Title: DATA SHARING AND ACCESS PROCEDURE FOR THE RELEASE OF DATA FROM MCRI SPONSORED INVESTIGATOR-INITIATED CLINICAL TRIALS

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Document History

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CONTENTS

1. PURPOSE

The purpose of this Data Sharing and Access Procedure is to set out the process to be followed for the release of data from Murdoch Children's Research Institute (MCRI) sponsored Investigator-Initiated clinical trials (IITs) to individuals or research groups outside of MCRI (Data Requesters). The procedure has been established to ensure that a plan for sharing data is outlined and that data transfers are carefully considered and documented, and to enable MCRI to comply with its data access responsibilities and legal obligations.

2. RESPONSIBILITY AND SCOPE

The scope of the procedure is to define how MCRI sponsored clinical trials will share research datasets in order to ensure that MCRI:

- Protects the research team's right to conduct and publish from first analyses of the data
- Protects the rights of the individuals who contributed to the dataset
- Protects patient's rights and confidentiality
- Mitigate the risk of shared datasets being used to misrepresent MCRI sponsored research
- Ensures requests for datasets are appropriately documented, reviewed, and determined
- Meets the expectations or express obligations of funders to share data
- Provided procedures for MCRI personnel to prepare datasets for sharing
- Provided procedures for third parties (Data Requesters) to request datasets and for MCRI to review and decide whether to approve such dataset requests
- Conforms to the requirements of the Australian Code for the Responsible Conduct of Research 2018 (the Code)
- Complies with its obligations under applicable privacy laws in Australia and where relevant overseas (such as the EU General Data Protection Regulation (GDPR)).

This SOP is applicable to all datasets derived from clinical trials sponsored by the MCRI, including both single site and collaborative multi-centre IITs.

3. BACKGROUND

The purpose of this document is to outline the procedure for sharing data from clinical trials sponsored by the MCRI with approved Data Requesters, in order to facilitate the transfer of knowledge among researchers. The objective of data sharing is to maximise the value of a dataset by promoting further opportunities for research.

As the sponsor of clinical trials conducted by its investigators, one of MCRI's core responsibilities is to act as the Data Custodian. A data custodian is defined as the individual, organisation, or committee with responsibility for the relevant collection of data and ensuring access to any datasets are done so in a controlled and authorised manner.

MCRI fosters a culture of openness, inclusion, and scientific collaboration. The sharing of data helps to avoid unnecessary duplication of resources and establishes a long-term legacy and research resource for the community. Data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health.

MCRI endorses the sharing of final research data to serve these important scientific goals and supports the view around data sharing that publicly funded research data is a public good which should be made available with as few restrictions as possible.

The approach to scientific data sharing must be responsible and must recognise legal, regulatory, ethical, and commercial constraints.

The most recent update to the National Statement on Ethical Conduct in Human Research, 2007 (updated 2018), provides new requirements for the collection, use and management of data and information pertaining to research with human participants. This includes researchers sharing data generated by their research unless there is a valid reason for not doing so.

In the case of medical research, the data collected relates to individual patients participating in a research study. Therefore, consideration must be given to:

- Participants having provided informed consent to have their data shared
- The risk of participant re-identification from shared de-identified datasets
- The risk of data being mis-used or mis-represented.

Furthermore, Good Clinical Practice (GCP) states that researchers undertake data management planning for research studies including planning for the sharing or access to published data. 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. This applies to all research studies and involves sharing and communicating research methodology, data, and findings openly, responsibly, and accurately.

Planning for data sharing should be an integral part of any new study and requests for previously created datasets should always be assessed for feasibility of sharing when a request for access is made. This procedure is to ensure MCRI has in place processes to enable the appropriate sharing of MCRI data in a research culture which increasingly encourages access to publicly funded research data.

4. APPLICABILITY

This Data Sharing and Access Procedure applies to all staff involved in conducting investigator-initiated trials sponsored by the MCRI: Principal Investigator/Sponsor-Investigator/Project Leads, Sub-Investigator(s), research coordinators, data managers and other staff involved in research duties.

All Sponsor-Investigators/Project Leads are directly responsible for implementing the Data Sharing procedures set out in this SOP within their study teams, to ensure that data is shared appropriately outside of the institute and in accordance with the research study requirements including but not limited to ethical and other approvals, participant consent, MCRI policy and requirements, and the terms and conditions of any funding agreements, if applicable.

Each MCRI employee with a responsibility for reviewing access requests submitted by Data Requesters and/or preparing datasets for sharing, must adhere to this Data Sharing and Access Procedure.

5. RESPONSIBILITY

5.1. Melbourne Children's Trials Centre (MCTC) Position

The Melbourne Children's Trial Centre (MCTC) recognises that research data is a valuable resource and often irreplaceable. MCTC supports sharing/access to data where appropriate. Sharing of data may not always be appropriate and researchers should carefully consider the implications of research data sharing during the preparation of the research study documentation (i.e. protocol, consent forms, data management plan, data sharing plan) to ensure that the sharing of any research data complies with MCRI policy and requirements, legislation (including privacy requirements), good data principles, contractual agreements and all other applicable requirements.

Factors to be considered by the Research team when developing their data sharing plan:

- Research data are valuable resources 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, MCRI/MCTC policies and guidelines, applicable legislation, and privacy requirements
- Research data ownership and rights – only those who own and/or has rights to control/use/disclose the research data, can give permission to share it?

Advice should be obtained from MCTC on data sharing policies and procedures.

5.2. Responsibilities of the Sponsor-Investigator / Project Lead / Research Lead

5.2.1. Be Familiar with all Requirements

The Sponsor-Investigator/Project Lead and members of the research team 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
- Applicable privacy laws (which may include overseas legislation such as the GDPR if MCRI is receiving personal data from your project's participating sites based in Europe)
- The requirement for a Data Sharing statement to be included within your clinical trial registry entry (i.e. clinicaltrials.gov registry; see section 5.3 below)

5.2.2. Requirements for a Data Sharing Plan and Data Sharing Statement

5.2.2.1. Requirements for a Data Sharing Plan (DSP)

MCRI campus employees who are involved in Investigator Initiated Trials (IITs) sponsored by MCRI have responsibilities with regards to data sharing.

It is expected that research studies are designed and managed in a way that ensures data will be shared. This means that a Data Management Plan (DMP) and Data Sharing Plan (DSP) should be in place prior to the generation of any data, so that there is clear scope for wider research use. A clearly defined DSP also ensures significant long-term value for datasets. MCRI employees are responsible for sharing data from research activities in accordance with their DSP, as well as the terms and conditions of any applicable grants and contracts.

5.2.2.2. Requirements for a Data Sharing Statement

In addition to documenting a DSP, in relation to 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. Accordingly, they have introduced new requirements for data sharing. The following points are now required as conditions of consideration for publication:

- Manuscripts submitted must contain a Data Sharing Statement (refer to Appendix 1 for the Lancet's Data Sharing requirements and an example Data Sharing Statement as reference)
- Clinical trials must include a DSP in the trial's registration. If the data sharing plan changes after registration, this should be reflected in the statement submitted and published with the manuscript and updated in the registry record.

Data Sharing Statements should indicate the following:

- Whether individual de-identified participant data (including data dictionaries) will be shared, or whether only summary or aggregated data will be shared
- What data (variables) will be shared?

- Whether additional, related documents will be available (e.g. Study protocol, statistical analysis plan, consent forms, metadata etc.)
- When the data will become available and for how long?
- By what access criteria will the data be shared (including with whom, for what types of analysis)?

In determining if and what research data should be made available for access by others at the end of a research project, researchers must consider many factors including the value of the research data (for example, commercial value), ownership and data rights (i.e. whether MCRI 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 MCRI research, potential to patent, etc.). Some points to consider include:

- Is there adequate protection of participant privacy?
- Who owns and/or has rights to the research data?
- Do you have permission to release/provide access to the data?
- Are there any restrictions that prevent data from being shared or re-used?

6. PROCESS

In keeping with MCTC's involvement in clinical trials and oversight of sponsorship at MCRI, the MCRI Sponsorship Committee will be reviewing, by way of approving or rejecting, all data access requests submitted by Data Requesters falling within this SOP. Whilst the Sponsor-Investigator will be the initial point of contact for all initial requests to access research data, the Sponsorship Committee will ultimately oversee all requests for data access/transfers, and if applicable, define the circumstances under which the data will be shared.

6.1. Data Access Governance

Data Access Governance covers the procedures for:

1. Data Requesters to contact the Sponsor-Investigator/Project Lead to make an initial enquiry regarding access to the MCRI data for the Data Requester's project
2. Data Requester to complete a Data Access Application form
3. The MCRI Sponsorship Committee and Sponsor-Investigator/Project Lead to review and assess completed Data Access Application forms and either approve or reject dataset applications
4. If the request is approved, Sponsor-Investigator/Project Lead (or delegated staff) to prepare datasets for transfer (noting that transfer must not proceed before a Data Transfer Agreement is executed as described in section 6.2 below)
5. MCRI Sponsorship Committee log all applications for datasets and the outcome of their review.

6.1.1. Applying to Access Data

Where research data will be available for sharing, the Sponsor-Investigator/Project Lead must outline this in the study-specific DSP, prior to collecting/generating any data for the study.

Initial enquiries regarding access to data should be directed to the Sponsor-Investigator/Project Lead of the study, in which with the data was generated. Data Requesters must formally request access to datasets by submitting a Data Access Application Form to the Sponsor-Investigator/Project Lead of that study. The data access application form asks for information intended to help facilitate a review of the request. This information includes the research proposal, statistical analysis plan, ethical review status and funding status of the proposed research.

Received Data Access Application forms will be forwarded by the Sponsor-Investigator/Project Lead (or delegate) to the MCRI Sponsorship Committee for assessment and review.

6.1.2. Reviewing a Data Access Application

Each request received is reviewed by the MCRI Sponsorship Committee in collaboration with the Sponsor-Investigator/ Project Lead.

The request will be reviewed and either accepted or rejected based on the following criteria[1]

- The value of the research proposal to medical science and or patient care
- The ability of the proposed statistical analysis plan to meet the scientific objective of the research proposal
- Potential conflicts of interest that may impact on the research proposal and measures to manage these conflicts
- The qualifications and expertise of the research team to conduct the proposed research
- MCRI staff resources required to process the request
- Risk of participants being re-identified, or their privacy being breached
- Failure of the Data Requester to demonstrate data can be kept secure
- For Data Requesters who have successfully applied for other MCRI datasets: failure to abide by the conditions of the previous transfer
- Risk of datasets being used to misrepresent MCRI research or bring MCRI's scientific credibility into disrepute.

The MCRI Sponsorship Committee has an established internal review process for approving and/or rejecting research data requests. Refer to the Sponsorship Committee Charter for further information.

The role of the Sponsorship Committee and Sponsor-Investigator/Project Lead is to review the request against the assessment criteria outlined above and either approve or reject the request on that basis. If the Sponsor-Investigator is no longer employed at MCRI and a delegate has not been nominated, the decision to approve or reject a request for data is forfeited to the Sponsorship Committee, representing MCRI as the data custodian.

The Sponsorship Committee membership should have the joint expertise to assess the scientific merit, ethical acceptability, legal implications, and the feasibility of the request in providing the requested data. Members are expected to include:

- MCTC Director
- Legal Team Representative
- Experienced Clinical Triallist Representative
- Research Ethics and Governance Representative
- Grants Office Representative
- Finance Office Representative
- Other Committee members, as required, i.e. a Statistical representative

Outcomes of the review of each data request application will be recorded on the Data Request Review Form and a log of all requests, whether approved or denied will be maintained by the Sponsorship Committee.

[1] 1 Based on the Wellcome Trust criteria used for requests made to https://www.clinicalstudydatarequest.com

6.1.2.1. Logging a Data Request

All data requests must be logged into the Sponsorship Committee database by the Sponsorship Committee Secretariat. Research staff must notify the Sponsorship Committee Secretariat of all requests received: MCTC@mcri.edu.au

6.1.2.2. Timeline for Reviewing and Acknowledging a Data Access Application

All data access applications will be reviewed at the next scheduled monthly Sponsorship Committee from the date when the data request application was received.

Data Requesters who have submitted a Data Access Application will be notified of the outcome by the Sponsorship Committee within 10 working days from the meeting date. The acknowledgement should indicate the decision (approved/rejected), or whether additional information is required from the Data Requester before a decision can be made.

6.1.2.3. Incomplete Data Access Applications Forms

Incomplete Data Access Request forms should be returned to the Data Requester with an instruction to complete and resubmit the form. Timelines will be reset once a completed application has been received.

6.1.2.4. Informal Data Access Applications/Requests for Data

Informal data applications are any requests made using a media other than the standard data application form. Should these requests be received, the Data Requester must be informed to complete and submit a Data Access Application Form, as per Section 5.5.1 above.

6.1.2.5. Accepting a Data Access Application

If the Sponsorship Committee and Sponsor-Investigator/Project Lead approves an access request, the Data Requester must be notified in writing and a timeline provided for when and how the data will be made available.

The outcome of the data request must be logged to the Sponsorship Committee database. All approvals are subject to review. Where demand exceeds availability of staffing resources to make the data available, access will be prioritised by the Sponsorship Committee on scientific merit.

6.1.2.6. Rejecting a Data Access Application

If the Sponsorship Committee and Sponsor-Investigator/Project Lead rejects a data access application, the Data Requester must be notified in writing and be provided with an explanation/justification as to why the request was rejected.

6.1.2.7. Subsequent Data Requests Post Rejection

The Sponsorship Committee does not have an appeals process for rejected requests, however, based on any feedback provided by the Sponsorship Committee or Sponsor-Investigator/Project Lead, a Data Requester may amend their original data access request application and submit a new access request following rejection.

The same procedure outlined above will be followed when reviewing amended data access applications.

6.1.2.8. When a Consensus cannot be Reached

Should the Sponsorship Committee and Sponsor-Investigator/Project Lead not be able to reach a consensus regarding whether or not to approve or reject a Data Access application, the decision of the Sponsorship Committee would prevail.

6.2 Data Transfer Agreement (required for all Data Requesters)

The Data Transfer Agreement (DTA) is a binding legal agreement which must be executed by a Data Requester and MCRI prior to the transfer of data to the Data Requester. The DTA sets out the obligations of the Data Requester in relation to storage and use of the data. It describes the terms and conditions which must be agreed to prior to the release of data including obligations to:

(a) only use the data for the purposes of the project described in the data access application

(b) comply with all applicable laws in relation to the use and storage of the data

(c) keep the data secure and not to further distribute it without MCRI's prior permission

(d) to give the MCRI investigator the opportunity to contribute and potentially be named as author on publications if appropriate, and to acknowledge MCRI as the source of the data.

The DTA also provides that MCRI retains all ownership and Intellectual Property rights in the data and the Data Requester is granted a limited licence to use the data for their specific project. The recipient is required to inform MCRI of any new Intellectual Property Rights developed from use of the data, and the parties will then negotiate their respective ownership rights.

6.3. Fees

Costs of preparing, processing and transfer of data requests will be the responsibility of the requester. MCRI will charge for statistician and/or administration time where required.

In addition, MCRI does not have the resources to address any additional queries relating to the provision of existing data sets. This includes proposed costs relating to:

- The collection and cleaning of new data and the associated cohort costs
- Ongoing data curation and preservation.

A relatively nominal cost would be involved in the time required to collate any requested data. This cost would be invoiced to the requester upon transfer of the dataset. Unless otherwise stated, MCRI will not seek to generate revenue through data sharing.

6.4. Data Release Process and Preparation of Datasets by Sponsor-Investigator/Project Lead

Release of the requested dataset must occur as soon as reasonably possible following approval of the request and receipt of the signed DTA at MCRI.

The dataset must be released as a Data Pack i.e. a prepared package of data and metadata to be provided to a requester by the organisation. Accompanying the Data Pack should be the Data Dictionary and the Transfer of Data form.

The Data Pack must be provided via a secure transfer channel acceptable to the MCRI. It may be useful to speak with MCRI IT to discuss acceptable file transfer platforms to use.

6.5. Confirmation of Data Transfer

Upon receipt of the requested dataset by the requester, the requester must confirm receipt of the data by completing the "Confirmation of Data Transfer" section within the Transfer of Data form, and returning a signed copy to the MCRI Sponsorship Committee at the following email address: MCTC@mcri.edu.au.

All confirmations of receipt will be logged within the Sponsor's database.

7. ASSOCIATED DOCUMENTS

- MCTC Data Access Application Form
- MCTC Data Request Review Form
- MCTC Transfer of Data Form
- MCTC Data Sharing Plan template
- CEBU Data Management Plan template

8. GLOSSARY

Case Report Form (CRF)
A paper or electronic data collection document used in human research. It is a tool used to collect data on each study participant. The CRF consists of CRF pages.

Clinical Research Development Office (CRDO)
CRDO provides education and training to facilitate and increase capacity for clinical and public health research across the Melbourne Children's campus. This includes the development and implementation of Standard Operating Procedures and templates to enable researchers to conduct high quality research.

Coordinating Principal Investigator (CPI)/Sponsor-Investigator
The Investigator who is the lead PI on a multi-centre investigator initiated clinical study. They will also be the principal point of contact between the groups of collaborating investigators/researchers and the approving HREC for a multi-centre ethics approval and have the role of Sponsor-Investigator (see definition below for further information). For MCRI sponsored Investigator-Initiated trials, where the CPI takes on responsibilities of the Sponsor, this role is termed the Sponsor-Investigator.

Custodian
The individual, organisation, body, or committee with responsibility for the relevant Dataset. Typically, this is the study Sponsor.

Data Dictionary
A document providing technical metadata about a dataset such as data types, constraints {i.e. range checks).

Data Pack
A prepared package of data and metadata to be provided to a requester by the organisation.

Data Requester
An individual or a group of researchers from a third party seeking access to data from a Sponsor-Investigator.

Dataset
A research dataset, including summary datasets, or set of human samples with associated data, in respect of a study conducted by MCRI.

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 subjects are protected.

Human Research Ethics Committee (HREC)
A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.

Intellectual Property
Means all intellectual and industrial property, and all rights therein, of any kind throughout the world, including without limitation patents, patent applications, inventions, discoveries, algorithms, formulas,

compositions, works of authorship, copyrights, moral rights, trademarks, trade secrets, processes, techniques, developments, know-how, specifications, and all other similar rights, whether or not registered or capable of being registered in any jurisdiction.

Investigator-initiated trials (IITs)
Trials where the investigator initiates and organises a trial with minimal involvement of the institution are referred to as investigator-initiated trials (IITs). In this case, the institution will be usually be responsible for the medico-legal risk and delegate the remaining Sponsor responsibilities to the lead investigator (i.e. Sponsor-Investigator), including the initiation, financing (or arranging the financing) conduct and management (including compliance with GCP and applicable regulatory requirements) of the trial.

Investigator/Principal Investigator
An individual responsible for the conduct of a study, ensuring that the study complies with GCP guidelines. If a study is conducted by a team of individuals at a study site, the investigator is the responsible leader of the team and may be called the Principal Investigator (PI). In this instance they may delegate tasks to other team members. If a study is conducted at more than one study site, the Principal Investigator taking overall responsibility for the study and for the coordination across all sites.is known as the Coordinating Principal Investigator (CPI). The Principal Investigator at each site will retain responsibility for the conduct of the study at their site.

Melbourne Children's
Melbourne Children's is a collaboration between campus partners The Royal Children's Hospital (RCH), Murdoch Children's Research Institute (MCRI) and The University of Melbourne.

Melbourne Children's Trial Centre (MCTC)
MCTC is a unique collaboration between the Royal Children's Hospital, The Murdoch Children's Research Institute, The Royal Children's Hospital Foundation and The University of Melbourne. This Centre bring together expertise in research, clinical practice, and education and incorporates anyone who initiates or carries out research under one or more of these institutional affiliations.

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.).

Participant Information and Consent Form (PICF)
The PICF provides information about research and its requirements so that the prospective participant can decide if they wish to take part in the research. In general, this includes the purpose, methods, demands, risks, and benefits of the research. It must provide information to participants in a concise format that they are likely to understand. It must be participant centred.

Research
"Includes at least investigation undertaken to gain knowledge and understanding or to train researchers" (National Statement on Ethical Conduct in Human Research 2007 [Updated May 2015]). For the purpose of this guidance, research includes any research that requires submission to and approval from an HREC and/or research governance office. This may include (but is not limited to) observational research, clinical trials, quality assurance projects and laboratory research.

Sponsor
An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. For investigator-initiated trials, MCRI or RCH will act as the Sponsor but delegate

many sponsor responsibilities to the Coordinating Principal Investigator. In this case the CPI has the role of both Sponsor and Investigator and hence the MCTC has adopted the term Sponsor-Investigator to reflect the dual role of the CPI in investigator-initiated trials.

Sponsor-Investigator
The Sponsor-Investigator is a term used for investigator-initiated studies. It is an individual who is responsible for both the initiation and conduct of a study. The term does not include any person other than an individual. This person will be:

- the Principal Investigator for single-site investigator-initiated studies
- the Coordinating Principal Investigator for multi-center investigator-initiated studies

Standard Operating Procedure (SOP)
Detailed, written instructions to achieve uniformity of the performance of a specific function.

Trial Master File (TMF)
The TMF contains all the essential trial specific documentation prepared/collected before the trial commences, during the conduct of the trial and at trial completion in accordance with Good Clinical Practice.

Data Sharing Agreement (DSA)
An agreement between MCRI and a Requester which sets out the terms upon which MCRI agrees to provide the Requester with access to certain data in a Collection for the purposes set out in the relevant approved Proposal.

Sponsorship Committee
The Sponsorship Committee is responsible for reviewing and determining applications for MCRI to act as sponsor for Investigator-Initiated Trials conducted on the Melbourne Children's campus. As an additional responsibility, the Sponsorship Committee reviews data access and sharing requests in respect of data in a collection and decides on requests where the study in question no longer has an active Custodian. The Sponsorship Committee includes senior representatives from MCRI's Statistics, Data Management, and IT Divisions. The Sponsorship Committee meets monthly.

Proposal
Means a proposal submitted by a Requester to the Sponsor-Investigator.

9. REFERENCES

1. “Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors” http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf

2. ‘National Health and Medical Research Council Open Access Policy’ https://nhmrc.gov.au/sites/default/files/images/open-access-policy.pdf

3. “National Statement on Ethical Conduct in Human Research, 2007” (updated 2018)

10. APPENDICES

Appendix 1: Data Sharing Requirements from the Lancet Journal

The Lancet's current requirement regarding Data Sharing states the following:

From July 1, 2018, all submitted reports of clinical trials must contain a data sharing statement, to be included at the end of the manuscript or in an appendix (please provide as a separate pdf). Data sharing statements must indicate:

- *Whether data collected for the study, including individual participant data and a data dictionary defining each field in the set, will be made available to others*
- *What data will be made available (de-identified participant data, participant data with identifiers, data dictionary, or other specified data set)*
- *Whether additional, related documents will be available (e.g. study protocol, statistical analysis plan, informed consent form)*
- *When these data will be available (beginning and end date, or "with publication", as applicable)*
- *Where the data will be made available (including complete URLs or email addresses if relevant)*
- *By what access criteria data will be shared (including with whom, for what types of analyses, by what mechanism – e.g. with or without investigator support, after approval of a proposal, with a signed data access agreement - or any additional restrictions).*

Clinical trials that begin enrolling participants on or after Jan 1, 2019, must include a data sharing plan in the trial's registration. If the data sharing plan changes after registration, this should be reflected in the statement submitted and published and updated in the registry record. For reports of research other than clinical trials, data sharing statements are encouraged but not required. Mendeley Data is a secure online repository for research data, permitting archiving of any file type and assigning a permanent and unique digital object identifier (DOI) so that the files can be easily referenced (https://scanmail.trustwave.com/?c=7264&d=sIP43Jdo5GiAB_wlhkM2F2bz3P8Bcc0S0g_oWMT16Q&u=https%3a%2f%2fdata%2emendeley%2ecom).

If authors wish to share their supporting data, and have not already made alternative arrangements, a Mendeley DOI can be referred to in the data sharing statement.

Appendix 2: Example Data Sharing Statement on clinicaltrials.gov

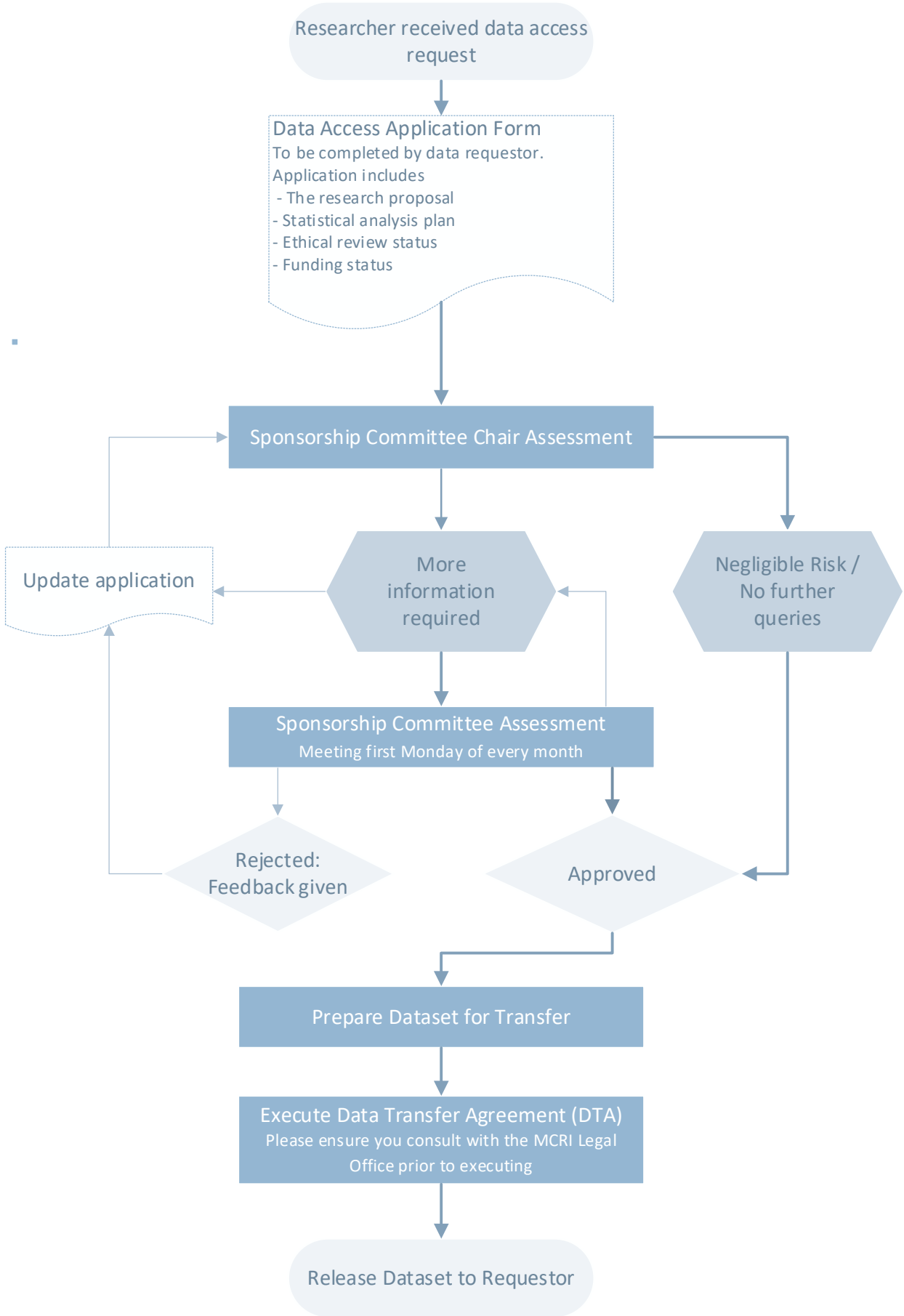
Below is an example Data Sharing statement from an MCRI sponsored clinical trial that has been registered on the clinicaltrials.gov registry:

The de-identified data set collected for this analysis of the <insert trial acronym> trial will be available six months after publication of the primary outcome.

The study protocol, analysis plan and consent forms will also be available. The data may be obtained from the Murdoch Children's Research Institute by emailing MCTC@mcri.edu.au. .

Supporting Information:	*Study Protocol* *Statistical Analysis Plan (SAP)* *Informed Consent Form (ICF)* *Clinical Study Report (CSR)* *Analytic Code*
Time Frame:	*6 months after publication of primary outcome*

Appendix 3



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