

## Research Data Management Plan Guideline

This document provides guidance for completing a project data management plan (DMP). This guidance document does not need to be submitted with your DMP. The level of detail required in each section of the form may vary depending on the nature and complexity of the research project.

Project	
Details	<i>The data manager for Mater is the person responsible for the data management of the project including set up, managing access and storage and organisation of the data.</i>
Data Details	
Type	Select each type of data required or created.
Source	<p><i>The source is the location where the data type originates from. Examples include</i></p> <ul style="list-style-type: none"> <li>• <i>Created for the project (e.g., from participants)</i></li> <li>• <i>Secondary use of data from biobank / databank</i></li> <li>• <i>Secondary use of data from Third Party (e.g., AIHW)</i></li> <li>• <i>Secondary use of data from Mater (e.g., health record, case mix)</i></li> </ul>
Identifiability	<p><i>Individually identifiable - Where the identity of a specific individual can reasonably be ascertained (e.g., name, image, telephone number, email, address).</i></p> <p><i>Re-identifiable data - Where identifiers have been removed and replaced by a code, but it remains possible to re-identify an individual by, for example, using the code or linking different data sets.</i></p> <p><i>Non-identifiable - Where data have either never been labelled with individual identifiers or where identifiers have been <u>permanently removed</u>, and by means of which no specific individual can be identified. A subset of non-identifiable data is that which can be linked to other data so it can be known that they relate to the same data subject, but the person's identity remains unknown.</i></p>
Form/s or format/s	<p>Examples include:</p> <ul style="list-style-type: none"> <li>• <i>REDCap (specify where the server is hosted)</i></li> <li>• <i>Excel, Word, PDF</i></li> <li>• <i>FileMaker database</i></li> <li>• <i>DICOM</i></li> <li>• <i>mp3 (audio file)</i></li> <li>• <i>Videos or audiotapes</i></li> <li>• <i>gif or jpeg</i></li> <li>• <i>Paper</i></li> </ul>

Location	<p>For digital data, document the file path/s. If digital data are stored on the Mater network, include the drive/s and location/s e.g. R drive, Mater OneDrive, Mater SharePoint.</p> <p>For hardcopy data, document the physical location. E.g. stored in locked filing cabinet secured within PI office (detail physical locations and security arrangements)</p> <p><b>Note 1</b> - Master code sheet/key for decoding re-identifiable data must be stored separately to the coded data (e.g., in a separate excel workbook, in a separate REDCap project)</p> <p><b>Note 2</b> - Portable devices (e.g. portable hard drives, USB's) are not permitted for storage of any research data as this contravenes ICH GCP.</p>
Access	<i>List who will have access to the data, listing project roles rather than individual names.</i>
<b>Data Sharing</b>	
Type	For each data type you intend to share, list the data type (see previous table), how you intend to share it, and where the data will end up.
Identifiability	<p><i>This is the identifiability of the data that is shared. Data shared with external parties must be de-identified. Any exceptions to this must be approved by Mater Privacy Office through the SSA review.</i></p> <p>Refer to "Examples of research data by identifiability", below.</p>
Method	<i>This includes the use of REDCap databases (or other electronic data capture (EDC) systems) hosted by external parties.</i>
End location	<i>Institution and storage location (if relevant) where the data type is being shared to.</i>
<b>Data Restrictions</b>	
Details	<p>Consider restrictions on access or storage due to commercialisation.</p> <p>Consider restrictions by funding bodies on copyright of Intellectual property (consult Mater Research Agreements for advice).</p> <p>Consider restrictions regarding re-use of third party and existing datasets (e.g., data obtained from AIHW). If relating to third party data, consider where the data is from, what consent was obtained for its collection.</p>
<b>Data organisation</b>	
Details	<p>Consider how the data are going to be organised in each storage location. In cases where only one storage location or dataset exists, this should be clearly indicated.</p> <p>Consistent naming conventions should be used to label documents so they can be located, identified and retrieved as quickly and easily as possible.</p> <p>Backups should be stored in a separate location to research data.</p> <p>Consider where, by whom and how often data will be backed up.</p>
<b>Data Quality Assurance</b>	
Details	Document all data quality assurance activities that are used for the project. Consider where, by whom and how often each activity will be performed.

<b>Data Retention</b>	
Duration	<ul style="list-style-type: none"> <li>• Adults - Minimum 15 years for clinical trials</li> <li>• Adults - Minimum 5 years from publication for non-clinical trials</li> <li>• Minors - Minimum until participant turns 18 plus 15 years from completion of study</li> <li>• Research involving gene therapy - permanent</li> <li>• Other (provide details)</li> </ul> <p>Additional considerations:</p> <ul style="list-style-type: none"> <li>• Data retention for future use</li> <li>• Indigenous data sovereignty</li> <li>• Work with community, cultural or historical value may mean research data should be kept permanently, preferably within a national collection.</li> </ul>
<b>Details</b>	
Details	<p>Physical data should be labelled with data retention period and Mater PI/contact prior to long term storage.</p> <p>Data retention costs should be included in study budget.</p>
<b>Data Disposal</b>	
Person/position responsible	Who is responsible for the disposal of data and how is this documented
Details	Consider all research data and relevant disposal methods. These may include secure shredding of physical data or deletion of digital data.

## References

National Statement on Ethical Conduct in Human Research, National Health & Medical Research Council (NHMRC), 2023.

Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2), Annotated with comments from the Therapeutic Goods Administration - Current Step 4 version dated 9 November 2016

## Related Mater policies and procedures

Health and Corporate Record Retention and Disposal Schedule - MPPL-04832

Management and Ownership of Research Data and Information – MPPL-07130

Research Data Collection, Entry, Storage, Movement and Destruction – MPPL-07058