Melbourne Children's Research Governance Framework

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Glossary and definitions

AI	Associate Investigator, the person(s) involved in and/or conducting the research project. Can also broadly refer to individuals supporting the conduct of research.
Approver	Approvers are responsible for approving individual research governance elements. These approvers are not authorising the commencement of a research project.
Authorisation	The process by which a research governance item, as detailed in this document, is deemed appropriate by the relevant officer (see Authorising Officer). Depending on the research project, a number of items require authorisation before a research project can commence (project authorisation).
Authorising officer	Also referred to as 'the decision maker', the officer (or their delegate) within an institution who has the authority to authorise the commencement of a research project at their site. For example, the CEO at RCH is the Authorising Officer for multisite health and medical research falling within the scope of the MOU between the Department of Health and Human Services (Victoria) and The Royal Children's Hospital Melbourne.
CDA	Confidentiality Disclosure Agreement, should be used any time someone who does not otherwise owe an obligation of confidentiality to the Melbourne Children's (for example, through a services agreement) requires access to information that is confidential to the Melbourne Children's
CEO	Chief Executive Office, RCH
CIO	Chief Information Officer, MCRI
COO	Chief Operating Officer, MCRI
CT	Clinical Trial
CTN/CTX	Clinical Trial Notification/Clinical Trial Exception form issued by the Therapeutic Goods administration
CTRA	Clinical Trial Research Agreement
DHHS	Department of Health and Human Services (VIC)
ED	Executive Director
Essential documents	Documents which individually and collectively permit evaluation of the conduct of research and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator and those that conduct the research with the standards of Good Clinical Practice and with all applicable regulatory requirements.

HREC	Human Research Ethics Committee, a body established in accordance with Chapter 5.1 of the National Statement that conducts the ethical review of a research project. The HREC may or may not belong to one of the institutions participating in the research project.
IIT	Investigator Initiated Trials, used in this context for any investigator initiated research project, not just trials
Institution	In this document, the term 'institution' refers broadly to mean a research institution or organisation under whose authority research is conducted. This may be one or more of the Melbourne Children's partner organisations.
LNR	Low or Negligible Risk (research)
MCRI	Murdoch Childrens Research Institute
MCTC	Melbourne Children's Trials Centre, a Melbourne Children's initiative
Melbourne Children's	Melbourne Children's refers collectively or individually to one or more of the following organisations: The Royal Children's Hospital's (RCH), the Murdoch Childrens Research Institute (MCRI) and the University of Melbourne, Department of Paediatrics (UMDP).
MIA	Multi-Institutional Agreement, must be used for all NHMRC funded clinical, public health and non-clinical research projects even if there are no funds being shared. The MIA will detail, for example, how the NHMRC funds will flow to the parties over the funding period and include details on who is the Administering Institution, intellectual property ownership, publication rights, insurance and indemnity obligations.
MTA	Material Transfer Agreement, required if the research projects involves a transfer of data, materials or samples (i.e. transfer of materials such as cell lines, blood, tissue, CT and MRI scans, clinical data and other health information) and does not require a CTRA or other collaboration agreement
NDA	Non-Disclosure Agreement
NEAF	National Ethics Application Form
PI	Principal Investigator, the person responsible – either as an individual or as the leader of investigators - for the conduct of a research project
Project Authorisation	The point at which a research project is given permission to commence. Project authorisation is only granted when authorisation of all necessary research governance items has been completed.
RCH	The Royal Children's Hospital Melbourne
REG	Research Ethics and Governance (Office)
Regulatory documents	Documents pertaining to drugs and devices and their registration status including the CTN and the CTX
Research Governance – institutional	The broad range of principles, standards, regulations, processes and procedures that achieve, and continuously improve, research quality across all aspects of healthcare. The system that manages the risks posed to the institution through its conduct of research.

Research Governance – of a project	The process of checking and ensuring a research project is designed, conducted and closed out in accordance with the institutional research governance framework.
RGO	Research Governance Office (at RCH = REG), the designated administrative area within an institution that is resources to enable research proposals to be appropriately assessed so to assist the decision-maker to determine whether or not the research project will be authorised.
RIC	Research, Innovation and Commercialisation (group within UoM with oversight of research governance)
RSO	Radiation Safety Officer
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a research project
UMDP	University of Melbourne Department of Paediatrics
UoM	University of Melbourne
VMIA	Victorian Managed Insurance Authority
VSM	Victorian Specific Module

1. Introduction

The Melbourne Children's Campus is an international leader in the field of paediatric research. As such, rigorous research governance processes are essential to:

- Safeguard participants;
- Protect researchers/investigators;
- Enhance ethical and scientific quality;
- Minimise risk;
- Monitor practice and performance;
- Promote good practice; and
- Ensure lessons are learned.

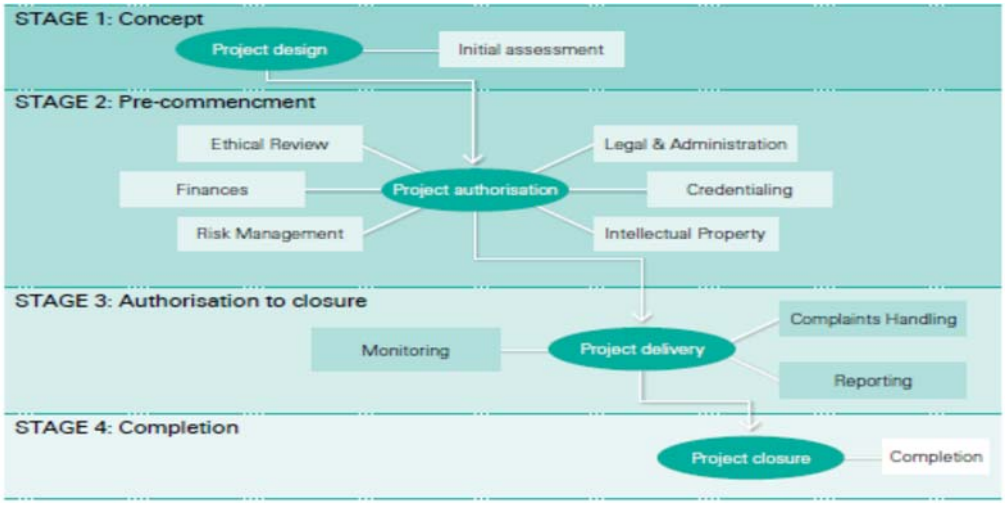
As the Melbourne Children's Campus includes The Royal Children's Hospital, the Murdoch Childrens Research Institute and the University of Melbourne Department of Paediatrics, it is critical that roles and responsibilities specific to research governance across the campus are clarified, and that a consistent approach is applied.

There are a number of binding instruments between institutional partners of Melbourne Children's and external groups that impact research governance, including but not limited to:

- Melbourne Children's Relationship Agreement (Melbourne Children's Campus Partners)
- MoU for Centralised Ethical Review (RCH & DHHS, on behalf of the State of Victoria)
- Research Excellence (REx): Streamlining Ethics & Governance (Parkville Precinct partners)
- MoU for the Melbourne Children's Trials Centre (RCH & MCRI)
- Shared Funding Agreement for Research Ethics & Governance (Melbourne Children's Campus Partners)

The purpose of the 'Melbourne Children's Research Governance Framework' is to provide a systematic, hierarchical aggregate of all research governance activities across campus, and provide guidance to ensure legislative and regulatory requirements, policy mandates, principles and best practice standards are met. In doing so, we aim to achieve and continuously improve the quality of research across the campus, from concept to completion.

An account of the research governance elements that comprise the framework is provided below.



NHMRC Research Governance handbook (2011)

2. Responsibilities for Research Governance

Within the Melbourne Children's Campus, a Memorandum of Understanding exists that appoints the Murdoch Childrens Research Institute (MCRI) as the custodian of research.

MCRI is responsible for setting the strategic direction for research on Campus, and assumes ultimate responsibility for research governance. However, in order to be effective, everyone involved in human research has a professional responsibility for the appropriate governance of their research.

The below represents a current overview of the roles and responsibilities associated with research governance at the Melbourne Children's:

ROLE	RESPONSIBILITY
COO (or delegate) of MCRI as the custodian of research	• Sets strategic directions for campus research • Authority for Clinical Trial Research Agreements (CTRA's) Indemnities and CTN Forms • Provides infrastructure and resourcing for research via the Melbourne Children's Trial Centre (MCTC) CEBU, CRDO, REG and the Grants office.
CEO (or delegate) of institution	• Issues governance authorisation on behalf of the institution (by signing the SSA)* • Authority for Indemnities, CTN Forms and CTRA's • Provides delegation of authority for senior level management staff for research and management level decision making
HREC	• Provides ethical approval for human research projects* • Provides ongoing monitoring and oversight of research • Provides expert advice to the CEO (or delegate) of institutions within the Melbourne Children's Campus.
Research Ethics and Governance Department	• Coordinates ethical and/or governance review for all human research projects • Provides advice and support to researchers, the HREC and the CEO (or delegate) of institutions within the Melbourne Children's Campus.
Line Manager (of Principal Investigator)	• Provides departmental authorisation for a project to be conducted / submitted for ethical approval / governance authorisation • Ensures resources are available to support the research • Provides ongoing oversight of the Principal Investigator, research team and support staff
Principal Investigator	• Responsible for all aspects of the research, as per the 'Research Policy' and 'Investigators Responsibilities Procedure'.
Research Team / Support Staff	• Responsible for all delegated aspects of the research, as per the delegations log, approved protocol, 'Research Policy' and 'Investigators Responsibilities Procedure'.

**It should be noted that to commence a research project, both ethical approval AND site specific governance authorisation is required.*

In addition to those listed above, other individuals or groups may provide advice to an 'approver' (or their delegate) in order for them to determine whether or not a research project may commence. This may include individuals or groups with legal, financial, technical, administrative, scientific or intellectual property expertise, or relevant institution-specific knowledge or information.

The nominated decision maker (as agreed by the Melbourne Children's partner institutions) will weigh up the recommendations provided by the individuals or groups against defined levels of acceptable institutional risk as well as the alignment of the research to meeting the strategic aims of Melbourne Children's. These individuals or groups have the authority to 'approve' certain research governance items within the Research Governance Framework. It is the particular combination of these approvals that results in authorisation of a research project, allowing the decision maker to authorise its commencement.

The remainder of this framework provides specific guidance to staff on a number of key governance elements, as outlined within the Australian Code for the Responsible Conduct of Research, the National Statement on the Ethical Conduct of Human Research, the TGA Note for Guidance on Good Clinical Practice, and the Campus Research Policy (RCH0464). This includes defining each element, describing why it is needed, who owns the process, who the approving authorities are, and how governance is maintained through ongoing monitoring and reporting.

3. Research Governance Elements

3.1. Personnel

Training and credentialing of Principal Investigator	
Item (what)	Training, credentialing and performance management of research responsibilities, includes oversight of research team (employing institute HR is responsible for clinical credentialing)
Why is this needed	National Statement on Ethical Conduct in Human Research (Section 5.1.2(b)): *Each institution needs to be satisfied that those conducting its human research are either adequately experienced and qualified or supervised.*
Origin and Process of completion (how)	PI training and experience detailed in the NEAF. PI (for research conducted at this site) must be an employee of Melbourne Children's. Identification (and management of) any conflict of interests is part of the Governance authorisation process.
Approver (who)	Researcher self declares by detailing experience and qualifications in NEAF/SSA. Line Manager responsible for signing off that resources (including human resources) are appropriate and available. Forms part of HREC approval and governance authorisation.
Governance controls	Responsible Conduct of Research at the RCH Campus Policy (MCRI4007) Responsible Scientific Conduct at MCRI Policy and Procedure (MCRI4003) Conflict of Interest policy and procedure (MCRI1015)
Reporting	No specific reporting
Monitoring	Annual performance reviews with line manager against Positon Description, which should include research responsibilities.

Training and credentialing of research team	
Item (what)	Training, credentialing and performance management of research tasks (employing institution HR is responsible for clinical credentialing)
Why is this needed	National Statement on Ethical Conduct in Human Research (Section 5.1.2(b)): *Each institution needs to be satisfied that those conducting its human research are either adequately experienced and qualified or supervised.*
Origin and Process of completion (how)	All members of the research team (including students) are listed on the NEAF or SSA. Identification (and management of) any conflict of interests is part of the Governance authorisation process.
Approver (who)	PI signs off on appropriateness of project team, including training and expertise, on NEAF.
Governance controls	REG authorisation Responsible Conduct of Research at the RCH Campus Policy (MCRI4007) Responsible Scientific Conduct at MCRI Policy and Procedure (MCRI4003) Conflict of Interest policy and procedure (MCRI1015)
Reporting	No specific reporting

Monitoring	Annual performance reviews with line manager against Positon Description, which should include research responsibilities

Performance of researchers and research staff	
Item (what)	Measuring and developing the performance of researchers and their staff
Why is this needed	To ensure ongoing quality in work output, address performance concerns, provide development and career pathways for staff.
Origin and Process of completion (how)	Annually (or as required) staff compete the Performance Review and Development Plan (PRDP) and hold a meeting with their line manager. Any complaints against the research staff, or governance findings will be communicated to the manager. Publication output is consider for researchers
Approver (who)	Manager of research personnel
Governance controls	Performance Review & Development Plan - Policy & Procedure (MCRI1006) Performance Management and Disciplinary Procedure (RCH0175) Clinical Research Leadership Appointments - RCH Campus Policy (RCH0645)
Reporting	Results of performance reviews are provided to the relevant HR department annually.
Monitoring	Annual performance reviews with line manager against Positon Description, which should include research responsibilities.

Supervision of students	
Item (what)	Appropriate supervision of research students
Why is this needed	Appropriate oversight and conduct of research, and requirement of the Australian Code
Origin and Process of completion (how)	Supervisor informs MCRI student administrator of a new student. Student admin records student's start and end dates, arranges necessary access and requests information from student re all supervisory details and information about research project (if lab related, arranges for mandatory OH&S training). All students working on campus will have a supervisor employed by a campus partner.
Approver (who)	Supervisor is responsible for the student conduct. Honours and PhD coordinators are responsible for student administration (UoM student's only). Relevant University is responsible for University enrolment and student academic performance. For the purposes of this document – the supervisor of the student is the 'approver'
Governance controls	Student policy (MCRI)
Reporting	Student admin contacts supervisor and student at the end of the contract period.

Monitoring	

3.2. Resources

Supporting department resources	
Item (what)	Head of Supporting Department agreement: Signed agreement from hospital and institute departments that there is the capacity and resources available to support activities required as per the protocol.
Why is this needed	Indication that proposed use of departmental resources is feasible Costs must be understood and covered by the project budget
Origin and Process of completion (how)	PI (or delegate) completes Head of Supporting Department Declaration Form for each department supplying resources. Provide this along with protocol and any other necessary supporting documents to supporting department dead of department (or delegate) Head of Department (or delegate) completes and signs the declaration and returns to the researcher to include in their application to REG
Approver (who)	Head of Department (or their delegate)
Governance controls	
Reporting	None
Monitoring	Monitoring of finances is performed by the supporting department to ensure appropriate reimbursement for resources

Radiation Safety	
Item (what)	Radiation Safety Review (if project includes the use of ionizing radiation)
Why is this needed	ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)
Origin and Process of completion (how)	Researcher completes VSM section 4 and other required documents and provides to RCH Director of Medical Imaging before submission to REG. If the radiation procedures are in addition to standard care a Radiation Assessment by a Medical Physicist is required (the Director of Medical Imaging organises this) and risk-wording included in the PICF. If radiation exposure is above constraints then an additional Medical Physicist must confirm the calculations of the first Medical Physicist.
Approver (who)	HREC will approve each research project where process confirms appropriate management of risk and informs participants accordingly
Governance controls	Ethics Application for research exposing humans to ionizing radiation (RCH0426)
Reporting	HREC, Medical Physicist & Researcher retains records (auditable by DHHS). REG reports to Department of Health Radiation Division for research that exceeds maximum dose constraints.
Monitoring	Department of Health & Human Services

3.3. Finance and Legal

Grants	
Item (what)	Process for applying for and administering grants from government or philanthropic bodies
Why is this needed	Appropriate use of public funds
Origin and Process of completion (how)	The MCRI Grants Office is the registered administrative contact for external peer-reviewed granting agencies and MCRI internal competitive funding schemes. A wide variety of internal, national and international funding opportunities are available for research (program grants, project grants, equipment grants and travel awards) and people support (fellowships and scholarships). Applications, guidelines and terms and conditions for funding differ between schemes and funders. The initial point of contact for all research related grant applications is the MCRI Grants Office. Applications should be prepared in consultation with the Grants Office.
Approver (who)	Relevant MCRI Theme Director must approve the submission of a grant application. MCRI Grants Office, COO or Director (dependant on grant type) is responsible for final sign off and submission the application. For successful grants, 'at award' documentation (e.g. Funding Agreements) are reviewed by the MCRI Grants Office prior to execution.
Governance controls	Assessment & Ranking of Multiple Grant Applications Policy (MCRI4101) Grant & Fellowship Application Policy & Procedures (MCRI4102) Grant Reporting Requirements (MCRI4105) Named Fellowships Policy (MCRI4103) Grants Donations Classification Policy (MCRI7004)
Reporting	According to relevant funding agreements (external) As required (internal)
Monitoring	No formal monitoring of expenditure against budget Group Leader, as owner of parent cost centre, has oversight as per normal financial management

Budget	
Item (what)	Budget
Why is this needed	Adequately and accurately price the cost of running the project. Allows an informed decision to be made regarding the viability of the project. Provides guidance on areas subject to cost recovery.
Origin and Process of completion (how)	Sponsor or researcher develops line item budget including each and every procedure from the protocol, all staff time (including in-kind support) and any other cost that will arise during the conduct of the project. Costs for support must be obtained from supporting departments. Infrastructure and on-costs must be included (as appropriate). Clinical trials must have a fully costed line item budget.

Approver (who)	The line manager is responsible for reviewing the resource requirements of the project and to ensuring (as per their sign-off) that these are available from their department (including any budget shortfalls), as required. This forms part of the governance approval process.
Governance controls	Budgeting Policy (MCRI2004) Theme Funding Policy (MCRI2011) Project Funding Policy (MCRI2010) Research Funding Top-Up Policy (MCRI2009) Research budget guidelines; how to set up and manage a project budget (uncontrolled document)
Reporting	As required per funding agreements, but this is external. No specific internal reporting
Monitoring	Velos eResearch provides tracking of activity against invoicing Trials managed through MCTC are monitored routinely by the Business and Operations Manager. Group Leader, as owner of parent cost centre, has oversight as per normal financial management

Binding Agreements	
Item (what)	Binding agreement, e.g. Clinical Trial Research Agreement (CTRA), Research Contract, Multi-Institutional Agreement (MIA), Material Transfer Agreement (MTA) or Funding Agreement
Why is it needed	NHMRC Australian Code for the Responsible Conduct of Research: *Organisations involved in a joint research project should ensure that an agreement is reached with the partners on the management of the research. It must cover intellectual property, confidentiality and copyright issues; sharing commercial returns, responsibility for ethics and safety clearances; and reporting to appropriate agencies. It should address the protocols to be followed by the partners when disseminating the research outcomes, and the management of primary research materials and research data.*
How is it completed	Appropriate agreement (National, State and Campus templates available) is drafted by the researcher or sponsor dependant on the type of research and collaboration. Research agreements are entered into with MCRI (as the custodian of research on behalf of the Melbourne Children's Campus) and the sponsor or other third party/site. Agreements must be approved by MCRI legal (or use an approved template/standard contract). Agreements are submitted to REG as part of the governance authorisation process (REG facilitates appropriate signatories).
Approver (who)	MCRI - Chief Operating Officer

	RCH – Head of Department or Executive Director (as per RCH Delegations Manual)
Governance controls	Contract Preparation and Management Procedure (RCH0485) Standard Attributions & Acknowledgements on MCRI Publications Policy (MCRI4004)
Reporting	None
Monitoring	Commercially sponsored studies: monitoring performed by the sponsor Investigator-Initiated studies: the PI (on behalf of MCRI) is responsible for ensuring the terms of the agreement and responsibilities of MCRI are met.

Insurance	
Item (what)	Insurance Certificate (Certificate of Currency) for all commercially sponsored clinical trials (to accompany the Indemnity). VMIA Insurance for RCH & MCRI sponsored projects.
Why is this needed	Victorian Managed Insurance Authority (VMIA) conditions for RCH & MCRI Insurance policy.
Origin and Process of completion (how)	For commercially sponsored projects: sponsor provides certificate of insurance, which meets VMIA and Melbourne Children's minimum requirements for commercially sponsored clinical trials (Schedule 4 of the CTRA). For IIT & collaborative group research: Insurance and indemnity is provided to individuals through their employment at the Melbourne Children's. Researchers recruiting private patients must have appropriate private insurance and indemnity cover in place. NB. For RCH/MCRI sponsored projects that are conducted outside of Australia, this is not covered under the VMIA insurance policy and separate insurance policies must be taken out.
Approver (who)	Authorised by REG as part of the governance authorisation process. Approved as per the authorised signatory of the CTRA.
Governance controls	Investigator Responsibilities in Research (RCH0498) VMIA insurance policy (MCRI and RCH) Conducting Research In Another Country (RCH uncontrolled document)
Reporting	Safety reporting to the VMIA
Monitoring	PI must keep an up to date Insurance Certificates for each project, monitored periodically by REG.

Indemnity	
Item (what)	Commercially sponsored projects: a Medicines Australia form of indemnity must be provided by the sponsor on the Medicines Australia Form of Indemnity listing MCRI as the contracting party. In the case that RCH HREC is the reviewing HREC for other sites, a Medicines Australia 'HREC Review Only' form of indemnity must be provided for the RCH HREC for each site.
Why is this needed	Victorian Managed Insurance Authority (VMIA) conditions for RCH & MCRI Insurance policy.
Origin and Process of completion (how)	Sponsor provides researcher with Medicines Australia Form of Indemnity (on letterhead) (Schedule 5 of the CTRA).
Approver (who)	MCRI – Chief Operating Officer RCH – Director, Research Ethics and Governance (HREC review only indemnity)
Governance controls	VMIA insurance policy (MCRI and RCH)
Reporting	None
Monitoring	None

Clinical Trial Notification	
Item (what)	Clinical Trial Notification (CTN) / Clinical Trials Exemption Form (CTX)
Why is this needed	Notification to the Therapeutic Goods Administration (TGA) – to allow use of a product not approved on the Therapeutic Goods Register.
Origin and Process of completion (how)	For commercially sponsored clinical trials the sponsor is responsible for completing the online form, providing payment and submitting it to the TGA. For Investigator Initiated Trials, the research is responsible for providing the information for the online form, and providing payment. The MCTC is responsible for submitting the form. The TGA provides a letter of receipt, but there is no requirement to wait for this before starting the trial.
Approver (who)	Overall responsibility for lodging the CTN lies with the sponsor i.e. pharmaceutical company (for commercially sponsored projects) and MCRI (for Investigator Initiated Trials). The MCTC is delegated by the MCRI COO to submit CTNs on behalf of the Melbourne Children's.
Governance controls	RCH Drug Usage Committee – Terms of Reference
Reporting	Adverse Event Reporting
Monitoring	Therapeutic Goods Administration (TGA)

Clinical Trial Registration	
Item (what)	Registration of Clinical trials on an approved clinical trial registry

Why is this needed	To prevent selective publication and selective reporting of outcomes, to prevent unnecessary duplication of research effort, to help patients and the public know what trials are planned or ongoing into which they might want to enroll, and to help give HRECs considering approval of new studies a view of similar work and data relevant to the research they are considering.
Origin and Process of completion (how)	Note there is no authorisation for this governance element. Ensuring a clinical trial is registered is the responsibility of the PI. Sponsor (or PI on behalf of MCRI for IIT) registers the trial on any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) or in ClinicalTrials.gov, which is a data provider to the WHO ICTRP. The ICMJE does not define the timing of first patient enrolment, but best practice dictates registration by the time of first patient consent
Approver (who)	Note: Melbourne Children's recommends the use of clinicaltrials.gov MCTC holds the institutional account for www.clinicaltrials.gov for the campus and must approve and release all trials.
Governance controls	
Reporting	Clinical trials registry must be updated when status of trial changes (Sponsor or PI responsibility)
Monitoring	www.clinicaltrials.gov prompts researchers (and the institutional account holder) when entries have not been recently updated.

3.4. Data and tissue

Prospective data Prospective collection & storage; including creation of Registries (databank)	
Item (what)	Collection and/or use of data collected for research. Registry (databank): a collection (for one or more purposes) of standardized information about a group of participants who share a health condition or experience.
Why is this needed	To ensure the collection and storage of data is ethically acceptable, and that utility remains compliant with the original scope of consent. In doing so, this preserves scientific and ethical integrity, minimises, duplication of effort, and ensures compliance with national and international guidelines, legislation and best practice standards.
Origin and Process of completion (how)	Application is submitted for consideration and approval by the HREC. Researcher notifies REG which database/system will be created and/or used and what data will be collected. This information is then entered onto a central register held by REG.
Approver (who)	HREC For any data proposed to be stored outside RCH /MCRI recognised systems, MCRI CIO to review and approve prior to HREC submission.
Governance controls	Guidelines for the establishment of a Research Databank / Biobank (uncontrolled document) Data Protection Policy & Procedure (MCRI5001) Privacy Data Security & Retention Policy (MCRI8002)

	Research Data Storage, Retention & Disposal Policy & Procedure (MCRI4002) Data Storage Policy & Procedure (MCRI5004) Health Information and the Registration of Databases used in research (RCH0594)
Reporting	Annual report to HREC and REG
Monitoring	HREC (or delegate)

Prospective tissue/biological samples Prospective collection & storage; including creation of Biobanks	
Item (what)	Collection and/or use of tissue collected for research. Biobank: a collection of biological or medical data and tissue samples, amassed for research purposes.
Why is this needed	To ensure the collection and storage of biological samples is ethically acceptable, and that utility remains compliant with the original scope of consent. In doing so, this preserves scientific and ethical integrity, minimises, duplication of effort, and ensures compliance with national and international guidelines, legislation and best practice standards.
Origin and Process of completion (how)	Application is submitted for consideration and approval by the HREC. Researcher notifies REG which samples will be collected and how. This information is then entered onto a central register held by REG. When creating a biobank, researcher discusses requirements with Biobank Advisory Group (BAG) chair and Melbourne Children's Biobank manager.
Approver (who)	HREC
Governance controls	Guidelines for the establishment of a Research Databank / Biobank (uncontrolled document) Retention of Samples in Cold Storage Policy (MCRI4204) Research - Tissue - collection, use and storage for research (RCH0539) Health Information and the Registration of Databases used in research (RCH0594)
Reporting	Annual report to HREC and REG
Monitoring	HREC (or delegate)

Existing (research or clinical) data Previously collected; existing sets of clinical and research information.	
Item (what)	Existing sets of health information, collected as part of clinical care or research
Why is this needed	To ensure the utility of data is ethically acceptable, and remains compliant with the original scope of consent. In doing so, this preserves scientific and ethical integrity, minimises, duplication of effort, and ensures compliance with national and international guidelines, legislation and best practice standards.
Origin and Process of completion (how)	Database Access Form (DAF) or equivalent document OR ad hoc A material transfer agreement (MTA) may be required
Approver (who)	Data custodian (as appropriate) HREC or delegate

Governance controls	Data Protection Policy & Procedure (MCRI5001) Privacy Data Security & Retention Policy (MCRI8002) Research Data Storage, Retention & Disposal Policy & Procedure (MCRI4002) Data Storage Policy & Procedure (MCRI5004) Removal of records from HIS for Research and Review (RCH0417) ESMR Access for External Collaborating Researchers, Monitors and Auditors (RCH0593)
Reporting	Annual report to HREC and REG
Monitoring	None

Existing (research or clinical) tissue & other biological samples Previously collected; clinical and/or research samples	
Item (what)	Clinical and research samples from patients/participants, collected either as part of clinical care or a previous research project.
Why is this needed	To ensure the utility of tissues and other biological samples is ethically acceptable, and remains compliant with the original scope of consent. In doing so, this preserves scientific and ethical integrity, minimises, duplication of effort, and ensures compliance with national and international guidelines, legislation and best practice standards. To also ensure the integrity of stored samples so that they are viable for use.
Origin and Process of completion (how)	Researcher includes information in ethics application then seeks approval from the relevant Custodian of the samples
Approver (who)	Relevant custodian of tissue and/or other biological samples (e.g. PI for research samples) HREC
Governance controls	Retention of Samples in Cold Storage Policy (MCRI4204) Research - Tissue - collection, use and storage for research (RCH0539)
Reporting	Annual report to HREC and REG
Monitoring	

Record Keeping	
Item (what)	Storage and maintenance of essential documents required for conducting research
Why is this needed	International and national requirements including International Conference Harmonisation on Good Clinical Practice.
Origin and Process of completion (how)	Each project is required to have a study binder (aka trial master file, investigator site file) where all study level documents are stored
Approver (who)	There is no authorisation required for this element, it is the responsibility of the PI that these controls are adhered to.
Governance controls	Managing Essential Documents for Clinical Research (RCH….) Data Protection Policy & Procedure (MCRI5001)
Reporting	Annual report to HREC and REG
Monitoring	Audits by HREC or delegate, audits and monitoring by sponsor

3.5. Ethics

Ethics approval	
Item (what)	Ethics Approval
Why is this needed	NHMRC *National Statement on Ethical Conduct in Human Research (2007)*
Origin and Process of completion (how)	Risk based system of review and approval of all human research. Single ethical review for multicentre research. Research is reviewed by an HREC for both scientific and ethical acceptability
Approver (who)	Human Research Ethics Committee (or delegate)
Governance controls	For RCH HREC: Standard Operating Procedures (SOP) Terms of Reference – RCH HREC (RCH0411) Informed Consent in Research (RCH0499)
Reporting	– Annual progress reports submitted to approving HREC – Final report submitted at close out of project – Safety reports submitted as required – Amendments/modifications to the research submitted as required – Dissemination of project results to participants
Monitoring	REG monitoring External monitoring/audit (e.g. TGA, FDA, commercial sponsor)

3.6. Complaints Management

Complaints Management	
Item (what)	Management of research related complaints
Why is this needed	Complaints must be managed efficiently, effectively and fairly to maintain public confidence in the research endeavours of the Melbourne Children's Campus.
Origin and Process of completion (how)	Each institution within the Melbourne Children's Campus has its own complaints management policy and procedure. This is important, as it allows site specific management protocols to be initiated in the event of a research related compliant. As such, each complaint should be managed in line with the relevant institution/s requirements. All research related complaints should also be reported to the Research Ethics and Governance Department for central management.
Approver (who)	As per relevant institutional policy.
Governance controls	Research Policy (RCH0464) Consumer Feedback – Management Policy (RCH0440) Handling and Resolving Breaches of the NHMRC Code and Scientific Misconduct at The Royal Children's Hospital Campus Policy (RCH0557) Research Complaints Management and Resolution (RCH0500)
Reporting	As per institutional policy. All research related complaints must also be reported to the Research Ethics and Governance department.
Monitoring	Research Ethics and Governance to monitor complaints, and provide advice as required.