Australian Government
National Health and Medical Research Council

NHMRC

Clinical Trials and Cohort Studies Grants 2023 Peer Review Guidelines

Opening date:	28 June 2023
Closing date and time:	17.00 ACT local time on 23 August 2023
Commonwealth policy entity:	National Health and Medical Research Council (NHMRC)
Sapphire assistance and enquiries:	NHMRC Research Help Centre Phone: 1800 500 983 (+61 2 6217 9451 for international callers) Email: help@nhmrc.gov.au Note: NHMRC's Research Help Centre aims to provide a reply to all requests for general assistance within two working days. This timeframe may be delayed during peak periods or for more detailed requests for assistance.
Clinical Trials and Cohort Studies Grants enquiries:	Phone: 1800 500 983 (+61 2 6217 9451 for international callers) Email: help@nhmrc.gov.au

Contents

Clinical Trials and Cohort Studies Grants 2023 Peer Review Guidelines 1

1. Introduction 4

2. Key changes 4

3. Principles, conduct and obligations during peer review 5

3.1. NHMRC's Principles of Peer Review 5

3.2. The Australian Code for the Responsible Conduct of Research 5

3.3. Disclosures of Interest 5

3.3.1. What is an interest? 5

3.3.2. What is a Conflict of Interest (CoI)? 6

3.3.3. Disclosure of Interests in the Peer Review Process 6

3.3.4. Failure to disclose an interest 6

3.4. Freedom of Information (FoI) 6

3.5. Complaints 6

4. Clinical Trials and Cohort Studies Grants 2023 peer review process 7

4.1. Overview of the Clinical Trials and Cohort Studies Grants 2023 peer review process 7

4.2. Roles and responsibilities 8

4.3. Reviewing Clinical Trials and Cohort Studies Grants 2023 applications 11

4.3.1. Identification of applications with an Aboriginal and Torres Strait Islander health focus 12

4.3.2. Receipt and initial processing of applications 12

4.3.3. Disclosure of interests and peer reviewer suitability 12

4.3.4. Establishment of panels and assignment of applications to panels 12

4.3.5. Briefing 12

4.3.6. Assessment of applications 12

4.3.6.1. Relative to opportunity and career disruption 13

4.3.6.2. Mitigating bias in peer review 13

4.3.6.3. Industry-relevant experience 14

4.3.6.4. Use of Impact Factors and other metrics 14

4.3.6.5. Enhancing reproducibility and applicability of research outcomes 14

4.3.6.6. Research Integrity Issues 14

4.3.6.7. Contact between peer reviewers and applicants 15

4.3.7. Panel meetings 15

4.3.7.1. Discussion of applications at panel meeting 15

4.3.7.2. Panel meeting process 15

4.3.8. Quorum/Minimum number of assessments 17
4.3.9. Principles for setting conditions of funding for NHMRC grants 17
4.3.10. Providing feedback on applications 18
4.3.11. Documentation 19
4.3.12. Funding Recommendation 19
4.3.13. Notification of Outcomes 19
Appendix A - Understanding the Principles of Peer Review 20
Appendix B - Guidance for Declaring and Assessing Disclosures of Interest 22
Appendix C – Clinical Trials and Cohorts Studies Grants 2023 Assessment Criteria 27
Appendix D – Clinical Trials and Cohort Studies Grants 2023 Category Descriptors 30
Appendix E - Indigenous Research Excellence Criteria 37
Appendix F – Guidance for assessing applications against the Indigenous Research Excellence Criteria 38
Appendix G – Guide to Evaluating Industry-Relevant Experience 39

1. Introduction

The National Health and Medical Research Council (NHMRC) is responsible for managing the Australian Government's investment in health and medical research in a manner consistent with Commonwealth legislation, guidelines and policies. NHMRC has a responsibility to ensure taxpayers' funds are invested appropriately to support the best health and medical research. Expert peer review assists us in fulfilling this responsibility.

This guide outlines the overarching principles and obligations under which the Clinical Trials and Cohort Studies Grants 2023 peer review process operates, including:

- obligations in accordance with legislation, guidelines and policies
- how to disclose interests and manage conflicts, and
- standards and best practice for the conduct of peer review.

NHMRC will publicly notify the sector of any change in peer review process via its communications, such as through NHMRC's website and newsletters.

This guide should be read in conjunction with the:

- Clinical Trials and Cohort Studies Grants 2023 grant guidelines, available on GrantConnect, which set out the rules, objectives and other considerations relevant to NHMRC funding.
- *Policy on the Disclosure of Interests requirements for prospective and appointed NHMRC committee members* (Section 39 Committees). This Policy outlines peer reviewers' responsibilities to ensure all disclosures of interests are addressed in a rigorous and transparent way throughout the period of a peer reviewer's participation in NHMRC Committees.

2. Key changes

NHMRC recognises the impacts of the COVID-19 pandemic on Australia's health and medical research community and has updated assessment processes to reflect these impacts.

Peer reviewers must follow these updated processes:

- In track record assessment, peer reviewers must consider COVID-19 related circumstances, as outlined by applicants, as part of career disruptions or other relative to opportunity considerations under the provisions of NHMRC's *Relative to Opportunity Policy*.
- Peer reviewers should note that applicants have been advised that they may include information on any potential significant and long-term impacts of the COVID-19 pandemic on their proposed research, and proposals for managing such risks, as part of their research risk management plan within the grant proposal.
- Peer reviewers are not to let the potential impacts of the COVID-19 pandemic on the proposed research affect the assessment of the research proposal of an application (e.g. the feasibility of accessing certain patient or population groups with social distancing restrictions in place).
- Peer reviewers must note that changes to the research proposal of a funded application, necessitated by the impacts of the COVID-19 pandemic (e.g. the commencement of a project needs to be delayed by six months until COVID-19 restrictions are eased) will be considered through NHMRC's Postaward management and grant variations processes. Such considerations do not form part of the peer review assessment of the proposal, particularly given that the long term impacts of the pandemic are still unknown.

3. Principles, conduct and obligations during peer review

The peer review process requires all applications to be reviewed by individuals with appropriate expertise. This carries an obligation on the part of peer reviewers to act in good faith, in the best interests of NHMRC and the research community and in accordance with NHMRC policies (outlined below).

3.1. NHMRC's Principles of Peer Review

NHMRC's Principles of Peer Review (the Principles) are high-level, guiding statements that underpin all NHMRC's peer review processes, and include:

- **Fairness.** Peer review processes are fair and seen to be fair by all.
- **Transparency.** Applies to all stages of peer review.
- **Independence.** Peer reviewers provide independent advice. There is also independent oversight of peer review processes by independent Chairs, Peer Review Mentors and Observers, where relevant.
- **Appropriateness and balance.** There is appropriate experience, expertise and representation of peer reviewers assessing applications.
- **Research community participation.** Persons holding taxpayer-funded grants should willingly make themselves available to participate in peer review processes, whenever possible, in accordance with the obligations in the Funding Agreement.
- **Confidentiality.** Participants respect that confidentiality is important to the fairness and robustness of peer review.
- **Impartiality.** Peer review is objective and impartial, with appropriate processes in place to manage disclosures of interest.
- **Quality and excellence.** NHMRC will continue to introduce evidence-based improvements into its processes to achieve the highest quality decision-making through peer review.

Additional details underpinning the Principles can be found at Appendix A.

3.2. The Australian Code for the Responsible Conduct of Research

The *Australian Code for the Responsible Conduct of Research* (the Code) requires researchers participating in peer review do so in a way that is 'fair, rigorous and timely and maintains the confidentiality of the content'.

The Code is supported by additional supplementary guidance, including *Peer Review: A guide supporting the Australian Code for the Responsible Conduct of Research.*

3.3. Disclosures of Interest

3.3.1. What is an interest?

NHMRC is committed to ensuring that interests of any kind are dealt with consistently, transparently and with rigour, in accordance with sections 16A and 16B of the *Public Governance, Performance and Accountability Rule 2014* (made under the subsection 29(2) of the *Public Governance, Performance and Accountability Rule 2013* (PGPA Act)).

In particular, under section 29 of the PGPA Act, "an official of a Commonwealth entity who has a material personal interest that relates to the affairs of the entity must disclose details of the interest". This obligation is ongoing and not limited to a particular point in time.

For the purposes of this document, the terms "material personal interest" and "interest" are regarded as interchangeable and whilst the term "interest/s" has been used for ease of reading, this policy includes guidance on each.

3.3.2. What is a Conflict of Interest (CoI)?

A CoI exists when there is a divergence between professional responsibilities (as a peer reviewer) and personal interests. Such conflicts have the potential to lead to biased advice affecting objectivity and impartiality. By managing any conflict, NHMRC maintains the integrity of its processes in the assessment of scientific and technical merit of the application. For NHMRC peer review purposes, interests may fall into the broad domains of:

- Involvement with the application under review
- Working relationships
- Professional relationships and associations
- Social relationships or associations
- Collaborations
- Teaching or supervisory relationships
- Financial relationships or interests
- Other relevant interests or relationships

For further information, peer reviewers should consult the NHMRC *Policy on the Disclosure of Interests Requirements for Prospective and Appointed NHMRC Committee Members* (Section 39 Committees).

Researchers frequently have a CoI that cannot be avoided. Decision making processes in research often need expert advice, and the pool of experts in a field can be so small that all the experts have some link with the matter under consideration. An individual researcher should therefore expect to be conflicted from time to time, be ready to acknowledge the conflict and make disclosures as appropriate. An outline of potential CoI situations and guidance is provided for peer reviewers at Appendix B.

3.3.3. Disclosure of Interests in the Peer Review Process

Peer reviewers must identify and disclose interests they may have with any of the Chief Investigators (CIs) and Associate Investigators (AIs) on applications they will be reviewing. After appointment as a peer reviewer, but before assessing any applications, peer reviewers are required to disclose their interests in writing. While interests must be disclosed at the beginning of the peer review process, new or previously unrecognised interests must be disclosed at any stage of the peer review process. Declarations must include details that substantiate when collaborations occurred (i.e. month and year). NHMRC will use these details to verify and determine the level of conflict. Any peer reviewer who has an interest that is determined by NHMRC to be a 'high' CoI will not be able to participate in the review of that application. However, they can provide scientific advice at the request of the Chair or NHMRC.

3.3.4. Failure to disclose an interest

A failure to disclose an interest without a reasonable excuse will result in the termination of the peer reviewer's appointment under section 44B of the NHMRC Act (section 44B also covers failure to comply with section 29 of the PGPA Act).

It is important for peer reviewers to inform NHMRC of any circumstances which may constitute an interest, at any point during the peer review process. Accordingly, peer reviewers are encouraged to consult the secretariat if they are uncertain about any disclosure of interest matter.

3.4. Freedom of Information (FoI)

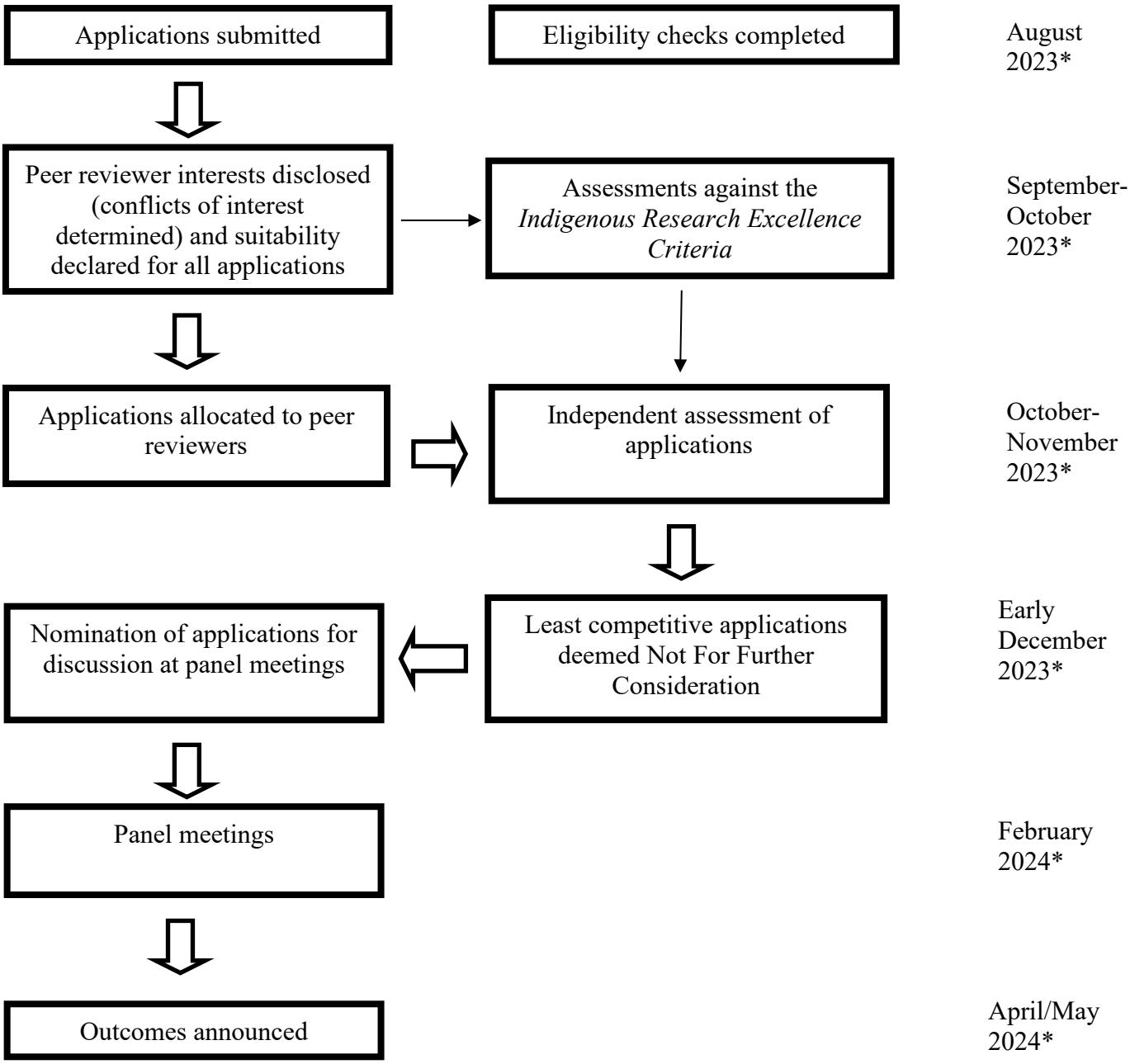
NHMRC is subject to the *Freedom of Information Act 1982* which provides a statutory right for an individual to seek access to documents. If documents that deal with peer review fall within the scope of a request, the FoI process includes consultation and exemptions. NHMRC endeavours to protect the identity of peer reviewers assigned to a particular application.

3.5. Complaints

NHMRC deals with any complaints, objections and requests for clarification on the peer review process. NHMRC may contact peer reviewers and/or Chairs involved to obtain additional information on particular application/s. Further information about the NHMRC complaints process can be found on the NHMRC website.

4. Clinical Trials and Cohort Studies Grants 2023 peer review process

4.1. Overview of the Clinical Trials and Cohort Studies Grants 2023 peer review process



*Dates are indicative

Date	Activity
23 August 2023	Deadline for Clinical Trials and Cohort Studies Grants 2023 application submission
August 2023	Application eligibility review and confirmation
September-October 2023	Peer reviewers disclose interests and suitability against applications
September-October 2023	Assessments against the *Indigenous Research Excellence Criteria* obtained
October 2023	Allocation of applications to peer reviewers
October-November 2023	Peer reviewers review applications and submit scores against Clinical Trials and Cohort Studies Grants 2023 assessment criteria for each allocated application
February 2024	Panel meetings
April/May 2024*	Notification of outcomes

*Date is indicative and subject to change.

Further information on the steps outlined in this process is provided in section 4.3 *Reviewing Clinical Trials and Cohort Studies Grants 2023 applications.*

4.2. Roles and responsibilities

The roles and responsibilities of those participating in the Clinical Trials and Cohort Studies Grants 2023 peer review process are identified in the table below.

Clinical Trials and Cohort Studies Grants 2023 Peer Review Participants Table

Roles	Responsibilities
Chair	The Chair's role is to ensure NHMRC's procedures are adhered to and that fair and equitable consideration is given to every application being discussed at the panel meeting. Chairs do not assess applications but manage the process of peer review in accordance with this Guide. Prior to the panel meeting Chairs need to: • familiarise themselves with this document and other material as identified by NHMRC staff • identify and advise NHMRC of all interests they have with applications assigned to their panel, and • familiarise themselves with ALL the applications assigned to their panel, excluding those for which they have been determined to have a high CoI. • assist peer reviewers with their duties and in understanding what is expected of them During the panel meeting, Chairs will: • take appropriate action for each CoI • keep discussions on time and focused • ensure NHMRC procedures are followed • promote good engagement by peer reviewers in all discussions • ensure that all peer reviewers consider 'relative to opportunity', including career disruptions, when discussing applications • ensure that any discussion and assessment is based on the Clinical Trials and Cohort Studies Grants 2023 assessment criteria and associated category descriptors (Appendices C and D). • ensure the panel consistently considers the assessment against the *Indigenous Research Excellence Criteria* for applications with an

	Aboriginal and Torres Strait Islander health focus • ensure peer reviewers are satisfied with the consistency and appropriateness of discussions for each application • record and notify NHMRC of any requests for clarification or advice, and • approve Meeting Attendance Record sheets.
Peer reviewers	Prior to the panel meeting, peer reviewers need to: • familiarise themselves with this Guide and other material as identified by NHMRC staff • identify and advise NHMRC of all interests they have with applications assigned to their panel/them • provide a fair and impartial assessment against the Clinical Trials and Cohort Studies Grants 2023 assessment criteria and associated category descriptors (Appendices C and D) in a timely manner, for each non-conflicted application assigned • assess track record by taking into consideration research achievements 'relative to opportunity', including any career disruptions, where applicable • consider the assessment against the *Indigenous Research Excellence Criteria* (Appendix E) provided for applications confirmed to have an Aboriginal and Torres Strait Islander health focus • provide written summaries for each application assigned to them. During the panel meeting, peer reviewers will: • disclose interests they have with other peer reviewers • prepare for and participate in the discussion for each application where they do not have a high CoI.
Primary Spokesperson (1SP)	Prior to the panel meeting: • assess the allocated applications against the Clinical Trials and Cohort Studies Grants 2023 assessment criteria and associated category descriptors (Appendices C and D). • assess track record by taking into consideration research achievements 'relative to opportunity', including any career disruptions, where applicable • consider the assessment against the *Indigenous Research Excellence Criteria* (Appendix E) provided for applications confirmed to have an Aboriginal and Torres Strait Islander health focus • prepare speaking notes to present the application at the panel meeting • rigorously assess the proposed budget to ensure that requests for Direct Research Costs (DRCs) are appropriate for the project and fully justified. At the panel meeting: • lead the discussion using prepared notes, considering research achievements 'relative to opportunity', including any career disruptions, and the assessment provided against the *Indigenous Research Excellence* Criteria, where applicable. • announce final scores for applications based on discussions • support the secondary spokesperson (2SP) in discussion about the appropriateness or otherwise, of the requested budget as required with reference to the individual elements of the budget ensuring PSPs,

	DRCs and equipment requests are appropriate for the project and fully justified.
Secondary Spokesperson (2SP)	Prior to the panel meeting: • assess allocated applications against the Clinical Trials and Cohort Studies Grants 2023 assessment criteria and associated category descriptors (Appendices C and D). • assess track record by taking into consideration research achievements 'relative to opportunity', including any career disruptions, where applicable • prepare speaking notes to present the application at the panel meeting • rigorously assess the proposed budget to ensure that the DRCs are appropriate for the project and fully justified • prepare a recommendation for the panel to either: leave the requested budget intact, propose modifying the budget, or seek advice from the panel regarding specific budget requests. At the panel meeting: • add to the 1SP comments using prepared notes • announce final scores for applications based on discussions • discuss the appropriateness or otherwise, of the requested budget as required with reference to the individual elements of the budget ensuring the requested DRCs are appropriate for the project and fully justified.
Tertiary Spokesperson (3SP)	Prior to the panel meeting: • assess allocated applications against the Clinical Trials and Cohort Studies Grants 2023 assessment criteria and associated category descriptors (Appendices C and D). • assess track record by taking into consideration research achievements 'relative to opportunity', including any career disruptions, where applicable. At the panel meeting: • support the 1SP and 2SP in discussion with reference to prepared notes. • write a brief summary to reflect the panel discussion in line with the Clinical Trials and Cohort Studies Grants 2023 assessment criteria and associated category descriptors (Appendices C and D).
NHMRC Staff	Under direction from the CEO, NHMRC staff will be responsible for overall administration of the peer review process and for the conduct of specific activities. Prior to the panel meeting, NHMRC staff will: • invite individuals to participate in the Clinical Trials and Cohort Studies Grants 2023 scheme peer review process as required • determine whether disclosed interests pose a conflict and the level of that conflict. • act as the first point of contact for peer reviewers • provide briefings to peer reviewers • determine eligibility of applications • assign applications and peer reviewers to the appropriate panel/ to the appropriate peer reviewers based on peer reviewers' declaration of

	interests and suitability, and • prepare provisional ranked lists for peer reviewers' consideration. • review peer reviewer written summaries for inappropriate comments. At the panel meeting NHMRC staff will: • support the operation of Sapphire • assist the Chair in running the discussions • fulfil the role of Chair/Assistant Chair where required (e.g. where the Chair/Assistant Chair is deemed to have a high conflict of interest with an application). • implement appropriate management plans for peer reviewers with 'high' interests or conflicts with applications and ensure that all participants (including community observers) are aware of disclosed interests • ensure that all peer reviewers are provided with the necessary information to review each application, and assisting and advising on the peer review process as required • maintain scoring records for each application • act as the first point of contact for peer reviewers and community observers, and • seek feedback from participants in the peer review process on improvements for future processes.
Indigenous health research peer reviewers	Indigenous health research peer reviewers will review how well each application addresses NHMRC's *Indigenous Research Excellence Criteria* (Appendix E) where applicable. Indigenous health research external peer reviewers will not participate in scoring. They will act as external experts and provide guiding comments to the peer reviewers relating to the *Indigenous Research Excellence Criteria*.
Community Observers	At the panel meeting, observers will: • identify and advise the Chair of all interests they have with applications to be discussed • monitor the procedural aspects of the meeting, and • provide feedback to NHMRC on the consistency of procedures across meetings. Observers may raise issues of a general nature for advice or action as appropriate with NHMRC staff. Observers are subject to the same disclosure of interest requirements as peer reviewers. Where a high CoI exists, the observer will not observe discussions of the respective application(s).

4.3. Reviewing Clinical Trials and Cohort Studies Grants 2023 applications

All Clinical Trials and Cohort Studies Grants 2023 applications are assessed against the Clinical Trials and Cohort Studies Grants 2023 Assessment Criteria and the associated Category Descriptors at Appendices C and D. Applications that are accepted by NHMRC as relating to the improvement of Aboriginal and Torres Strait Islander health (see section 4.3.1) are also assessed against the *Indigenous Research Excellence Criteria* as set out at Appendix E.

4.3.1. Identification of applications with an Aboriginal and Torres Strait Islander health focus

Applications relating specifically to Aboriginal and Torres Strait Islander people's health will be identified by information provided in the application. Peer reviewers with Aboriginal and Torres Strait Islander health expertise will check whether these applications have at least 20% of their research effort and/or capacity building focused on Aboriginal and Torres Strait Islander health.

For applications confirmed as relating specifically to Aboriginal and Torres Strait Islander health research, NHMRC will endeavour to obtain at least one external assessment against the *Indigenous Research Excellence Criteria* (Appendix E) from an assessor with expertise in Aboriginal and Torres Strait Islander health. For further information on assessing applications that have a focus on the health of Indigenous Australians, see *Guidance for Assessing applications against the Indigenous Research Excellence Criteria* at Appendix F.

The assessment against the *Indigenous Research Excellence Criteria* will be considered by peer reviewers when scoring the assessment criteria at Appendix C.

4.3.2. Receipt and initial processing of applications

NHMRC staff will verify that Clinical Trials and Cohort Studies Grants 2023 applications meet eligibility criteria. Applicants will be advised if their application is ineligible. However, in some instances these applications will remain in the peer review process until their ineligibility is confirmed. Eligibility rulings may be made at any point in the peer review process.

4.3.3. Disclosure of interests and peer reviewer suitability

Peer reviewers will be provided with a summary of each application and disclose their interests within Sapphire, in accordance with the guidelines provided at Section 3.3 and Appendix B.

Some peer reviewers may have a disclosure of interest for which they require a decision. In this case, NHMRC will assess the information provided by the peer reviewer and provide a ruling on the level of CoI.

Peer reviewers are also required to select their level of suitability to assess each application, based on the information available to them in the application summary. Further information and tutorials are available from Sapphire.

4.3.4. Establishment of panels and assignment of applications to panels

Taking into account CoIs and peer reviewer suitability, NHMRC staff will assign applications and peer reviewers to panels of up to 15 members. This is subject to change, depending on the number and peer review area of applications. Each application will be assigned up to three initial reviews.
The number of panels formed will depend on the total number and type of applications received.

Applications are allocated to a panel primarily based on the applicant's nominated peer review areas. Allocation may also be informed by the proposed field of research and other key words entered into Sapphire. Where the applicant has nominated a peer review area that is unlikely to provide appropriate expertise, NHMRC scientific staff will identify an appropriate panel to conduct the peer review assessment.

4.3.5. Briefing

NHMRC will provide peer reviewers briefing material with further details on their duties and responsibilities in the Clinical Trials and Cohort Studies Grants 2023 peer review process. This will be made available to peer reviewers prior to assessing applications. Further information may be provided as necessary throughout the peer review process. Further information and tutorials are available from Sapphire.

4.3.6. Assessment of applications

Peer reviewers will be given access to applications (where no high CoI exists) and will be required to assess and enter their scores in Sapphire. Peer reviewers will assess all applications assigned to them against the assessment criteria, using the category descriptors, taking into account career disruptions and other 'relative to opportunity' considerations (NHMRC Policy and Priorities), where applicable.

To ensure they provide independent scores, peer reviewers are not to discuss applications with other peer reviewers, except at the panel meeting.

Peer reviewers must ensure scores are completed by the nominated due date. If peer reviewers are unable to meet this requirement, they must contact NHMRC promptly to discuss alternative arrangements.

Peer reviewers' scores will be used to create ranked lists of applications from which will be used to shortlist applications that will proceed to the grant review panel. The overall score for each application will be determined using each peer reviewer's score for each of the assessment criteria. The overall score, as calculated arithmetically to three decimal places, will take account of the weighting of each criterion.

4.3.6.1. Relative to opportunity and career disruption

Peer reviewers must assess productivity relative to opportunity and, where applicable, career disruption considerations, in the assessment of all applications. This reflects NHMRC's policy that peer reviewers should assess an applicant's track record of research productivity and professional contribution in the context of their career stage and circumstances, by taking into consideration whether the applicant's productivity and contribution are commensurate with the opportunities available to them. To assist peer reviewers with their assessment, further details of the *Relative to Opportunity Policy* are provided on NHMRC's website.

4.3.6.2. Mitigating bias in peer review

NHMRC is raising peer reviewers' awareness of unconscious bias in the assessment process, in alignment with international practice and to ensure that NHMRC grant applications continue to receive objective and impartial assessments. Understanding bias enables peer reviewers' to critically and independently review applications and avoid suboptimal or unfair outcomes.

This is underpinned by NHMRC's document: *Peer Review: A guide supporting the Australian Code for the Responsible Conduct of Research*, which states that peer reviewers should be aware of how their own biases (conscious or unconscious) could affect the peer review process, including in relation to gender, ethnicity, nationality, institutional employer and research discipline.

To minimise or avoid bias, peer reviewers are encouraged to take action to address the unintended and systematic biases which prevent unprejudiced consideration of an application. To increase peer reviewers' awareness of the types of cognitive biases that can occur during peer review, NHMRC recommends the San Francisco Declaration on Research Assessment (DoRA) guidance on Rethinking Research Assessment.

NHMRC is also committed to addressing gender equality to promote fairness, transparency, equality and diversity in health and medical research. Fostering gender equality in peer review is a strategic objective, underpinned by NHMRC's *Gender Equity Strategy*.

Peer reviewer participation in the online Harvard Implicit Association Test (IAT) for gender and science

In support of the objective, NHMRC encourages peer reviewers to complete the online IAT for gender and science. The IAT for gender and science, used by several research funding agencies nationally and internationally, is designed to help participants identify any implicit associations they may have between gender and participation in a science career.

By completing the test, peer reviewers gain a better understanding and increased awareness of how unconscious attitudes may affect their decisions, which prepares them to carry out their duties to the high standards of fairness and rigour expected by NHMRC. Peer reviewers should continue to follow all peer review principles and processes outlined in these guidelines, ensuring that each application is accurately reviewed against the assessment criteria (Appendix C). NHMRC does not have access to, nor does it seek, peer reviewers' information and results for the IAT for gender and science in the peer review process.

Peer reviewers must also familiarise themselves with any additional materials provided by NHMRC about unconscious bias awareness and implicit associations during the peer review process.

Use of gender-neutral language
To reduce unconscious gender bias, NHMRC has strongly advised applicants to use gender-neutral language. This will limit the opportunity for unconscious gender bias to affect the assessment process.

NHMRC also encourages peer reviewers to use gender-neutral language in the assessment of applications. This means that during panel discussions or when preparing written material peer reviewers should:

- avoid the use of gendered pronouns such as he/she or her/his, and instead use gender-neutral alternatives such as CIA/CIB, CI last-name or plural pronouns (they/their) when referring to applicants.
- avoid the use of first names, and
- use gender-neutral nouns where appropriate e.g. parental leave rather than maternity/paternity leave.

The use of gender-neutral language in applications is encouraged, but does not form part of the assessment criteria and therefore should not influence your scoring of applications. Peer reviewers are required to consider the proposal on its merits, taking relative to opportunity considerations into account when assessing track record.

Where gender dimensions are important for the research being proposed, applicants have been advised they should be included in the application. Please refer to scheme-specific category descriptors at Appendix D for information on whether gender dimensions are to be considered as a part of assessment.

4.3.6.3. Industry-relevant experience

Peer reviewers are to recognise an applicant's industry-relevant experience and outputs. To assist peer reviewers with their assessment, the *Guide to Evaluating Industry-Relevant Experience* is provided at Appendix G.

4.3.6.4. Use of Impact Factors and other metrics

Peer reviewers are to take into account their expert knowledge of their field of research, as well as the citation and publication practices of that field, when assessing the publication component of an applicant's track record. Track record assessment takes into account the overall impact, quality and contribution to the field of the published journal articles from the grant applicant, not just the standing of the journal in which those articles are published.

It is not appropriate to use publication metrics such as Journal Impact Factors.

The San Francisco Declaration on Research Assessment (DoRA) makes recommendations for improving the evaluation of research assessment. NHMRC is a signatory to DoRA and adheres to the recommendations outlined in DoRA for its peer review processes.

4.3.6.5. Enhancing reproducibility and applicability of research outcomes

Peer reviewers are required to consider the general strengths and weaknesses of the experimental design of the proposal to ensure robust and unbiased results. Assessment of the experimental design should include consideration of the following, as appropriate:

- scientific premise of the proposed research (i.e. how rigorous were previous experimental designs that form the basis for this proposal)
- techniques to be used
- details for appropriate blinding (during allocation, assessment and analysis)
- strategies for randomisation
- details and justification for control groups
- effect size and power calculations to determine the number of samples/subjects in the study (where appropriate)
- consideration of relevant experimental variables, and
- sex and gender elements of the research to maximise impact and any other considerations relevant to the field of research necessary to assess the rigour of the proposed design.

4.3.6.6. Research Integrity Issues

The peer review process can sometimes identify possible research integrity issues with applications or applicants (e.g. concerns about possible plagiarism, inconsistencies in the presentation of data, inaccuracies in the presentation of track record information) or the behaviour of other peer reviewers. NHMRC has established specific processes for addressing research integrity concerns that arise in peer review. Peer reviewers must not

discuss their concerns with other peer reviewers as this may jeopardise the fair assessment of an application. Instead, these issues should be raised with NHMRC separately from the peer review process. Advice about how to raise concerns and a description of how this process is managed are provided on the NHMRC website.

Applications that are the subject of a research misconduct allegation will continue to progress through NHMRC peer review processes while any investigations are ongoing. NHMRC liaises with the institution regarding the outcome of any investigation and, if necessary, will take action under the *NHMRC Research Integrity and Misconduct Policy* available on the NHMRC website.

4.3.6.7. Contact between peer reviewers and applicants

Peer reviewers must not contact applicants about their application under review. If this occurs, the peer reviewer may be removed from the process, and there is the potential for exclusion from future NHMRC peer review.

Where an applicant contacts a peer reviewer, the relevant application may be excluded from consideration.

In either case, contact between applicants and peer reviewers may raise concerns about research integrity and NHMRC may refer such concerns to the relevant Administering Institution.

4.3.7. Panel meetings

It is expected that Clinical Trials and Cohort Studies Grants 2023 panel meetings will occur via videoconference.

Each panel will meet for up to two days (depending on the number of applications per panel).

4.3.7.1. Discussion of applications at panel meeting

The least competitive applications within the provisional ranked list of applications for each panel will form a Not For Further Consideration (NFFC) list. Once the NFFC list has been finalised, NHMRC staff will release a running order for the panel meeting. Applications not on the NFFC list will proceed to full review.

An application will be excluded from NFFC for the following reasons:

- NHMRC has not received a score and an assessment for all criteria from at least three spokespersons
- If a spokesperson has a high CoI after the initial assessment has been undertaken
- The application may be excluded if it relates to an NHMRC strategic priority, as determined by NHMRC, and achieves an overall score of 5.001 or higher.

4.3.7.2. Panel meeting process

The purpose of the panel meeting is not for individual peer reviewers to regress their scores to the panel mean. It is an opportunity to discuss divergent opinions or aspects of an application that a peer reviewer may have overlooked and adjust their scores as necessary. Peer reviewers should be able to justify how their scores align with the category descriptors.

The process for the panel meeting is as follows:

Declaration of inter-relationships
Suggested time limit: 20 minutes

When panel members (including the Chair and secretariat) meet, each panel member will be invited to briefly describe their expertise and previous peer review experience. During their introductions, members will be asked to declare any relationships with other panel members including:

- current and previous collaborations
- former student/teacher/mentoring relationships
- common employment/institutional relationships

- other relationships that may, or be perceived to, impair fair and impartial assessment.

Chair to announce the application
Suggested time limit: 2 minutes

The Chair will announce the application to be discussed including the title, Administering Institution/s and the CIs.

The Chair will identify any panel members who have a previously identified CoI with the application. Those members with a high CoI will be temporarily blocked from the videoconference by the secretariat (the videoconference connection will remain active).

The Chair will invite panel members to disclose any late interests with the application. If a panel member discloses a new interest, or wishes to discuss any concerns related to an existing CoI, the matter will be discussed with the panel. It is up to the remaining panel members to determine if the new interest constitutes a high CoI and if the declaring panel member should be temporarily blocked from the videoconference by the secretariat. The details of the late interest will be recorded by NHMRC. As this decision making can take extra time, it is important that all interests are disclosed and decided upon well in advance of the meeting, where possible.

If an interest is disclosed at the panel meeting by a SP and it is determined to be a high CoI, a new SP may be assigned to the application and the scores from the initial SP will be discarded. Discussion of the application may be moved to a later time where possible to give the new SP time to prepare.

Once highly conflicted members have been temporarily blocked from the videoconference by the secretariat (those with a low CoI remain)/, the Chair will announce the category of funding the application relates to (e.g., NHMRC and/or Cancer Australia). The Chair will then identify the 1SP and 2SP and announce the Spokesperson scores for each of the four assessment criteria.

1SP and 2SP to comment on the application
Suggested time limit: 5 minutes (1SP) and 3 minutes (2SP)

The Primary and Secondary Spokespersons will:

- discuss the application's strengths and weaknesses against the assessment criteria, referring to the Category Descriptors
- 2SP only to add anything not addressed by the 1SP, or explain why they disagree with the 1SP, if applicable, and
- not make reference to the budget at this stage.

Full panel discussion
Suggested time limit: 5 minutes

The Chair will open discussion to the panel, beginning with 3SP. Panel members have an opportunity to ask questions of all Spokespersons, discuss the strengths and weaknesses of the application and ensure that relevant considerations are taken into account.

The Chair must ensure adequate review of the application occurs, that all members have a fair opportunity to comment and that no member exerts undue influence over others.

The 3SP will write a brief summary to reflect the panel discussion in line with the Category Descriptors (Appendix D).

Scoring by panel members
Suggested time limit: 3 minutes

Following the panel's discussion, the Chair will ask all the Primary spokesperson to confirm their three criterion scores noting that these may change as a result of the panel discussion.

The Chair will then ask if any member intends to score two or more away from the 1SP criterion scores. If so, the panel member must declare this and provide a brief justification, which will be recorded by the secretariat.

All panel members in the videoconference, excluding the Chair, must independently score the application in Sapphire. All scoring panel members will provide scores against the three assessment criteria using the seven-point scale outlined in the *Clinical Trials and Cohort Studies Grants 2023 Category Descriptors* (Appendix D), as a reference. While the category descriptors provide panel members with some benchmarks for appropriately scoring each application, it is not essential that all descriptors relating to a given score are met. Panel members should consider this and ensure the entire seven-point scale is considered when scoring applications.

At the completion of scoring, the panel secretariat will announce the following results:

Overall score- the overall score will be determined by including each panel member's score for each of the assessment criteria. The overall score, as calculated arithmetically to three decimal places and will take account of the weighting of each criterion.

Where panel members have concerns regarding the final score, the Chair should invite further discussion. If the panel collectively determines that reassessment is warranted, members will be invited to independently rescore that application. Panel members should not aim to achieve a consensus score, nor take into consideration the potential overall ranking or funding outcome of an application.

Discussion by exception of proposed budget
Suggested time limit: 5 minutes

Budget discussions should not commence until the NHMRC secretariat has announced the overall score and advised that the application may progress to budget discussion.

Budget discussions occur only where the 2SP has made a recommendation to discuss the budget. The Chair will facilitate the budget discussion to ensure applications are considered fairly and equitably. The 2SP will lead the budget discussion and comment on the appropriateness of the outlined costs and provide recommendations. The other SPs should be prepared to assist, if required. Other panel members may also provide relevant comments. Where the panel deems the proposed budget exceeds that required to accomplish the research objectives, appropriate reductions may be recommended and reasons recorded by the NHMRC secretariat.

NHMRC will record budget recommendations as agreed by the panel. NHMRC will check the budget recommendations to ensure the budgets have been recorded correctly and approved by the Chair.

NHMRC research staff may amend the budget recommended by the panel for any application, if necessary. NHMRC reserves the right to recommend funding levels which are less than those requested in the application and a duration of funding which differs from that requested.

4.3.8. Quorum/Minimum number of assessments

A quorum is regarded as 50 percent plus one of the appointed panel members. If there is an uneven number of panel members, a majority is the next full number after 50 percent (e.g. seven in the case of 13 members).

NHMRC will endeavour to identify, prior to panel meetings, those applications that do not have a scoring quorum and obtain a suitably qualified member from another panel to participate in panel discussion and to score that application.

However, in situations where a number of members have a high CoI with an application and a suitably qualified member(s) cannot be recruited from another panel, the scoring quorum cannot be less than one-third of the panel membership present at the meeting.

4.3.9. Principles for setting conditions of funding for NHMRC grants

Setting a condition of funding (CoF) on a grant through the peer review process is, and should be, a rare event. When this does occur, the panel will use the principles set out below to decide the CoF. These principles aim to achieve a consistent approach, minimise the number of conditions set and ensure conditions are unambiguous and able to be assessed.

CoFs relate to the award of funding, the continuation of funding or the level of funding. They do not relate to

conditions which affect either eligibility to apply or subsequent peer review.

The principles are:

- NHMRC seeks to minimise the administrative burden on researchers and Administering Institutions.
- CoFs must not relate to the competitiveness of an application (e.g. project requires more community engagement); these issues should be considered during peer review and be reflected in the scores for the application.
- Any CoFs must be clear and measurable, so that the condition can be readily assessed as having been met.

4.3.10. Providing feedback on applications

When conducting assessments, peer reviewers are required to provide constructive qualitative feedback to applicants that focus on the strengths and weaknesses of the application.

When providing feedback, you should use neutral language and focus only on what has been provided in the application, avoiding extraneous comments or considerations you might have about the research/er. Feedback should be factual and dispassionate. Avoid reference to your own experience of reviewing the application or overly expressive words that convey emotion. You should be always mindful to frame your feedback against the **assessment criteria and category descriptors.**

The table below provides guidance to peer reviewers on what NHMRC considers appropriate or inappropriate when providing feedback on grant applications.

Avoid comments that:	Instead:
• Make specific comparisons between applications/applicants • Are discourteous, derogatory, unprofessional or use emotive or overly expressive (positive or negative) language • Employ an overly negative or critical tone (i.e. instead of “the applicant failed to”, use “it would improve the application if”) • Use overly expressive language and words that convey emotion (e.g. “disappointingly”, “unfortunately”, “failed to”) • Represent your personal views or attitudes towards a statement written by the applicant/s • Focus on the faults or shortcomings of the application or applicant/s • Refer to your ability/suitability to review the application • Employ a negative or critical tone • Refer to issues that are out of the applicant’s/reviewer’s control (e.g. “This application deserves to be funded”) • Provide broad statements which suggest the application is worthy or not worthy of funding • Minimise accomplishments or claims made by the applicant/s • Use dismissive language or statements that discount or belittle an application or applicant/s • Use stylistic choices that convey the feelings of the reviewer such as rhetorical questions, speculation or punctuation such as exclamation marks. • Use universal language (e.g. “any expert knows”) • Question issues of eligibility or integrity of the application or applicant/s. This should be raised with NHMRC separately.	• Highlight the key elements of the application that influenced your scores • Consider the strengths and weaknesses of the application against each assessment criterion • Use category descriptors associated with the assessment criteria and ensure they are addressed • Focus on the information that is provided in the application • Provide constructive feedback that reflects your scores • Provide neutral statements • Write with an objective tone • Provide specific advice or references to relevant bodies of work you think the applicant/s may have overlooked.

4.3.11. Documentation

Peer reviewers may be required to retain personal notes that they made during the peer review process for a certain period, and if so, these must be held securely and in accordance with reviewers' obligations of confidentiality. NHMRC will notify peer reviewers of any such requirements prior to the peer review process.

4.3.12. Funding Recommendation

After the panel meetings, application scores from all panels are used to create a ranked list. This final ranked list will be used to prepare funding recommendations to NHMRC's Research Committee and Council for advice to the CEO, who will then make recommendations to the Minister for Health.

4.3.13. Notification of Outcomes

NHMRC will notify applicants and their Administering Institution's Research Administration Officer of grant application outcomes.

Feedback will be provided to all applicants in the form of an Application Assessment Summary and a written summary from each assigned peer reviewer. The Application Assessment Summary will contain numerical information on the competitiveness of the application that will be drawn from the scores given by peer reviewers.

Appendix A - Understanding the Principles of Peer Review

Fairness

- Peer review processes are designed to ensure that peer review is fair and seen to be fair by all involved.
- Peer reviewers have an obligation to ensure that each application is judged consistently and objectively on its own merits, against published assessment criteria. Peer reviewers must not introduce irrelevant issues into the assessment of an application.
- Peer reviewers must only address information provided in the application based on its relevance to the assessment criteria. Any information or issues relating to the applicant(s) outside of the application must not be considered in the peer reviewers assessment. Applications will be subject to scrutiny and evaluation by individuals who have appropriate knowledge of the fields covered in the application.
- Peer reviewers should ensure that their assessments are accurate and that all statements are capable of being verified.
- Complaints processes are outlined on the NHMRC website. All complaints to NHMRC relating to the peer review process are dealt with independently and impartially.

Transparency

- NHMRC will publish key dates, all relevant material for applicants and peer reviewers, and grant announcements on its website and/or via GrantConnect.
- NHMRC publicly recognises the contribution of participants in the peer review process, through publishing their names on the NHMRC website.[1]

Independence

- Peer reviewers must provide independent and impartial assessment of applications. Peer reviewer assessments may be informed by input from other experts (e.g. in panel meetings or when considering expert reports) but must not be unduly influenced by the views of other researchers or stakeholders.
- The order of merit determined by peer reviewers is not altered by NHMRC. However, additional applications may be funded 'below the funding line' in priority or strategic areas.
- Chairs are independent and are not involved in the peer review of any application. Chairs act to ensure that NHMRC's processes are followed for each scheme, including adherence to the principles of this Guide.

Appropriateness and balance

- Peer reviewers are selected to meet the scheme's objectives and to ensure adequate expertise to assess the applications received.
- NHMRC endeavours to ensure that peer reviewers are selected with regard to an appropriate representation of gender, geography and large and small institutions.

Confidentiality

- NHMRC provides a process by which applications are considered by peer reviewers in-confidence. In addition NHMRC is bound by the provisions of the *Privacy Act 1988* in relation to its collections and use of personal information, and by the commercial confidentiality requirements under section 80 of the NHMRC Act.

[1] Such information will be in a form that prevents applicants determining which particular experts were involved in the review of their application.

- Peer reviewers are to treat applications in-confidence and must not disclose any matter regarding applications under review to people who are not part of the process.
- Any information or documents made available to peer reviewers in the peer review process are confidential and must not be used other than to fulfil their role.
- NHMRC is subject to the *Freedom of Information Act 1982* which provides a statutory right for an individual to seek access to documents. If documents that deal with peer review fall within the scope of a request, there is a process for consultation and there are exemptions from release. NHMRC will endeavour to protect the identity of peer reviewers assigned to a particular application.

Impartiality

- Peer reviewers must disclose all interests and matters that may, or may be perceived to, affect objectivity in considering particular applications.
- Peer reviewers must disclose relationships with other members of the panel, and interests with applications being reviewed, including:
    - research collaborations
    - student, teacher or mentoring relationships
    - employment arrangements
    - any other relationship that may, or may be seen to, undermine fair and impartial judgement.
- Disclosures of interest are managed to ensure that no one with a high conflict is involved in the assessment of relevant applications.

Quality and Excellence

- NHMRC will continue to introduce evidence-based improvements into its peer review processes.
- Any significant change will be developed in consultation with the research community and may involve piloting new processes.
- NHMRC will strive to introduce new technologies that are demonstrated to maximise the benefits of peer review and improve the efficiency and effectiveness of the process while minimising individual workloads.
- NHMRC will undertake post-scheme assessment of all its schemes with feedback from the sector.
- NHMRC will provide advice, training and feedback for peer reviewers new to NHMRC peer review.
- Where NHMRC finds peer reviewers to be substandard in their performance, NHMRC may provide such feedback directly to the peer reviewer or their institution.

Appendix B - Guidance for Declaring and Assessing Disclosures of Interest

Peer reviewers are required to disclose all interests that are relevant, or could appear to be relevant, to the proposed research.

An interest is a collaboration or relationship which may, or could be perceived to, affect impartial peer review and thus needs to be disclosed and transparently managed (where necessary) to safeguard the integrity of the peer review process. It is essential that peer reviewers not only disclose their own actual interests relating to proposed research (real interest), but also collaborations and relationships that could be perceived by stakeholders to affect impartial peer review (perceived interest). Failure to do so without a reasonable excuse may result in the peer reviewer being removed from the peer review process in accordance with subsection 44B (3) of the NHMRC Act.

A disclosure does not always equate to a conflict of interest (CoI). In determining if an interest is a conflict, peer reviewers should give consideration to the following values that underpin the robust nature of peer review:

- **Impartiality:** The benefits of peer reviewers' expert advice needs to be balanced with the risk of real or perceived interests affecting an impartial review.
- **Significance:** Not all interests are equal. The type of interest needs to be considered in terms of its significance and time when it occurred.
- **Integrity through disclosure:** Peer review rests on the integrity of peer reviewers to disclose any interests and contribute to transparently managing any real or perceived conflicts in a rigorous way. The peer review system cannot be effective without trusting peer reviewers' integrity.

In determining if an interest is a 'High', 'Low', or 'No' conflict, the responsibility is on the peer reviewer to consider the specific circumstances of the situation. This includes:

- the interest's significance
- its impact on the impartiality of the reviewer, and
- maintaining the integrity of the peer review process.

Once a peer reviewer discloses an interest they can provide an explanation of the interest in Sapphire to enable a judgement of its significance. Wherever possible, peer reviewers are required to provide sufficient detail in the explanation, such as date (month and year) and nature of the interest.

The written declaration of interest is retained for auditing purposes by NHMRC. The details below provide general examples and are not to be regarded as a prescriptive checklist.

HIGH Conflict of Interest		
Situation		**Example**
Associated with Application and/or Chief Investigator (CI)	✓	Peer reviewer is a CI or AI on the application under review.
	✓	Peer reviewer has had discussions/significant input into the study design or research proposal of this application.
Collaborations	✓	Peer reviewer is actively collaborating or has collaborated with the CI in the last three calendar years on publications (co-authorship), pending grant applications and/or existing grants.
Working relationships	✓	Peer reviewer and a CI currently work or are negotiating future employment in the same: • research field at an independent Medical Research Institute. • Department or School of a university. • Department of a hospital.
	✓	Peer reviewer is in a position of influence within the same organisation as a CI, or has a pecuniary interest in the organisation (either perceived or real) e.g. Dean of Faculty or School/Institute Directors.
	✓	Peer reviewer and a CI are on the same committee/board and the peer reviewer or their affiliated organisation would stand to benefit from, or be affected, by the outcome of the application (i.e. vested interested in the proposed research). For example, peer reviewer and CI are both on the same governing board within their organisation.
Professional relationships and interests	✓	Peer reviewer or a peer reviewer's employer is directly affiliated or associated with an organisation(s) that may have, or may be perceived to have, a vested interest in the research. For example, a pharmaceutical company, which has provided drugs for testing, has a vested interest in the outcome.
Social relationship and / or interests	✓	The peer reviewer or a peer reviewer's immediate family member has a personal or social relationship with a CI on the application.
Teaching or supervisory relationship	✓	Peer reviewer has taught or supervised a CI for either undergraduate or postgraduate studies within the last three years.
	✓	Peer reviewer and a CI co-supervise an undergraduate or postgraduate student and collaborate with each other on the student's research.
Direct financial interest in the application	✓	Peer reviewer has the potential for financial gain if the application is successful, such as benefits from: payments from resulting patents, supply of goods and services, access to facilities, and provision of cells/animals as part of the collaboration.
	✓	Peer reviewer receives research funding or other support from a company and the research proposal may involve collaboration/association with that company.
	✓	Peer reviewer receives research funding or other support from a company and the research proposal may affect the company.

HIGH Conflict of Interest		
Situation		**Example**
Other interests or situations	✓	Peer reviewer had or has an ongoing scientific disagreement and/or dispute with a CI. This may still be ruled as a high conflict if the events in question occurred beyond the last three years.
	✓	There are other interests or situations not covered above that could influence/or be perceived to influence the peer review process. In these instances, sufficient details must be provided to allow NHMRC to make a ruling.

LOW Conflict of Interest		
Situation		**Example**
Collaborations	✓	Peer reviewer and a CI on the application have collaborated more than three years ago.
	✓	Within the last three years, the peer reviewer was part of large collaborations involving the CI, but did not interact or collaborate with the CI directly. Examples include: • publication(s) as part of a multi-author collaborative team (i.e. ≥10 authors) • pending grant applications or existing grants involving more than ten CIs (e.g. large collaborative research centres and network grants)
	✓	A colleague is planning future collaborations with a CI.
	✓	Peer reviewer and a named AI on the application are actively collaborating or have previously collaborated within the last three years.
	✓	Without financial gain or exchange, a peer reviewer and a member of the research team have shared cells/animals/reagents/specialist expertise (biostatistician) etc. but have no other connection to each other.
	✓	Collaboration between a peer reviewer's colleague/research group and a CI on the application, where the peer reviewer did not participate or have a perceived interest (e.g. direct leadership or responsibility for the researchers involved in the collaboration) in the collaboration, or vice versa.
	✓	Peer reviewer is considering, planning or has planned a future collaboration with a CI on the application but has no current collaborations, including joint publications/applications under development.
	✓	Peer reviewer and CI have previously proposed or planned a collaboration that did not progress.
Working relationships	✓	Peer reviewer and a CI currently work or are negotiating future employment in: • the same institution but have no direct association or collaboration. • the same Faculty or College of a university but in different Schools or Departments and do not know each other.
	✓	Peer reviewer and a CI work for two organisations that are affiliated but there is no direct association/collaboration.
	✓	Peer reviewer and a CI are on the same committee/board, but otherwise have no working or social relationships that constitute a high conflict and the peer reviewer or their affiliated organisation would not benefit from, or be affected by, the outcome of the application (i.e. do not have a vested interest in the proposed research). For example, the peer reviewer and CI are both on an external government advisory committee.

LOW Conflict of Interest		
Situation		**Example**
Professional relationships and interests	✓	Peer reviewer and CI's organisations are affiliated but there is no direct association/collaboration between the CI and peer reviewer and there is no other link that would constitute a high conflict.
Social relationship and/or interests	✓	Peer reviewer's partner or immediate family member has a known personal/social (non-work) or perceived relationship with a CI on the application, but the peer reviewer themselves does not have any link with the CI that would be perceived or constitute a high conflict.
Teaching or supervisory relationship	✓	Peer reviewer taught or supervised the CI for either undergraduate or postgraduate studies, co-supervised a CI or the peer reviewer's research was supervised by a CI, more than three years ago.
	✓	Peer reviewer and a CI are co-supervisors of an undergraduate or postgraduate student, but they are not collaborating with each other on the student's research (e.g. where one of the supervisors may provide additional expert input or guidance to the student's project or thesis).
Financial interest in the application	✓	Peer reviewer has an associated patent pending, supplied goods and services, improved access to facilities, or provided cells/animals etc. to a named CI for either undergraduate or postgraduate studies.
	✓	Peer reviewer has intellectual property that is being commercialised by an affiliated institution. Peer reviewer has previously provided and/or received cells/animals to/from a CI on the application, but has no other financial interests directly relating to this application that would constitute a high conflict.
Other interests or situations	✓	Peer reviewer may be, or may be perceived to be, biased in their review of the application. For example, peer reviewer is a lobbyist on an issue related to the application.

Appendix C – Clinical Trials and Cohorts Studies Grants 2023 Assessment Criteria

Applications for the Clinical Trials and Cohort Studies Grant scheme are assessed by peers against the assessment criteria listed below and the category descriptors at Appendix D.

1. **Significance (40%)**

Significance for this grant opportunity is the extent to which the research findings will substantially advance knowledge to improve the prevention, diagnosis or treatment of medical conditions, or to improve health and wellbeing. Significance will be assessed in terms of, but not limited to, the following considerations:

- Is the research proposal directly relevant to the objectives and desired outcomes of the Clinical Trials and Cohort Studies Grant opportunity? Specifically:
  - high-quality clinical trials and/or cohort studies that address important gaps in knowledge, leading to relevant and implementable findings for the benefit of human health.
  - improvements in health and wellbeing, health care practice or policy, as a result of:
    - high-quality clinical trials that provide reliable evidence of the effects of health-related interventions on health outcomes (or appropriate surrogates), and/or
    - high-quality cohort studies that provide reliable evidence on the relation of important risk factors and other exposures to health-related outcomes.
- Is the rationale for the proposed research strongly supported by evidence?
  - What are the aims and hypotheses to be tested?
  - What previous research has occurred?
  - Has the applicant referred to or conducted a systematic review or a thorough literature review? Do the points of difference between these studies and the proposed research provide strong justification for the proposed research?
  - Are there any supporting data and how do they support the proposal?
  - Does the research question(s) meet the needs of other researchers, consumers, policy makers and clinical practitioners?
  - If the research objectives are achieved, would the research have a significant and sustainable impact on the health issue in question? This may include contributing to knowledge, health, economic and social impacts.
  - The NHMRC Research Impact Position Statement (https://www.nhmrc.gov.au/research-policy/research-translation-and-impact/research-impact) should be consulted.
- Is the proposed research developed with meaningful community consumer involvement, to ensure that the results are relevant, and the project is feasible?
  - The NHMRC Statement on consumer and community involvement in health and medical research (https://www.nhmrc.gov.au/about-us/publications/statement-consumer-and-community-involvement-health-and-medical-research) states that ‘Consumers are patients and potential patients, carers, and people who use health care services’.
  - Is consumer representation integrated in all aspects of the project?
  - What are the governance arrangements and the support available to consumers?
  - How experienced is the team in working with consumers?
  - What are the diversity considerations for this project, and will they improve on the significance, impact, and relevance to consumers at a broader level?

2. Research quality (40%)

Research quality for this grant opportunity encompasses the quality and feasibility of the proposed research, incorporating theoretical concepts, hypothesis, research design and robustness. Research quality will be assessed in terms of, but is not limited to, the following considerations:

- Is there a clear research question(s)?
- Are the clinical trial and/or cohort study design and methodologies appropriate for the research question(s)? For example:
  - Are the SPIRIT or STROBE items detailed and clearly presented, if appropriate?
  - Have the risks associated with the study been identified and strategies employed to mitigate them (e.g. recruitment shortfalls, participant attrition, legal-ethical barriers, political issues)?
  - Are the proposed inclusion and exclusion criteria appropriate and justified? This includes appropriate consideration of sex and gender, and other factors such as ethnicity, culture and language.
  - Are the proposed methodological approaches appropriate? Are the participants' intervention/exposure and comparators/controls clearly specified? Are data collection, management and statistical analyses described?
  - Have barriers and enablers been thoroughly considered and managed through an implementation plan?
- Is the clinical trial and/or cohort study feasible? For example:
  - Are the required techniques established? Are the required expertise and resources available, including infrastructure, equipment and facilities?
  - Are the methods and targets for the recruitment of participants realistic? Is the sample size achievable and sufficient to detect meaningful effect differences within the population of interest?
  - Does the supporting data presented provide evidence of feasibility and acceptability of the research methods and study procedures?
  - Does the proposal include appropriate and realistic milestones and performance indicators, timeframes and monitoring strategies? Can the endpoints be measured and are they achievable and appropriate to the aims of the study?
  - Has a proposed budget been developed that matches the scope and scale of the project, and is feasible, sustainable and appropriate to conduct the work?
  - If the proposal is a retrospective cohort study, are the data available of high quality, with low confounding factors and of sufficient volume to be informative, in relation to the health-related questions being asked?

3. Team quality and capability (20%)

This criterion is used to assess whether the CI team named in your application has the appropriate mix of research skills and experience to undertake the clinical trial and/or cohort study and achieve the stated objectives of the proposed research. Team quality will be assessed in terms of, but not limited to, the following considerations:

- Do the CIs collectively provide an appropriate mix of research skills and experience to successfully undertake this clinical trial and/or cohort study?
- Do the CIs have sufficient expertise to anticipate and solve potential obstacles (e.g. higher than anticipated non-adherence rates or new competing therapies) to the success of the proposal? Do they have expertise in all aspects of the research proposal? Does the expertise include the methodological and scientific underpinnings (e.g statistics, bioinformatics and health economics) of the research proposal?
- Do the CIs have the networks, influence and experience to manage all aspects of the study?
- Do the CIs have high-quality track records over the last ten years? Have the CIs previously delivered high-quality research outputs and outcomes in this area of research? Does this demonstrate the team's capability to undertake the clinical trial and/or cohort study?
- Does the CI team reflect the contribution of early- and mid-career researcher/s to the clinical trial and/or cohort study?

- Does the CI team reflect the experience to meaningfully involve consumers in all aspects of the clinical trial/cohort study?

Track records are assessed Relative to Opportunity, taking into consideration any career disruptions, where applicable.

It is recognised that Aboriginal and Torres Strait Islander applicants often make additional valuable contributions to policy development, clinical/public health leadership and/or service delivery, community activities and linkages, and are often representatives on key committees. If applicable, these contributions will be considered when assessing research output and track record.

Appendix D – Clinical Trials and Cohort Studies Grants 2023 Category Descriptors

The following category descriptors are used as a guide to scoring an application against each of the assessment criteria.
While the category descriptors provide peer reviewers with some benchmarks for appropriately scoring each application, it is not essential that all descriptors relating to a given score are met.
The category descriptors are a “best fit” outcome. Peer reviewers will consistently refer to these category descriptors to ensure thorough, equitable and transparent assessment of applications.

Assessing Aboriginal and Torres Strait Islander Contributions
To assist in assessing Aboriginal and Torres Strait Islander health research applications, the criteria for Indigenous health research have been integrated in the table below. This is to be used as a guide only.

Significance (40%)

SCORE						
7	**6**	**5**	**4**	**3**	**2**	**1**
The proposed clinical trial and/or cohort study: • will comprehensively and convincingly address the objective of this grant opportunity and the aims will strongly deliver against the desired outcomes • is informed by an exemplary analysis or review of existing and ongoing studies in the field and supported by very strong data • is developed with extremely broad and meaningful community involvement, meaning the proposal is extremely feasible • has consumer involvement that is fully integrated into all aspects of the planning, conduct, publication and translation of the project • if successful, will have very significant knowledge/ health/economic/social impact.	The proposed clinical trial and/or cohort study: • will strongly address the objective of this grant opportunity and the aims will deliver against the desired outcomes • is informed by a thorough analysis or review of existing and ongoing studies in the field and supported by strong data • is developed with very broad and meaningful community involvement, meaning the proposal is very highly feasible • has consumer involvement that is integrated into most aspects of the planning, conduct, publication and translation of the project • if successful, will have significant knowledge/ health/economic/social impact.	The proposed clinical trial and/or cohort study: • will address the objective of this grant opportunity with only minor concerns and the aims will mostly deliver against the desired outcomes • is informed by a good analysis or review of relevant existing and ongoing studies in the field and supported by solid data • is developed with broad community involvement, meaning the proposal is very feasible • has consumer involvement that is integrated into some aspects of the planning, conduct, publication and translation of the project • if successful, will have appreciable knowledge/ health/economic/social impact.	The proposed clinical trial and/or cohort study: • will partially address the objective of the grant opportunity and the aims will partially deliver against the desired outcomes • has several minor concerns about the analysis or review of existing and ongoing studies which informs the research and supported by moderate data • is developed with good community involvement, meaning the proposal is feasible • has consumer involvement that is evident in some aspects of the planning, conduct, publication and translation of the project • if successful, may have moderate knowledge/ health/economic/social impact.	The proposed clinical trial and/or cohort study: • will not convincingly address the objective of this grant opportunity and the aims are unlikely to deliver against the desired outcomes • has significant or major concerns about the analysis or review of existing and ongoing studies which informs the research and supported by some data • is developed with some community involvement, meaning the proposal is somewhat feasible • has consumer involvement that is evident in a few aspects of the planning, conduct, publication and translation of the project • if successful, it is unlikely to have anything other than minor knowledge/ health/economic/social impact.	The proposed clinical trial and/or cohort study: • will not address the objective of this grant opportunity or is unclear in its approach to doing so and the aims are unclear in delivering the desired outcomes • is informed by a very limited analysis or review of existing and ongoing studies in the field and is supported by limited data • is developed with limited community involvement, meaning the proposal is somewhat feasible • has consumer involvement that is minimal in most aspects of the planning, conduct, publication and translation of the project • will not translate into knowledge/ health/economic/social impact.	The proposed clinical trial and/or cohort study: • will not address any of the objectives of this grant opportunity • is informed by a poor analysis or review of existing and ongoing studies in the field and is not supported by any data • is not developed with community involvement, meaning the proposal is probably not feasible • has no consumer involvement in any aspects of the planning, conduct, publication and translation of the project • will not translate into knowledge/ health/economic/social impact.

SCORE						
7	**6**	**5**	**4**	**3**	**2**	**1**
Significance of the grant outcomes: Indigenous criteria						
Sustainability and transferability • The outcomes of the study will definitely lead to major and effective health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project • The outcomes of the study will have a very high impact on health services delivery or other community priorities. **Benefit** • The outcomes of the study will have a very significant health benefit for Aboriginal and Torres Strait Islander peoples.	**Sustainability and transferability** • The outcomes of the study will lead to considerable and effective health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project • The outcomes of the study will have a high impact on health services delivery or other community priorities. **Benefit** • The outcomes of the study will have a significant health benefit for Aboriginal and Torres Strait Islander peoples.	**Sustainability and transferability** • The outcomes of the study will lead to effective health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project • The outcomes of the study will have an impact on health services delivery or other community priorities. **Benefit** • The outcomes of the study will have some health benefit for Aboriginal and Torres Strait Islander peoples.	**Sustainability and transferability** • The outcomes of the study may lead to effective health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project • The outcomes of the study may have an impact on health services delivery or other community priorities. **Benefit** • The outcomes of the study may have some health benefit for Aboriginal and Torres Strait Islander peoples.	**Sustainability and transferability** • The outcomes of the study may lead to limited or short- term health gains for Aboriginal and Torres Strait Islander peoples • The outcomes of the study may have a moderate impact on health services delivery or other community priorities. **Benefit** • The outcomes of the study are likely to have a minimal health benefit for Aboriginal and Torres Strait Islander peoples.	**Sustainability and transferability** • The outcomes of the study are unlikely to lead to any health gains for Aboriginal and Torres Strait Islander peoples • The outcomes of the study are unlikely to have any impact on health services delivery or other community priorities. **Benefit** • The outcomes of the study are likely to have little or no health benefit for Aboriginal and Torres Strait Islander peoples.	**Sustainability and transferability** • The outcomes of the study will not lead to any health gains for Aboriginal and Torres Strait Islander peoples • The outcomes of the study will not have any impact on health services delivery or other community priorities. **Benefit** • The outcomes of the study will have no health benefit for Aboriginal and Torres Strait Islander peoples.

Research Quality (40%)

SCORE						
7	**6**	**5**	**4**	**3**	**2**	**1**
The proposed clinical trial and/or cohort study: • has very strong, well defined and coherent design and research methodologies, with the project plan strongly addressing the essential components of the research question • is comparable with the best international research in the field • is highly feasible with all of the required techniques and resources established • has a proposed budget that very accurately matches the scope, feasibility and scale of the proposed project with no budgeting concerns • includes highly effective milestones and performance indicators • was developed with outstanding risk management strategies and implementation plan that include a thorough barriers and enablers analysis to ensure success of the project.	The proposed clinical trial and/or cohort study: • has strong, well defined and coherent design and research methodologies, with the project plan strongly addressing the essential components of the research question • is comparable with strong proposals in the field internationally • is feasible with required techniques and resources established • has a proposed budget that accurately matches the scope, feasibility and scale of the proposed project with negligible budgeting concerns • includes effective milestones and performance indicators • was developed with very good risk management strategies and implementation plan that include a very good barriers and enablers analysis to ensure success of the project.	The proposed clinical trial and/or cohort study: • is generally clear in its research methodology, with the project plan addressing the essential components of the research question • raises only very few minor concerns with respect to the study design • is feasible in almost all areas: required techniques and resources established or nearly established • may not be highly competitive with similar research proposals internationally • has a proposed budget that matches the scope, feasibility and scale of the proposed project with minimal budgeting concerns • raises a few very minor concerns about the appropriateness of milestones and performance indicators •was developed with good risk management strategies and implementation plan that include a good barriers and enablers analysis to ensure success of the project.	The proposed clinical trial and/or cohort study: • is generally solid in design and is appropriate to the research question, but may not always be clear in its intent and focus • raises several minor concerns regarding the study design and research methodologies • raises doubts about feasibility in a number of areas • is not likely to be competitive with similar research proposals internationally • has a proposed budget that matches the scope, feasibility and scale of the proposed project but with some budgeting concerns • raises minor concerns about the appropriateness of milestones and performance indicators • was developed with adequate risk management strategies and implementation plan that include a barriers and enablers analysis to ensure success of the project..	The proposed clinical trial and/or cohort study: • is somewhat unclear in its design • is not appropriate to the research question or contains some major design or methodological flaws • raises major concerns about the feasibility and thus the likelihood of successful completion • has a proposed budget that somewhat matches the scope, feasibility and scale of the proposed project but with moderate budgeting concerns • raises significant concerns about the appropriateness of milestones and performance indicators • was developed with some or marginal risk management strategies and implementation plan.	The proposed clinical trial and/or cohort study: • is unclear in its design • contains several major flaws in study design and research methodologies • has a proposed budget that marginally matches the scope, feasibility and scale of the proposed project and with significant budgeting concerns • raises several major concerns about the feasibility and thus the likelihood of successful completion • was developed with poor risk management strategies and implementation plan.	The proposed clinical trial and/or cohort study: • has a poorly developed research proposal which does not seem to be feasible and is unlikely to be successfully completed • has a proposed budget that does not match the scope, feasibility and scale of the proposed project • did not consider any risk management strategies nor included an implementation plan.

SCORE						
7	**6**	**5**	**4**	**3**	**2**	**1**
Research quality: Indigenous criteria						
Community Engagement The proposal has a research plan that: • has outstanding levels of community engagement, ensuring that the proposal is highly feasible • demonstrates how the research and potential outcomes are a priority for the community to an outstanding degree.	**Community Engagement** The proposal has a research plan that: • has excellent levels of community engagement, ensuring that the proposal is feasible • demonstrates how the research and potential outcomes are a priority for the community to an excellent degree.	**Community Engagement** The proposal has a research plan that: • has very good levels of community engagement, ensuring that the proposal is likely to be feasible • clearly demonstrates how the research and potential outcomes are a priority for the community.	**Community Engagement** The proposal has a research plan that: • has good levels of community engagement • raises some concerns whether the proposal is feasible • demonstrates how the research and potential outcomes are a priority for the. community the community.	**Community Engagement** The proposal: • has limited community engagement • raises several concerns whether the proposal is feasible and achievable.	**Community Engagement** The proposal: • has little or no community engagement • is unlikely to be feasible and achievable.	**Community Engagement** The proposal: • has no community engagement • will not be feasible.

Team Quality and Capability (20%)

SCORE						
7	**6**	**5**	**4**	**3**	**2**	**1**
Relative to opportunity, the Chief Investigators (CIs): • have a high level of expertise and experience in all aspects of the proposed research • have a very high level of influence and strong networks to contribute to the proposed research • have over the last 10 years, a combined record of research achievement that is outstanding by international standards commensurate with their field of research (research achievement, quality and productivity) • have outstanding national and international reputations in clinical trial or cohort study methodology and relevant research fields • may include junior members who are strong contributors to overall team capability • • may include consumer members with experience supporting meaningful engagement of consumers in all aspects of the study.	Relative to opportunity, the CIs: • have expertise and experience that is highly relevant to the proposed research • have a high level of influence and strong networks to contribute to the proposed research • have over the last 10 years, a combined record of research achievement that is excellent by international standards commensurate with their field of research (research achievement, quality and productivity) • have excellent national and/or international reputations in clinical trial or cohort study methodology and relevant research fields • may include junior members who contribute to overall team capability • may include team members with experience supporting meaningful engagement of consumers in all aspects of the study.	Relative to opportunity: • there are only minor concerns about the CIs' level of expertise and experience required to undertake the proposed research • the CIs have an appropriate level of influence and networks to contribute to the proposed research • the CIs have, over the last 10 years, a combined record of research achievement that is well above average by international standards commensurate with their field of research (research achievement, quality and productivity) • the CIs have very good national and/or international reputations in clinical trial or cohort study methodology and relevant research fields • the CIs may include junior members who have the potential to add to the team capability • • may include team members with consumer involvement experience who contribute to overall team capability.	Relative to opportunity: • there are significant concerns about the CIs' level of expertise and experience required to undertake the proposed research • the CIs have some level of influence and networks to contribute to the proposed research • the CIs have, over the last 10 years, a combined record of research achievement that is average by international standards commensurate with their field of research (research achievement, quality and productivity) • the CIs have good national and/or international reputations in clinical trial or cohort study methodology and the relevant research fields • the CIs may include junior members who have the potential to add to the team capability • may include team members with consumer involvement experience who have the potential to add to the team capability.	Relative to opportunity, the CIs: • have made contributions to the field of research but there are significant concerns regarding the depth and breadth of relevant expertise of the team • have limited influence and networks to contribute to the proposed research • have, over the last 10 years, a combined record of research achievement (research achievement, quality and productivity) that places them at an average level for their peers • have made limited progress towards research achievements warranting national or international recognition.	Relative to opportunity, the CIs: • are deficient in some areas of expertise required to successfully complete the proposed research • have very limited influence and networks to contribute to the proposed research • have published only a few works in relevant fields of research • are not well recognised nationally or internationally for their achievements in the relevant research fields.	Relative to opportunity, the CIs: • are deficient in the relevant expertise required to successfully complete the proposed research • have no influence and networks to contribute to the proposed research • are not productive to any significant extent in relevant fields of research • are not well recognised nationally or internationally for their achievements in the relevant research fields.

SCORE						
7	**6**	**5**	**4**	**3**	**2**	**1**
Team quality and capability: Indigenous criteria						
Building capability • The team has an outstanding track record in working with communities and building capability among Aboriginal and Torres Strait Islander people • The proposal will build outstanding capability among Aboriginal and Torres Strait Islander people.	**Building capability** • The team has an excellent track record in working with communities and building capability among Aboriginal and Torres Strait Islander people • The proposal will build excellent capability among Aboriginal and Torres Strait Islander people.	**Building capability** • The team has a very good track record in working with communities and building capability among Aboriginal and Torres Strait Islander people • The proposal will build very good capability among Aboriginal and Torres Strait Islander people.	**Building capability** • The team has a good track record in working with communities and building capability among Aboriginal and Torres Strait Islander people • The proposal may build good capability among Aboriginal and Torres Strait Islander people.	**Building capability** • The team has a marginal track record in working with communities and building capability among Aboriginal and Torres Strait Islander people • The proposal may build minimal capability among Aboriginal and Torres Strait Islander people.	**Building capability** • The team has an unsatisfactory track record in working with communities and building capability among Aboriginal and Torres Strait Islander people • The proposal is unlikely to build capability among Aboriginal and Torres Strait Islander people.	**Building capability** • The team has a poor track record in working with communities and building capability among Aboriginal and Torres Strait Islander people • The proposal will not build capability among Aboriginal and Torres Strait Islander people.

Appendix E - Indigenous Research Excellence Criteria

To qualify as Aboriginal and Torres Strait Islander health research, at least 20% of the research effort and/or capacity building must relate to Aboriginal and Torres Strait Islander health.

Qualifying applications must address the NHMRC *Indigenous Research Excellence Criteria* as follows:

- Community engagement - the proposal demonstrates how the research and potential outcomes are a priority for Aboriginal and Torres Strait Islander communities with relevant community engagement by individuals, communities and/or organisations in conceptualisation, development and approval, data collection and management, analysis, report writing and dissemination of results.

- Benefit - the potential health benefit of the project is demonstrated by addressing an important public health issue for Aboriginal and Torres Strait Islander people. This benefit can have a single focus or affect several areas, such as knowledge, finance and policy or quality of life. The benefit may be direct and immediate, or it can be indirect, gradual and considered.

- Sustainability and transferability - the proposal demonstrates how the results of the project have the potential to lead to achievable and effective contributions to health gain for Aboriginal and Torres Strait Islander people, beyond the life of the project. This may be through sustainability in the project setting and/or transferability to other settings such as evidence based practice and/or policy. In considering this issue, the proposal should address the relationship between costs and benefits.

- Building capability - the proposal demonstrates how Aboriginal and Torres Strait Islander people, communities and researchers will develop relevant capabilities through partnerships and participation in the project.

Peer reviewers will consider these in their overall assessment of the application, when scoring the *Assessment Criteria* set out in Appendix C.

Appendix F – Guidance for assessing applications against the Indigenous Research Excellence Criteria

Peer reviewers should consider the following when assessing applications that have a focus on the health of Indigenous Australians. The points below should be explicit throughout the application and not just addressed separately within the Indigenous criteria section.

Community Engagement

- Does the proposal clearly demonstrate a thorough and culturally appropriate level of engagement with the Aboriginal and Torres Strait Islander community or health services prior to submission of the application?
- Is there clear evidence that the level of engagement throughout the project will ensure the feasibility of the proposed study?
- Has the application demonstrated evidence that any of the methods, objectives or key elements of the proposed work have been formed, influenced or defined by the community?
- Were the Indigenous community instrumental in identifying and inviting further research into the health issue and will the research outcomes directly benefit the 'named' communities?
- Is there a history of working together with the 'named' communities e.g. co-development of the grant, involvement in pilot studies or how the 'named' communities will have input/control over the research process and outcomes across the life of the project?

Benefit

- Does the proposal clearly outline the potential health benefits (both intermediate and long term, direct and indirect) to Aboriginal and Torres Strait Islander people?
- Does the proposal demonstrate that the benefit(s) of the project have been determined or guided by Aboriginal and Torres Strait Islander people, communities or organisations themselves?

Sustainability and Transferability

- Does the proposal:
    - Provide a convincing argument that the outcomes will have a positive impact on the health of Aboriginal and Torres Strait Islander peoples, which can be maintained after the study has been completed?
    - Have relevance to other Indigenous communities?
    - Clearly plan for and articulate a clear approach to knowledge translation and exchange?
    - Demonstrate that the findings are likely to be taken up in health services and/or policy?
- Will the outcomes from the study make a lasting contribution to Aboriginal and Torres Strait Islander communities and their wellbeing?

Building Capability

- Does the proposal outline how Aboriginal and Torres Strait Islander people and/or communities will benefit from capability development?
- Does the proposal outline how researchers and individuals/groups associated with the research project will develop capabilities that allow them to have a greater understanding/engagement of Aboriginal and Torres Strait Islander peoples?

Appendix G – Guide to Evaluating Industry-Relevant Experience

Principles

NHMRC is committed to ensuring that knowledge from health and medical research is translated through commercialisation (e.g. by pharmaceutical or medical devices companies), improvements to policy, health service delivery and clinical practice.

Therefore, as a complement to other measures of research excellence (e.g. publication and citation rates), NHMRC considers industry-relevant skills, experience and achievements in its assessment of applicants' track records.

These measures recognise that applicants who have invested their research time on technology transfer, commercialisation or collaborating with industry, may have gained highly valuable expertise or outputs relevant to research translation. However, NHMRC acknowledges that these researchers will necessarily have had fewer opportunities to produce traditional academic research outputs (e.g. peer reviewed publications).

Therefore, peer reviewers should:

- appropriately recognise applicants' industry-relevant experiences and results
- allow for the time applicants have spent in commercialisation/industry for 'relative to opportunity' considerations.

Who might have industry experience or be preparing for industry experience?

Many applicants to NHMRC may have had industry experiences of various kinds. Examples include, but are not limited to:

1. Researchers who have left academia to pursue a full time career in industry (e.g. in pharmaceutical, biotechnology or start-up companies). In such instances, outputs must be assessed 'relative to opportunity', as there may have been restrictions in producing traditional research outputs (such as peer reviewed publications), but highly valuable expertise gained or outputs produced relevant to research translation (such as patents or new clinical guidelines).
2. Academic researchers whose work has a possible commercial focus. These researchers might not have yet entered into commercial agreements with industry and have chosen to forego or delay publication in order to protect or extend their intellectual property (IP).
3. Academic researchers who have translated their discovery into a collaborative agreement with industry. The researcher may be collaborating with the company in further research and development; may have a licensing agreement; or may have licensed or assigned their IP to the company. A researcher may ultimately leave the academic institution and become Chief Executive Officer, Chief Scientific Officer, Chief Technology Officer, Scientific Advisory Board Member or consultant for a start-up or other company, based on their experience.
4. Academic researchers who are actively collaborating with companies, for example by providing expert research services for fees. Publications of such work might be precluded or delayed according to contract arrangements. The specialised nature of this research might also restrict publication to specialised journals only, as opposed to generalist journals.

Relevant industry outputs

Level of experience/ output	IP	Collaboration with an industry partner	Established a start-up company	Product to market	Clinical trials or regulatory activities	Industry participation
Advanced	• Patent granted: consider the type of patent and where it is granted. It can be more difficult to be granted a patent in, for example, the US or Europe than in Australia, depending on the patent prosecution and regulatory regime of the intended market • National phase entry and prosecution or specified country application	• Executed a licensing agreement with an established company • Significant research contract with an industry partner • Long term consultancy with an industry partner	• Achieved successful exit (public market flotation, merger or acquisition) • Raised significant (>$10m) funding from venture capital or other commercial sources (not grant funding bodies) • Chief Scientific Officer, Executive or non-executive role on company boards	• Produce sales • Successful regulator submission to US Food and Drug Administration (FDA), European Medicines Agency, TGA etc. • Medical device premarket submission e.g. FDA 510(k) approved	• Phase II or Phase III underway or completed	• Major advisory or consultancy roles with international companies
Intermediate	• Patent Cooperation Treaty (PCT) or 'international application' • Provisional patent	• Established a formal arrangement such as a consultancy or research contract and actively collaborating	• Incorporated an entity and established a board • Has raised moderate (>$1m) funding from commercial sources or government schemes that required industry co-participation (e.g. ARC Linkage, NHMRC	• Generated regulatory standard data set • Successful regulatory submission to Therapeutic Goods Administration or European Conformity (CE) marking • Medical device: applications for pre-market	• Phase I underway or completed • Protocol development • Patient recruitment	• Advisory or consultancy role with a national company

			Development Grant)	**approval**		
Preliminary	**• IP generated • Patent application lodged • Invention lodged with Disclosure/s with Technology Transfer/Commercialisation Office**	**• Approached and in discussion with an industry partner under a non-disclosure agreement. No other formal contractual arrangements.**	**• Negotiated licence to IP from the academic institution**	**• Developed pre-good manufacturing practice (GMP) prototype and strong supporting data • Established quality systems**	**• Drug candidate selected or Investigative New Drug application filed • Preclinical testing**	