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**PRIMARY AUTHOR**      Sarah Rickard

**IMPLEMENTATION STRATEGY**      Email update to all employees and uploaded to the Melbourne Health 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**      The Data Management in Research Guideline replaces the Guideline for Data Management in Research 2015 and has been developed to clearly set out the roles and responsibilities of Melbourne Health (MH) and persons conducting research at MH. Updated and new information is provided in the context of appropriate Data management throughout the entire Data lifecycle including generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of Data.

These guidelines have been written in accordance with the *Australian Code for the Responsible Conduct of Research (2018)* and guide for Management of Data and Information in Research (2019).

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**EXECUTIVE SUMMARY**

1. MH recognises that Data are a valuable product of research that should be appropriately managed to allow appropriate analysis, verification and where applicable future use.
2. Good Data management practices should be followed, and data should be curated throughout the entire Data lifecycle from conception of a study to archiving and destruction of Data.
3. A Data Management Plan (DMP) should be developed for all MH research studies to outline what research Data will be used and created during the course of a research project.
4. Elements of a DMP should address Data issues throughout all stages of the Data lifecycle including a Source Data Identification Log (SDIL), ownership and intellectual property , agreements, ethical and governance approvals, consent, documentation of participation, use of Data, Data storage , Data security, access during the active phase of the study, removal or movement of Data from MH, creation of databanks/registries and access to Data from databanks/registries, archiving and retention periods, Data sharing and access plan (DSAP) for published data, destruction of Data and Data breaches.
5. Agreements should be established for any project that involves two or more organisations (i.e. collaborations, eternally funded research, where study procedures are conducted by external parties etc.).
6. MH and all study team members should be aware of and abide by the conditions of study agreements.
7. MH owns its data and any transfer of data to third parties (including researchers who leave the organisation and request to take a copy of Data) should only occur after an appropriate agreement has been executed between the parties.

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**1.   ASSOCIATED MELBOURNE HEALTH POLICY**

MH Research Policy MH 18

Documentation and Records Management MH 05

MH Intellectual Property Policy MH12

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## 2. PURPOSE AND SCOPE

The purpose of this document is to provide guidance on appropriate generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of Data at Melbourne Health (MH).

These guidelines apply to, but are not limited to:

- All individuals paid by, under the control of, or affiliated with MH, such as scientists, trainees, technicians, other staff members, students, fellows, guest researchers, or collaborators who are engaged in research at MH

- Data collected and/or used/ and/or disclosed for all research or quality assurance (QA) purposes;

- Data entered into a Database or registry that may be used in the future for research or QA purposes;

- Data collected by doctors, nurses and allied health staff and other health professionals as notes from patients of MH maintained outside of MH patient records or organisational computer systems e.g. Homer and CIS, which will be the source of information for research studies or quality assurance projects.

## 3. DEFINITIONS

Refer to Appendix A for the list of definitions.

## 4. RESPONSIBILITIES

### 4.1 Melbourne Health

MH supports and promotes good research practice through the provision of policy and procedures, infrastructure systems (e.g. Office for Research (research review, approval, management and governance), Information Technology (IT), Health information Services (HIS)), legal services and business development support.

Melbourne Health's procedures include requirements for:

- Justification and verification of the outcomes of research (via research application and reporting)

- Ownership, stewardship and control of research Data;

- Storage, retention and disposal of research Data;

- Safety, security and confidentiality of research Data;

- Considering potential for future use of research Data and conditions under which access by interested parties is permitted via Data Management and Data Access plans;

- Minimise waste of resources of value to researchers and the wider community.

### 4.2 Heads of Departments

Heads of Departments are required to:

- Promote research integrity including through good documentation practices for research Data and MH policy, guidelines and procedures;

- Ensure access to suitable physical and electronic storage for research Data that meets security and confidentiality requirements;

- Facilitate processes within the department and organisation for storage and retention of research Data;

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- Heads of Departments are responsible for ensuring that Databanks within their department are kept according to these guidelines;

- Authorise destruction of research Data on recommendation of the Principal Investigator;

- Ensure that researchers have planned for the ongoing custodial responsibilities for the Research Data and Primary Materials, if they leave the organization;

- Evaluate authorization for researchers who leave the organization take a copy of non-identifiable or coded research Data and/and or Primary Materials for further use in accordance with this guideline and other MH requirements such as consents, project agreements, legal requirements, Intellectual Property (IP) considerations and privacy requirements;

- Ensure that Research Data and Primary Materials are transferred from departmental storage locations to a longer-term archiving facility according to MH policy, this guideline and any other applicable requirement; and

- Ensure that destruction of and Research Data and Primary Material occurs only after minimum retention periods have been completed, that further retention for a special reason is not required.

**4.3    Principal Investigators and members of study teams**

All persons conducting research at MH or with MH Data are responsible for conducting research with integrity and in accordance with the Code and other applicable requirements relation to all aspects of research including Data integrity as all stages of the Data lifecycle.

In accordance with the Code, researchers should adhere to their institution's policies related to management of Data and information, relevant laws, regulations and guidelines, and research discipline-specific practices and standards.

Principal Investigators are required to:

- Complete a Data Management Plan, a Source Data Identification, a Data Access Plan and a Data Monitoring Plan for each study the manage;

- Ensure there is a written agreement is where the project involves at least one external partner and that the agreement includes clauses for storage and ownership of research Data;

- Maintain adequate, clear and accurate records of study methods, source Data/documents (including for clinical trials, all pertinent observations on each of the site's trial participants) and study records including any approvals granted, during and after conduct of the study that;

- Manage Research Data and Primary Materials according to ethical approvals, legislative, organisational and any other applicable requirements;

- Ensure that appropriate Research Data and Primary Materials are maintained to ensure accurate reporting and justify research outcomes, and to defend the findings of the research if challenged;

- Ensure the accuracy, completeness, legibility, and timeliness of the Data in project documents and in all required reports;

- Ensuring that source documentation meets applicable GCP requirements including; be attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring and available when needed. This requirement applies for all study documentation. For definitions of the terms refer to SOP 7 CRFs, Source Documents, Record Keeping and Archiving;

- Ensure that Research Data and Primary Materials are maintained in a safe and secure environment, and that Research Data is stored in a retrievable manner;

- Ensure backup, archival and monitoring activities are in place to prevent loss on Research Data;

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- Plan for ongoing custodial responsibilities for the Research Data and Primary Materials at the conclusion of the project or on departure from the organization;

- Maintain confidentiality of Research Data and Primary Materials when given access to confidential information;

- Ensure that all members of the study team, including students and third parties were applicable, are aware of their responsibilities in relation to the management of Research Data and Primary Materials; and

- Supervise staff, students or and third parties were applicable, delegated tasks on research studies or quality assurance projects.

## 5. PROCEDURE/GUIDELINE/POLICY

### 5.1 INTRODUCTION

MH recognises that Data are a valuable product of research that should be appropriately managed to allow appropriate analysis, verification and where applicable future use.

Good Data management practices should be followed during the conduct of research studies and are essential to:

- Support Data integrity and ensure protection against loss. As well as being inefficient to recollect the same type of Data in future, it may also be impossible.
- Protecting participant and community safety.
- Optimise research outcomes.
- All stages of the Data lifecycle for the study.
- Ensure compliance with all applicable requirements including ethical standards that protect the rights, dignity, health, safety and privacy of research participants and wider community.
- Facilitate appropriate and efficient access, identification, and retrieval of documents during the study or archive period for monitoring, verification, reporting, future use if applicable, or if challenged, to justify, and defend the outcomes of the research.
- Ensure that researchers meet any obligations related to Data retention and reuse by protecting against Data loss.

Good Data management is important to ensure Data integrity throughout the entire Data lifecycle including:

- Identification of relevant Data to be collected for a study;
- Data collection;
- Disclosure of Data to collaborators;
- Data storage, including Databanks and registries;
- Use/reuse of Data (including disclosure to external parties after publication etc.); and
- Destruction of Data.

Research staff should plan Data management requirements and processes for each study as soon as the study planning activities begin i.e. with the start of protocol development or on approach by a sponsor for a feasibility review.

Data management should protect the rights, safety, and well-being of the research participants and the wider community and be in accordance with this guideline and other MH requirements (including legal and intellectual property requirements), ethical standards, funding bodies' requirements, as well as any relevant legislation, codes or guidelines.

> **IMPORTANT NOTE:**
>
> ICH GCP principle 2.10 indicates that all clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification. This principle applies to all records, irrespective of the type of media used.
>
> *MH applies this principle to data in ALL research studies, not just clinical trials*

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### 5.2 DATA MANAGEMENT PLAN

A Data management plan (DMP) should be developed for all MH research studies.

A DMP typically outlines what research Data will be used and created during the course of a research project including how it will be created, used, plans for sharing and preserving the Data and any restrictions that may need to be applied.

Principal Investigators are responsible for developing, implementing, managing and documenting a DMP for each study that they manage.

The DMP should be completed at the planning stage of the project. However, for active projects that do not have one, a DMP can be completed at any stage during the study.

To ensure the information remains current, the DMP should be reviewed annually and after any change that may affects the management of the study Data.

Elements of a DMP should address Data issues throughout all stages of the Data life cycle including:

- Source Data Identification Log
- Ownership and Intellectual Property
- Agreements
- Ethical and Governance Approvals
- Consent process and information
- Documentation of Participation
- Description of what information from the DMP, if any, should be communicated to participants
- Use of Data
- Data Storage - physical, network
- Data Security - system security and any other technological security measures
- Access during the active phase of the study, removal or movement of Data
- Creation of Databanks/registries and access to Data from Databanks/registries
- Archiving and retention periods
- Data access plan (post study access)
- Destruction of Data
- Data Breach

> TIP:
>
> Preparing a DMP at the planning stage of a study can be useful in identifying issues or area of concern for the management of Data for a study i.e. Data types, storage requirements, ownership of Data/Intellectual Property created in collaborative research, identifying under what circumstances it is appropriate for Data to be shared with external parties, what restrictions/conditions apply to use/sharing of Data, defining responsibilities of parties etc.

Information regarding the above elements of Data management are provided in this guideline and supporting documents.

*DMP FORM:*

A template form and instructions on completing a DMP are outlined in OFR SOP Data Management Plan.

Note: The detail in the DMP will be dependent on the complexity of the Data management requirements for the study. Researchers can tailor the DMP to the study by adding required elements. Existing elements should not be deleted but noted as not applicable if they are not involved in the study.

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### 5.3 SOURCE DATA IDENTIFICATION LOG

Source Document Identification Log (SDIL) is an index that identifies the various source documents for a study. It also indicates where the source document will be located at the site and the person responsible for the document.

The PI should establish a SDIL for the study.

Completion of the SDIL at the protocol development stage of the study will aid researchers to identify process that maintain Data integrity for individual Data types.

The detail in the SDIL will be dependent on the complexity of the Data to be collected/accessed and stored for the study.

The log should identify:

- Each document in which any source Data is recorded (i.e. progress notes/medical record, CRF, DCF, X-ray, photographs, electronic Data capture systems etc.);
- The name of these source documents;
- Document storage locations;
- The title of the person responsible for access/management for each type of source document used in the study.

> **IMPORTANT NOTE:**
>
> A SDIL should be completed for all research studies where Data/documents are created or stored at MH.
>
> The SDIL should be tailored to each study.

The study SDIL should be reviewed annually to ensure maintain its currency.

FORM:

The Office for Research has developed a template SDIL. A template form and instructions on completing a SDIL are outlined in MH GCP SOP 7 CRFs Source Documents Record Keeping and Archiving.

### 5.4 OWNERSHIP AND INTELLECTUAL PROPERTY

MH12 Intellectual Property Policy outlines the ownership of IP created at MH and by MH employees.

Subject to any written agreements, MH will remain the custodian of study research Data, Meta Data, Research Results, Primary Materials and Intellectual Property.

Contact the Office for Research for advice specific to a study.

Refer to the following documents for information and requirements:

- Intellectual Property Policy MH12

- Agreements, Ownership and Intellectual Property Guideline

### 5.5 AGREEMENTS

MH Research Policy MH18 requires that when a research study involves more than one organisation, an agreement between the organisations be executed before the study is started.

Study agreements should cover all pertinent aspects of the management and conduct of the study including each organisations' role and responsibilities, funding, management, investigational products, warranties, insurance and indemnity, ownership of Data and research results, reporting and publication etc. as appropriate to the study to be undertaken.

The PI is responsible for ensuring that MH's obligations regarding research agreements are met.

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Contact the Office for Research or refer the website for advice or further information including; confirmation that the study requires an agreement, agreement temples, content and signing according to appropriate MH delegations.

Refer to the MH Agreements, Ownership and Intellectual Property Guideline for information and requirements.

## 5.6 USE STUDY DATA IN ACCORDANCE WITH ETHICAL AND GOVERNANCE APPROVALS

Information provided in the study ethics and governance applications should outline details on study Data management including the consent, confidentiality, identification (identifiable, coded, non-identifiable), collection, use or disclosure of Data.

Ethical and governance approvals should be obtained before starting any research study or quality assurance study that requires ethical review.

Data should be used in accordance with the ethics and governance approvals.

Where participants are provided a choice/s for use of Data via the participant informed consent form, researchers should implement a means of tracking the choices (i.e. consent database) so that Data is used in accordance with the individual participant's permission.

Refer to the Office for Research website for details on the submission process for ethics, governance and quality assurance applications at https://www.thermh.org.au/research .

## 5.7 PARTICIPANT CONSENT IN RELATION TO DATA COLLECTION, USE AND RELEASE

In most cases where Data are to be collected, used, stored or disclosed for the purposes of research, consent for the use of the Data, either written, verbal or implied (as appropriate), **is required**. That is: that consent is obtained where it is inappropriate to use the information without consent.

There are two areas relating to consent Data:

- Information that records consent was obtained in accordance with the ethical approval.

- Ensuring Data activities are in accordance with the ethical approval and the consent obtained.

**Participant Consent**

Participant consent:

- Should be conducted in accordance with the ethically approved process, consent form and other consent documentation.

- Should be documented in a manor appropriate to the method of consent obtained.

- Documentation should include details of what the participant has consented to i.e. collection of Data/tissues, Data labelling (identified, coded etc.), sharing of Data with other researchers/organisations, participation in sub-studies, consent to future contact, consent to future research etc.,

> TIP:
>
> A consent data base will facilitate tracking of and use of data in compliance with the participant consent.
>
> Research teams should construct a consent database on REDCap, a database platform that is hosted on MH

- Should be actively managed – the management system i.e. Database, should be able to identify a participant's terms of consent and allow for changes to consent i.e. amended PICF options, withdrawal from some or all of the study so that the Data can be appropriately used/stored/shared etc. during all phases of the Data life cycle.

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- Where a participant consents to Data sharing, researchers should abide by the conditions of consent when sharing Data and to provide the conditions/restrictions of consent to the third party/ies with whom they share the Data so that part can abide by the participants conditions of consent.

- If the participant consents to future use of their Data, researchers should abide by the conditions of consent when using the Data in future studies. If the future use will include sharing of Data with a third party, the researchers should provide the conditions/restrictions of consent to party with whom they share the Data.

### 5.4.1 Maintain Privacy of Study documentation

Study Data and documents should be maintained in a manner that maintains participant privacy during all phases of the Data/documentation life cycle.

Note: Consent forms (and copies of), by their nature, contain identifiable Data and should be treated as identifiable source Data.

### 5.4.2 Consent for Future Use

Generally, information should only be used in ways agreed to by those who have provided the information. Therefore, consideration should be given to the potential to reuse the study Data in future research, either related or all future research during development of the study protocol and appropriate wording/ consent options included in the approved PICF to ensure that consent is obtained in such a way that will allow the use of the Data in the future.

Create a consent database to track conditions of participant study consent and include information on whether the participants have consented to future use of their Data.

Note: when considering approval of a project using Data already collected or in a Databank/registry, the HREC will review the application in view of the type/limitation of consent that was provided for the use of the Data.

### 5.4.3 Documenting Participation in Research at MH

Participation in research studies is documentation in a variety of different documents, locations and systems throughout the organization including researcher held records, organization management systems and medical records. Researchers should identify and document the storage locations of the source Data collected/documented for research study.

- **Consent form –** according to the ethical approval.

- **Registration of Participants at MH -** All people that are participating in clinical research being conducted at MH should be registered as MH patients and be assigned a MH patient number.

- **Completion of Medical Records -** The MH Research Policy MH18 and Documentation and Records Management MH 05 require documentation of consent and other study visits entry of information about patient research participation into the medical record.

- **Completion of the Research Tab on iPM -** For instructions on how to enter research participation on to iPM go to the Office for Research website at https://www.thermh.org.au/research/researchers/governance/post-approval-study-management/recording-research-participation.

  Exclusions apply to certain studies – refer to MH GCP SOP 7 CRFs Source Documents Record Keeping and Archiving for details.

- **Research Records -** Documents that are not stored in the participant's medical record such as the original PICF, patient diaries and completed case report forms should be stored in the study files.

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### 5.4.4 Communicating information from the Data Management Plan (DMP) to study participants

Where information may affect a person's decision to participate in a study, the information should be communicated to the person.

Information relating to the identifiability of a participant's data, movement of data off site, sharing, publishing, archiving or any other relevant element of the data plan etc. should be communicated to persons considering participating in the study.

Information provided should include details such as:

- Description of the event i.e. sharing with external parties, storage off-site

- Description of the information involved

- Whether the information can identify participants

- Format of information

- Security measures


## 5.8 LABELING RESEARCH DATA

Labelling of Data should be considered and be appropriate to each phase of the research study.

Data may be labelled as identifiable, re-identifiable or non-identifiable depending on the requirements of the study protocol and ethical approval obtained.

In determining the appropriate method for labelling Data, the PI and research team should ensure that:

- Researchers given access to confidential information should maintain confidentiality.

- The protocol describes a plan for the protection of participants' privacy.

- The research team has SOP(s) to describe the identification and protection of participant Data and privacy.

Refer to the MH Data Storage and Security Guideline for further information and requirements.


## 5.9 DATA STORAGE AND SECURITY

All study team members are responsible for maintaining Data in a secure manner and allowing only appropriate, approved access to the study Data.

During the active phase of the research study Data should be stored safely, securely and in a manner that maintains confidentiality, in accordance with the terms and conditions of research agreements.

All members of the research team are responsible for ensuring appropriate security for confidential information.

The MH server should be the Primary site of electronic Data Storage.

Refer to the MH Data Storage and Security Guideline for further information on Data storage and security including for:

- Paper Data
- Audiotape, audio-visual records and photographs
- Electronic Data
- The REDCap Database
- Portable storage devices
- Naming Electronic Files

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## 5.10 DATABANKS AND REGISTRIES

Data in MH Databanks and registries, like all research Data, should be collected, stored, used, accessed, secured etc., in compliance with this Guideline for Data Management in Research, other MH policy and procedure as well as any other applicable guideline, legislation guideline or requirement.

Researchers who establish databanks and registries should develop terms and conditions describing for the submission and access of Data in the Databank/registry.

Researchers who submit Data to external databanks/registries should ensure that doing so does not breach MH responsibilities including but not limited to Data management, Data integrity, privacy, ownership or IP implications.

Refer to the Databanks and Registries Guideline for further details specific to databanks and registries.

## 5.11 MONITIRING OF DATA AND DATA MONITORING PLANS

Research Data should be monitored to verify study conduct was in accordance to approvals and relevant requirements and that the Data was collected, stored and used in a manner that maintains participant safety and Data integrity.

Research Data should be recorded in a form that is adequate for verification of research results.

The PI should develop a monitoring plan tailored to the specific to the research study.

Principal Investigators should allow monitoring and audit of research Data and records.

For further information, refer to SOP Data Management Plan for further information and monitoring plan templates.

Note: Data monitoring can be undertaken as part of overall study monitoring activities.

## 5.12 PUBLICATION

R23 of The Code requires researchers to disseminate research findings responsibly, accurately and broadly. Where necessary, take-action to correct the record in a timely manner.

Publication of research results should be in accordance with the MH Research Publication and Authorship Guideline and any other applicable requirements.

## 5.13 REPLACEMENT OF STUDY PERSONNEL

If a team member leaves the study, handover to and training of replacement personnel in all aspects of the study including Data procedures and integrity should be managed and documented.

If the replacement study personnel *is* a current study team member, update the signature and delegation log.

If the replacement study personnel *is not* a current study team member, submit an amendment to the governance application formalise the new team member, train the new personnel as required and update the signature and delegation log.

For a replacement PI:

- Prior to leaving the study, the study PI should identify a MH researcher to continue as, and accept the responsibility of, the study PI.

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For a replacement Databank Trustee:

- In cases where the person leaving MH is the Databank Trustee who is not the study PI, the PI should identify a new Databank Trustee and supervise training and other requirements as appropriate. Document handed over of all study documents, Data including storage locations and passwords (if required), information and related tasks.

Note, researchers should not remove any study Materials (i.e. Data or associated Metadata, Primary Materials etc.) from MH without approval and appropriate agreements in place prior to cover movement of Data. This includes when researchers leave the organisation. Refer to 5.14 for information on the process for researchers to study Materials request to take study Materials

### 5.14 TRANSFER, REMOVAL OR DULICATION OF STUDY DATA OR OTHER MATERIALS

Researchers should not transfer, remove or duplicate and transfer any study Materials (i.e. Data or associated Metadata, Primary Materials etc.) from MH without prior approval and execution of appropriate agreements that include movement of study Materials. This includes when researchers leave the organisation.

Movement of study Materials should be in accordance with ethical and research governance approvals, agreements and any other requirements applicable to the study Materials.

All original clinical study Data (trial or other clinical research) generated at MH SHOULD be stored at MH and SHOULD NOT leave MH premises except for the purpose of secure archiving or in accordance with the approved study protocol and agreements.

Copies of identifiable  Data  should never leave MH premises unless approved under the ethical and research governance and the transfer also complies with any relevant agreements or other requirement applicable to the study/Data.

Secure electronic Data transfer – Data transfer should be undertaken in a manner that protects the Data security and integrity:

- Use of password protected portable devices or encrypted

- Determine if the Data needs to be encrypted (i.e. is the data identifiable of non-identifiable).

Where coded Data is transferred from MH, the key to coded Data must not leave the MH premises.

**Where a researcher leaves MH and requests to take a copy of research Data:**

In the event of a researcher or Databank Trustee leaving MH, they may request and be permitted to maintain a copy of the research Data for further use.

Requests will be considered on a case by case basis.

Requests will be reviewed consideration of conditions of MH study governance including ethical approval and participant consent, privacy requirements, potential uses of the data, ownership of body of work already existing, existing agreements for the study/Materials and if the release of the Materials will be for work that will be in conflict with MH requirements, an existing project, collaboration or future studies.

Only copies of non-identifiable or re-identifiable (coded Data but not the key to the code) research Data and records may be requested.

Original Data and records (including the key to the code) are the property of MH and SHOULD not be removed from MH.

Subject to ethical, governance, legal, statutory, privacy, intellectual property, and funding body requirements, MH will not withhold permission for any reasonable request from researchers to obtain a copy of the research Material for future use.

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In instances where MH agrees to the request then an appropriate agreement should be in place between MH and the researcher's new organization BEFORE any Material is transferred. The agreement should recognize the prior work, ownership and existing agreements for the study.

FORM – researchers wishing to request a copy of study data from MH should complete a Researcher request for copies of study Materials when leaving Melbourne Health form and submit it together with supporting information to the MH Office for Research. The form covers requests for data and/or samples. The Office for Research will coordinate the review of the request. for review. Refer to the form for further details.

NOTE: Any future use of the data will require ethical approval by a HREC.

## 5.15 USE/REUSE OF HEALTH CARE DATA

The principles outlined in the following regulations and guidelines allow for, and encourage, use of information obtained for the provision of health care for research and quality assurance activities to improve knowledge of diseases, develop treatments or potential cures and to assess and improve practice:

- The Health Records Act 2001,

- Health Privacy Principles,

- *National Statement on Ethical Conduct in Human Research (2018),*

- *The Australian Code for the Responsible Conduct of Research (2018)*, and

Researchers should, where possible and appropriate, allow access and reference to Data by interested parties. For this to be possible, research staff in consultation with MH should manage research Data by addressing ownership, storage and retention, and access, during and after the active phase of the research study. These processes should be documented.

## 5.16 ACCESS TO, and USE OF, RESEARCH DATA BY EXTERNAL PERSONS

Principle R8 of the Code requires that institutions, where possible and appropriate, allow access and reference research Data, records and Primary Materials.

This means that access to, use and disclosure of Data should not be permitted unless all appropriate requirements have been met including ethics and governance approvals, participant consent, agreements and/or other applicable requirements.

For registries and data banks, follow the standard approved access plan.

For other research studies the data management plan, where developed, should be followed.

Where the sharing of research data has been requested and access has been refused, researcher should provide to the person who requested the data, the reasons for not sharing the data. These should be transparent and justifiable.

Important issues that must be considered when a request for access to, and use of, research Data held by MH is received:

- Ethical approvals of future research studies – Does the use of the data require, have ethical approval from an HREC?

- Participant consent - where participants are provided a choice/s for use of Data via the participant informed consent form, researchers should implement a means of tracking the choices so that Data is used in accordance with the individual participant's permission (i.e. create a study consent database).

- Use Data as per the participant information and consent form - Data should be used only as described in the ethically approved project protocol and participant informed consent form or participant information sheet i.e. ensure the consent forms state that the Data will

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be used for future research if this is a possibility.

- Disclosure as per the participant information and consent form - disclosure of Data should only be made to other people and /or organisations as declared in the participant information and consent form.

- Data collected under waiver of consent - in studies where an approving HREC has waived the requirement for consent, Data may only be used for the purposes stated to the approving HREC in the study submission.

- New uses for study Data - if during or after completion of a study a new use for the Data is identified that was not previously identified and declared when the study was approved by the HREC, the researcher should apply to an HREC for approval to use the Data in the new way.

- Legal Action - In the event of legal action, research Data and records may be accessed by MH and its legal counsel to determine their relevance to any litigation and, if relevant, removed for use in the litigation. Research Data are subject to subpoena including confidential research Data and records.

- If licensing of the data is appropriate – providing access to the data via a license provides a standardised way for researchers and institutions to share research data with others and to govern subsequent use of that data. Licensing options should be discussed with the Office for Research and the Business Development Unit and agreements in place prior to any data transfer.

- Freedom of Information (FOI) requests - Under the Freedom of Information Act 1982 (Vic), MH may be required to allow persons access to documents which are in MH's possession under defined circumstances. FOI requests should be submitted according to MH standard procedure. Further information and requirements of POI requests should be obtained from the MH FOI Officer and MH legal office before any such access is given.

## 5.17 DATA ACCESS PLAN FOR SHARING OF RESEARCH DATA AT THE END OF THE STUDY

A Data Sharing and Access Plan (DSAP) defines what Data will be shared and under what circumstances the Data will be shared at the end of the study.

Before completing a DSAP or sharing research Data it is important to consider of whether it is appropriate to share the research Data.

Reasons for not allowing access to research Data may include:

- Participant privacy:
  - o The Data may identify the participants i.e. small eligible participant population;
  - o The Data cannot be adequately de-identified to maintain privacy;

- The Data is commercially sensitive (in this case the discuss the project with the Business Development Unit to determine if any further action is required to protect the Data);

- Terms and conditions of agreements covering the Data do not allow sharing of the Data i.e. MH does not own/have permission to share the Data. This may occur when:
  - o The Data was obtained from a third-party including collaborators or registries;
  - o The Data is from a commercially sponsored study

> TIP:
>
> A consent data base will facilitate tracking of and use of data in compliance with the participant consent.

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Consider limiting the access to a certain time period i.e. the Data will be available for access 5 years after publication for a period of 5 years. This may be reasonable considering the type of study, the Data and processes

Principal Investigators are responsible for developing, implementing, managing and documenting a DSAP. The PI should prepare DSAP tailored to each study in accordance with:

- MH Policy (including IP Policy) and guidelines, legislation and external guidelines;

- Study agreements

- Principle P3 of the Code which requires:

    o Transparency in declaring interests and reporting research methodology, Data and findings:

    o Share and communicate research methodology, Data and findings openly, responsibly and accurately.

    o Application of the Principle to all research studies.

Special note for clinical trials: The International Committee of Medical Journal Editors (ICMJE) believes there is an ethical obligation to responsibly share Data generated by interventional clinical trials because trial participants have put themselves at risk.

- As of 1 July 2018, manuscripts submitted to International Committee of Medical Journal Editors (ICMJE) journals that report the results of clinical trials should contain a Data sharing statement as described below.

- Clinical trials that begin enrolling participants on or after 1 January 2019 should include a Data sharing plan in the trial's registration

- If the Data Access Plan changes after registration this should be reflected in the statement submitted and published with the manuscript and updated in the registry record.

Refer to SOP Data Sharing and Access Plan further information the DSAP template.


### 5.18    ARCHIVING AND RETENTION PERIODS

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.

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


#### 5.18.1. Archiving

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

Archiving, retention and disposal requirements should be described in the study DMP.

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

Refer to the Archiving retention and disposal of data Guideline further MH information.


#### 5.18.2. 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 and any other requirements including study agreements, archives and records legislation etc.

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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.

Refer to the [Archiving, retention and disposal of data Guideline](#) further MH information.

### 5.19   DESTRUCTION 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 should be disposed of according to Melbourne Health Policy MH05 Documentation and Records Management, Archiving, retention and disposal of data Guideline and any other applicable requirement.

The destruction of research Data should only be authorised by the Department Head and for sponsored studies, with confirmation from the sponsor.

For further information refer to:

- [Documentation and Records Management MH 05](#)

- [Archiving, retention and disposal of data Guideline](#).

### 5.20   DATA BREACHES

Data breaches include:

- The collection, use, disclosure and storage of Data without consent or the HREC providing a waiver of the need for consent. (Note: this may also constitute research misconduct).

- Inappropriate destruction of data.

- Loss of Data, for example: the researcher or Database trustee being unable to locate the whereabouts of a paper file or an electronic storage device on which Data is held.

- The removal of Data from the researcher's work premises including unapproved sharing/transfer or theft of data.

Data breaches may also result in privacy breaches. MH takes its privacy obligation very seriously.

A breach of the Privacy Policy may have serious consequences.

Further in the case of information used in research, a breach may constitute research misconduct.

**Reporting a Data breach**

All data breaches, including breaches of confidentiality, should be reported in a timely to the reviewing HREC, and the MH Office for Research if the ethical review of the project was not conducted at MH, using the Serious Breach reporting form.

Details to be included in the report:

- type of breach i.e. loss of Data, release of Data

- The situation that lead to the breach

- Number and type of Data involved i.e. 10 patient Data sets, coded/identifiable

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- If the participants have been told about the breach

- What has been done to avoid repetition of the breach i.e. change of practice such as logging in to REDCap from of site to upload Data directly into the project record.

6. **ASSOCIATED POLICIES/PROCEDURES/GUIDELINES**

- MH Research Policy MH18

- Intellectual Property Policy MH12

- Documentation and Records Management MH 05

- Research Integrity Guideline

- Research Publications and Authorship Guideline

- Agreements, Ownership and Intellectual Property Guideline

- Data Storage and Security Guideline

- Databanks and Registries Guideline

- Archiving retention and disposal of data Guideline

- Guidelines for the Use of Human Tissue Samples in Research

- 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 (2007 updated 2018)

- Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018)

- Authorship - A guide supporting the Australian Code for the Responsible Conduct of Research

- Management of Data and Information in Research - A guide supporting the Australian Code for the Responsible Conduct of Research

- Conflicts of Interest (to be released in 2019)

- Research Supervision (to be released in 2019)

- Dissemination of Research (to be released in 2019)

- Collaborative Research across Organisations (to be released in 2019)

- National Statement on Ethical Conduct in Human Research (2007updated 2018)

- Therapeutic Goods Act (1989)

- Access to unapproved therapeutic goods – Clinical Trials in Australia (2004)

- The Australian Clinical Trial Handbook – A simple practical guide to the conduct of clinical trials to international standards of Good Clinical Practice (GCP) in the Australian Context (2018)

- Safety monitoring and reporting in clinical trials involving therapeutic goods

- Code of Conduct for the Victorian Public Sector (Victorian Government)

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- International Conference on Harmonisation / Good Clinical Practice (ICH/GCP) Guidelines

- 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)

- Australian code for the care and use of animals for scientific purposes 8th edition (2013)

- Gene Technology Act (2000)

- Gene Technology Regulations (2001)

- The Office of the Gene Technology Regulator (OGTR) requirements

- Singapore Statement.

## 8. FURTHER INFORMATION

Contact the Office for Research o 03 9342 8550 or research@mh.org.au for further information or assistance

## 9. DOCUMENTATION

- Research Collaboration agreement (MACH template)

- Source data identification log template form refer to GCP SOP OO7

- Data Management Plan template form refer to SOP Data Management Plan

- Data Sharing and Access plan for published data template form refer to SOP Data Sharing and Access Plan

- Application to share/access research data template form refer to SOP Data Sharing and Access Plan

- DSAP internal review process template form refer to SOP Data Sharing and Access Plan

- Researcher request for copies of study materials when leaving Melbourne Health form

## 10. REVISION AND APPROVAL HISTORY

| Date | Version | Author* and contributors |
|---|---|---|
| 3 September 2019 | 1 | Sarah Rickard, Manager Research Governance and Audit |

## 11. APPENDICIES

Appendix A: Definitions

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### APPENDIX A: DEFINITIONS

| | |
|---|---|
| **Background Intellectual Property** | Means all Intellectual Property:<br><br>1) Belonging to or under the control of a Party at the Commencement Date of the study; or<br><br>2) Developed or created by a Party after the commencement date but independently to and separately from the study agreement; and<br><br>Are made available for the conduct of the study, including all rights subsisting in background materials; and as set out in the Schedule of the study agreement. |
| **Data** | Data are facts, observations or experiences on which an argument, theory or test is based. Data may be numerical, descriptive or visual. Data may be raw or analysed, experimental or observational. Research Data includes:<br><br>• Laboratory and field notebooks.<br>• Primary research data (including research data in hardcopy or in computer readable form).<br>• Information obtained directly from a person in interview, questionnaire, focus groups, personal and medical histories, demographics, biographies, audiotape, audiovisual records, photographs, film.<br>• 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.<br>• Test responses.<br>• Models.<br>• Information derived from human tissue such as blood, bone, muscle, organ and waste products, including genetic and radiological information.<br>Research collections may include slides; artefacts; specimens; samples. Provenance information about the data might also be included: the how, when, where it was collected and with what (for example, instrument).<br><br>The software code used to generate, annotate or analyse the data may also be included. |
| **Data Management Plan** | A Data Management Plan (DMP) typically outlines what research Data will be used and created during the course of a research project and as well as plans for sharing and preserving the Data and any restrictions that may need to be applied. |
| **Databank / Database** | The terms Databank and Database are considered to have the same meaning. A Databank is a collection of Data or information, as defined above. It may be stored on paper and kept in files or stored electronically and kept on a hard drive or on disk.<br><br>A Databank may be established with the intent to use the information contained within for a use other than research such as disease surveillance, trend identification and the stimulation of ideas for possible future research. It is foreseeable at some time in the future that such Databanks may be useful for future research. Therefore, such Databanks are subject to these guidelines. |
| **Identifiable Data** | Where the identity of an individual can reasonably be ascertained. Examples of identifiers include individuals' names, photos, UR numbers, and address. |

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| **Intellectual Property** | Means all patents, discoveries, inventions, know-how and improvements in any equipment, device, process, procedure, method, formula, code, chemical or biological substance or the like, trade marks (registered or unregistered), designs (registered or unregistered), any literary work within the meaning of the Copyright Act 1968 (including computer programs and adaptations thereof and any applications), any development or potential development, research or practice in the fields of surgical, medical, dental and therapeutic treatment and care, social welfare or health (including mental health) created under the auspices of MH and all associated rights |
| **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.<br><br>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.<br><br>For laboratory research Metadata could include notes in laboratory notebooks, batches of chemicals used, facility temperatures etc.<br><br>Refer to https://www.ands.org.au/guides/metaData-working for further information. |
| **Non-identifiable Data** | Data that have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can ever be identified. A subset of non-identifiable Data is one that can be linked with other Data, so it can be known that they are about the same Data participant, although the person's identity remains unknown. |
| **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. |
| **REDCap** | Research electronic Data capture (REDCap) is a workflow methodology and software solution designed for rapid development and deployment of electronic Data capture tools to support clinical and translational research. REDCap was developed by Vanderbilt University. MH hosts an instance of the MH system on its servers. |
| **Re-identifiable Data** | Data from which identifiers have been removed and replaced by a code. It remains possible to re-identify a specific individual by, for example, using the code or linking different Data sets. |
| **Research Results** | All results of the Project including, without limitation, outcomes, deductions, conclusions, assumptions, inferences, or suppositions drawn, processes, formulae, reports, software, designs, and research data produced in the conduct of the Project and all Intellectual Property Rights therein but specifically excludes Materials. |
| **Source Document Identification Log** | An index to identify the various source documents for a study. It also indicates where the source document will be located at the site and the person responsible for the document. |