

MELBOURNE HEALTH		OFFICE FOR RESEARCH	
		STANDARD OPERATING PROCEDURE: OFR SOP002	
		DATA SHARING and ACCESS PLAN	
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1. AIM

To describe the process of developing and implementing a Data Sharing and Access Plan (DSAP) for sharing of data from research studies conducted at Melbourne Health (MH).

2. SCOPE

Applicable to all data for research studies conducted at MH, including single site research, collaborative research and investigator-initiated clinical trials.

3. APPLICABILITY

Principal Investigator/ Investigator, Sub-Investigator(s), research coordinators, data managers, and other staff involved in research duties.

Principal Investigators are responsible for developing, implementing, managing and documenting a DSAP for each study that they manage to ensure that data is shared appropriately and in accordance with the research study requirements including but not limited to ethical and other approvals, participant consent, MH policy and requirements, the terms and conditions of agreements.

Principal Investigators are responsible for training research study team members in the requirements of the DSAP and associated procedures and documents including terms and conditions of research study agreements.

4 PROCEDURE

4.1 Introduction

A DSAP defines what data will be shared at the end of a research study and under what circumstances the data will be shared/accessed.

Melbourne Health's Guideline for Data Management in Research requires that researchers undertake data management planning for research studies including planning for sharing/access to published data. The DSAP must be consistent with the study Data Management Plan (DMP) and may be considered as a subsection of the DMP.

Research data management is a requirement of the Australian Code for the Responsible Conduct of Research 2018 (the Code):

- Principle P3 of the Code outlines the definition of transparency in research as declaring interests and reporting research methodology, data and findings:
 - Share and communicate research methodology, data and findings openly, responsibly and accurately.

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- This applies to all research studies.

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. Furthermore, all clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration (refer to Taichman et al).

4.2 MH position

MH recognises that research data are a valuable resource and often irreplaceable.

MH supports open sharing/access to research data where appropriate.

Sharing of research data may not always be appropriate and researchers should carefully consider the implications of research data sharing during the preparation of the research study to ensure that the sharing of any research data complies with MH policy and requirements, legislation (including privacy requirements), good data principles, contractual agreements and all other applicable requirements before implementing the DSAP.

Note: for commercially sponsored clinical trials, the trial sponsor will be responsible for data management and preparation of the study DSAP

Factors to consider during development of a DSAP:

- Research data are a valuable resource and often irreplaceable.
- Research data should only be published/shared/accessed in accordance with applicable requirements including but not limited to ethical approvals, participant consent, MH policies and guidelines, applicable legislation and privacy requirements.
- Research data ownership and rights – who owns and/or otherwise has rights to control/use/disclose the research data and can give permission to share it.

Advice should be obtained from the Office for Research on the content of DSAPs.

4.3 Be familiar with the ALL requirements

Before completing a DSAP, the PI and other researchers should be familiar with the following documents as well as any other requirements applicable to the study and/or data:

- Australian Code for the Responsible Conduct of Research 2018 (the Code)
- National Statement of Ethical Conduct in Human Research 2018
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018
- MH18 Research Policy
- MH12 Intellectual Property Policy
- MH12.01 Intellectual Property Procedure
- MH05 Documentation and Records Management Policy
- MH05.01 Clinical Documentation
- MH03.08 Privacy and Confidentiality of Patient Information
- Applicable privacy laws
- Any other requirement affecting the research study data

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4.4 Points to consider BEFORE completing a DSAP

In determining if, and what, research study data should be available for access by others at the end of a research study, researchers must consider many factors including the value of the research data (for example, commercial value), ownership and data rights (i.e. whether MH has the right to release the data and for what purpose/use), the potential for the research data to identify participants, and any potential restriction on the research data and unintended consequences of releasing the research data (i.e. for future MH research, potential to patent, etc.).

Some points to consider include:

a. Will the research data be made available for sharing?

Consider if there are reasons for not sharing some or all of the research data (e.g. terms and conditions restricting sharing/disclosure/use of the research data under a contractual agreement with third parties), or in contrast, if there is an obligation to share some or all of the research data (e.g. mandatory deposit etc.).

Make explicit mention of consent, confidentiality, anonymisation and other ethical considerations, where appropriate, in the DSAP.

If research data are openly available, the name(s) of the research data repositories should be provided, as well as any persistent identifiers or accession numbers for the dataset.

If the research data are not openly available, the research data access statement should direct users to a permanent record that describes any access constraints or conditions that must be satisfied for access to be granted.

Note that any disclosure of MH research data to a third party or into the public domain (e.g. deposit, publication, presentation, etc.) is always subject to MH12 Intellectual Property Policy and MH12.01 Intellectual Property Procedure which details the disclosure, confidentiality and intellectual property protection requirements to be met before disclosing any MH research data

b. Is there adequate protection of participant privacy?

Confirm that the research data will be anonymised or de-sensitised before being shared. This should be consistent with ethical approvals, information provided to the participants in the PICF, legislation, etc.

Note: genetic data are considered to be potentially identifiable.

Note: in cases of rare diseases, the research data are considered to be potentially re-identifiable.

c. Who owns and/or has rights to the research data?

Does MH exclusively own and/or have exclusive rights in and to ALL the research data and supporting information (i.e. protocol, procedures etc.) used and created during the research study? This information is referred to as Project Intellectual Property.

Where pre-existing Background Intellectual Property, and Project Intellectual Property are exclusively owned by MH, sharing of, or access to, MH research data must not infer or otherwise imply that MH will share its Background Intellectual Property or Project Intellectual Property with the third parties wishing to access the research data.

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Alternatively, MH may not have exclusive ownerships of and/or rights to some research data as other parties (such as collaborators) may also have an interest in the study Background Intellectual Property and Project Intellectual Property. In these cases, a DSAP should be developed in consideration of existing interests including agreements and/or consultation with the other parties. Sharing of or access to the research data must not infer or otherwise imply that the parties will share their Background Intellectual Property or Project Intellectual Property with the third parties wishing to access the research data.

If there are multiple parties that own and/or have licensed rights to the research data (for e.g. under a research collaboration agreement with collaborators), ALL owners must agree to share the research data and the process of research data sharing.

If you did not collect the research data yourself but instead used existing data obtained from another source, its use, sharing and disclosure must be in accordance with the terms and conditions of that source (if applicable) and this source should be credited.

In all cases, any disclosure of MH research data including Background Intellectual Property and Project Intellectual Property (whether solely or jointly owned by MH) to a third party or into the public domain (e.g. deposit, publication, presentation, etc.) is always subject to MH12 Intellectual Property Policy and MH12.01 Intellectual Property Procedure which details the disclosure, confidentiality and intellectual property protection requirements to be met before disclosure. Please seek advice from the Office for Research and Business Development Unit.

d. Do you have permission to release/provide access to the data?

Have the participants consented to the research data being shared?

Check the Participant Information and Consent form (PICF). If the PICF states that the research data will NOT be used for any other purpose, then the research data must not be shared.

For third party information obtained under licence, e.g. from a registry, from a third party collaborator, etc., confirm that the research data license allows for data sharing, if not that research data must not be shared.

e. Are there any restrictions that prevent data from being shared or re-used?

In cases where access to research data is restricted, researchers should document and justify a strong case for any restrictions on sharing as there is a common expectation that publicly funded research data will be openly available as soon as possible. These justifications may also be of use in the event of a Freedom of Information request for your research data.

Examples of justifications may include:

- To safeguard research participants e.g. the patient information may identify the participant. This is applicable to small studies with small groups of participants, or where the participant groups is rare, and also where the particular data collected during the research study are not able to be made non-identifiable i.e. is genetic data or collectively the research data may be able to be used to re-identify the participants.
- To gain appropriate intellectual property protection and/or enable commercialisation of the research study results. Note that research study data of potential commercial value must be disclosed to Office of Research and Business Development to pre-approve any proposed disclosure of research data to third parties or for public disclosure. PIs should also demonstrate that they have sought advice on and addressed all copyright, intellectual property, moral and other rights management issues that apply to all research study data. Refer to MH12 Intellectual Property Policy and MH12.01 Intellectual Property Procedure regarding confidentiality, disclosure and intellectual

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property protection requirements to be met BEFORE disclosing or sharing any research data.

- Embargo periods.
- Conditions of use of third-party data. Identify if the data can be released/ accessed by, shared with, or provided to other parties and on what terms. Note this may also apply to research results created in the study that contains/incorporates a third party's data (for example third party Background Intellectual Property). For use of third-party data under a licence, refer to the license for conditions of use (for example study agreement, research collaboration agreement, sponsored research agreement, material/data transfer agreement, etc.). Be aware of any restrictions this may place on subsequent deposit and data sharing. For collaborations, refer to the agreement for conditions of use of data obtained from the collaborator.

f. Preserved links

It is important that any links to the data are persistent.

Digital Object Identifiers (DOI) are a type of persistent URL that are provided for datasets by many specialist data archives.

g. Do cultural elements of the data need to be considered

This is a study specific requirement and may be dependent on the study aims, target population and significance of study outcomes to a particular cultural group..

For example, if the study was aimed at research into, or identified significant implications for, Aboriginal and Torres Strait Islander people and communities then specific considerations about whittom and how the data should be shared may need to be considered in the context of the respect for the customs and beliefs of the Aboriginal and Torres Strait Islander people and communities.

Refer to the 'Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018'.

4.5 Completing a DSAP and associated processes

4.5.1 The DSAP and data sharing statement

Complete the DSAP as early as possible and during the planning of your study. Completion of the DSAP should occur as an element of the Data Management Planning.

Note: For clinical trials, complete a DSAP prior to commencement and conform to the International Committee of Medical Journal Editors (ICMJE) requirements (refer to Taichman et al):

- As of 1 July 2018, manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement based on the DSAP.
- Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration.

DSAP statements should indicate the following details:

- Whether individual non-identifiable participant data (including data dictionaries) will be shared.
- A description of what data will be shared.

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- Whether additional, related documents will be available (e.g. metadata including the research study protocol, statistical analysis plan etc.).
- When the research data will become available and for how long.
- Terms and conditions of sharing (i.e. by what access criteria research data will be shared including with whom), for what types of analyses, and by what mechanism (i.e. data transfer method).

Researchers should seek advice from the Office for Research and the Business Development Unit regarding ownership and disclosure of Background Intellectual Property and Project Intellectual Property related issues.

4.5.2 Develop a process to manage data requests

Where research data will be available for sharing from MH, Principal Investigators should develop the supporting processes.

The process must include:

- a. Research data request process.

State whom (position title) the applicant should direct research data access requests to and how the requests must be sent (i.e. email address). Note that the email address must be valid and monitored for the entire access period (as stated in the plan).

Will there be an initial form to fill in or will this be sent after the initial request email has been received?

Information provided by the applicant to support the research data request should include:

- Purpose of obtaining the research data – the applicants are to provide a protocol or study summary including a statement of aims and methods to support the research data request.
- Evidence of ethical approval.
- Details of the research data and information requested.
- A statement to confirm that the requesting party will only use the research data for the purpose requested and according to and applicable requirements such as ethical approvals, participant consent, ownership etc.
- A statement to appropriately attribute MH research data source in any publications.
- An agreement to document acceptance of conditions of use of the research data as per approvals and participant consent or other conditions etc.
- Any other requirements needed for the research data set.

- b. Process for MH review of the research data request

Refer to the DSAP, DMP, research study agreements and any other applicable requirements BEFORE releasing research data.

Establish an internal review process for approving/denying research data requests and include:

- Define who will review the request i.e. PI/data manager/data committee etc.
- Criteria for accepting/denying the request.
- The process for communicating the decision.

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- Requests for further information.
 - How research data will be sent.
- c. Maintain records of research data access requests

Keep a log (i.e. on REDCap) to record research data access requests (and include approved and rejected requests):

- Details of applicant (name/organisation/contact information).
- Reason for the request (title of research study).
- Evidence of ethics approval (ethics committee name, approval number).
- Whether the request was approved or denied and the name of the person reviewing the application for research data.
- If approved, what research data and associated records were sent to the applicant.

4.6 What to do with your completed DSAP

The DSAP is an essential research study document and should be filed in the research study folder.

The DSAP should be made available for review, by auditors or regulatory authority(ies) and the sponsor's representatives (if sponsored).

For MH investigator initiated clinical trials:

- Submit the DSAP if required when registering the trial on a clinical trials registry such as Australian New Zealand Clinical Trials Registry (<http://www.anzctr.org.au/>) or ClinicalTrials.gov (<https://clinicaltrials.gov/>)

Note: Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration to be published in ICMJE journals (refer to Taichman et al).

- The DSAP if required when submitting manuscripts to journals

Note: as of 1 July 2018, manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement (refer to Taichman et al).

4.7 Reviewing the DSAP

The DSAP is a living document and should be reviewed as data management requirements change throughout the study. These may include:

- Identification of issues that were not previously considered.
- Evolving protocol - amendment to the protocol that affect the research data collected, generated for the study i.e. addition of an external data source (e.g. registry).
- Addition of an external researchers or a site to the research study.
- Change in technologies - data creation, storage.
- Change in policies, legislation or other requirements.

If the DSAP is for a clinical trial, the updated DSAP should be forwarded to the clinical trial registry.

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5. DISSEMINATION AND IMPLEMENTATION

This SOP will be disseminated by the Office for Research. Updates will be made available with details of planned dates of implementation.

6. MONITORING COMPLIANCE AND EFFECTIVENESS

Compliance with this SOP will be monitored as part of the Office for Research monitoring process. Any problems or potential problems concerning the effectiveness of this SOP may be identified during the Office for Research monitoring process or through users informing the Office for Research.

7. REVIEW AND UPDATING

This SOP will be reviewed every three years, or whenever there are changes to legislation or working practices that impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

8. GLOSSARY

Background Intellectual Property

Means all Intellectual Property:

- 1) Belonging to or under the control of a Party at the Commencement Date of the study; or
- 2) Developed or created by a Party after the commencement date but independently to and separately from the study agreement; and
- 3) 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 Dictionary

A centralized repository of information about data such as meaning, relationships to other data, origin, usage, and format. Also referred to as a metadata repository.

Digital Object Identifier (DOI)

Is a computing term for a persistent identifier or handle. A DOI is a character string or 'digital identifier used to identify objects uniquely by a standardized system managed by the International Organization for Standardization (ISO). DOIs are widely used to identify academic, professional, and government information, such as journal articles, research reports and data sets, and official publications. For more information about DOIs see the [Wikipedia page](#).

Essential Documents

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

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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.

International Conference on Harmonisation (ICH)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Investigator

An individual responsible for the conduct of a research study including clinical trials at a research/trial site and ensures that it complies with GCP guidelines. If a research/trial is conducted by a team of individuals at a research/trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.

Metadata

Metadata means "data about data". It is information about an object or resource that describes characteristics such as content, quality, format, location and contact information. Metadata can be used to describe physical items as well as digital items (documents, audio-visual files, images, datasets, etc.).

Project Intellectual Property

All Intellectual Property developed or discovered in the course of the research, excluding the copyright for any student thesis.

Site File

A file that contains all the applicable essential documentation for the research study / clinical trial. This may also be called the Investigator file.

Sub Investigator

Any individual member of the research/clinical trial team designated and supervised by the investigator at a research/trial site to perform critical trial-related procedures and/or to make important research/trial-related decisions (e.g., associates, residents, research fellows).

9. REFERENCES

1. Australian Code for the Responsible Conduct of Research 2018 (the Code)
2. National Statement of Ethical Conduct in Human Research 2007 (updated 2018)
3. Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018
4. MH18 Research Policy
5. Documentation and Records Management Policy MH05
6. Clinical Documentation MH05.01
7. Privacy and Confidentiality of Patient Information MH03.08

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8. MH12 Intellectual Property Policy
9. MH12.01 Intellectual Property Procedure
10. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, 2018
11. <https://www.andsof.org.au/working-with-data/metadata>
12. <http://www.bath.ac.uk/research/data/archiving-data/writing-a-data-access-statement/>
13. Taichman et al. Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors. 2017. JAMA 317(24):2491-2492.

10. APPENDICES

- Appendix 1: SOP Change Log
- Appendix 2: Examples of data sharing statements that fulfil ICMJE requirements
- Appendix 3: Further Examples of Data Access Statements
- Appendix 4: Template DSAP form (Example template)
- Appendix 5: Application to share/access Melbourne Health research data (Example template)

APPENDIX 1: SOP CHANGE LOG

<i>Version No. and date</i>	<i>Author and contributors</i>	<i>Reason for Issue</i>
Version 1 2/9/2019	Sarah Rickard, Manager Research Governance and Audit	First issue
Version 2 15/4/2020	Sarah Rickard, Manager Research Governance and Audit	Include references to Aboriginal and Torres Strait Islander people and communities

DOCUMENT END

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Appendix2: EXAMPLES OF RESEARCH DATA SHARING STATEMENTS THAT FULFIL ICMJE REQUIREMENTS

	Example 1: No access	Example 2: Limited access	Example 3: Limited Access	Example 4: Full access
Will individual participant data be available (including data dictionaries)?	No	Yes	Yes	Yes
What data in particular will be shared?	Not available	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices)	All of the individual participant data collected during the trial, after deidentification.
What other documents will be available?	Not available	Study Protocol.	Study Protocol, Statistical Analysis Plan, Analytic Code	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code
When will data be available (start and end dates)?	Not applicable	Beginning 9 months and ending 36 months following article publication.	Beginning 3 months and ending 5 years following article publication.	Immediately following publication. No end date.
With whom	Not applicable	Investigators whose proposed use of the data has been approved by an independent review committee (learned intermediary) identified for this purpose.	Researchers who provide a methodologically sound proposal	Anyone who wishes to access the data.
For what types of analyses?	Not applicable	For individual participant data meta-analysis.	To achieve aims in the approved proposal.	Any purpose
By what mechanism will data be made available?	Not applicable	Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our MH but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at (Link to be provided).	Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third-party website (Link to be included).	Data are available indefinitely at (Link to be included).

Adapted from the ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals Updated December 2017

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APPENDIX 3: FURTHER EXAMPLES OF RESEARCH DATA SHARING STATEMENTS

• Where there are ethical restrictions

"Due to ethical concerns, supporting data cannot be made openly available. Further information about the data and conditions for access are available on request from [<enter contact information for research team/department i.e. generic email for study/department>](#)."

"Due to the [<describe sensitive nature i.e. \(commercially, politically, ethically\)>](#) sensitive nature of the research, no participants consented to their data being [<retained for future use or shared>](#). Additional details relating to other aspects of the data and conditions for access are available on request from [<enter contact information for research team/department i.e. generic email for study/department>](#)."

"Supporting data are available to bona fide researchers. Details of the data and conditions for access are available on request from [<inset contact information for research team/department i.e. generic email for study/department>](#)."

• Where there are commercial restrictions

"Supporting data will be available after a [<insert time - suggest 5 years>](#) embargo from the data of publication to allow for commercialisation of research findings. Enquiries to [<inset contact information for research team/department i.e. generic email for study/department>](#)"

"Due to confidentiality agreements with research collaborators, supporting data can only be made available to bona fide researchers subject to a non-disclosure agreement. Details of the data and how to request access are available at [<inset contact information for research team/department i.e. generic email for study/department >](#)."

• Where the research data are openly available

"All data created during this research are openly available from [<inset contact information for research team/department i.e. generic email for study/department OR enter name of registry OR archive>](#) at [<enter weblink>](#)."

"All data supporting this research study are provided as supplementary information accompanying this paper."

"All research data are provided in full in the results section of this paper."

• Research studies consisting of secondary analysis of existing data

"This research study was a re-analysis of existing data that are publicly available from [<insert name of database i.e. EMBL>](#) at [<insert webpage link>](#). Further documentation about data processing are available from MH on request (if applicable) at [<insert appropriate MH contact/link to application process>](#)."

"The research study brought together existing data obtained upon request and subject to licence restrictions from a number of different sources. Full details how these data were obtained are available in the documentation available at [<insert reference webpage containing information>](#)."

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Appendix 4: Template DSAP form

<Example Template>

Note: Information may be added/amended as required

<h2 style="margin: 0;">Melbourne Health</h2> <h3 style="margin: 0;">Data Share/Access Plan for published data</h3>	
<p><i>Notes:</i></p> <ul style="list-style-type: none"> <i>Data sharing/access plans must be prepared in accordance the Data Sharing and Management Plan SOP and any other applicable requirements including requirements of the protocol, approvals, agreements, governing law, guidelines and MH policy and procedures.</i> <i>Advise should be obtained from the Office for research (including for legal and intellectual property advice) if applicable and on a case by case basis.</i> 	
MH study title:	Click here to enter text
MH Principal Investigator:	Click here to enter text
MH ethics approval number:	Click here to enter text
Data Share/Access Plan details	
Will any data be shared	Click here to choose Yes/No
If no, provide justification. Do not complete the remainder of the form	Click here to enter text
If Yes, continue completing the remainder form	
Will individual participant data be available	Click here to choose Yes/No
If Yes, will this include data dictionaries?	Click here to choose Yes/No
What data in particular will be shared? Refer to Appendix 2 and 2 for examples of text	Click here to enter text

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What other documents will be available?	Click here to enter text
If data will be shared, When will data be available? Enter event that triggers availability AND/OR enter start and end dates	Click here to enter text Start Date Click there to enter a date End Date Click there to enter a date
With whom will data be shared? (enter restrictions if applicable)	Click here to enter text
For what types of analyses?	Click here to enter text
By what mechanism will data be made available? Enter information of person to contact / request process (this may be an email or link to a website if appropriate)	Click here to enter text
List of supporting documents – if applicabel (Alternatively, you may provide an attachment with this form)	Click here to enter the list of documents OR indicate if attached in a separate document.
Data Sharing statement	
Data Sharing statement to be included in clinical trial registries or forwarded to journals (Based on above information. Refer to Appendix 2 and 3 for examples)	Click here to enter text
Principal Investigator declaration	
<i>I confirm that the data access and sharing plan is appropriate for the research study and complies with all applicable requirements.</i>	
Principal Investigator Signature	
Date	

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Appendix 5: Template DSAP application form and internal review process form

<Example Templates>

Note: Information may be added/amended as required

<h2 style="margin: 0;">Melbourne Health</h2> <h3 style="margin: 0;">Application to Share/Access Research Data</h3>	
<p><i>Note: Data must be accessed/shared in accordance with the study data sharing and access and any applicable requirement including governing law, guidelines and MH policy and procedures.</i></p>	
Application details	
Name of Applicant:	Click here to enter text
Applicant organisation:	Click here to enter text
Date of application:	Click there to enter a date
Reason for request:	Click here to enter text
Items requested:	Click here to enter text or provide an attachment with a description of the data sets and /or other information requested
Applicant Study title	Click here to enter text
Has the study received ethical review and approval/favourable opinion?	Click here to choose Yes/No
If Yes, provide the name of the ethical review body that reviewed the application:	Click here to enter text
Provide the ethical review board number assigned to the study:	Click here to enter text
Has the evidence of the ethical review been attached to the application	Click here to choose Yes/No
List of supporting documents (Alternatively, you may provide an attachment with this form)	Click here to enter the list of documents OR indicate if attached in a separate document.

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Melbourne Health

DSAP internal review process

Study Data Manager (or delegate) to complete

MH study title:	Click here to enter text	
MH Principal Investigator:	Click here to enter text	
MH ethics approval number:	Click here to enter text	
Date application received	Click there to enter a date	
Person processing application	Click here to enter text	
Application complete?	Click here to choose Yes/No	
Committee review (if applicable)	Click here to choose Yes/No	
Does the data requested meet the specifications of the DSAP?	Click here to choose Yes/No	
Application approved?	Click here to choose Yes If Yes, issue draft agreement for signing.	Click here to choose No If no, inform applicant of decision. Click there to enter a date
Data Agreement issued	Click there to enter a date	
Data agreement agreed by all parties:	Click there to enter a date	
Fully signed data agreement received:	Click there to enter a date	
Data sent on:	Click there to enter a date	
Date application closed:	Click there to enter a date	

***NOTE- Printed or downloaded version are uncontrolled and subject to change ***

Melbourne Health OFR SOP: DATA SHARING AND ACCESS PLAN

Version: 2 Dated 15 April 2020

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