Monash Partners Health Translation Network

Data Sharing Agreement and Principles

November 2025. Version 4.5

Adapted from Sydney Health Partners Health Data Sharing protocol
Version: 3.6

Our Partners

Our Associate Partners

MONASH PARTNERS MEMBER ORGANISATIONS

Bayside Health (Alfred Care Group)

Baker Heart and Diabetes Institute Cabrini Health

Eastern Health

Hudson Institute of Medical Research Monash Health

Monash University

Bayside Health

(Peninsula Care

Group)

The Macfarlane Burnet Institute for Medical Research and Public Health

Contents

MONASH PARTNERS MEMBER ORGANISATIONS ii

MONASH PARTNERS DATA SHARING AGREEMENT 1

EXECUTION 8

SCHEDULE 1 – PARTICULARS 12

SCHEDULE 2 – DATA SHARING PRINCIPLES 19

SCHEDULE 3 – DE –IDENTIFIED DATA REQUIREMENTS 43

SCHEDULE 4 – IDENTIFIABLE OR RE-IDENTIFIABLE DATA REQUIREMENTS 54

SCHEDULE 5 – MONASH PARTNERS GOVERNANCE STRUCTURE 79

MONASH PARTNERS DATA SHARING AGREEMENT

1. PARTIES

(Relevant Partner organisation)

And –

The Parties named at item 1 of Schedule 1 (A Partner or Partners)

2. RECITALS

A. The Partners have established a centre known as 'Monash Partners Health Translation Network' under which they collaborate on healthcare projects, research and clinical services (the **Centre**).

B. The Partners' strategic plan prioritises data-driven healthcare improvement.

C. The Partners have developed data-sharing principles to document the objectives and requirements pursuant to which the Partners will exchange health care data (the **Principles).**

D. The Principles require each of the Partners to comply with the Principles where they choose to disclose certain personal and health information between each other that has been collected by a Partner upon request by another Partner (the **Information**).

E. The Partners recognise that the disclosure and sharing of health information collected by one Partner to another Partner is subject to strict compliance with certain laws and obligations.

F. The Partners agree that disclosure of the Information to each other is strictly in accordance with the terms and conditions of this Agreement.

3. DATA SHARING PRINCIPLES

3.1 The Partners have established the Principles to document how each Partner will efficiently and lawfully share Information where appropriate to improve patient clinical care, prevention, screening and treatment and to streamline research processes where data is shared across the Partners.

3.2 At all times, the Partners must comply with the relevant law applicable to them.

3.3 The Principles are set out at Schedule 2 to this Agreement

3.4 Subject to the terms and conditions of this Agreement, the Partners must:

(a) comply with the Principles;

(b) exercise due care, skill and judgement at all times and act in accordance with the highest professional principles and standards applicable to data sharing in medical research;

(c) comply with all applicable policies, procedures and guidelines applicable to the collection, storage, disclosure and destruction of Information and data sharing; and

(d) act in good faith.

(e) Where feasible, Partners should leverage AI-based tools to optimise data sharing processes, ensuring compliance with legal and ethical standards while improving efficiency and accuracy.

(f) The Partners agree to adopt Australia's national Health Information Exchange (HIE) principles to ensure secure, standardized, and interoperable data sharing, facilitating real-time access to patient health information across systems for clinical care, research, and quality improvement.

3.5 For clarity, if a Partner determines that the proposed application of any of the terms and conditions of this Agreement or the Principles are inconsistent with its regulatory/legislative obligations, then the regulatory/legislative obligations prevail.

3.6 The Data Sharing Agreement and Principles are to guide the sharing of data outside of individual patient information for the purposes of personalised clinical care. HIE standards should align with national and international interoperability frameworks, such as HL7 Fast Healthcare Interoperability Resources (FHIR) to streamline secure and efficient exchange of health data.

4. INCONSISTENCIES

The terms of this Agreement override any inconsistent terms of the Principles, any communications between the Partners or any industry practices or earlier conduct by a Partner in relation to the disclosure and sharing of any personal or health information by one Partner to another Partner.

5. TERM

This Agreement will commence on the Commencement Date set out in Item 2 of Schedule 1 and will continue unless terminated earlier in accordance with clause 16.

6. HEALTH AND PERSONAL INFORMATION - PRIVACY

6.1 Each Partner acknowledges and accepts that the Partners are:

6.1.1 obliged to comply with the regulatory regimes applicable to their organisations.

6.1.2 not to knowingly or recklessly do anything that would compromise another Partner's compliance with its obligations, and

6.1.3 to facilitate compliance by other Partners with their obligations as reasonably requested.

6.2 Each Partner acknowledges and accepts that:

6.2.1 a number of the Partners **(Relevant Health Service Partner/s)** are public health services within the meaning of the Health Services Act 1988 (HSA) and are obliged to comply with the applicable provisions of the HSA, including section 141 concerning confidentiality

6.1.1. a number of the Partners are bound by the provisions of the Mental Health Act 2014, and are obliged to comply with section 346 with respect to disclosure of patient information

6.1.2. a number of Partners are bound by the Health Records Act 2001 (Vic) (HRA) and the Privacy and Data Protection Act 2014 (Vic)

6.2. All Partners agree to:

6.2.1. comply with the requirements of the legislation referred to in clause 6.2 irrespective of whether the Partner is bound to comply with the legislation, to the extent that the legislation referred to in clause 6.2 applies to the Information;

6.2.2. comply with any written request from a Partner to another Partner which the requesting Partner determines is required to ensure that the requesting Partner complies with its obligations under the legislative regimes referred to in clause 6.2, and arising under any Commonwealth or State privacy health records or similar legislation or regulations; and

6.2.3. take all reasonable measure in accordance with any applicable laws, standards and guidelines to protect the security and integrity of the Information including preventing unauthorised access to that Information. Partners should explore AI-enhanced security systems such as real-time anomaly detection and automated encryption tools to safeguard health information against unauthorized access.

6.2.4. The health information exchange process must ensure robust encryption, access control, and auditing mechanisms to ensure compliance with privacy laws and data integrity standards.

6.3. A Partner must ensure that its employees, agents and contractors do not:

6.3.1. take or disclose or make available information received under this Agreement unless strictly in accordance with the terms of this Agreement

6.3.2. allow information received pursuant to this Agreement to be taken disclosed or made available outside Australia

6.4. A Partner must immediately notify the relevant Partner if it becomes aware of a breach of this clause 6.

6.5. Each Partner acknowledges and accepts that a breach of this clause 6 (howsoever caused) is a fundamental breach of this Agreement and entitles the Partners to immediately terminate the offending Partner's right to continue to remain a party to this Agreement.

7. TRANSFER OF DE-IDENTIFIED DATA

7.1. The Partners acknowledge and accept that except as outlined in clause 8 of this Agreement, Information disclosed by one Partner to another Partner under this Agreement must not identify a person, or from which a person's identity can be reasonably identified.

7.2. Except as permitted under the legislation referred to in clause 8, each Partner must ensure that prior to disclosure of Information to another Partner, the Information has been de-identified, modified, and encrypted in accordance with the requirements set out at Schedule 3 to this Agreement, so that it does not identify a person, or is not in a form by which a person's identity can be reasonably identified.

8. TRANSFER OF IDENTIFIABLE OR RE-IDENTIFIABLE DATA

8.1. The Partners acknowledge and accept that, a Partner must not disclose, whether directly or indirectly, any health information where a person can be identified from that information, or reasonably identifiable, unless the Partner is satisfied that the disclosure is permitted under the applicable legislation as set out in clause 8.2.

8.2. A Partner may be satisfied that the disclosure is permitted under the legislation, where:

(a) the person to whom the Identifiable or Re-Identifiable information relates expressly authorises or permits the sharing of that information; or

(b) the use of this information is necessary (meaning that use of non-Identifiable or Re-Identifiable information cannot achieve the relevant purpose) for the medical or social research that has been approved by an appropriate research ethics committee; and

(c) the disclosure is necessary for research, or the compilation or analysis of statistics, in the public interest and -

(i) it is impracticable for the Partner to seek the person's consent before the use or disclosure; and

(ii) the purpose cannot be served by the use or disclosure of non-Identifiable information; and

(iii) the use or disclosure is in accordance with any guidelines issues or approved by the Health Complaints Commissioner in respect of

Health Privacy Principle (HPP) 2.2(g) from time to time.

9. DATA SHARING PROTOCOLS AND DATA SECURITY

9.1. Each Partner must comply with the data quality (HPP 3) and data security and data retention principles (HPP 4), with respect to Information it has or receives notwithstanding if the Partner is not ordinarily subject to the Health Records Australia (HRA).

9.2. In relation to the use of the Information received from another Partner, a Partner must not:

a) use the Information for any purpose other than those contemplated by the Principles and this Agreement;

b) purport to sell, let for hire, assign rights in or otherwise dispose of any Information;

c) copy, decompile, modify, reverse engineer or create derivative works out of any of the Information; or

d) alter the Information in any way, other than contemplated by the Partners.

9.3. Each Partner must establish and maintain safeguards for all Information in the possession, custody or control of the Partner against its:

a) destruction, loss or alteration;

b) misuse, or interference; and

c) unauthorised access, modification or disclosure,

that:

d) are no less rigorous than those safeguards employed by a Partner, and in any event, are no less rigorous than safeguards that meet generally accepted industry standards, and

e) comply with all laws.

9.4. Without limiting the rights or obligations of a Partner under this Agreement, a Partner must promptly on request by another Partner (discloser) provide the requesting Partner (requestor) with a copy of all Information that the discloser provided to the requestor and stored on the requestor's servers or otherwise in its possession or control, in such format as is reasonably directed.

9.5. If a recipient Partner becomes aware or suspects that:

a) any of its personnel is using or disclosing, or has used or disclosed the Information in contravention of this Agreement (Data Contravention); or

b) there has been unauthorised access to, or unauthorised disclosure of any Information (Data Breach); or

c) Information has been lost in circumstances where unauthorised access to, or unauthorised disclosure of, it may occur (Loss of Data),

d) then that recipient Partner must immediately notify the disclosing Partner of that Data Contravention, Data Breach or Loss of Data, and co-operate

with the disclosing Partner with any investigations.

9.6. References to Information in this clause 9 mean any health or personal information shared by a Partner under this Agreement

10. NO WARRANTY

No Partner warrants as to the accuracy or completeness of any information provided under this Agreement.

11. GOVERNANCE

The governance structure of the Partners is detailed at Schedule 5 to this Agreement.

12. PARTNERS' PERSONNEL

12.1. Each Partner must appoint key persons as:

12.1.1. Contract manager for this Agreement,

12.1.2. Data Steward

12.1.3. Organisation Data Custodian

with the names and contact details set out at item 3 of Schedule 1 to this Agreement.

12.2. If the persons identified in Item 3 of Schedule 1 are unavailable or otherwise unable to participate in this Agreement, that Partner must promptly notify the other Partners and provide details of alternate, suitably qualified and experienced replacement staff.

13. INTELLECTUAL PROPERTY

13.1. The Information disclosed by a Partner is the property of the disclosing Partner (discloser)

13.2. The discloser grants to the receiving Partner (recipient) a non-exclusive right to use the Information under the terms and conditions of this Agreement.

13.3. If a recipient Partner creates new intellectual property from the discloser's Information, unless otherwise agreed in writing, the recipient must negotiate in good faith with the discloser and enter into a separate agreement regarding collaboration and/or commercialisation of this intellectual property.

13.4. In the absence of any agreement referred to in clause 13.3, the recipient and the discloser will own the intellectual property referred to in this clause 13 in equal shares as tenants in common.

14. INSURANCE

14.1. Each Partner must obtain and maintain insurance coverage sufficient to cover any loss or costs that may be incurred and for which the Partner is liable in connection

with the disclosure and receipt of information under this Agreement

14.2. On request, the Partners must provide the requesting Partner with evidence of the currency of any insurance it is required to obtain.

15. LIABILITY AND INDEMNITY

15.1. Each Partner (compensating Partner) will reimburse or otherwise compensate each other Partner (compensated Partner) and their representatives from and against all loss, damage, claim, action or expense (including legal expense) (Liability) which may directly arise from or are in any way related to the:

15.1.1. disclosure or use of any information in breach of this Agreement by the compensating partner, its employees, officers or agents or contractors;

15.1.2. any unlawful or negligent act, error or omission of the compensating partner, its employees, officers, agents or contractors relating to this Agreement;

15.1.3. any breach of the terms and conditions of this Agreement by the compensating party, its employees, officers, agents or contractors, except to the extent that the Liability was caused or contributed to by the negligent or unlawful act or omission of compensated Partner, its employees, officers, agents or contractors.

15.2. No Partner shall be liable to another Partner for any special indirect or consequential loss or damages arising under this Agreement.

16. TERMINATION

16.1. Without prejudice to its other rights and remedies under this Agreement, including without limitation under clause 6.6, and those rights and remedies otherwise available in equity or at law, a Partner (the Terminating Partner) may terminate this Agreement at any time by giving the other Partners 30 days' written notice, or such longer period as specified in the notice.

16.2. The Terminating Partner's termination of the Agreement does not terminate the Agreement for the remaining Partners. To avoid doubt, the Agreement in its entirety will remain operative for the remaining Partners and the terms of the Agreement survive termination in relation to any information that has already been shared by the Terminating Partner.

17. VARIATION

This Agreement may only be varied with the written consent of all Partners.

18. GENERAL

18.1. A Partner must not assign its rights under this Agreement.

18.2. Nothing in this Agreement creates a partnership, joint venture, agency or employment relationship between the Partners. A Partner has no authority to incur

any obligation or make any representation on behalf of another Partner

18.3. This Agreement is governed by the law in force in Victoria. Each Partner submits to the non-exclusive jurisdiction of the courts of Victoria.

18.4. This Agreement constitutes the entire agreement of the Partners about its subject matter and supersedes all previous agreements, understandings and negotiations on that subject matter.

EXECUTION

Executed as an agreement.

Signed for and on behalf of **Bayside Health** (**Alfred Care Group)** by its duly authorised officer:

.....	.....
Name	Signature
.....	.....
Position	Date

Signed for and on behalf of the **Baker Heart and Diabetes Institute** by its duly authorised officer:

.....	.....
Name	Signature
.....	.....
Position	Date

Signed for and on behalf of **Cabrini Health** by its duly authorised officer:

.....	.....
Name	Signature
.....	.....
Position	Date

Signed for and on behalf of the **Eastern Health** by its duly authorised officer:

.....	.....
Name	Signature
.....	.....
Position	Date

Signed for and on behalf of the **Hudson Institute for Medical Research** by its duly authorised officer:

.....	.....
Name	Signature
.....	.....
Position	Date

Signed for and on behalf of **Monash Health** by its duly authorised officer:

.....	.....
Name	Signature
.....	.....
Position	Date

Signed for and on behalf of the **Monash University** by its duly authorised officer:

.....	.....
Name	Signature
.....	.....
Position	Date

Signed for and on behalf of **Bayside Health (Peninsula Care Group)** by its duly authorised officer:

.....	.....
Name	Signature
.....	.....
Position	Date

Signed for and on behalf of the **The Macfarlane Burnet Institute of Medical Research and Public Health** by its duly authorised officer:

.....	.....
Name	Signature
.....	.....
Position	Date

SCHEDULE 1 – PARTICULARS

Item 1	Parties	Details
		BAYSIDE HEALTH (ALFRED CARE GROUP) ABN 27 318 956 319, a body corporate established under the *Health Services Act 1988* (Vic) of 55 Commercial Road, Melbourne, Victoria 3004 **('Alfred Health')**
		BAKER HEART AND DIABETES INSTITUTE ABN 98 131 762 948, of 75 Commercial Road, Melbourne, Victoria 3004 **('Baker')**
		CABRINI HEALTH LIMITED ABN 33 370 684 005, ACN 108 515 073, of 183 Wattletree Road, Malvern Victoria 3144 **('Cabrini')**
		EASTERN HEALTH ABN 68 223 819 017, of 5 Arnold Street, Box Hill Victoria 3128 **('Eastern')**
		HUDSON INSTITUTE OF MEDICAL RESEARCH ABN 48 132 025 024, of27-31 Wright Street, Clayton VIC 3168 **('Hudson')**
		MONASH HEALTH ABN 82 142 080 338, a body incorporated pursuant to the Health Services Act 1988 (Vic) of 246 Clayton Road, Clayton VIC 3168 **('Monash Health')**
		MONASH UNIVERSITY ABN 12 337 614 012, a body incorporated under the Monash University Act 1958 (Vic) of Wellington Road, Clayton, Victoria 3800 **('Monash')**
		BAYSIDE HEALTH (PENINSULA CARE GROUP) ABN 52 892 860 159, of2 Hastings Rd, Frankston Victoria 3199 **('Peninsula')**
		THE MACFARLANE BURNET INSTITUTE FOR MEDICAL RESEARCH AND PUBLIC HEALTH LIMITED ACN 007 349 984, of 89 Commercial Road, Melbourne, Victoria 3004 **('Burnet')**

Item 2 Commencement Date:

This Agreement is made on the day of 20

Item 3: Partners' Key Contact Personnel

Contract Manager for this Agreement

The contract manager is responsible for contract changes, close-out, extension and renewal. They also communicate contractual changes to all stakeholders. The Contract Manager is expected to resolve any contract-related issues that come up, whether internally or externally. This responsibility may be combined with the Organisation Data Custodian role or their delegate.

The Data Steward

The Data Steward (or designated person) will support the adoption and dissemination of the Agreement and accompanying Principles within the Monash Partners (MP) Organisation. They will be responsible for monitoring and reviewing compliance with these Principles within their organisation and dealing with any concerns or complaints received. The Data Steward will escalate any related material risks or issues to the Data Custodian (Organisation) for review. (Schedule 2 Sections 5.2 and 7.1)

Organisation Data Custodian

The Organisation Data Custodian is responsible for data storage and disposal, and their organisation's compliance with relevant legislation and policies, administration, quality assurance and data access (this may be the Health Information Services Manager, Ethics and Governance Manager, Data Governance Officer or Legal officer that acts as the Organisation's Data Custodian. (Schedule 2

A statement of the principles and assurances to govern the activity of information sharing for healthcare improvement

Principles for the Sharing of Health Data across Monash Partners Health Translation Network

FOREWORD

Established in 2011 and accredited by the National Health and Medical Research Council (NHMRC) in 2015 as an Advanced Health Research Translation Centre, Monash Partners is a collaboration between leading health service, research and teaching organisations.

Monash Partners Strategic Plan highlights Data-Driven Healthcare Improvement (DDHCI) as a fundamental priority. Monash Partners (MP) wishes to develop a Data Sharing Agreement and Principles (throughout this document referred to as 'Data Sharing Agreement', or 'Agreement'; 'Data Sharing Principles' or 'Principles'; 'Data Sharing Agreement and accompanying Principles' or 'Agreement and Principles') to guide the activity of information sharing for healthcare improvement across our Partner organisations. Access to data, for health care improvement and research, provides our greatest opportunity to unlock the value in this data and benefit the public through improvements in clinical care, prevention, screening and treatment.

The Data Sharing Agreement and Principles are intended to augment existing ethics and grant review practices as well as internal custodian processes. They provide a consistent, thorough and informed approach to decisions about the sharing of data. They do not dictate a particular process that must be followed, nor restrict an organisation from using its own data policies. The Principles acknowledge that data usage is made in the context of a partner's core business requirements, which include support of research.

The Agreement and Principles support the streamlining of efficient data access and sharing across our partner organisations, and align with the National Health and Medical Research Council (NHMRC), 'Principles for accessing and using publicly funded data for health research'[1].

Monash Partners members hold many publicly funded data sets, including registries, administrative databases, clinical datasets and survey data. The Agreement and Principles will guide staff when requesting access to datasets held by other Monash Partners member organisations. Health and medical information enables health service executives, clinicians, purchasers and policy makers to make informed decisions that improve health care at both the individual and population level. Typically, questions central to improving health outcomes and guiding policy decisions can only be answered by obtaining data from large, heterogeneous populations.

Advanced digital technologies that streamline data collection, management and analysis of large datasets are needed to generate this type of 'real-world' evidence in an efficient manner. The MP Agreement and accompanying Principles supply a framework that facilitates this, while ensuring appropriate safeguards are in place to protect the rights of data subjects.

The aim is to establish a data sharing relationship to facilitate safe, lawful and appropriate sharing of health data across the MP organisations. With agreed data handling solutions in place, the delay and frustration of having to reinvent a data extraction, encryption, storage and access solution for each individual project can be circumvented.

The Agreement and Principles clarify the laws and regulations that all MP Organisations must comply with when managing the sharing of health-related data.
Issues relating to intellectual property and commercialisation opportunities resulting from any research activities are to be managed through the relevant Organisation's policies and procedures.

[1] National Health and Medical Research Council 2016, *Principles for accessing and using publicly funded data for health research*, Commonwealth of Australia, Accessed 24 August 2020, <https://www.nhmrc.gov.au/about-us/publications/principles-accessing-and-using-publicly-funded-data-health-research>

ACKNOWLEDGMENTS

We wish to acknowledge that this document was initially developed by Sydney Health Partners and has been adapted to meet the needs of Monash Partners.

Our thanks and appreciation are extended to all those below who generously gave their time and shared their insights to shape the development of the Data Sharing

Agreement and Principles.
The Data Sharing Agreement and Principles have been informed by the Australian Health Research Alliance (AHRA) data committee and the Sydney Health Partners
Data Accord upon which this document is based.

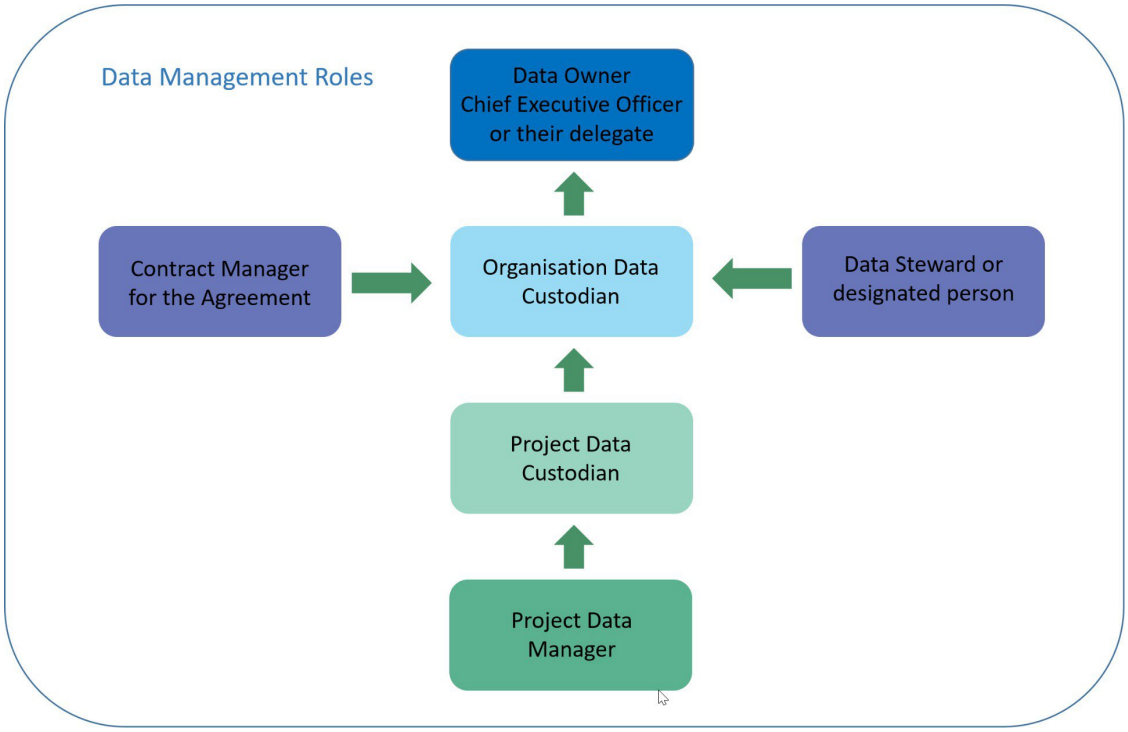
GLOSSARY/DEFINITIONS

Contract Manager for this Agreement	The contract manager is responsible for contract changes, close-out, extension and renewal. They also communicate contractual changes to all stakeholders. The Contract Manager is expected to resolve any contract-related issues that come up, whether internally or externally. This responsibility may be combined with the Organisation Data Custodian role or their delegate.
Data Steward or designated person	The Data Steward (or designated person) will support the adoption and dissemination of the Agreement and accompanying Principles within the MP Organisation. They will be responsible for monitoring and reviewing compliance with these Principles within their organisation and dealing with any concerns or complaints received. The Data Steward will escalate any related material risks or issues to the Organisation Data Custodian for review (Schedule 2 Sections 5.2 and 7.1)
Organisation Data Custodian	The Organisation Data Custodian is responsible for data storage and disposal, and their organisation's compliance with relevant legislation and policies, administration, quality assurance and data access (this may be the Health Information Services Manager, Ethics and Governance Manager, Data Governance Officer or Legal officer that acts as the Organisation's Data Custodian. (Schedule 2 Section 5.2)).
eMR	Electronic Medical Record
HREC	Human Research Ethics Committee
MP	Monash Partners
MP Organisation	Monash Partners Organisation*. (A formally affiliated organisation of Monash Partners.)
Project Data custodian	The Project Data Custodian of the newly created combined data set is the Chief/ Principle Investigator listed on the data sharing project. The Project Data Custodian has responsibility for correct data storage, access and disposal (section 7) for the project. They report any issues to the Data Custodian (Organisational).
Project Data Manager	Each Monash Partners (MP) Organisation contributing data to a project should have its own Data Manager appointed (and communicated to other partners) to oversee the sharing of data for that project. The Project Data Manager (who is not the Data Custodian) is the nominated employee of the MP Organisation that will facilitate the disclosure of the data. The Project Data Manager will be involved in coordinating the validation, cleaning and de-identification of data prior to transfer out of the MP Organisation. (Section 6.6). They report any issues related to the project and compliance with the Agreement and Principles to the Project Data Custodian

*The Monash Partners Organisations include: Bayside Health (Alfred Care Group), Monash Health, Monash University, Bayside Health (Peninsula Care Group), Eastern Health, Cabrini Health, Burnet Institute, Hudson Institute and Baker Heart and Diabetes Institute. Our associate partners include: La Trobe University, Latrobe Regional Hospital and Outcome Health.

The following diagram (Figure 1) provides a concept of work flows and how each of these roles relate to each other.

Figure 1: Data Management Roles



De-Identifiable data

Personal information is de-identified if the information is no longer about an identifiable individual or an individual who is reasonably identifiable.

De-identification is a process that renders personal information into a form that is not identifiable. As a consequence, it is lawful for it to be shared or disseminated, or put to uses, which may otherwise not be permitted.

De-identification involves two steps. The first is the removal of direct identifiers. The second is taking one or both of the following additional steps:

- the removal or alteration of other information that could potentially be used to re-identify an individual, and/or
- the use of controls and safeguards in the data access environment to prevent re-identification.

If you are not clear whether data has been de-identified, set up processes for the

research project that comply with the Identifiable or Re-Identifiable data pathways (pathways 2 and 3).

Data Sharing Application

Pathway 1: Governance approvals for sharing of De-identified Data Project

Information:

1. Title of the project

2. Confirm that the research is to be carried out using **De-identified** information
   ☐ Yes ☐ No

3. If NO then change to the "Identifiable or Re-Identifiable Data" pathway instructions (Pathways 2 (with consent) or 3 (without consent)).

4. Provide the name of (all) organisation(s) proposing to collect, use or disclose health information (must involve 2 or more Monash Partners Organisations)

   ☐ Bayside Health (Alfred Care Group)
   ☐ Baker Heart and Diabetes Institute
   ☐ Burnet Institute
   ☐ Cabrini Health
   ☐ Eastern Health
   ☐ Hudson Institute
   ☐ Monash Health
   ☐ Monash University
   ☐ Bayside Health (Peninsula Care Group)
   ☐ Other Organisations

5. Confirm that this document will be lodged at each participating organisation
   ☐ Yes ☐ No
   Comments

6. Has a Human Research and Ethics Application (HREA) been completed?
   ☐ Yes ☐ No
   If yes, complete these details. If no, continue to next question

   Supply Human Research and Ethics Committee (HREC) reference number

   HREC Application Title

   Principal Investigator's Name

7. Has a Victorian Specific Module (VSM) Application been completed?
   ☐ Yes ☐ No
   If yes, complete these details. If no, continue to next question

Supply the VSM reference number

VSM Application Title

Principal Investigator's Name

8. Has a Victorian Site Specific Assessment (SSA) Application been completed?
   ☐ Yes ☐ No
   If yes, complete these details. If no, continue to next question

   Supply the SSA reference number

   SSA Application Title

   Principal Investigator's Name

9. Provide the Names and scientific or other credentials of those involved in conducting the study

10. Provide the name/s of people that you believe should review this governance approval request (if known)

11. What are the aims and purposes of the project?

De-identification Processes

12. Is the data to be De-identified or Anonymised?
    (*De-identification* is the removal of identifying information from a dataset, and this data could potentially be re-identified e.g. if the identifying information is kept (as a key) and recombined with the de-identified dataset.

    Anonymisation is the permanent removal of identifying information, with no retention of the identifying information separately.)
    De-identified ☐ Anonymised ☐
    Comment if relevant

13. Describe the De-identification/Encryption/ Anonymisation process

14. Describe how/where the encryption key will be stored
    ☐ Encryption key ☐ No Encryption key
    Description

15. List who has access to the encryption key (e.g. Project Data Manager. Include role or name, if known)

Data Selection and Access

16. Which Information system(s) from within the MP Organisations will be accessed to provide the data? eg eMR, eMaternity, Auslab etc.

17. Which AI tools used for data extraction, validation or linkage?

……

18. Has written authority to securely share data from MP Organisations been obtained? (This may be the Health Information Services Manager, Ethics and Governance Manager or legal officer that acts as the Organisation's Data Governance Officer)
    ☐ Yes ☐ No
    Comments

    If Yes – Attach PDF of all authorities to this submission

19. What data items are sought? (e.g. birth date, treatment, medical condition etc)

20. What is the approximate number of medical records involved?

21. Specify over which time period the data sources are being accessed. (E.g. 5 years, from January 2015 to December 2020)

Data Extraction and Handling

22. What is the frequency of extraction? Will there be a single extract, or multiple extracts (e.g. daily, weekly, monthly)

23. Who will perform the data extraction? (e.g. an employee of the MP Organisation or a third-party contractor?)
    ☐ Employee ☐ Third Party Contractor ☐ Other
    Details

24. If a third-party contractor is involved, has a contract been signed between the contractor organisation extracting the data and the funding organisation?
    ☐ Yes ☐ No ☐ No third party contractor involved

    If a third party contractor is involved, and the answer is 'No' here - Contact Human Resources for guidance for the processes at your specific organisation.

25. Has a Project Data Manager been appointed for each MP Organisation contributing data? (The Project Data Manager should be an employee of the source MP Organisation and a member of the research team.)
    ☐ Yes ☐ No
    Provide details if yes or explanation if no

26. Are there any processes to evaluate the *quality* of the data extracted?
    ☐ Yes ☐ No
    Comments

Data Storage and Security

27. Describe the Data Storage Facility of extracted data

OR

☐ Unknown

Disclosure and secure transfer of data

28. Describe how data will be securely transferred (E.g. Accellion Secure File Transfer, CloudStor)

29. Who will perform the data transfer/s (either name or role/ position)?

30. Does your project need to comply with the specific guidelines for the release of Aboriginal health information?

☐ Yes ☐ No

Provide details

31. Does the project involve data exchange based on Australia's Health Infromation Exchange principles? If yes, please provide details of the HIE standards and security protocols applied.

Storage and access to data for data analysis

32. Describe the Data Storage Facility of extracted data after disclosure and transfer from the source MP Organisation(s)

☐ Known ☐ Unknown

Details

33. Describe the Governance structure of the newly formed data set:

(For Example: Who owns the data? (E.g. the MP Organisations providing data. Who is the data custodian? (E.g. responsible for data storage, access and disposal – e.g. Chief Investigator of data sharing project.)

☐ Known ☐ Unknown

Details

34. What hardware/software will be used to analyse the data and where is it located?

☐ Known ☐ Unknown

Details

Publication and Report Requirements

35. Do all organisations agree that new information arising from the combined dataset will be reported back to the contributing MP Organisations prior to publication/dissemination of any findings?

☐ Yes ☐ No ☐ Unknown

36. Do all organisations confirm that the names of the MP Organisations providing data will be acknowledged in any publication or report that arises from the use of that data?

☐ Yes ☐ No ☐ Unknown

Data Retention and Destruction schedule

37. Specify the agreed time-period for retaining the data and the data disposal plan.

☐ Known ☐ Unknown

Details

Statement of truth

I confirm that all information provided is to the best of my knowledge, accurate.

By typing your name here, you hereby indicate your agreement with this statement.

SCHEDULE 4 – IDENTIFIABLE OR RE-IDENTIFIABLE DATA REQUIREMENTS

Data Sharing Application

Pathway 2: *Governance approvals for sharing of* ***Identifiable or Re-Identifiable data – With consent***

Foreword

Completing this Application will provide the information that needs to be considered in order to achieve the goal of safe and effective data sharing across Monash Partners Organisations.

The ultimate purpose is to reduce the time taken for approvals and reduce risk for the disclosing Organisation and those involved with data sharing projects/ activities.

This application should be completed with reference to the **Monash Partners Data Sharing Agreement and Principles for the Sharing of Health Data across Monash Partners Health Translation Network**. The Agreement and Principles covers requirements for:

Studies where personal health information is extracted from health data sources within MP Organisations (including data linkage activities).

It is recognised that projects wishing to use health data shared across MP (Monash Partners) Organisations faces similar challenges and requires similar safety and technical processes to be developed.

Inevitably, the components and team structures of data sharing projects vary and they need to satisfy the Human Research Ethics Committee (HREC) and Site-Specific Assessment (SSA) (Governance) requirements of the individual MP Organisations that are involved.

In order to make this document as useful as possible, it has been structured to follow the path of the data as it is selected, accessed, extracted, stored, transferred and analysed.

The Data Sharing Application is divided into nine sections:

1. Project Information
2. De-identification or Consent related information
3. Data selection and Access
4. Data extraction and handling
5. Data storage and security
6. Disclosure and secure transfer of data

7. Storage and access to data for data analysis
8. Publication and report requirements
9. Data retention and destruction schedule.

As projects start to anticipate these operational requirements and develop a consistency in method, confidence in the safety of such data sharing projects will rise. Ethical and Governance approvals will be easier to obtain. This in turn will facilitate approvals for future projects and health improvements across MP.

Process

Both Ethics and Governance approvals are required for disclosure of Identifiable or Re-Identifiable patient information.

Where a Human Research and Ethics Application, Victorian Specific Module and/ or a Site-Specific Assessment *has* been completed –any questions/answers already provided in those applications will not be duplicated here. (A skip logic will be utilised in electronic processes for completion of the application).

Complete this form when the **Identifiable or Re-Identifiable data has patient consent** for the data sharing proposed. Submit this form to the Human Research Ethics committee, Health Information Service or Business Analyst Unit (as per specific organisation requirements).

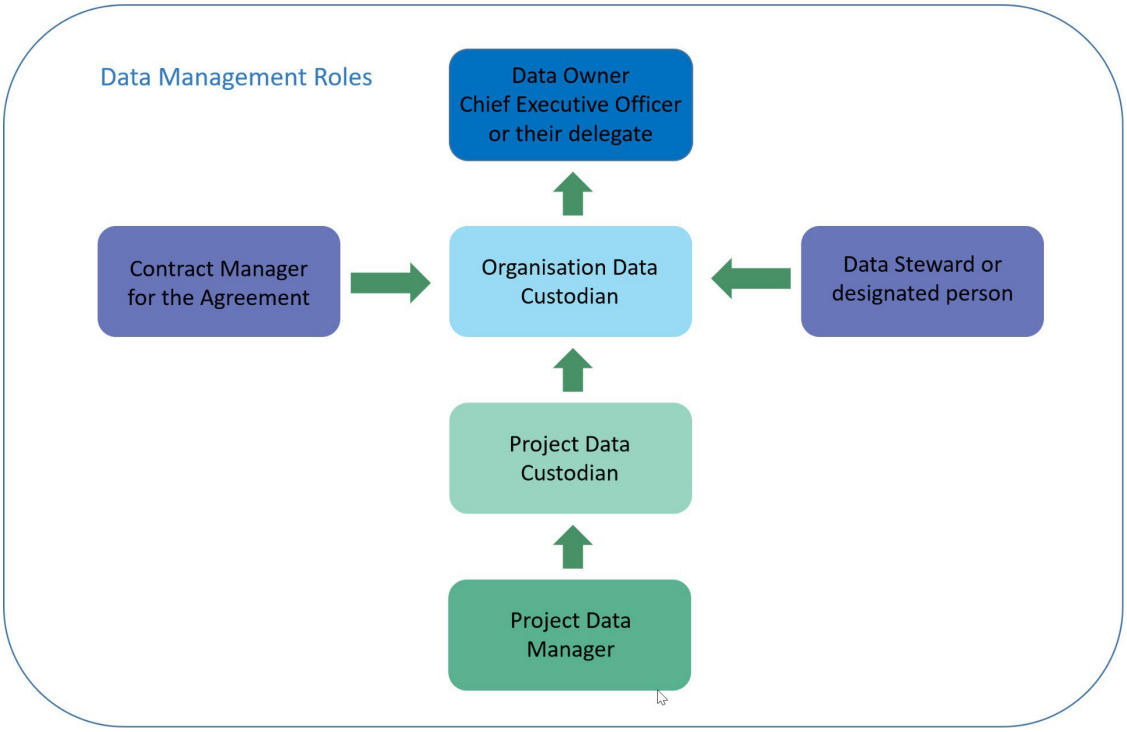
GLOSSARY/DEFINITIONS

Contract Manager for this Agreement	The contract manager is responsible for contract changes, close-out, extension and renewal. They also communicate contractual changes to all stakeholders. The Contract Manager is expected to resolve any contract-related issues that come up, whether internally or externally. This responsibility may be combined with the Organisation Data Custodian role or their delegate.
Data Steward or designated person	The Data Steward (or designated person) will support the adoption and dissemination of the Agreement and accompanying Principles within the MP Organisation. They will be responsible for monitoring and reviewing compliance with these Principles within their organisation and dealing with any concerns or complaints received. The Data Steward will escalate any related material risks or issues to the Organisation Data Custodian for review (Schedule 2 Sections 5.2 and 7.1)
Organisation Data Custodian	The Organisation Data Custodian is responsible for data storage and disposal, and their organisation's compliance with relevant legislation and policies, administration, quality assurance and data access (this may be the Health Information Services Manager, Ethics and Governance Manager, Data Governance Officer or Legal officer that acts as the Organisation's Data Custodian. (Schedule 2 Section 5.2)).
eMR	electronic Medical Record
HREC	Human Research Ethics Committee
MP	Monash Partners
MP Organisation	Monash Partners Organisation*. (A formally affiliated organisation of Monash Partners.)
Project Data Custodian	The Project Data Custodian of the newly created combined data set is the Chief/ Principle Investigator listed on the data sharing project. The Project Data Custodian has responsibility for correct data storage, access and disposal (section 7) for the project. They report any issues to the Organisation Data Custodian.
Project Data Manager	Each Monash Partners (MP) Organisation contributing data to a project should have its own Data Manager appointed (and communicated to other partners) to oversee the sharing of data for that project. The Project Data Manager (who is not the Data Custodian) is the nominated employee of the MP Organisation that will facilitate the disclosure of the data. The Project Data Manager will be involved in coordinating the validation, cleaning and de-identification of data prior to transfer out of the MP Organisation. (Section 6.6). They report any issues related to the project and compliance with the Agreement and Principles to the Project Data Custodian

*The Monash Partners Organisations include: Bayside Health (Alfred Care Group), Monash Health, Monash University, Bayside Health (Peninsula Care Group), Eastern Health, Cabrini Health, Burnet Institute, Hudson Institute and Baker Heart and Diabetes Institute. Our associate partners include: La Trobe University, Latrobe Regional Hospital and Outcome Health.

The following diagram (Figure 1) provides a concept of work flows and how each of these roles relate to each other.

Figure 1: Data Management Roles



Pathway 2: Governance approvals for sharing of Identifiable or Re-Identifiable data – With consent

If data will not be de-identified, then the sharing of data must comply with the legislative obligations, policies and protocols of the MP Organisation that owns the data.

The risk of harm to an individual whose health information is to be collected, used or disclosed in the proposed research or the compilation or analysis of statistics, should be considered

Definition In practise

Sharing Identifiable or Re-Identifiable data **with consent** must be done in a manner that is compliant with privacy regulations. Data must not be used for any other purpose other than that for which the consent was provided. There are situations where there are acceptable exceptions to this requirement. Utilise Pathway 3 if sharing of Identifiable Re-Identifiable data without consent is proposed.

Explanation

Health information is often particularly sensitive; therefore, consumers need to be confident that their information will be handled appropriately and confidentially. This makes it critical that at the time of collecting information, the consumer is provided with information about their privacy. The consumer privacy information brochure "Your Information, It's Private" has been developed to assist in this process[5].

MP Organisations will be clear and open with patients about how their information will be used. Where required, a patient should be told the identity of the MP Organisation/s collecting and recording the data, the reasons or purposes for doing so (including any statistical or analytical purposes), and any extra information that a patient needs in the circumstances to ensure that their information is being processed fairly. This information is usually provided through each MP Organisation's privacy leaflet.

Data Sharing Application

Pathway 2: Governance approvals for sharing of Identifiable or Re-Identifiable data – With consent

Project and Consent-related Information:

1. Title of the project

2. Confirm that the research is to be carried out using **Identifiable or Re-Identifiable information with consent**

   ☐ Yes ☐ No

3. **If NO then change to the 'De-Identifiable Data' - Pathway 1 OR 'Identifiable or Re-Identifiable Data without consent' – Pathway 3**

4. Provide the name of (all) organisation(s) proposing to collect, use or disclose health information (must involve two or more Monash Partners Organisations)

   ☐ Bayside Health (Alfred Care Group
   ☐ Baker Heart and Diabetes Institute
   ☐ Burnet Institute
   ☐ Cabrini Health
   ☐ Eastern Health
   ☐ Hudson Institute
   ☐ Monash Health
   ☐ Monash University
   ☐ Bayside Health (Peninsula Care Group)
   ☐ Other Organisations

5. Confirm that this document will be lodged at each participating organisation

   ☐ Yes ☐ No

   Comments

6. Has a Human Research and Ethics Application (HREA) been completed?

   ☐ Yes ☐ No

   If yes, complete these details. If no, continue to next question

   Supply Human Research and Ethics Committee (HREC) reference number

   HREA Application Title

   Principal Investigator's Name

7. Has a Victorian-Specific Module (VSM) Application been completed?
   ☐ Yes ☐ No
   If yes, complete these details. If no, continue to next question

   Supply the VSM reference number

   VSM Application Title

   Principal Investigator's Name

8. Has a Victorian Site-Specific Assessment (SSA) Application been completed?
   ☐ Yes ☐ No
   If yes, complete these details. If no, continue to next question

   Supply the SSA reference number

   SSA Application Title

   Principal Investigator's Name

   Questions hereafter will only require an anwer if not already included in the applications completed as per the details provided in Q 6,7 and/ or 8. (A skip logic will be utilised in the electronic form).

9. Provide the Names and scientific or other credentials of those involved in conducting the study

10. Provide the name/s of people that you believe should review this governance approval request (if known)

11. What are the aims and purposes of the project?

12. Does the study involve contact with participants?
    ☐ Yes ☐ No

13. Provide details for procedures or controls that will be applied to ensure participants are treated with integrity and sensitivity, including whether questions to be asked or procedures to be employed are intrusive

Data Selection and Access

14. Which Information system(s) from within the MP Organisations will be accessed to provide the data? eg eMR, eMaternity, Auslab etc.

15. Has written authority to securely share data from any MP Organisations been obtained (This may be the Health Information Services Manager, Ethics and Governance Manager or legal officer that acts as the Organisation's Data Governance Officer)
    ☐ Yes ☐ No
    Comments

    If Yes – Attach PDF of all authorities to this submission

16. What data items are sought? (e.g. birth date, treatment, medical condition etc)

17. What is the approximate number of medical records involved?

18. Specify over which time period the data sources are being accessed. (E.g. 5 years, from January 2015 to December 2020)

19. Will access to health information be restricted to appropriate personnel involved in conducting the proposed study?
    ☐ Yes ☐ No
    Provide details:
20. Will the project leverage Health Information Exchange principles for data interoperability? If yes, specify the standards and safeguards applied.

Data Extraction and Handling

21. What is the frequency of extraction? Will there be a single extract, or multiple extracts (e.g. daily, weekly, monthly)

22. Who will perform the data extraction? (e.g. an employee of the MP Organisation or a third-party contractor?)
    ☐ Employee ☐ Third Party Contractor ☐ Other
    Details

23. If a third-party contractor is involved, has a contract been signed between the contractor organisation extracting the data and the funding organisation?
    ☐ Yes ☐ No ☐ No third party contractor involved

    If a third party contractor is involved, and the answer is "No" here - Contact Human Resources for guidance for the processes at your specific organisation.

24. Has a Project Data Manager been appointed for each MP Organisation contributing data? (The Project Data Manager should be an employee of the source MP Organisation and a member of the research team.)

☐ Yes ☐ No

Provide details if yes or explanation if no

25. Are there any processes to evaluate the *quality* of the data extracted?

☐ Yes ☐ No

Comments

Data Storage and Security

26. Describe the Data Storage Facility of extracted data

Disclosure and secure transfer of data

27. Describe how data will be securely transferred (E.g. Accellion Secure File Transfer, CloudStor)

28. Who will perform the data transfer/s (either name or role/ position)?

29. Does your project need to comply with the specific guidelines for the release of Aboriginal health information?

☐ Yes ☐ No

Provide details

Storage and access to data for data analysis

30. Describe the Data Storage Facility of extracted data after disclosure and transfer from the source MP Organisation(s)

☐ Known ☐ Unknown

Details

31. Describe the Governance structure of the newly formed data set:

    (For Example: Who owns the data? (E.g. Chief Executive/s of the MP Organisations providing data.
    Who is the data custodian? (E.g. responsible for data storage, access and disposal – e.g. Chief Investigator of data sharing project.)
    ☐ Known ☐ Unknown
    Details

32. What hardware/software will be used to analyse the data and where is it located?
    ☐ Known ☐ Unknown
    Details

Publication and Report Requirements

33. Do all organisations agree that new information arising from the combined dataset will be reported back to the contributing MP Organisations prior to publication/dissemination of any findings?
    ☐ Yes ☐ No ☐ Unknown

34. Do all organisations confirm that the names of the MP Organisations providing data will be acknowledged in any publication or report that arises from the use of that data?
    ☐ Yes ☐ No ☐ Unknown

35. Procedures are in place to ensure the information will not be published in a form that identifies particular individuals or from which an individual's identity can be reasonably ascertained.
    ☐ Yes ☐ No

Data Retention and Destruction schedule

36. Specify the agreed time-period for retaining the data and the data disposal plan.
    ☐ Known ☐ Unknown
    Details

Statement of truth

I confirm that all information provided is to the best of my knowledge, accurate.

By typing your name here, you hereby indicate your agreement with this statement.

Pathway 3: *Governance approvals for sharing of* ***Identifiable or Re-Identifiable data – Without consent***

Foreword

Completing this Application will provide the information that needs to be considered in order to achieve the goal of safe and effective data sharing across Monash Partners Organisations.

The purpose is to reduce the time taken for approvals and reduce risk for the Organisation disclosing and those involved with data sharing projects/ activities.

The application form for sharing of Identifiable or Re-Identifiable data – *Without* consent is quite extensive, as compliance with the legislation is complex and therefore the risk of non-compliance with the legislation, and so for an organisation, is greater.

This application should be completed with reference to the **Monash Partners Data Sharing Agreement and Principles for the Sharing of Health Data across Monash Partners Health Translation Network**. The Agreement and Principles covers requirements for:

Studies where personal health information is extracted from health data sources within MP Organisations (including data linkage activities).

It is recognised that projects wishing to use health data shared across MP (Monash Partners) Organisations faces similar challenges and requires similar safety and technical processes to be developed.

Inevitably, the components and team structures of data sharing projects vary and they need to satisfy the Human Research Ethics Committee (HREC) and Site-Specific Assessment (SSA) (Governance) requirements of the individual MP Organisations that are involved.

In order to make this document as useful as possible, it has been structured to follow the path of the data as it is selected, accessed, extracted, stored, transferred and analysed.

The Data Sharing Application is divided into nine sections:

1. Project Information
2. De-identification or Consent related information
3. Data selection and Access
4. Data extraction and handling
5. Data storage and security
6. Disclosure and secure transfer of data
7. Storage and access to data for data analysis

8. Publication and report requirements

Data retention and destruction schedule. As projects start to anticipate these operational requirements and develop a consistency in method, confidence in the safety of such data sharing projects will rise. Ethical and Governance approvals will be easier to obtain. This in turn will facilitate approvals for future projects and health improvements across MP.

Process:

Both Ethics and Governance approvals are required for disclosure of Identifiable or Re-Identifiable patient information.

Where a Human Research and Ethics Application, Victorian-Specific Module and/ or a Site-Specific Assessment *has* been completed – any questions/answers already provided in those applications will not be duplicated here. (A skip logic will be utilised in electronic processes for completion of the application.)

Complete this form when the **Identifiable or Re-Identifiable data has not received patient consent for the data sharing proposed**. Submit this form to the Human Research Ethics committee, Health Information Service or Business Analyst Unit (as per specific organisation requirements).

GLOSSARY/DEFINITIONS

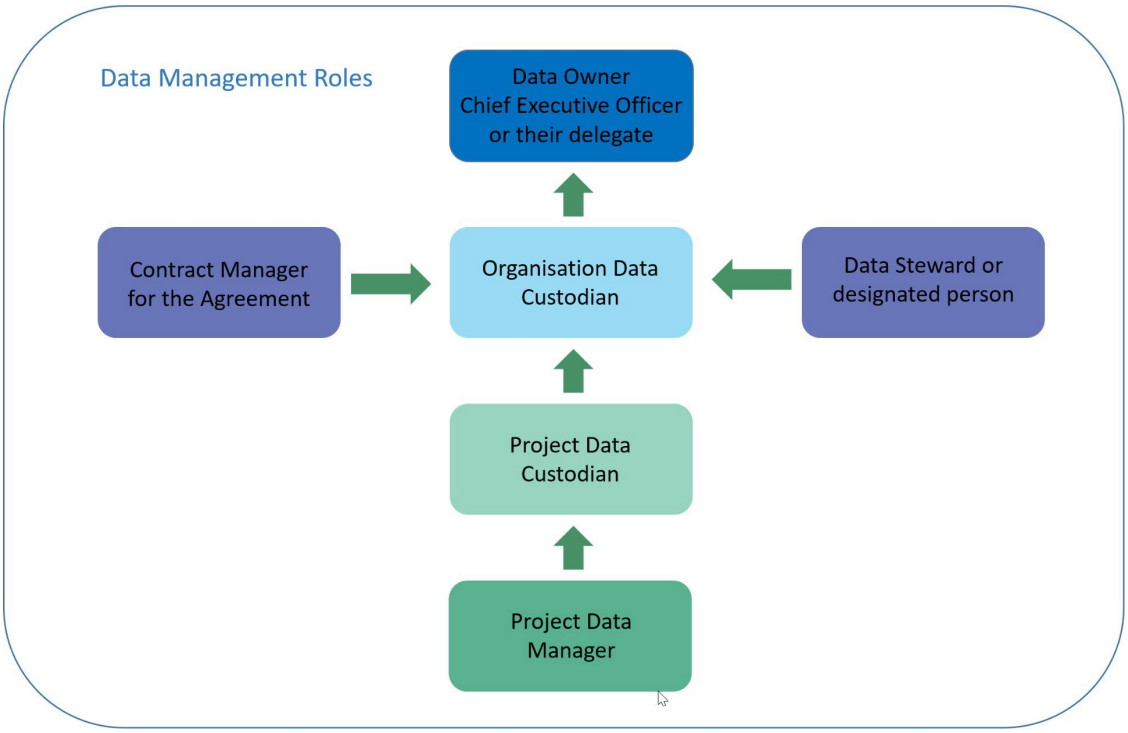
Contract Manager for this Agreement	The contract manager is responsible for contract changes, close-out, extension and renewal. They also communicate contractual changes to all stakeholders. The Contract Manager is expected to resolve any contract-related issues that come up, whether internally or externally. This responsibility may be combined with the Organisation Data Custodian role or their delegate.
Data Steward or designated person	The Data Steward (or designated person) will support the adoption and dissemination of the Agreement and accompanying Principles within the MP Organisation. They will be responsible for monitoring and reviewing compliance with these Principles within their organisation and dealing with any concerns or complaints received. The Data Steward will escalate any related material risks or issues to the Organisation Data Custodian for review (Schedule 2 Sections 5.2 and 7.1)
Organisation Data Custodian	The Organisation Data Custodian is responsible for data storage and disposal, and their organisation's compliance with relevant legislation and policies, administration, quality assurance and data access (this may be the Health Information Services Manager, Ethics and Governance Manager, Data Governance Officer or Legal officer that acts as the Organisation's Data Custodian. (Schedule 2 Section 5.2)).
eMR	Electronic Medical Record
HREC	Human Research Ethics Committee
MP	Monash Partners
MP Organisation	Monash Partners Organisation*. (A formally affiliated organisation of Monash Partners.)
Project Data custodian	The Project Data Custodian of the newly created combined data set is the Chief/ Principle Investigator listed on the data sharing project. The Project Data Custodian has responsibility for correct data storage, access and disposal (section 7) for the project. They report any issues to the Organisation Data Custodian.
Project Data Manager	Each Monash Partners (MP) Organisation contributing data to a project should have its own Data Manager appointed (and communicated to other partners) to oversee the sharing of data for that project. The Project Data Manager (who is not the Data Custodian) is the nominated employee of the MP Organisation that will facilitate the disclosure of the data. The Project Data Manager will be involved in coordinating the validation, cleaning and de-identification of data prior to transfer out of the MP Organisation. (Section 6.6). They report any issues related to the project and compliance with the Agreement and Principles to the Project Data Custodian

*The Monash Partners Organisations are: Bayside Health (Alfred Care Group), Cabrini Health, Eastern Health, Monash Health, Bayside Health (Peninsula Care Group), Monash University, Baker Heart and Diabetes Institute, Burnet Institute and Hudson Institute of Medical Research.

Affiliate members will be engaged as they join the partnership.

The following diagram (Figure 1) provides a concept of work flows and how each of these roles relate to each other.

Figure 1: Data Management Roles



Pathway 3: *Governance approvals for sharing of* ***Identifiable or Re-Identifiable data – Without consent***

Introduction

Sharing Identifiable or Re-Identifiable data **without consent** must be done in a manner that is compliant with privacy regulations. Data must not be used for any other purpose other than that that the consent was provided for **except in certain exceptions**.

A 'waiver of consent' is the term used when an exception to the requirement for consent is granted by an appropriate HREC. An application to HREC is required, in this situation.

Data Sharing Application

Pathway 3: Governance approvals for sharing of Identifiable or Re-Identifiable data – Without consent

The application form for sharing of Identifiable or Re-Identifiable data – *Without* consent is extensive, as compliance with the governing legislation is complex. You can save and return to the application at a later time.

Project and Consent-related Information:

1. Title of the project

2. Could the research be carried out using de-identified information?

☐ Yes ☐ No

If Yes then change to the 'De-Identifiable Data' – Pathway 1
If no, why not?

3. Could consent be obtained?

☐ Yes ☐ No

If Yes then change to the 'Identifiable or Re-Identifiable Data with consent' - Pathway 2

If No. Why not?

4. Provide the name of (all) organisation(s) proposing to collect, use or disclose health information (must involve 2 or more Monash Partners Organisations)

☐ Bayside Health (Alfred Care Group)
☐ Baker Heart and Diabetes Institute
☐ Burnet Institute
☐ Cabrini Health
☐ Eastern Health
☐ Hudson Institute
☐ Monash Health
☐ Monash University
☐ Bayside Health (Peninsula Care Group)

Other Organisations

5. Confirm that this document will be lodged at each participating organisation

☐ Yes ☐ No

Comments

6. Has a Human Research and Ethics Application (HREA) been completed?

☐ Yes ☐ No

If yes, complete these details. If no, continute to next question

Supply Human Research and Ethics Committee (HREC) reference number

HREA Application Title

Principal Investigator's Name

7. Has a Victorian Specific Module (VSM) Application been completed?

☐ Yes ☐ No

If yes, complete these details. If no, continue to next question

Supply the VSM reference number

VSM Application Title

Principal Investigator's Name

8. Has a Victorian Site Specific Assessment (SSA) Application been completed?

☐ Yes ☐ No

If yes, complete these details. If no, continue to next question

Supply the SSA reference number

SSA Application Title

Principal Investigator's Name

Questions hereafter will only require an answer if not already included in the applications completed as per the details provided in Q 6,7 and/ or 8. (A skip logic will be utilised in the electronic form).

9. Provide the Names and scientific or other credentials of those involved in conducting the study (Refer to Data Sharing Principles Section 5, 6.5 and 'Glossary and Definitions' at start of this application form)

10. Provide the name/s of people that you believe should review this governance approval request (if known)

11. What are the aims and purposes of the project?

12. Does the public interest in the research substantially outweigh the public interest in protecting privacy of the individual?

☐ Yes ☐ No ☐ Unsure

If NO then change to the 'De-Identifiable Data' – Pathway 1 OR "Identifiable or Re-Identifiable Data with consent" - Pathway 2

If yes or unsure -
The following section (Questions 13- 23) is to gain a better understanding of *why* the public interest outweighs the public interest in protecting privacy of the individual. At least one of these will need to be met in order for approval to be granted.

13. Will the the research or the compilation or analysis of statistics contribute to the **identification, prevention or treatment of illness, injury or disease**?

☐ Yes ☐ No
Comments

14. Will the the research or the compilation or analysis of statistics contribute to scientific understanding relating to health?

☐ Yes ☐ No
Comments

15. Will the the research or the compilation or analysis of statistics contribute to the **protection of the health of individuals and/or communities**?

☐ Yes ☐ No
Comments

16. Will the the research or the compilation or analysis of statistics contribute to any **likely benefits to individuals, to the category of persons to which they belong, or the wider community**?

☐ Yes ☐ No

Comments

17. Will the the research or the compilation or analysis of statistics contribute to the **improved delivery of health, disability or aged care services**?

☐ Yes ☐ No

Comments

18. Will the research or the compilation or analysis of statistics contribute to **enhanced scientific understanding or knowledge**?

☐ Yes ☐ No

Comments

19. Will the the research or the compilation or analysis of statistics contribute to **enhanced knowledge within the fields of social science and the humanities**?

☐ Yes ☐ No

Comments

20. Are there issues that might arise if the research or the compilation or analysis of statistics **was not** conducted in the manner proposed? (This may include cost to government, the public, the health care system, etc or 'Public Importance' of the research)

☐ Yes ☐ No

Comments

21. Specific consideration should be given to any likely benefits to individuals that belong to certain categories where the information may be of a particularly personal or sensitive nature. Please indicate if any of the following are included in this project

☐ (i) children and young people; or

☐ (ii) persons with intellectual or psychiatric disability; or

☐ (iii) persons highly dependent on medical care; or

☐ (iv) persons in dependent or unequal relationships; or

☐ (v) persons who are members of collectivities; or

☐ (vi) Aboriginal and Torres Strait Islander peoples; or

☐ (vii) persons whose information relates to their mental or sexual health;

Comments, if any:

22. Consideration is required, of any potential risk of harm to individuals if their identity is discovered. Please rate the liklihood and severity of consequences of harm (for example: Embarrassment/ humiliation; reduced likelihood of accessing health services; compromise of the individual's relationships; compromise of the individuals work or home life; compromise of insurance availability etc) for the following:

	Liklihood (High. Medium, Low)	Consequences
Physical harm		
Psychological harm		
Disclosure of sensititve personal information		
Exposure of illegal activity		
Economic harm		
Discrimination, stigma or other social harm		
Devaluation or harassment		
Familial distress		
Harm to any member of a vulnerable population		
Reputational harm		

23. Do you believe that the risk of harm to an individual whose health information is to be collected, used or disclosed in the proposed research or the compilation or analysis of statistics is minimal?

☐ Yes ☐ No

Comments

Data Selection and Access

24. Which Information system(s) from within the MP Organisations will be accessed to provide the data? eg eMR, eMaternity, Auslab etc.

25. Has written authority to securely share data from any MP Organisations been obtained? (This may be the Health Information Services Manager, Ethics and Governance Manager or legal officer that acts as the Organisation's Data Governance Officer)

☐ Yes ☐ No

Comments

If Yes – Attach PDF of all authorities to this submission

26. What data items are sought? (e.g. birth date, treatment, medical condition etc)

27. What is the approximate number of medical records involved (if appropriate)?

28. Specify over which time period the data sources are being accessed. (E.g. 5 years, from January 2015 to December 2020)

29. Will access to health information be restricted to appropriate personnel involved in conducting the proposed study?
☐ Yes ☐ No
Provide details:

Data Extraction and Handling

30. What is the frequency of extraction? Will there be a single extract, or multiple extracts (e.g. daily, weekly, monthly)

31. Who will perform the data extraction? (e.g. an employee of the MP Organisation or a third-party contractor?)
☐ Employee ☐ Third Party Contractor ☐ Other
Details

32. If a third-party contractor is involved, has a contract been signed between the contractor organisation extracting the data and the funding organisation? (Refer to Section 6.5 of Principles)
☐ Yes ☐ No ☐ No third party contractor involved

If a third party contractor is involved, and the answer is 'No' here – Contact Human Resources for guidance for the processes at your specific organisation.

33. Has a Project Data Manager been appointed for each MP Organisation contributing data? (The Project Data Manager should be an employee of the source MP Organisation and a member of the research team.) (Refer to Section 6.5 in Principles)

☐ Yes ☐ No

Provide details if yes or explanation if no

34. Are there any processes to evaluate the *quality* of the data extracted?

☐ Yes ☐ No

Comments

Data Storage and Security

35. Describe the Data Storage Facility of extracted data

Disclosure and secure transfer of data

36. Describe how data will be securely transferred (E.g. Accellion Secure File Transfer, CloudStor)

37. Who will perform the data transfer/s (either name or role/ position)?

38. Does your project need to comply with the specific guidelines for the release of Aboriginal health information? (Refer to Section 6.3 in the Principles)

☐ Yes ☐ No

Provide details

Storage and access to data for data analysis

39. Describe the Data Storage Facility of extracted data after disclosure and transfer from the source MP Organisation(s)

☐ Known ☐ Unknown

Details

40. Describe the Governance structure of the newly formed data set:

(For Example: Who owns the data? (E.g. the MP Organisations providing data.
Who is the data custodian? (E.g. responsible for data storage, access and disposal – e.g. Chief Investigator of data sharing project.)

☐ Known ☐ Unknown

Details

41. What hardware/software will be used to analyse the data and where is it located?

☐ Known ☐ Unknown

Details

Publication and Report Requirements

42. Do all organisations agree that new information arising from the combined dataset will be reported back to the contributing MP Organisations prior to publication/dissemination of any findings?

☐ Yes ☐ No ☐ Unknown

Details

43. Do all organisations confirm that the names of the MP Organisations providing data will be acknowledged in any publication or report that arises from the use of that data?

☐ Yes ☐ No ☐ Unknown

Details

44. Procedures are in place to ensure the information will not be published in a form that identifies particular individuals or from which an individual's identity can be reasonably ascertained.

☐ Yes ☐ No

Details

Data Retention and Destruction schedule

45. Specify the agreed time-period for retaining the data and the data disposal plan.

☐ Known ☐ Unknown

Details

Statement of truth

I confirm that all information provided is to the best of my knowledge, accurate.

By typing your name here, you hereby indicate your agreement with this statement.

SCHEDULE 5 – MONASH PARTNERS GOVERNANCE STRUCTURE

Introduction

Monash Partners is a partnership between leading health service, teaching and research organisations focused on innovating for better health. Our partners include: Bayside Health (Alfred Care Group), Monash Health, Monash University, Bayside Health (Peninsula Care Group), Eastern Health, Cabrini Health, Burnet Institute, Hudson Institute and Baker Heart and Diabetes Institute. Our associate partners are La Trobe University, Latrobe Regional Hospital and Outcome Health.

Monash Partners is one of seven NHMRC-accredited Advanced Health Research and Translation Centres whose aim it is to enable and support the translation of research and innovation into better health outcomes for the Australian community. Monash Partners is a member of the Australian Health Research Alliance with national reach and engagement.

Purpose and commitment

The purpose of Monash Partners is to connect researchers, clinicians and the community to innovate for better health for around three million Australians, and beyond.

Monash Partners is a health service led partnership committed to:

- Responsibility and accountability
- Transparency and communication
- Collaboration and inclusiveness
- Leadership
- Excellence in research, healthcare, education and translation
- Innovation from discovery to healthcare improvement
- Focus where need, benefit and strengths are greatest

Governance

The governance structure of Monash Partners is:

(a) Member Council- representative, providing strategic direction including approval of aims, objectives, and major projects of Monash Partners; and

(b) Executive- chaired by the Executive Director, comprising the leads of our clinical themes, enabling platforms and Partner representatives who have a leadership role in collaborating, implementing and monitoring the strategic plan with the Monash Partners team.