertaken at MH, including investigator-initiated research, collaborative research and all phases of clinical investigation of medicinal products, devices and diagnostics.

3. DEFINITIONS

Data	Data is information obtained directly or indirectly for research purposes and information that may be used for research purposes. For example: • Information obtained directly from a person in interview, questionnaire, focus groups, personal and medical histories, demographics, biographies, audiotape, audiovisual records, photographs. • Clinical, social or observational information from a source other than the person whose information it is, such as from medical history notes, doctors' notes, surgical notes, carer or relative. • Information derived from human tissue such as blood, bone, muscle, organ and waste products, including genetic and radiological information. • Laboratory notes and records.

Metadata	Metadata is information that describes your Data or primary materials, and normally includes such details as the means of creation of the data, the purpose of the data, time and date of creation, the creator or author of data, the location of the data, etc. It assists in the discovery, use/re-use and management of the data, and in allowing correct attribution to the creators of the work. For example, recording a participant's pulse is the data (result) but the Metadata is that data that goes around the result that makes it worthwhile and includes the protocol, visit number, information on the instruments used, their settings, whether the participant was sitting or lying down, time of day etc. For laboratory research Metadata could include notes in laboratory notebooks, batches of chemicals used, facility temperatures etc. Refer to https://www.ands.org.au/guides/metaData-working for further information.
Primary Materials	Physical objects acquired through a process of scholarly investigation from which research data may be derived. It may include raw physical materials such as ore, soil samples or biological material, or physical or digital objects such as artefacts, questionnaires, sound recordings or video. Depending on discipline, primary materials may be considered research data, and may be required to be retained if they are required to validate the outcomes of research and defend those outcomes against challenge.

4. RESPONSIBILITIES

Heads of Departments (HOD) are responsible for:

- providing or arranging archival storage that meets the requirements of this guideline and any other appropriate requirement, where research Data is archived on site at MH.
- maintaining a department research database of studies and storage locations of archived Data, metadata etc. The database must identify minimum retention periods, identify contact persons and information to access/retrieve records when required.
- ensuring PIs list study archiving information on the departmental research database.

PIs are responsible for ensuring good stewardship of archived study Data.

All study team members are responsible for managing research Data and confidential information appropriately and in accordance with any applicable requirements including for the archiving, retention and disposal of data.

5. PROCEDURE/GUIDELINE/POLICY

5.1. INTRODUCTION

MH recognises that research Data and associated Metadata, Primary Materials etc. as a valuable product of research that may be irreplaceable and should be appropriately managed.

Data should be stored with Metadata. For the remainder of this section all references to Data include Metadata.

Appropriate archiving and retention of research Data should follow good data management practices and are essential in supporting Data integrity.

Archiving, retention and disposal requirements should be described in the study Data Management Plan (DMP).

The storage, retention and disposal of research Data should:

- be consistent with study approvals.

- be consistent with any copyright or licensing arrangements or any other study agreements that are in place.
- be in accord with research discipline-specific practices and standards.
- comply with relevant privacy, ethical and publication requirements.
- comply with other relevant laws, regulations and guidelines.

5.2. ARCHIVING

Archiving of study records should occur after the close out of a study.

The following are requirements for archival storage of research Data:

- the Data must not deteriorate.
- secure access to prevent from theft, accidental loss or destruction.
- controlled environmental conditions appropriate to the type of Data (i.e. paper, electronic, film, video, tape recordings) being stored i.e. temperature, moisture, light controlled.
- protection from floods or other environmental impacts that would cause loss of Data/information.

Research Data may be stored on-site at MH or externally in appropriate storage facilities.

Where research data will be stored at external locations, off-site the standard MH process and provider must be used.

HODs are responsible for providing or arranging archival storage that meets the above requirements where research Data is archived on site at MH.

HODs are also responsible for:

- maintaining a department research database of studies and storage locations of archived Data, metadata etc. The data base must identify minimum retention periods, identify contact persons and information to access/retrieve records when required.
- ensuring PIs list study archiving information on the departmental research database.

PIs are responsible for ensuring good stewardship of archived study and data. This includes ensuring that:

- a data custodian has been identified for the records to be archived.
- study records to be archived are complete.

  there is an index of the study data that is archived.
- study records are archived in an appropriate manner and location.
- information about the study is listed on their departments research database and includes all storage locations of Data, metadata etc., minimum retention periods, contact persons and information to access/retrieve records when required.

The DMP should describe the frequency and process for monitoring archived research Data.

The frequency and process for monitoring archived research Data should be determined with consideration to the type of data archived and the retention period.

Monitoring archived research Data is the responsibility of the Data custodian.

In instances where the Data custodian has left MH and a replacement has not been identified, the HODs will be the Data custodian.

5.3. RETENTION

At a minimum, research Data should be retained for the periods specified in the NHMRC Management of Data and Information in Research Guide to the Code (refer to the below table for further information) and any other requirements including agreements, archives and records legislation etc.

In general, the minimum period for retention of research Data is five (5) years from the date of publication.

However, for any particular case, the period for which the Data should be retained should be determined by the specific type of research, subject to any applicable state, territory or national legislation.

IMPORTANT NOTES:

a) funding bodies - may have specific requirements for retention of Data and records. Researchers should be aware of any conditions of any award or obligations of contracts supporting their research.

b) legal action - If a legal action is taken involving a research project, all Data and records must be kept until after all avenues of legal action have been exhausted.

c) community value - Consideration should be given to the long-term preservation of research Data and records of archival value. For example, projects that:

- made a major contribution to research;
- were controversial, challenged, subject to extensive debate or interest;
- involve the use of major new or innovative techniques; and/or
- involve a "first of a kind" process or product or significantly improved or changed procedures.

d) for clinical trial Data and information:

- For legal reasons, sites may consider indefinite archiving periods.
- The TGA position on document retention states: *"The TGA requires records to be retained by the sponsor for 15 years following the completion of a clinical trial. However, in Australia the overriding consideration for sponsors with respect to record retention is the issue of product liability and the potential need for sponsors of products to produce records at any time during, and possibly beyond, the life of a product in the event of a claim against the sponsor as a result of an adverse outcome associated with the use of the product"*

Type of Research	**Minimum Data retention period**	**Comments**
Short term research projects e.g. Quality Assurance and student research	1 year from the completion of project	Most activity should be kept for 1 year after completion of the project. However, if the project results are published, or the results are controversial or are the basis for a significant change in practice they should be kept for 5 years. There may be value in keeping some quality assurance project Data for more than one year and up to or longer than 5 years.
General research	5 years	
Clinical trials	15 years or more from the end of the trial	This is the minimum retention period. However, permanent archiving should be considered. Refer to TGA comments.

Gene therapy	Permanent record	e.g. patient records
Community or heritage value	Permanent record	preferably within a national collection. (Confidentiality issues would need to be addressed).

Table: Minimum archiving periods as set out in the NHMRC Management of Data and Information in Research Guide to the Code.

Note: specific studies may have other specific requirements that affect retention periods.

5.4. DISPOSAL OF DATA

The National Statement requires that Data, information and biospecimens used in research should be disposed of in a manner that is safe and secure, consistent with the consent obtained and any legal requirements and appropriate to the design of the research.

At MH research Data must be disposed of according to Melbourne Health Policy MH05 Documentation and Records Management, AND

- the destruction of research Data must only be authorised by the HOD and for sponsored studies, with confirmation from the sponsor.
- the HOD should liaise with the coordinator of the department register, the study PI or for Databanks, the Databank trustee, to establish that it is appropriate to destroy the documents as per this guideline.
- A record of approval for destruction must be recorded on the departmental research database.

When Data are destroyed this should be done so in such a way as to ensure complete destruction of the information:

- 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 systems pointers to the Data incorporated in the system software have also been removed. MH Information Technology department should be consulted regarding destruction of copies of backed up data.
- Audiovisual tapes should be destroyed by "magnetic field bulk eraser".

Note: at the time of destruction of Data, researchers should ensure that they employ the most effective method since this may change over time with technological advances.

6. ASSOCIATED POLICIES/PROCEDURES/GUIDELINES

- MH Research Policy MH18
- Intellectual Property Policy MH12
- Documentation and Records Management MH 05
- Privacy and Confidentiality of Patient Information MH03.08
- Data Management in Research Guideline
- Data Storage and Security Guideline
- Agreements, Ownership and Intellectual Property Guideline
- Archiving retention and disposal of data Guideline
- Databanks and Registries Guideline
- Guidelines for the Use of Human Tissue Samples in Research
- Research Publications and Authorship Guideline
- Guidelines for Managing Conflict of Interest in Research

- Guidelines for Handling Complaints in Research
- Investigating Breaches of the Code for the Responsible Conduct of Research Guideline

7. REFERENCES

- Australian Code for the Responsible Conduct of Research (2018)
- Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018)
- National Statement on Ethical Conduct in Human Research (2007updated 2018)
- Management of Data and Information in Research (2019)
- ICH Good Clinical Practice (GCP) - Integrated Addendum to ICH E6 (R1) Guideline for Good Clinical Practice E6 (R2) (formerly adopted by the TGA with annotations on 8 February 2018)
- International Conference on Harmonisation / Good Clinical Practice (ICH/GCP) Guidelines

8. FURTHER INFORMATION

Contact the Office of the Office for Research on 9342 8530 or email: research@mh.org.au

9. DOCUMENTATION

9.1. Associated forms and charts (including IP/OP numbers)

9.2.

10. REVISION AND APPROVAL HISTORY

Date	Version	Author and contributors
10 September 2019	1	Sarah Rickard, Manager Research Governance and Audit

<Template>

Archiving, Retention and Disposal Log
(Data and Metadata)

Study number	Enter study number (i.e. 2019.XXX)
Study title	Enter study title
MH Department	Enter department name
Principal Investigator	Enter name
Coordinator	Enter name
Data Custodian (if PI no longer at MH)	Enter name

Notes:

- complete this log as part of the data management plan
- information held in medical records is maintained and destroyed as per MH documentation policy separately to research requirements.
- Before destruction of any data:
  - confirm if it is appropriate to destroy some or all the data or if it has value in being maintained
  - check the minimum retention period has been met
  - check that the HOD (and sponsor for sponsored studies) has authorised the destruction of the data and this has been documented

Document	Location type	Location details	Document type	Minimum retention period		Do not destroy before	Disposal Method	Disposal completed
	Choose an item.		Choose an item.			Enter date.	Select method	Enter date.
	Choose an item.		Choose an item.			Enter date.	Select method	Enter date.
	Choose an item.		Choose an item.			Enter date.	Select method	Enter date.
	Choose an item.		Choose an item.			Enter date.	Select method	Enter date.