SOP 14 - Data Sharing and Access Procedure for the Release of Data from University of Melbourne Sponsored Investigator-Initiated Clinical Trials

1.1 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 University of Melbourne sponsored Investigator-Initiated clinical trials (IITs) to individuals or research groups outside of the University of Melbourne. 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 the University of Melbourne to comply with its data access responsibilities and legal obligations.

1.2 Scope & Responsibilities

This SOP is applicable to all datasets derived from clinical trials sponsored by the University of Melbourne, including both single site and collaborative multi-centre IITs. The scope of the procedure is to define how the University of Melbourne sponsored clinical trials will share research datasets in order to ensure that the University of Melbourne:

- 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 University of Melbourne 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 University of Melbourne personnel to prepare datasets for sharing
- Provided procedures for third parties (Data Requesters) to request datasets and for the University of Melbourne 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))

Research data is a valuable resource and often irreplaceable. Where appropriate data should be shared/accessed. 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 applicable 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 is a valuable resource and often irreplaceable.
- Research data should only be published/shared/accessed in accordance with applicable requirements, including but not limited to ethical approvals, participant consent, site 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.

Responsibilities of the Sponsor-Investigator

a) Be Familiar with all Requirements
The Sponsor-Investigator 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 2023
- Applicable privacy laws (which may include overseas legislation such as the GDPR if University of Melbourne 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 below).

Requirements for a Data Sharing Plan and Data Sharing Statement

b) Requirements for a Data Sharing Plan (DSP)
University of Melbourne employees who are involved in Investigator Initiated Trials (IITs) sponsored by the University of Melbourne 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. University of Melbourne 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.

c) 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:
- 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 the University of Melbourne 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 University of Melbourne 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?

1.3 Procedure

In keeping with The University of Melbourne's involvement in clinical trials and oversight of sponsorship, the University of Melbourne must be made aware of any data requests to facilitate the accurate review and signing of appropriate legal agreements.

Whilst the Sponsor-Investigator will be the initial point of contact for all initial requests to access research data, the University of Melbourne contracts team will ultimately oversee all requests for data access/transfers, and if applicable, define the circumstances under which the data will be shared.

a) Applying to Access Data

Where research data will be available for sharing, the Sponsor-Investigator 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 of the study, in which with the data was generated. Data Requesters must formally request access to datasets in writing. The written request must ask 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.

b) Preparing the agreement for data transfer for review and signing

- You must submit your documentation through *Cayuse Proposals*. RIC Contracts will not be able to review a research contract or arrange for it to be signed on behalf of the University without a Cayuse Proposal.
- Once a Cayuse Proposal has been received, the submission will be allocated to a Contracts Officer in the Contracts Team who will assist you to finalise the agreement.
- The Contracts Officer will first evaluate your agreement to confirm that it falls within RIC Contracts' delegation to assist you with. Certain research agreements that exceed a particular risk threshold or which seek to establish a master relationship

with an external party must be reviewed by the University's Legal Services team. The Contracts Officer will advise you if the research contract needs to be referred to Legal Services and will assist you with making this referral if necessary.
- RIC Contracts will otherwise conduct the review and draft any necessary amendments to the terms of the research contract (if any). If any amendments have been proposed, RIC Contracts will negotiate these terms with the external party.
- Once the terms of the research contract are agreed between the parties, RIC Contracts will arrange for the contract to be signed on behalf of the University.
- The process is further outlines on *Research Gateway*.

c) 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 agreement. 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. The Data Pack must be provided via a secure transfer channel acceptable to the University of Melbourne. It may be useful to speak with University of Melbourne IT to discuss acceptable file transfer platforms to use.

d) Confirmation of Data Transfer

Upon receipt of the requested dataset by the requester, the requester must confirm receipt of the data by email. The Sponsor-Investigator/Project Lead should store this email as confirmation.

1.4 References & Useful Links

- *Australian Code for the Responsible Conduct of Research 2018 (The Code)*
- *National Statement of Ethical Conduct in Human Research 2023*
- *EU General Data Protection Regulation (GDPR)*

1.5 Supporting Templates and Work Instructions

- University of Melbourne Research Gateway for *managing contracts*
- University of Melbourne *research contract review pathway*
- University of Melbourne *standard research agreements*

1.6 Glossary

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

1.7 Revision Chronology

Document History			
Version	**Effective Date**	**Summary of Changes**	**Author**
1.0	12 November 2025	Initial Version	Renata Phyland
2.0	02 January 2025	Updated footer	Renata Phyland