Responsible Scientific Conduct at MCRI Policy & Procedure (MCRI4003)

1. Summary
1.1 This Policy has been developed to promote good scientific practice at the MCRI. All staff, students and visiting scientists are required to adhere to this Policy and corresponding procedures and are advised to maintain awareness of current policies and guidelines relevant to their work including those from:

- The MCRI
- Victorian Clinical Genetics Services (VCGS)
- The University of Melbourne
- The Royal Children’s Hospital
- Funding Bodies
- Government
- Any other relevant stakeholders

1.2 All staff must read the Australian Code for the Responsible Conduct of Research (2007) (the Code).

2. Introduction
2.1 The Murdoch Childrens Research Institute endorses the Australian Code for the Responsible Conduct of Research (2007) (the Code) developed by the National Health and Medical Research Council, Australian Research Council and Universities Australia. MCRI has adopted the Code and will continue to implement and maintain policies and administrative procedures which address all the issues raised in the Code.

2.2 Our researchers and research-related staff have a duty to ensure that their work enhances the good name of MCRI and the profession to which they belong. All MCRI staff must commit to high standards of professional conduct, and this policy should be read in conjunction with the Research Data Storage, Retention & Disposal Policy.

3. Policy on Scientific Practice
3.1 The Director is ultimately responsible for all research undertaken within the Institute but has delegated the day-to-day oversight of research undertaken within the Institute to Research Theme Directors, who are charged with managing the Research Theme of the MCRI. All new major research projects and proposed research grant applications should be discussed with the appropriate Theme Director or their nominee in the first instance and, where necessary, the Director of the Institute, as all are responsible for monitoring the observance of this Policy and these Procedures.

3.2 All research staff and staff in research-related positions, scientific visitors, fellows, associates and students are expected to maintain the highest standards of responsible scientific research and professional conduct. Researchers must:

- Plan and conduct research using appropriate research methods to achieve the aims of each research proposal;
- Record, document and preserve observations with honesty, diligence and objectivity;
- Interpret results cautiously;
- Fully and critically discuss original results with colleagues and senior scientific staff;
- Cite awards, degrees and research publications accurately, including the status of any publication (for example: in press, under review, etc.);
- Promote responsible conduct of scientific research and avoid departures from responsible research conduct, including obtaining appropriate ethics committee approval; and
- Conform to policies from MCRI and funding bodies.

3.3 Research must be planned and conducted with respect for research participants (including animals), and comply with ethical approvals and their inherent principles of integrity, respect for persons, justice and beneficence.

3.4 In general, research results and methods should be open to scrutiny by colleagues within the Institute and, through appropriate publications and conference presentation, to the wider scientific community.

3.5 Confidentiality must be observed for data of a confidential nature, for example from individual patient records. Confidentiality may also be necessary for a limited period in the case of research with commercial interest. See the MCRI Confidentiality & Intellectual Property Policy for more information.

3.6 As much as possible, research should be conducted in a manner which respects the environment and minimizes adverse effects on the wider community and environment.

3.7 Breaches of the NHMRC Code and research misconduct must be reported in a timely manner, in accordance with MCRI policies and procedures, as detailed in the Breaches of the NHMRC Code and Scientific Research Misconduct at the MCRI Policy.

4. Research Governance and Approvals to Conduct Research
4.1 Royal Children’s Hospital Human Ethics Committee & Special Interest Groups
4.1.1 If the research involves patients and/or their families or other community participants, tissues, cells, or data from the Royal Children’s Hospital (RCH) the application to conduct research must be approved by the RCH Human Ethics Committee. Information on the RCH Ethics and Research Department can be found here.

4.1.2 Research involving genetic modification (GM) must be approved by the Institutional Biosafety Committee (IBC).

4.1.3 All other research, for example, public health research where participants may not be patients of the RCH, etc., must be approved by the ethics committee with the most appropriate jurisdiction over that research.

4.1.4 Guidance and principles for research involving human participants can be found in The National Statement on Ethical Conduct in Human Research and Values (NHMRC 2007).

4.1.5 Specific guidance for research involving Aboriginal and Torres Strait Islander peoples can be found in Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (NHMRC 2003) and the Guidelines for Ethical Research in Indigenous Studies (Australian Institute of Aboriginal and Torres Strait Islander Studies 2004).

4.1.6 Appropriate consumer involvement in research is encouraged by MCRI. Guidance for consumer involvement in research can be found in the Statement on Consumer and Community Participation in Health and Medical Research (NHMRC and Consumers’ Health Forum of Australian Inc, 2002, 2005).

4.2 Institutional Biosafety Committee (IBC)
4.2.1 All work conducted with Genetically Modified Organisms (GMOs) must be carried out in accordance with the legislation outlined in the Gene Technology Act 2000 and regulated by the Office of the Gene Technology Regulator (OGTR). The Gene Technology Act 2000 prescribes conditions for conduct, management and containment of work involving GMOs. The Act delegates authority to assess, review and approve all genetic modification works to the Institutional Biosafety Committee (IBC). The ICR and RCH IBC registers and approves all applications. Where genetic modification experiments involve animals, the applicant must first obtain IBC approval before Animal Ethics approval can be granted. For further information, please consult with the Chair or the Secretary of the IBC in the first instance.

4.3 Australian Quarantine & Inspection Service (AQIS) Regulations & Permits - Importation of Biological Materials
4.3.1 MCRI is registered to use imported biological material and is required to maintain an inventory of all items. The Institute is also required to obtain permits before it can import any material of biological origin.

4.3.2 On no account may a staff member bring samples or agents (e.g. Sera, cult lines, deoxyribonuclease acid (DNA), yeast, artificial chromosomes (YACs) etc.) into the Institute or Institute-related premises without a
valid permit. Likewise, staff members must not encourage the receipt of such material from colleagues from overseas without first informing them of the correct AQIS and International Air Transport Association (IATA) arrangements. It is the researcher's responsibility to consult with the MCRI Purchasing Officer before any overseas liaisons are made. The MCRI Purchasing Officer is responsible for all permits and information on the importation of goods. The Scientific Services team are responsible for exports and interstate shipments.

4.4 Use of Animals

4.4.1 All experiments involving animals must be conducted in accordance with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes and approved by the MCRI's Animal Ethics Committee. In the same way that projects involving humans are referred to the Ethics Committee of the Royal Children's Hospital or other appropriate Human Research Ethics Committee, animal experiments are referred to the MCRI Animal Ethics Committee. In some cases researchers may be required to hold a licence to undertake experiments using animals. Further information can be obtained by consulting the resources on the Animal Ethics Committee page on the MCRI intranet.

5. Safety

5.1 MCRI provides a comprehensive safety management structure and is committed to continually improving the effectiveness of its safety management systems. Theme Directors and Heads of Research Groups/work areas are responsible for ensuring the safety of all those associated with the research and the timely and effective application of safety management requirements.

5.2 All staff must complete orientation in safety management for their research and must be familiar with appropriate requirements for safety, such as the Laboratory Safety Manual. See the Environmental Health and Safety section on the MCRI intranet for complete safety information, policies and procedures.

5.3 All research conducted in the Institute must comply with appropriate legislation and guidance material governing occupational health and safety, and conditions of use of hazardous materials and dangerous goods, including ionising substances, toxic chemicals, recombinant DNA technology and waste disposal. Guidance in these requirements may be sought from the EHS team.

5.4 Each Head of Research Group/work area must ensure that all members of the Group/work area are aware of MCRI and/or legal requirements and that appropriate approvals have been obtained before a research program commences.

6. Use of Computer Software

6.1 Most MCRI computers are connected to the Internet. In general, an email account will be provided to all staff. This applies to some students and visiting researchers who must then agree to MCRI's IT policies and procedures. Web browsers are available for access to databases e.g. Medline. Published, etc.

6.2 MCRI provides network storage for data. Access to files is controlled by MCRI IT. Data size limits are determined by MCRI policies.

6.3 The Institute provides the standard software e.g. operating system, email, anti-virus, Adobe reader. All other software requiring a license fee must be purchased by the user. Non-standard software must be approved by the IT Manager.

6.4 "Trend Scan" is installed on most computers. It is expected that staff using email engage in good email practices to ensure protection from unwanted viruses. Connected computers are scanned once a week including local hard drives. It is important to note that Internet traffic is monitored on an ongoing basis.

6.5 All research staff must adhere to MCRI's Use of IT Systems, the Internet Policy and Email Policy in their appointment within MCRI. Staff affiliated with MCRI and working within the auspices of the Institute must also adhere to this Policy at all times.

7. Discoveries and Inventions

7.1 All Intellectual Property (IP) developed by an employee of the MCRI in the course of their employment will be the property of the MCRI.

7.2 MCRI is entitled to recover all reasonable costs associated with the development, protection and commercialisation of its IP. Reasonable costs will be determined by the Board on the advice of the IP/Commercialisation Committee.

7.3 Subject to a decision of the IP/Commercialisation Committee, having reviewed all the circumstances of each case, net proceeds after cost recovery should be applied: 30% for the purposes of the Institute as determined by the Director, 30% for the inventors and 40% to the research in the originating laboratory and the staff of the Institute as determined by the Board on the advice of the Director.

7.4 The precise percentage participation by inventors, and the division between them based on contribution to IP and the commercialisation processes will be determined at the discretion of the Board on the recommendation of the IP/Commercialisation Committee. For guidance on handling conflicts of interest see Section 14 below and the Conflict of Interest Policy & Procedure.

7.5 The policy should be flexible in circumstances where MCRI's IP rights may be converted into equity in a spinoff company. In such circumstances the Board in principle supports researcher participation in that equity on a similar basis.

7.6 Should the Institute decide, it may with the agreement of the inventor(s), transfer and assign to each inventor all its rights, title and interest in and to the intellectual property, at the cost of the inventor(s).

7.7 Any dispute that arises under the implementation of the MCRI Collaboration and Intellectual Property Policy would be considered by the IP/Commercialisation Committee in the first instance in an endeavour to mediate a resolution and to make a recommendation to the Board.

8. Supervision of Students/Research Trainees

8.1 Responsibility for the supervision of each research student/trainee investigator (including honours, masters, doctoral and junior postdoctoral research workers) will be assigned to a specific senior research worker in each Research Group. Supervisors must provide guidance in all matters of safety, data management and good research practice. The University of Melbourne Department of Paediatrics and other University of Melbourne Schools/Department students and supervisors also need to comply with The University of Melbourne Higher Research Degree policies and School/Department-specific requirements for students. Students from other universities must refer to the appropriate policies for their institutions.

8.2 The ratio of students/trainees to supervisors should be small enough to ensure effective guidance and interaction, and effective supervision of the research at all stages.

8.3 Research supervisors should advise each student/trainee of applicable guidelines regarding research ethics, research design and methods and responsible conduct of research including those of government, university, funding bodies or other institutions.

8.4 All students, trainees and new staff are required to undertake induction training covering research ethics, EHS, environmental protection and technical matters appropriate to the discipline. In relation to these matters, general awareness training will be offered by the MCRI upon commencement of the student/trainee investigator but the supervisor must also offer significantly more in-depth local induction training.

8.5 Ongoing education for students, trainees and staff will be provided by MCRI and will involve, where applicable, training in research methods, ethics, confidentiality, data storage and records retention, regulation and governance, MCRI policies regarding responsible research conduct, relevant NHMRC and other guidelines and other relevant skills such as the ability to interact with industry and work with diverse communities.

8.6 Research supervisors should provide mentoring and guidance in all matters relating to research conduct, oversee all stages of the research process including identifying research objectives and approaches, obtaining ethics and other approvals, obtaining funding, conducting research, and reporting research outcomes in appropriate forums and media.

8.7 Supervisors and students have joint responsibility for accurate and timely reporting (both oral and written) of the progress of their research. Supervisors must ensure, as far as possible, the validity of research data obtained by a student under his/her supervision. Information on laboratory notebook management can be obtained from the Commercialisation Committee page on the MCRI intranet.

8.8 Supervisors and researchers must ensure that research trainees and students receive appropriate credit for their work.

8.9 Research trainees and students are expected to seek guidance and demonstrate a professional attitude towards research. Frequent meetings with supervisors are important and require cooperation of both trainees and supervisors to arrange. Research trainees should not wait to be approached but should be active in maintaining an appropriate schedule of meetings with their supervisors.

9. Data Storage, Retention and Disposal

9.1 Research staff must be aware of and adhere to the MCRI Data Storage, Retention and Disposal Policy.

10. Authorship

10.1 The criteria for authorship of a research output are that each person listed as an author should have participated actively and significantly in:

- The conception and design or analysis and interpretation of data
- The preparation and drafting of or critical revising for important intellectual content of the final manuscript submitted for publication; and
- The final approval of the version to be published.

For guidance on uniform requirements for manuscripts to be submitted to biomedical journals, please also refer to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication produced by the International Committee of Medical Journal Editors and also known as the V astronomical Guidelines.

10.2 Participation solely in the acquisition of funding, the provision of materials, routine technical support, or the collection of data will not justify authorship, nor will general supervision of the Research Group. Any part of an article critical to its main conclusion must be the responsibility of at least one author. An author should be able to take public responsibility for at least the area of their expertise within the paper.

10.3 Unacceptable inclusions of authorship are not permitted. The following in and of themselves do not justify including a person as an author:

- Being head of department, holding other positions of authority, personal friendship with authors;
10.4 Authorship of a research output is a matter that should be discussed between researchers at an early stage in a research project and reviewed whenever there are changes in participation. Authorship must be offered to all people, including research trainees, who meet the criteria for authorship outlined in clause 10.1. No person who is an author consistent with clause 10.1 must be included or excluded as an author without their written permission.

10.5 Where the research is published, including electronically, all MCRI co-authors of a publication must acknowledge their authorship in writing in terms of, at least, the minimum acceptable definition at clause 10.1 above, in an acknowledgement of authorship document. Those offered authorship must accept or decline in writing and include a brief description of their contribution to the work.

10.6 Where there is more than one author of a research output, one co-author (by agreement among the authors) must take responsibility for the entire research output including record keeping regarding the research output.

10.7 The senior author must ensure that authorship is properly determined and that a written acknowledgement of consent to authorship is provided and signed by all authors and held by the Senior MCRI Author. In the case of a publication resulting from collaboration between different institutions, each institution should nominate a person responsible for the part of the work emanating from that institution.

10.8 If, for any reason, one or more co-authors are unavailable or otherwise unable to provide an original handwritten signature on an acknowledgement of authorship document, faxed or emailed consent is acceptable. This also applies in the case of published conference abstracts and similar publications. If an author is deceased or cannot be contacted, publication can proceed provided that there are no grounds to believe that this person would have objected to being included as an author.

10.9 Authors must ensure that others who have contributed to the research project, including research assistants and technical officers, are properly acknowledged in the research output. When individuals are to be named, their written consent must be obtained. Individuals and organisations providing funding and facilities should also be acknowledged. All MCRI publications must acknowledge the Victorian Government’s Operational Infrastructure Funding, as described in the Standard Attributes and Acknowledgements for MCRI Publications Policy.

10.10 These Procedures apply equally to papers that may be completed and submitted after a staff member has left MCRI. In such papers the proper practice is to include the affiliation where the work was completed in the listing of addresses at the top of the paper and to deal with the new address, if this is necessary, by a footnote.

11. Publication and Dissemination of Research Findings

11.1 Publication of multiple papers based on the same set(s) or subset(s) of data is not acceptable, except where there is full cross-referencing within the papers, for example, in a series of closely related works, review articles, or where a complete work grew out of a preliminary publication and this is fully acknowledged.

11.2 An author who submits substantially similar work to more than one publisher must disclose this to the publishers at the time of submission.

11.3 As a general principle research findings should not be reported in the public media before they have been reported to a research audience of experts in the field of research - preferably by publication in a peer-reviewed journal, except where there is a contractual arrangement.

11.4 It is acknowledged that where issues of public policy and concern may arise prior advice desirable, such advice must be tendered first to the public or professional authorities responsible, and the unreported status of the findings must be advised at the same time. Only where responsible authorities fail to act can prior reporting to the media be justified, and again the unreported status of the findings must be reported simultaneously.

11.5 Confidentiality requirements of a sponsor or prospective sponsor may prevent or delay peer review until after research results are delivered to the sponsor or prospective sponsor, and any communications restrictions agreed with the sponsor must be honoured. In such cases, researchers must inform sponsors or prospective sponsors that the work has not been peer-reviewed. Where this occurs, and especially when it is reported to prospective financial sponsors, researchers have an obligation to explain fully the status of the work and the peer review mechanisms to which it will be subjected.

11.6 Research outcomes with a strong commercial element may have to be presented to a stock exchange or financial body before any public release.

11.7 Publications must include information on all sources of financial and in-kind support for the research and any potential conflicts of interest, and must also acknowledge the host institution. Financial sponsorship that carries an embargo on such naming of a sponsor should be avoided.

11.8 Deliberate inclusion of inaccurate or misleading information relating to research activity in curriculum vitae, grant applications, job applications or public statements, or the failure to provide relevant information, is a form of research misconduct. Accuracy is essential in describing the state of publication (in preparation, submitted, accepted), research funding (applied for, granted, funding period), and awards conferred, and where any of these relates to more than one researcher.

11.9 All reasonable steps must be taken to ensure that published reports, statistics and public statements about research activities and performance are complete, accurate and unambiguous. If researchers become aware of misleading or inaccurate statements about their work, steps must be taken to correct the record as soon as possible.

11.10 Researchers have a responsibility to disseminate all research findings and a full account of their research as broadly as possible. This includes the publication of negative or unexpected findings and results contrary to hypotheses where applicable.

11.11 Publication must take account of any restrictions due to intellectual property or culturally sensitive data. For further guidance see Clause 4.1. Royal Children's Hospital Human Ethics Committee and Special Interests Groups above.

11.12 To avoid misunderstanding, researchers should promptly inform these directly impacted by the research including interested parties, participants and funding bodies, before informing the public media.

11.13 Where feasible, researchers should also provide researchers with an appropriate statement of research results. For more information, refer to the NHMRC's Statement on Consumer and Community Participation in Health and Medical Research.

11.14 Researchers must cite the work of other authors fully and accurately. The use of work of other authors without acknowledgement is plagiarism and is unethical and constitutes a breach of good scientific practice. Self-plagiarism, whereby you quote or use work without citation that you have published elsewhere is also unethical and constitutes a breach of good scientific practices.

For more information regarding plagiarism, see The University of Melbourne academic honesty and plagiarism website: http://academichonesty.unimelb.edu.au/

A number of software packages are available to detect similarities in published papers, one of which is ETBLAST, available at: http://retenc.vbi.vt.edu/etblast3/

11.15 Researchers must take all reasonable steps to obtain permission from the original publisher before republishing material.

11.16 All clinical trials must be registered with a recognised register to promote access to information regarding clinical trials.

11.17 The MCRI will assist researchers to communicate research findings to the wider public through the provision of media relations training or a science communications officer or similar when communicating research findings through the media. All contact with media and journalists is managed by the PR & Development team. Researchers are encouraged to notify PR & Development about expected publications. In some instances, PR & Development, in consultation with the Director, MCRI will promote the launch of new research, a funding announcement for research, or highlight research in connection with a human interest story. See the MCRI PR Media Policy and Procedures for more information.

11.18 When reporting research results for publicity purposes, MCRI must make every effort to acknowledge partner institutions and sponsors involved in collaborative research endeavours.

12. Peer Review

12.1 MCRI recognises the importance of the peer review process and encourages and supports researchers to engage in the process of peer review. When conducting peer review, reviewers must:

• Be fair and timely in their review;
• Act in confidence and not disclose the content or outcome of any process in which they are involved;
• Display all conflicts of interest, not permit personal prejudice to influence the peer review process, nor introduce considerations that are not relevant to the review criteria;
• Not take undue or calculated advantage of knowledge obtained during the peer review process;
• Ensure that they are informed about, and comply with, criteria to be applied;
• Not agree to participate in peer review outside their area of expertise;
• Give proper consideration to research that challenges or changes accepted ways of thinking.

12.2 When being reviewed, researchers must not interfere during the peer review process or seek to influence the process or outcomes.

12.3 Supervising researchers have a responsibility to assist trainee researchers in developing the necessary skills and recognise the obligation to participate in peer review.

12.4 When participating in the peer review process, researchers must declare all relevant conflicts of interest. For more information see the Conflict of Interest Policy & Procedures.

13. Collaborative Research Across Institutions

13.1 While research practices differ between countries, the MCRI endorses the Code and its requirement that researchers supported by Australian public funding should make every effort to comply with the Code even when conducting research outside Australia. Any need to deviate from the Code must be submitted to the Director, who will be advised by the MCRI Executive, for approval.

13.2 Researchers collaborating on a joint research project with researchers at other institutions should ensure that an agreement is reached regarding the management of the research which follows the general principles of the Code. This agreement must be in writing and must cover IP, confidentiality and copyright, sharing commercial returns, responsibility of ethics and safety clearances, reporting to appropriate agencies, protocols to disseminate research outputs, management of primary research materials and data.

13.3 Researchers must be aware of and comply with all MCRI policies and written agreements affecting multi-institutional research projects, and must declare and manage any conflicts of interest. For more information, see the Conflict of Interest Policy & Procedures.

14. Disclosure of Potential Conflicts of Interest

14.1 Disclosure of any affiliation with, or financial involvement in, any organisation with a direct commercial interest in the research of any staff must be forwarded in writing to the Director on an annual basis. Details of any benefits (direct or indirect) should be included. Any statement on confidentiality disclosures (e.g., concerning results of drug trials on patients) must be included. Disclosure should cover any situation in which the conflict of interest may, or may be perceived, to affect any decision regarding other people. For more information see the Conflict of Interest Policy & Procedures.

14.2 Any staff member offered or receiving support, financial or in kind, towards research costs or personal costs (e.g., travel to meetings) by a commercial organisation, or entering into an agreement of collaboration with a commercial organisation, should discuss the offer/arrangement with the Chief Operating Officer and/or the Director. All such offers or arrangements must be recorded and where necessary, public disclosure to journals and to granting agencies must occur.

14.3 The NHMRC requires disclosure of all affiliations with, or financial involvement in, any organisation with a direct commercial interest in research which is also being funded by NHMRC grants.

14.4 Researchers have an obligation to disclose at the time of reporting or proposing research (e.g., in a grant application), any conflict of interest which has the potential to influence research and investigations, publication and media reports, grant applications, applications for appointment and promotion.

14.5 Researchers are required to keep records of activities that may lead to conflicts of interest. When invited to join a committee or equivalent, researchers must review their activities for actual or apparent conflicts of interest and bring these to the attention of those running the process.

14.6 Where circumstances constitute a conflict of interest, or a perceived conflict of interest, the researcher concerned must not take part in decision making processes. If the details of the conflict of interest are confidential or sensitive they need not be disclosed, but the existence of the conflict must be declared as soon as it becomes apparent and the researcher must withdraw from the situation.

15. Related Policies

Research Data Storage, Retention and Disposal Policy
Responsible Conduct of Research at the Royal Children's Hospital Campus Policy
Breaches of the NHMRC Code and Scientific Research Misconduct at the Murdoch Childrens Research Institute Policy
Conflict of Interest Policy & Procedures
PR Media Policy & Procedures
Standard Attributions and Acknowledgements on MCRI Publications Policy

The current, official version of this Policy and associated Procedures is maintained on the Policies and Procedures database. Printing this Policy or transforming it into a 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:

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