RESEARCH CONDUCT POLICY

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Policy owner: Research and Education

1. Policy Statement

The Australian College of Optometry (ACO) and National Vision Research Institute (NVRI) are committed to fostering and supporting a research culture that is honest, responsible, accountable and ethical. This policy describes the research integrity standards required by the ACO and NVRI, and facilitates compliance with the Australian Code for the Responsible Conduct of Research 2018 ('the Code'), and Marra Ngarrgo Marra Goori (the Victorian Aboriginal Health, Medical, and Wellbeing Research Accord = 'the Accord').

All who are engaged in research activities undertaken at the ACO or NVRI (for the purposes of this policy, 'researchers'), will:

a. Adhere to the Principles and Responsibility of responsible research conduct outlined in the Code and the Accord
b. Adhere to the Procedures and Procedural principles in Section 3 in this Policy
c. Engage with Aboriginal and Torres Strait Islander peoples to recognise, respect their rights and local laws, customs and protocols for research which could be deemed of particular significance to Aboriginal and Torres Strait Islander peoples
d. Only participate in research activities they are qualified for, or under the supervision of researcher(s) who are appropriately qualified.

2. Scope

The policy applies to:

Employees	**Directors**	**Officers**	**PhD Students**	**Contractors** (including employees of contractors)	**Volunteers**	**Suppliers**	**Consultants**
✓	✓	✓	✓	✓	✓	x	✓

3. Procedures and Procedural principles

3.1. Research Proposals

If not already, all researchers should familiarise themselves with the ACO's Strategic Plan when considering proposing research at the ACO. New research should align with the plan, be feasible, financially sustainable and delivered in a manner that minimises the impact on staff and patients' routine clinical care. Researchers are expected to identify, assess and mitigate risks associated with all new research activities.

Principal Investigators (PIs) should discuss their project proposals with the relevant people who will be involved. In practice, this means that the PI communicates with the relevant members of the Executive Team, General Managers, Managers, Duty Managers where significant impacts on resources or potential risks are involved in their area(s) of responsibility.

When a new research proposal has received acknowledgement and approval from relevant ACO and NVRI staff, the project should be reported to the Clinical Governance Advisory Group (CGAG) and included in the Research and Audit Registry ('the Registry'). The CGAG may assess the need for research ethics approval or provide an exemption.

3.2. Principal Investigator Requirements

All research being conducted at the ACO must have a site Principal Investigator responsible for the safe and ethical conduct of the research project. The Director of Research and Education or a researcher with a recognised appointment at the ACO, must be nominated as the site PI to ensure there is a line of accountability. The PI may delegate research activities, however they still retain overall responsibility.

Student researchers undertaking PhD or Master degree can be the site PI at ACO, only if approved by the Director of Research and Education.

The application of a particular investigator category (i.e. PI or Co-Investigator) for the purpose of research ethics and governance consideration does not influence or reflect the authorship nomenclature or ownership of the protocol, it is simply an indication of who is responsible for the conduct of the research at the ACO.

3.3. Funding sources

Funding support for a research project can come from a variety of sources and may take many forms. This includes but is not limited to:

- monetary payments from a commercial sponsor;
- in-kind support or donated time from researchers, departments, laboratories or collaborators;
- donated investigational products from commercial entities; and
- grant funding from ACO or NVRI, commercial entities, government agencies such as the NHMRC and other not-for-profit organisations.

Any form of funding arrangement for the conduct of research at ACO must have an appropriate and transparent financial management process in place.

3.4. Training compliance

3.4.1. Good Clinical Practice

Good Clinical Practice (GCP) guidelines are the internationally-agreed standard for conducting human research.

All researchers directly involved in clinical trials are required to provide evidence of GCP training within the last 3 years. GCP training must be updated every 3 years from a TransCelerate recognised GCP providers. A list of providers can be found at https://transcelerate-gcp-mutual-recognition.com/home.

All other researchers are recommended to complete GCP training, as many principles can be applicable to other areas of research.

3.5. Conflicts of Interest

Researchers must comply with the *ACO Conflict of Interest Policy (2020-008)* and *ACO Conflict of Interest Declaration Guidelines*. This includes disclosing to the ACO, funding bodies, ethics committees, publishers, and other relevant parties any/all actual, potential or perceived conflicts of interest and manage them accordingly.

3.6. Research Ethics

3.6.1. Human research ethics

Researchers that conduct research involving humans are required to ensure that any research projects protect the rights and safety of participants, that is, it is 'ethical'. While it is important to ensure all activities are ethically sound, not all projects require review by a properly constituted Human Research Ethics Committee (HREC). The level of review will be commensurate with the level of risk to which participants are exposed. Risks include physical, emotional, psychological, social, legal and reputational risks to participants, their families and communities, researchers, and/or institutions involved in the research.

Researchers must:

- Discuss with the ACO CGAG or the Director of Research and Education on whether the project would be considered as negligible risk, low-risk or more than low-risk research
- Obtain the approval of a properly constituted HREC for more than low-risk research
- Obtain the approval of a properly constituted HREC or low-risk subcommittee or Human Ethics Advisory Group (HEAG) for low-risk research
- Obtain the exemption approval from the CGAG or Research team for negligible risk research. In practice, this means that the CGAG or Research team will organise an appropriate level of review and can produce letters that outline approval that will satisfy funding bodies and journals where necessary.
- Carry out human research only as approved
- Obtain approval for any amendments to the approved human research activity before implementing any amendment or change
- Act on and promptly report adverse events or deviations in accordance with the relevant process
- Report annually on the progress of the approved human research to either ACO CGAG and the respective HREC.

3.6.2. Quality assurance / Quality improvement / Evaluation activities

A Quality Assurance (QA) or Quality Improvement (QI) or Evaluation (also known as clinical audit) activity is an organised data collection process designed to evaluate whether the health service being provided is what has been agreed to be best practice and/or is achieving outcomes and measures against National Standards. The NHMRC publication, NHMRC *Ethical Considerations in Quality Assurance and Evaluation Activities (March 2014)* sets out guidance for appropriate oversight of QA and evaluation activities including triggers for consideration of ethical review where required. QA, QI and evaluation activities should comply with procedures outlined by CGAG.

3.6.3. Animal research ethics and welfare

Researchers that conduct research involving animals are required to ensure that it is necessary and minimises impact on animals, and receive approval from an Animal Ethics Committee (AEC).

The ACO currently has an Affiliation Agreement with The University of Melbourne. Researchers will adhere to the *Policy Principles of animal ethics and welfare* and *Procedural principles of Animal ethics and welfare*, as outlined in *The University of Melbourne Research Ethics and Biorisk Management Policy* (MPF1341).

3.6.4. Biorisk management

The ACO currently has an Affiliation Agreement with The University of Melbourne. Researchers will adhere to the *Policy Principles of working safely with regulated biological material* and *Procedural principles of Biorisk management*, as outlined in *The University of Melbourne Research Ethics and Biorisk Management Policy* (MPF1341).

3.7. Research Data Management

Researchers must comply with the *ACO Records Management Policy and Procedure (005)* and the Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research. It is the responsibility of the researcher to:

- Ensure the proper management and retention of research data during the conduct and after the completion of a research project to ensure a justification and defence of the outcomes can be provided if results are challenged.
- Ensure appropriate security and privacy measures are in place for confidential or sensitive research records, research data, source material, and/or primary material to prevent unauthorised access to or inappropriate disclosure of the material
- Report, immediately upon becoming aware of or suspecting on reasonable grounds, any inappropriate or unauthorised use of, access to or loss of confidential or sensitive research data and records

3.7.1. Electronic data and documents

Researchers are required to store electronic data and documents on ACO approved network(s) or platform servers. Approval should only be provided to servers that have adequate security and are backed up at regular intervals. Documents and data should be retrievable from the backed-up copies should the need arise. Research documents or data must not only be stored on ACO local drives / desktops. The latest version of the amended file or document must be saved to the relevant network drive / cloud server at the earliest opportunity. Research documents or data must not be stored on removable storage devices or non-ACO devices unless approved by the Director of Research and Education.

Researchers must comply with the *Use of Information Technology Policy* (2020-020). The ACO's IT Support, is responsible for maintaining network drives in workable order and for managing backup protocols.

Creating, managing and using information from research databases is the responsibility of the research team.

3.7.2. Hard copy data and documents

Hard copy data should be securely stored at the ACO or ACO approved location where only researchers on the relevant project(s) have access.

3.8. Research Publications and Dissemination

ACO has the responsibility to ensure that findings and advances in knowledge from publicly funded research are disseminated to other researchers and the wider community, subject to the relevant restrictions on the publication of results.

In addition to their responsibilities under the Code and the Accord, researchers must:

- ensure accuracy, transparency and completeness when reporting and communicating research findings, where appropriate, acknowledge limitations of research, provide appropriate caution when the research has not undergone peer review and include discussion of relevant negative, contrary or unexpected results;
- appropriately cite and acknowledge previous work including their own, whether published or unpublished;
- take all reasonable steps to obtain permission from the original publisher or copyright owner before republishing their own or others' research findings;
- appropriately identify and attribute the host institution/s of the research;
- not submit substantially similar work to more than one publisher without disclosing this to the publishers at the time of submission, unless this is expressly permitted by the publisher or if a third-party submission service is employed;
- accurately disclose all actual, perceived or potential conflicts of interest, in accordance with *ACO Conflict of Interest Policy (2020-008), ACO Conflict of Interest Declaration Guidelines*, and if necessary, publisher's guidelines;
- accurately disclose all forms of financial research support including, but not limited to, fellowships, course fee sponsorship and fee remissions, scholarships, contracted research, and project grant funding;
- when publishing research that affects or is of particular significance to Aboriginal and Torres Strait Islander peoples, to undertake consultations with Aboriginal and Torres Strait Islander peoples to ensure that what is published is culturally appropriate;
- honour restrictions on publication or dissemination imposed by law, under an agreement or relevant committee such as ethics or biosafety committees;
- foster transparency in research publication where appropriate e.g. by registering plans or protocols, disclosing ethics and other approvals, allowing access to interested parties at the conclusion of a project, engaging with open access infrastructure, uploading data in accordance with *ACO Records Management Policy and Procedure (005)*;
- approve the research output and final version before publication; and
- take active, reasonable and timely steps to correct the public record upon becoming aware of errors or misleading information in their published outputs.

3.9. Authorship

This Procedure applies to the authorship of all research outputs (including non-traditional research outputs) and the attribution of authorship in other documents related to research. Authorship recognises those who have made a significant intellectual and scholarly contribution to research and its output.

3.9.1. Authorship criteria

The criteria for authorship and the responsibilities of authors are outlined in the Code, the supporting NHMRC Authorship Guide, and the International Committee of Medical Journal Editors Recommendations.

3.9.2. Researcher responsibilities

All researchers have a responsibility to ensure that reasonable efforts are made to properly recognise all contributors to the research and its output, either through authorship or acknowledgement.

At the earliest possible stage of planning a research output, all researchers should discuss authorship between potential co-authors and contributors reaching an Authorship Agreement. To identify and reflect any changes in circumstances and/or contributions to the research, authorship discussions can continue throughout the course of the research.

Authorship discussions should be held with all potential co-authors, that include:

- the expectations of individuals and the collaboration;
- the expected outcomes from the research;
- the probable research outputs that will be generated;
- the roles and responsibilities of researchers who will contribute to the work;
- who will be an author (inclusive of authorship order and consideration of co-authorship);
- who will receive acknowledgement; and
- who will be the Coordinating/Corresponding Author.

An Authorship Agreement should include:

- author's preferred name and title;
- author's affiliation(s);
- a description of author's contribution made to the research and its output
- the agreed authorship order, where applicable; and
- identification of the Coordinating/Corresponding Author

In addition to fulfilling the authorship criteria, the Coordinating/Corresponding Author is responsible for:

- communicating between co-authors;
- managing and implementing the Authorship Agreement;
- maintaining records of an Authorship Agreement and any amendments; and
- communicating with the publisher.

If the Coordinating/Corresponding Author is not an ACO staff member or student, the NVRI research team must obtain copies of the Authorship Agreement and any amendments.

A written agreement to be included or excluded from each author/research contributor is required and a record must be kept.

If an author cannot be contacted after reasonable attempts have been made, all the co-authors must still have confidence in the accuracy and integrity of the author's contribution before including or excluding them. The Director of Research and Education may sign on behalf of an author that cannot be contacted. An author should not be included if there are grounds to believe that the person would have objected to being included. Where contributing individuals are not named as authors, the Coordinating/Corresponding author will retain documentary evidence of reasonable attempts made to obtain consent.

3.9.3. Authorship dispute management

An authorship dispute occurs when two or more researchers are unable to reach an agreement regarding acknowledgement or authorship inclusion. If the dispute occurs amongst ACO/NVRI researchers, the following procedures should be followed.

Researchers involved in the dispute are to attempt to reach a resolution through direct dialogue, with records of the discussion maintained and the outcomes communicated to all involved. Where this is unsuccessful, authorship disputes should be referred by the researchers involved or the Coordinating/Corresponding author to the Director of Research and Education.

If there is a conflict of interest with the Director of Research and Education, the Research Committee or an appropriate impartial third-party will be appointed to facilitate dispute resolution.

If a power imbalance exists between researchers involved, junior researchers can seek the support of an impartial third party.

If the dispute occurs amongst ACO researcher(s) and external parties, external parties may be required to comply with their own policy, thus it is at the discretion of the Director of Research and Education, guided by the principles and responsibilities of the Code, to determine the appropriate course and facilitate dispute resolution.

3.10. Intellectual Property

Researchers must comply with the *ACO Intellectual Property Policy (CS/018)*.

3.11. Collaborative Research

Where a project involves the ACO and another organisation (i.e. Commercial Sponsor, Contract Research Organisation (CRO), institute, hospital or Collaborative Research Group (CRG)), all parties much adhere to their responsibilities under the Code and the accompanying Collaborative research: A guide supporting the Australian Code for Responsible Conduct of Research (2020).

An agreement on the management of the research must be in place before the project can be authorised to commence. This agreement must be in writing and include:

- The intellectual property rights,
- Confidentiality and copyright issues,
- Sharing commercial returns,
- Management of conflict of interest,
- Insurance and indemnity arrangements,
- Responsibility for ethics and safety clearances and reporting to appropriate agencies,

- Protocols to be followed when disseminating the research outcomes,
- Management of primary research materials and research data, and
- Budget and Payment arrangements.

3.12. Insurance and Indemnity

ACO must be satisfied that sponsors of clinical research have indemnity, insurance and compensation arrangements in accordance with applicable regulatory requirements. ACO must also have arrangements to compensate participants for harm resulting from negligence in research. ACO has the following insurances with Tresidder Insurance Brokers which provides cover for key risks associated with clinical research:

- Liability Insurance
- Professional Indemnity
- Cyber Liability
- Industrial Special Risks
- Corporate Travel

3.13. Complaints Management

The ACO Risk and Business Improvement Officer is responsible for receiving complaints about research conducted at the ACO. Complaints may also be directed to the approving research ethics committee for assessment or further investigation.

Complaints on site will be directed to the relevant members of the Executive Team or General Manager for assessment, and investigation as required.

3.14. Breaches of the Code and Research Misconduct

ACO and the NVRI regards any conduct in breach of the Code or Research Conduct Policy as unacceptable and will manage concerns and complaints related to, or findings of, the breach. This means a failure by a researcher to:

- meet one or more of the principles or responsibilities in the Code
- adhere to the Research Conduct Policy and Procedures

Any person who suspects a breach of the code or research misconduct is required to promptly report, verbally or in writing, to the Director of Research and Education. If the reported breach or misconduct is considered a disclosable conduct, the Whistleblower Policy should be followed.

If the Director of Research and Education is implicated in any way, then a report can be made to the General Manager of People and Culture for advice towards reporting to a Whistleblower Investigation Officer (refer to *Whisteblower Policy* 023) and/or the ACO Research Committee.

3.14.1. False reports

Reports of breaches of the Code and/or research misconduct should only be reported if they have reasonable grounds to suspect that a breach or misconduct has occurred. Knowingly making a false report might result in disciplinary action, including termination of employment, appointment or contractual relationship.

3.14.2. Anonymity and confidentiality

Those who report a breach or misconduct can do so anonymously. If the report is not made anonymously, the reporter can request for their identity to be kept confidential. If the request is made, the Director of Research and Education (or General Manager of People and Culture) must take all reasonable steps to maintain confidentiality.

3.14.3. Investigation

The Director of Research and Education (or alternate party if the Director of Research and Education is implicated) will carry out or supervise an investigation. All reasonable efforts will be made to ensure the investigation is conducted fairly, without bias, and promptly.

All reasonable efforts will be made to preserve the confidentiality of the investigation and the identity of the parties involved, including the reporter and the alleged perpetrator/s.

All reasonable steps will be taken to ensure the alleged perpetrator is treated fairly. This might include:

- Information the perpetrator on the substance of the allegation
- Offering them to provide a response to the claim as part of the investigation
- Information them of any adverse finding that affects them.

All reasonable steps will also be taken to protect the reporter. The ACO and NVRI do not tolerate any victimisation, detrimental treatment or retaliatory action against the reporter.

At the end of the investigation, a report will contain the investigation's findings and a summary of evidence. Based on the report, the Director of Research and Education (or alternate part if the Director of Research and Education is implicated) will take appropriate action.

4. Legislation and Related Resources

4.1. Legislation

- *Health Records Act 2001* (Vic)
- *Privacy Act 1988* (Cth)
- *Privacy and Data Protection Act 2014* (Vic)
- *Guardianship and Administration Act 2019* (Vic)
- *Human Tissue Act 1982* (Vic)
- *Therapeutic Goods Act 1989* (Cth)
- *Drugs, Poisons and Controlled Substances Act 1981* (Vic)
- *Gene Technology Act 2000* (Cth)
- *Gene Technology Act 2001* (Vic)
- *Research Involving Human Embryos Act 2002* (Cth)
- *Prohibition of Human Cloning for Reproduction Act 2002* (Cth)
- *Radiation Act 2005* (Vic)
- *Radiation Regulations 2017* (Vic)

4.2. Resources

Reference	Source
The Australian Code for the Responsible Conduct of Research, 2018 (the 2018 Code)	https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018
Marra Ngarrgo Marra Goori – The Victorian Aboriginal Health, Medical, and Wellbeing Research Accord	https://www.vaccho.org.au/accord/
TransCelerate recognised GCP providers	https://transcelerate-gcp-mutual-recognition.com/home
The National Clinical Trials Governance Framework and User Guide for Health Service Organisations Conducting Clinical Trials	https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide
National Statement on Ethical Conduct in Human Research 2023	https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023
AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (AIATSIS code), 2020	https://aiatsis.gov.au/sites/default/files/2020-10/aiatsis-code-ethics.pdf
A Guide to applying The AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research	https://aiatsis.gov.au/research/ethical-research/code-ethics
Keeping research on track II. A companion document to Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders	https://www.nhmrc.gov.au/about-us/resources/keeping-research-track-ii
Australian code for the care and use of animals for scientific purposes	https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes
International Committee of Medical Journal Editors Recommendations	https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
NHMRC Guides supporting the Code: • Authorship • Collaborative Research • Disclosure of interests and management of conflict of interests • Guide to managing and investigating potential breaches • Management of data and information in research • Peer review • Publication and dissemination of research • Supervision • Research Integrity Advisors	https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

5. Feedback

ACO Staff may provide feedback about this document by emailing the policy owner.

6. Appendices

6.1. Appendix A: Definitions

Author	An individual who has made a significant intellectual or scholarly contribution to research and its output and who has agreed to be listed as an author.
Authorship Agreement	A record of contributions to research and its output, inclusive of the agreed authorship inclusions and exclusions.
Breach of the Code	A failure to meet the obligations and requirements of the Code
CGAG	Clinical Governance Advisory Group, the ACO internal group tasked with guiding clinical governance, continuous quality improvement in clinical services, alignment of clinic activities with organisational risk framework, and alignment with Safer Care Victoria frameworks
Clinical Trial	Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
Conflict of interest	A conflict of interest arises when an individual's personal, financial, or other interests could compromise or appear to compromise their judgement, decisions, or actions in their role within the ACO.
Disclosable conduct	Misconduct that is covered by one or more of the Commonwealth or Victorian laws that the Whistleblower Policy (023) addresses
Electronic data	Electronic data means information, concepts and facts collected from research participants and converted to a form useable for communications, interpretation, processing or analysis by computer software including systems and applications software. This can include text, numbers, images, audio and video.
Hard copy data	Hard copy data means information, concepts and facts collected from research participants or researchers that are recorded onto a physical medium such as paper or notebooks.
Low-risk research	Projects where there is no risk of harm but where there is a risk of discomfort.
Minimal-risk research	Projects where there is no risk of harm or discomfort but where there may be a potential for minor burden or inconvenience.
More than low-risk research	Projects where the risk, even if unlikely, is more serious than discomfort.
Negligible-risk research	Research in which the only foreseeable risk is no more than inconvenience.
The Accord	*Marra Ngarrgo Marra Goori – The Victorian Aboriginal Health, Medical, and Wellbeing Research Accord*
The Code	*The Australian Code for the Responsible Conduct of Research (2018)*
The Registry	Research and Audit Registry, administered by ACO's Clinical Governance Advisory Group