Conflicts of Interest Policy and Procedures

This document explains the Conflicts of Interest Policy & Procedure that applies at the Murdoch Children's Research Institute (**MCRI**) and Victorian Clinical Genetics Services (**VCGS**).

For the purpose of this document references to MCRI relate to both MCRI and VCGS.

1. Summary

1.1 This Policy applies to all employees, students and , honorary appointees and those working at MCRI under specific contract arrangements with MCRI (**MCRI Staff**). The Policy clarifies the responsibilities of MCRI Staff with respect to conflicts of interest and the process MCRI has in place to deal with conflicts of interest.

2. Introduction

2.1 The purpose of this Policy is:

- To protect the reputation of MCRI and MCRI Staff by maintaining ethical standards of good judgement, fairness and integrity in all dealings.
- To ensure that outside or private interests of MCRI Staff are managed in a manner that does not interfere with the performance of their obligations to MCRI or create conflicts of interest.
- To ensure MCRI meets its obligations under the Australian Code for the Responsible Conduct of Research 2018.

2.2 The key principles of this Policy are that:

- Disclosure of relevant interests is required when there may be an actual or perceived conflict;
- Conflicts must be promptly and fully declared; and
- Procedures to manage identified conflicts of interest must be open, accountable and documented.

2.3 The commercialisation and translation of research outputs to maximise impact is important to MCRI and it is recognised that substantial benefits can arise from collaborations and relationships with industry in the licensing and marketing of research discoveries and in the creation of spin-off companies. These activities may also be a source of potential conflicts of interest which need to be appropriately managed.

3. Definitions

3.1 A conflict of interest exists in a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests.

3.2 At MCRI, a conflict of interest can occur where an individual's relevant interests or activities have, or could be seen to have, the potential to interfere or affect the performance of their obligations to MCRI.

3.3 A relevant interest or activity is one which might reasonably be considered to be related to a person's employment or engagement at the MCRI or have the potential to have a significant impact on a person's employment or engagement at MCRI, or their actions as an employee/appointee/contractor.

3.4 A financial conflict of interest means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research. For funding specific definitions see Appendix 1 NIH/PIH or for Significant Financial Interests see here.

4. Responsibilities

4.1 MCRI Staff must, as soon as a relevant interest arises or comes to their attention, ensure that the process for dealing with conflicts of interest set out below is complied with as soon as practicable.

4.2 MCRI requires MCRI Staff to comply with this policy by:

a) Avoiding conflicts of interest where feasible (see section 5)
b) Appropriately disclose relevant interests (see section 6);
c) Work with their manager or other relevant staff to identify whether these interests constitute a conflict of interest (see section 8) and;
d) Manage and disclose those conflicts of interests as determined by a conflicts of interest management plan (see section 8).

4.3 MCRI Staff must also comply with the conflicts of interest policies and procedures of external bodies that the researcher or other staff member is employed by or otherwise affiliated with. This includes but is not limited to, MCRI's campus partners, other universities, hospitals or medical research institutes.

4.4 Where required, relevant interests and/or conflicts of interest may also need to be disclosed to other parties funding bodies, ethics committees, publishers and journal editors, collaborators, research participants and the public. Please see Appendix 1 for funder-specific requirements.

4.5 A breach of this policy may be regarded as misconduct or serious misconduct and a breach by MCRI Staff of their contracts, including employment contracts, with MCRI. A breach of this policy may result in disciplinary action being taken.

4.6 This policy and the processes set out for dealing with disclosure of interests and conflicts of interest are managed by the Research Integrity Unit. The Research Integrity Unit will coordinate conflicts of interest disclosure and management plan review with MCRI Legal, People and Culture and/or the Chief Operating Officer as required.

5. Avoidance of Conflicts

5.1 Health and medical research and clinical research are inherently sensitive areas of research. Given the potential impact on human lives, MCRI's position is that, as a general rule, researchers should not receive any personal benefit (such as direct payments into personal bank accounts from third parties) and must disclose any direct or indirect benefit from the outcome of research projects, studies and clinical trials.

5.2 MCRI staff where feasible, must also avoid ethical, legal, financial, or other conflicts of interest and avoid being placed in a situation where they take action, make a decision or have the ability to influence any action or decision of MCRI that would result in a conflict of interest, or the reasonable perception of a conflict of interest.

For example, this may arise where MCRI Staff have the following relevant interests:

- a direct or indirect financial interest in an outcome, such as an involvement with a company or consultancy (through, for example, employment or shareholding) that has dealings or contractual arrangements with MCRI;
- a personal relationship with persons in a company or consultancy (through, for example, a shareholding) that has dealings or contractual arrangements with MCRI;
- involvement as a director, executive or partner of an entity that has dealings or contractual arrangements with MCRI; or
- involvement as an employee or member of a scientific committee of a commercial entity that has dealings or contractual arrangements with MCRI.

6. Disclosure of Relevant Interest, Identification and Management of Conflicts of Interest

6.1 If MCRI Staff believe or suspect that a relevant interest or interests constitute an actual or perceived conflicts of interest, the following steps must be taken using the Disclosure of Interests and Management of Conflicts of Interest Form.

a) **Disclose**: MCRI Staff must, as soon as is practicable, disclose the relevant interests to their Line manager/ Group Leader using the Disclosure of Interests and Management of Conflicts of Interest Form.
b) **Identify**: MCRI Staff will then work with their Line manager/ Group Leader to identify whether these relevant interests constitute a conflicts of interest.
c) **Manage**: MCRI Staff will then work with their Line manager/ Group Leader to develop a management plan to manage all identified conflicts of interest.
d) If MCRI Staff or their Line manager/ Group Leader are in doubt as to whether a conflict exists and/or need assistance with managing their conflicts of interest, they must promptly seek advice from the Research Integrity Unit who will liaise with MCRI legal and/or HR as required.
e) MCRI Staff should review their disclosure periodically (as negotiated with their Line manager/Group Leader) or when new relevant interests arise to ensure they are up to date.

6.3 Where MCRI Staff wish to object to actions required by MCRI in relation to a conflict of interest, they may refer the matter to their Theme Leader or Chief Operating Officer who will review the decision made under this Policy. Where necessary, the Research Integrity Unit, MCRI Legal team or other management may escalate a matter and ask that the Theme Leader and/or Chief Operating Officer review(s) and approve(s) a Conflicts of Interest Management plan to ensure these have been sufficiently considered. Any decision by the Theme Leader or Chief Operating Officer under this Policy will be regarded as final.

7. Confidentiality

7.1 Disclosures regarding a conflict of interest may include personal, sensitive or otherwise confidential information. Disclosures will always be treated with discretion and confidentiality will be respected where possible.

7.2 MCRI adheres to the Australian Privacy Principles and will treat information provided in accordance with these principles. Any individual who is concerned about the potential ramifications of disclosing particular information may raise their concerns directly Research Integrity Unit, particularly if they feel it is inappropriate to disclose such information to their supervisor.

7.3 The Research Integrity Unit with advice from the Head of Legal will work with the researcher determine how and to whom any information is subsequently disclosed bearing in mind the requirements of this Policy and the privacy of the MCRI Staff concerned.

8. Management of Conflicts of Interest

8.1 A management plan must detail the following matters:

- the nature of the MCRI Staff's interest;
- the interest/s of MCRI with which the MCRI Staff's personal interest, conflicts or has potential to conflict;
- the likelihood of the interests actually coming into conflict;
- the action, including any undertakings to cease activities, that the MCRI Staff agrees to take to address the conflicts of interest.

8.2 Once a management plan is documented it must be:

- endorsed by all parties and placed on the MCRI Staff's Staff file; and
- reviewed annually or on an as needs basis as identified by the line manager.

8.3 There may be occasions when additional information relevant to a conflict (including other conflicts) becomes known after the conflicts of interest form has been finalised. In these cases, as soon as the additional information becomes known it must be reported to the relevant Line Manager/ Group Leader and if required the form updated for further review in accordance with this policy.

9. Acceptance of Gifts or Benefits

9.1 MCRI Staff should not solicit any gifts or benefits (including money), or accept any gifts or benefits (including money) that might in any way appear to compromise or influence them in their role at MCRI. As a general rule, a gift or benefit is inappropriate if others may consider that gift or benefit as an inducement that could place an individual under an obligation.

9.2 Generally it is acceptable for MCRI Staff to accept small token gifts of a personal nature, gifts of nominal value generally used for promotional purposes by the donor, or moderate acts of hospitality. If in doubt, guidance should promptly be sought from the Head of Legal or the Chief Operating Officer.

9.3 Where it appears that a gift or benefit has been offered in an attempt to induce favourable treatment, the intended recipient should report the circumstances to the Head of Legal or the Chief Operating Officer.

9.4 Gifts to MCRI or a particular theme area of more than nominal value e.g. a painting, or a piece of equipment may be acceptable, but should first be disclosed to the Head of Legal or the Chief Operating Officer.

9.4 If MCRI is engaged in a tender process no gift or benefit, however small or insignificant, should be accepted from any of the tenderers either during the tender process or after the award of the tender.

9.5 For further information please see the Acceptance of Gifts & Benefits Policy.

Related Policies

Framework for Handling and Resolving Breaches of the NHMRC Code and Scientific Misconduct at the Royal Children's Hospital Campus (RCH & MCRI)

Australian Code for the Responsible Conduct of Research 2018 (The Code)

Disclosure of interests and management of conflicts of interest (Supporting Guide of the Code)

Performance Improvement & Unacceptable Behaviour Policy & Procedure

Intellectual Property Policy

The current, official version of this Policy and associated Procedures is maintained on the MCRI Policies and Procedures database. Printing this Policy or transferring it into another electronic format will result in the document being an uncontrolled copy which might not be current. Please refer any feedback to the Policy Owner via the link below:

Policy Sponsor :	Office of Research
Policy Owner :	Research Integrity
Policy Status:	Mandatory
Policy Approved By :	MCRI Executive
Policy Review By Date:	2025

Appendix 1: Funder Specific Requirements - Public Health Services/National Institutes of Health (PHS/NIH)

A.1 In addition to the requirements set out in this policy, the US Public Health Services/National Institutes of Health (PHS/NIH) have additional specific requirements in relation to conflicts of interest and significant financial interests. All organisations in receipt of NIH funding are required to demonstrate compliance with the NIH Financial Conflict of Interest Policy. The policy applies to funding awarded directly or indirectly by the NIH.

A.2 The PHS/NIH policy applies to any staff involved in or responsible for the design, conduct, or reporting of research funded by the NIH which including (but not limited to): Principal Investigators (First named investigators), Co-Investigators, Honorary Staff, Post-Doctoral Researchers; Students, Technicians, External collaborators or consultants. For this policy and PHS/NIH requirements, all such individuals are referred to as 'Investigators' and the Group or Theme Leader are the Institutions Designated Officer.

A.3 Investigator Responsibilities:

A.3.1 Prior to commencing any PHS/NIH funded research at the MCRI, Investigators must be familiar with this policy and undertake COI training prior to engaging in PHS/NIH research and at least every four years. This training outlines the Investigator's responsibilities regarding disclosure of significant financial interests and is available through the NIH Financial COI Online Tutorial. This applies to new staff impacted by this funding-specific requirement, non-compliant investigators, or existing investigators upon revision of this policy.

A.3.2 Disclose any identified, related (foreign and domestic) significant financial interests for Investigator's and their spouse/common law partner and dependent children using the *Disclosure of Interests & Conflict of Interests Form* and submit to the relevant Group or Theme Leader as outlined in this policy at the following time points: No later than at the time of application for PHS/NIH-funded research, prior to expenditure of funding; annually post-award; within 30 days of a new significant financial interest arising during the project; within 30 days of new investigators joining the project.

A.3.3 Assist with the development of and comply with management plan for any identified significant financial interests that directly and significantly affect the design, conduct or reporting of the PHS/NIH project.

A.4 Pre and Post funding award Investigator responsibilities:

A.4.1 Pre-award: If applicable, MCRI Investigators complete the *Disclosure of Interests & Conflict of Interests Form* and submit to the Grants Office at the pre-award stage;

A.4.2 Post-award: Confirm that the information disclosed pre award is still current and, if not, update the Form; and ensure that all MCRI Investigators involved in the PHS/NIH project are aware of, comply with and make any disclosures required under this Guidance.

A.5 Designated Official responsibilities:

A5.1 Maintain, and review actions taken related to all PHS/NIH disclosures for at least three years from the date of the final expenditures report is submitted to NIH, or, where applicable, from other dates specified in NIH policy.

A5.2 Determines whether a FCOI exists for the purposes of the NIH policy.

A5.3 Determine whether the significant financial interest may reasonably be said to be related to or affected by the PHS/NIH research and if so whether it could directly and significantly affect the design, conduct, or reporting of the PHS/NIH research and therefore require management.

A5.4 Develop and implement a management plan within 60 days of the FCOI being identified that specifies the actions that have been, and shall be, taken to manage such financial conflict of interest.

A5.5 If non-compliance, suspected non-compliance or bias is identified, Investigators and Designated Officials must immediately report the non-compliance or suspected non-compliance to the Integrity Unit and take all necessary steps to retrospectively comply with this Guidance relating to disclosure, determination and management of SFIs.

A.6 MCRI's Responsibilities:

A.6.1 Provide annual and ad hoc COI reports when requested to PHS/NIH including report within 60 days of any changes to COIs arising

A.6.2 Develop and implement Institutional-level processes and guidelines to comply with PHS/NIH policy and provide these to Designated Officials and investigators.

A.6.3 Provide Institutional-level monitoring and assurance, and record completion of training by all Investigators.

A.6.4 Maintain central records relating to all Investigator disclosures of financial interests and review of and actions taken related to such disclosures for at least three years from the date of the final expenditures report is submitted to NIH, or, where applicable, from other dates specified in NIH policy.

A.6.5 Notify relevant parties and address: non-compliance, bias, take relevant corrective actions, receipt of COIs, review of COIs and register changes to COIs.

A.6.6 Publish this policy on the Institute's public-facing website and make available information concerning identified FCOIs held by senior/key personnel. This must be reviewed and if required, updated annually and remain available for three years from the date the final expenditures report is submitted to the PHS (NIH).

A.6.7 In the event of non-compliance, the Grants Office & Integrity Unit will, within 120 days of detecting any suspected non-compliance, review the Investigator's activities and the PHS/NIH project under its research integrity processes in order to determine whether

research misconduct may have occurred and whether any PHS/NIH research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct, or reporting of such research. Investigators must fully and promptly cooperate with this review. If found, PHS/NIH will be promptly notified and provided all required information.

A.6.8 Where non-compliance relates to PHS/NIH research investigating the safety or effectiveness of a drug or device, the MCRI may require the Investigators to disclose the FCOI in each public presentation and request an addendum to previously published outcomes relating to the research, and the Investigators must comply with this requirement.

A.7 Principal Investigators, Investigators and Designated Officials must create, maintain, and store all local-level records relating to implementation of this policy for at least three years following the submission of the final report to the NIH (or such other period as required under the NIH policy)

A.8 MCRI delegates responsibility for compliance with the NIH COI policy relating to identification, disclosure, determination and management of COIs to each sub-awardee. This will be established in written agreements with the sub-awardee and may require the sub-awardee organisation to certify that its FCOI policy complies with PHS/NIH requirements.