Clinical Trials and Cohort Studies Grants 2020 Peer Review Guidelines

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<thead>
<tr>
<th><strong>Opening date:</strong></th>
<th>4 March 2020</th>
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<tbody>
<tr>
<td><strong>Closing date and time:</strong></td>
<td>17.00 AEST on 29 April 2020</td>
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<tr>
<td><strong>Commonwealth policy entity:</strong></td>
<td>National Health and Medical Research Council (NHMRC)</td>
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<td><strong>RGMS assistance and enquiries:</strong></td>
<td>NHMRC Research Help Centre</td>
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<tr>
<td></td>
<td>Phone: 1800 500 983 (+61 2 6217 9451 for international callers)</td>
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<tr>
<td></td>
<td>Email: <a href="mailto:help@nhmrc.gov.au">help@nhmrc.gov.au</a></td>
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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.

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<tr>
<th><strong>Clinical Trials and Cohort Studies Grants 2020 enquiries:</strong></th>
<th>Phone: 1800 500 983 (+61 2 6217 9451 for international callers)</th>
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<tbody>
<tr>
<td></td>
<td>Email: <a href="mailto:CTCS.grants@nhmrc.gov.au">CTCS.grants@nhmrc.gov.au</a></td>
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Clinical Trials and Cohort Studies Grants 2020 Peer Review Guidelines

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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 2020 peer review process operates, including:

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

NHMRC will advise the sector of any change to the peer review process via its communications such as, NHMRC’s website and newsletter.

This guide should be read in conjunction with the:

- Clinical Trials and Cohort Studies Grants 2020 Guidelines, 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 in order 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 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 and Observers.
- **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\(^1\) of any kind are dealt with consistently, transparently and with rigour, in accordance with Part 5, section 42A of the *National Health and Medical Research Council Act 1992* (NHMRC Act) and sections 16A and 16B of the *Public Governance, Performance and Accountability Rule 2014*\(^2\) (made under the subsection 29(2) of the *Public Governance, Performance and Accountability Rule 2013* (PGPA Act)).

In particular, under:

- subsection 42A(3) of the NHMRC Act, peer reviewers of Council and Committees must “give to the CEO a written statement of any interest the peer reviewer has that may relate to the activity of the Council or Committee” before starting to hold office. “Interest” is defined in section 4 of the NHMRC Act as meaning “any direct or indirect, pecuniary or non-pecuniary interest.”

- section 29 of the PGPA Act, “an official… who has a material personal interest that relates to the affairs of the entity must disclose details of the interest”. This obligation (unlike the obligation in subsection 42A(3) of the NHMRC Act) 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.

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\(^1\) An “Interest” is defined in section 4 of the NHMRC Act as meaning “any direct or indirect, pecuniary or non-pecuniary, interest”. Under section 29 of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act), “an official … who has a material personal interest that relates to the affairs of the entity must disclose details of the interest”.

\(^2\) Made under subsection 29(2) of the PGPA Act.
Although many positives may emerge from collaborations and partnerships with industry, there is potential for conflicts of interest to arise. These conflicts may arise from competing commitments and Financial Interests that may, or may be perceived to affect scientific endeavours.

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 in 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 disclosures of interest must be declared at the beginning of the peer review process, new or previously unrecognised disclosures of interest must be declared 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 have 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.

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 2020 PEER REVIEW PROCESS

4.1 Overview of the Clinical Trials and Cohort Studies Grants 2020 peer review process

Applications submitted → Eligibility checks completed 29 April to 4 May 2020*

Peer reviewer interests disclosed (conflicts of interest determined) and suitability declared for all applications → Assessments against Indigenous Research Excellence criteria (4-20 May 2020*) 6-22 May 2020*

Applications allocated to peer reviewers (3 per application) → 12 June 2020*

Independent assessment of applications → 12 June to 10 July 2020*

Least competitive applications deemed Not For Further Consideration → 25 July 2020*

Peer reviewers to review applications allocated to panel → 17 August to 8 September 2020*

Funding recommendation generated → Outcomes announced

October 2020* November-December 2020*

*Dates are indicative and subject to change.
<table>
<thead>
<tr>
<th>Date*</th>
<th>Activity</th>
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<tbody>
<tr>
<td>29 April 2020</td>
<td>Deadline for Clinical Trials and Cohort Studies Grants 2020 application submission</td>
</tr>
<tr>
<td>29 April to 4 May 2020</td>
<td>Application eligibility review and confirmation</td>
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<tr>
<td>6-22 May 2020</td>
<td>Peer reviewers disclose interests and suitability against applications</td>
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<tr>
<td>4-20 May 2020</td>
<td>Indigenous assessments obtained</td>
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<tr>
<td>12 June 2020</td>
<td>Allocation of applications and members to panels</td>
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<tr>
<td>12 June to 10 July 2020</td>
<td>Peer reviewers review applications and submit scores against Clinical Trials and Cohort Studies Grants 2020 assessment criteria for each allocated application</td>
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<tr>
<td>25 July 2020</td>
<td>Least competitive applications are deemed ‘not for further consideration’ (NFFC)</td>
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<tr>
<td>17 August to 8 September 2020</td>
<td>Panel meetings</td>
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<tr>
<td>November to December 2020</td>
<td>Notification of outcomes</td>
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*Dates are indicative and subject to change.

Further information on the steps outlined in this process is provided in section 3.3 Reviewing Clinical Trials and Cohort Studies Grants 2020 applications.

### 4.2 Roles and responsibilities

The roles and responsibilities of those participating in the Clinical Trials and Cohort Studies Grants 2020 peer review process are identified in the table below.

**Clinical Trials and Cohort Studies Grants 2020 Peer Review Participants Table**

<table>
<thead>
<tr>
<th>Roles</th>
<th>Responsibilities</th>
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<tbody>
<tr>
<td>Panel Chair (Chair)</td>
<td>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, however they must manage the process of peer review in accordance with this Guide.</td>
</tr>
<tr>
<td></td>
<td>Prior to the panel meeting Chairs need to:</td>
</tr>
<tr>
<td></td>
<td>1. familiarise themselves with this document and other material as identified by NHMRC staff</td>
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<tr>
<td></td>
<td>2. identify and advise NHMRC of all interests they have with applications assigned to their panel, and</td>
</tr>
<tr>
<td></td>
<td>3. familiarise themselves with ALL the applications assigned to their panel, excluding those for which they have been determined to have a high CoI.</td>
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<td>During the panel meeting Chairs will:</td>
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<tr>
<td></td>
<td>• take appropriate action for each CoI</td>
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<td></td>
<td>• keep discussions on time and focused</td>
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<td></td>
<td>• ensure NHMRC procedures are followed</td>
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</table>
- assist peer reviewers with their duties and in understanding what is expected of them
- 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 the discussion leads to an outcome where the applications are appropriately considered against the Clinical Trials and Cohort Studies Grants 2020 assessment criteria and associated category descriptors (Appendices C and D).
- ensure the panel consistently considers the assessment against the Indigenous Research Excellence Criteria (Appendix E) 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 relevant 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
- provide a fair and impartial assessment against the Clinical Trials and Cohort Studies Grants 2020 assessment criteria and associated category descriptors (Appendices C and D) for each non-conflicted application assigned, in a timely manner
- 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 with an Aboriginal and Torres Strait Islander focus

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 have no high CoI.

Primary Spokesperson (1SP)

Prior to the panel meeting:
- assess the allocated applications against the Clinical Trials and Cohort Studies Grants 2020 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
- if required, advise NHMRC if an application identified as relating to Aboriginal and Torres Strait Islander health meets the Indigenous Research Excellence Criteria (Appendix E), following assessment by an Indigenous health expert
- score the applications using the category descriptors (Appendix D)
- prepare speaking notes to present the application at the panel meeting
- rigorously assess the proposed budget to ensure that Personnel Support Packages (PSPs), Direct Research Costs (DRCs) and equipment requests are appropriate for the project and fully justified
- if applicable, review the Cancer Australia Priority-driven Collaborative Cancer Research Scheme (PdCCRS) proposal against the category descriptors and prepare a recommendation for the GRP to either provide the same score to Cancer Australia or rescore.
<table>
<thead>
<tr>
<th>Role</th>
<th>Prior to the panel meeting:</th>
<th>At the panel meeting:</th>
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</table>
| Secondary Spokesperson (2SP) | - assess the allocated applications against the Clinical Trials and Cohort Studies Grants 2020 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  
  - if required, advise NHMRC if an application identified as relating to Aboriginal and Torres Strait Islander health meets the Indigenous Research Excellence Criteria (Appendix E), following assessment by an Indigenous health expert  
  - prepare speaking notes to present the application at the panel meeting  
  - rigorously assess the proposed budget to ensure that PSPs, DRCs and equipment requests 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. | - lead the discussion using prepared notes  
  - provide advice to the GRP on the impact of career disruptions if applicable  
  - announce final 1SP scores for applications based on discussions  
  - if applicable, lead the panel discussion and work towards an agreed score for the Cancer Australia Priority-driven Collaborative Cancer Research Scheme (PdCCRS) proposal  
  - 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. |
| Tertiary Spokesperson (3SP) | - assess the allocated applications against the Clinical Trials and Cohort Studies Grants 2020 assessment criteria and associated category descriptors (Appendices C and D).  
  - if required, advise NHMRC if an application identified as relating to Aboriginal and Torres Strait Islander health meets the Indigenous Research Excellence Criteria (Appendix E), following assessment by an Indigenous health expert  
  - support the 1SP and 2SP in discussion with reference to prepared notes. |  

Senior NHMRC Staff

NHMRC staff with appropriate expertise may be involved in:  
- reviewing allocation of applications and peer reviewers to panels  
- assisting and advising on the peer review process, and  
- act as stand-in Chairs when Chairs are conflicted.

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 as peer reviewers or as a Chair  
- 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, and
- prepare provisional ranked lists for peer reviewers’ consideration.

At the panel meeting NHMRC staff will:
- support the operation of NHMRC’s granting system
- assist the Chair in running the discussions
- 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
- maintain scoring records for each application
- act as the first point of contact for peer reviewers and community observers, and
- seek feedback from Chairs, peer reviewers and community observers on improvements for future processes.

### Indigenous health research experts

Applications related to Aboriginal and Torres Strait Islander health research will be sent to Indigenous health experts who will consider the application based on the NHMRC Indigenous Research Excellence Criteria (Appendix E). Their reports will be made available to all panel members who are not conflicted, in order to inform their assessment of the applications.

### 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 2020 applications

All Clinical Trials and Cohort Studies Grants 2020 applications are assessed against the Clinical Trials and Cohort Studies Grants 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. Researchers 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 Aboriginal and Torres Strait Islander health expert. 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 reports against the Indigenous Research Excellence Criteria will be made available to peer reviewers to inform their decision-making when scoring based on 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 2020 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 an overview of applications within NHMRC’s granting system, and will need to disclose their interests 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. For these, NHMRC will assess the information provided by the peer reviewer and specify in NHMRC’s granting system a level of peer review participation for the peer reviewer.

Peer reviewers are also required to select their level of suitability for applications, based on the information available to them in the application summary.

Taking into account potential CoIs and suitability, peer reviewers will be assigned to applications.

4.3.4 Establishment of panels and assignment of applications to panels

The number of grant review 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. These allocations may also be informed by the proposed field of research and other key words entered into NHMRC’s granting system. 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 which that application will be allocated.

4.3.5 Briefing

NHMRC will provide briefing material that will provide peer reviewers further details on their duties and responsibilities associated with the Clinical Trials and Cohort Studies Grants 2020 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.

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 NHMRC’s granting system. 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 (Appendix G), where applicable.

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

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 provisional ranked lists of applications for each panel.

4.3.6.1 Relative to opportunity and career disruption

Panel members must take into account productivity relative to opportunity and, where applicable, career disruption considerations in the assessment of all applications. This reflects NHMRC’s policy that assessment processes should accurately assess an applicant’s track record and associated productivity relative to stage of career, including consideration as to whether productivity and contribution are commensurate with the opportunities available to the applicant. To assist peer reviewers with their assessment, further details regarding relative to opportunity and career disruptions are provided at Appendix G.

4.3.6.2 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 H.

4.3.6.3 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.

4.3.6.4 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.

4.3.6.5 Research Integrity Issues

The peer review process can sometimes identify possible research integrity issues with 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 is 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.

4.3.6.6 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 2020 panel meetings will occur face to face. 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. Once the Not For Further Consideration (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 review by the peer review panel.

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
• If an application relates to an NHMRC strategic research investment priority, as determined by NHMRC, and achieves a notional score of 4.001 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: 30 minutes

When panel members (including the Chair and Secretariat) meet face-to-face for the first time, 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 asked to leave the room.

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 leave the room. 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 as accurately as possible 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 will be assigned to the application and the scores from the initial SP will be discarded. Discussion of the application will be moved to later in the week where possible to give the new SP time to prepare.

Once highly conflicted members have left the room (those with a low CoI remain in the panel room), 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, 2SP and 3SP and announce the Spokesperson scores for each of the three 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).

- 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, including the 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 get a fair opportunity to comment and that no member exerts undue influence over others.

Panel members must take into account the Indigenous Research Excellence Criteria report from the Indigenous health experts when discussing and scoring Aboriginal and Torres Strait Islander health research applications.

**Scoring by panel members**
Suggested time limit: 3 minutes

Following the panel’s discussion, the Chair will ask the Primary, Secondary and Tertiary Spokespersons 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 room, excluding the Chair, must independently score the application through NHMRC’s e-scoring platform. 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 2020 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:

1. Rating - the rating will be determined by including each panel member’s score for each of the
assessment criteria. The rating, as calculated arithmetically to three decimal places, will take account of the weighting of each criterion.

2. Category - this will be deemed, based on the calculated rating, as follows:

<table>
<thead>
<tr>
<th>Rating range</th>
<th>Deemed category</th>
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<tbody>
<tr>
<td>1.001 - 1.500</td>
<td>1</td>
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<tr>
<td>1.501 - 2.500</td>
<td>2</td>
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<td>2.501 - 3.500</td>
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<td>3.501 - 4.500</td>
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<td>5.501 - 6.500</td>
<td>6</td>
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<tr>
<td>6.501 - 7.000</td>
<td>7</td>
</tr>
</tbody>
</table>

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 Cancer Australia PdCCRS applications (where applicable)**

Suggested time limit: 5 minutes

Discussion of the PdCCRS component of applications will be by exception only, following scoring of the application by the entire panel. If the score for each criterion is in line with 1SP’s recommendation for the PdCCRS modified proposal, then no discussion needs to occur.

If the panel score for any criterion not reflective of the 1SP’s recommendation for the PdCCRS modified proposal, the 1SP should recommend a different score be provided to Cancer Australia.

**Discussion by exception of proposed budget**

Suggested time limit: 5 minutes

Budget discussions should not commence until the NHMRC secretariat has announced the rating and category. Once the category has been announced, the secretariat will advise if 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

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). In situations where a number of members have a high CoI with an application, the scoring quorum cannot be less than one-third of the panel membership present at the meeting.

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.

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 awarding 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 Panel documentation

Peer reviewers must retain their speaking notes and any other notes they make of the peer review process until the outcomes of the panel’s deliberations are finalised. For panel meetings, this is when the final scores have been determined. After this time, both hard copy and electronic notes are to be disposed of appropriately.

4.3.11 Funding Recommendation

After the panel meeting/s, 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.
4.3.12 Notification of Outcomes

Applicants will be notified of the outcomes via NHMRC’s granting system and their Administering Institution’s Research Administration Officer.
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.
• 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.3

Independence

• The order of merit determined by peer review panels is not altered by NHMRC. However, additional applications may be funded ‘below the funding line’ in priority or strategic areas.
• Panel Chairs are independent and are not involved in the peer review of any application before that panel. 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 program’s objectives and to ensure adequate expertise to assess the applications received.
• NHMRC endeavours to ensure that panels are constituted with 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

3 Such information will be in a form that prevents applicants determining which particular experts were involved in the review of their application.
requirements under section 80 of the NHMRC Act.

- 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.

- Panel members must disclose relationships with other members of the panel, or with grants being reviewed by other panel members, 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 decision making on 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-program 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

Conflicts frequently are regarded as a positive indicator that peer reviewers are recognised leaders who:

- have expert advice or skills
- have been given professional opportunities
- have received government funding, and
- are supported by the companies working to raise the standard of individual and public health throughout Australia.

A disclosure of interest does not mean that a peer reviewer has engaged in an inappropriate activity. It is a collaboration which may, or could be perceived to, impact 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 the peer reviewer’s responsibility to disclose all interests. Failure to do so without a reasonable excuse may result in the peer reviewer being removed from the panel in accordance with subsection 44B(3) of the NHMRC Act.

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:

- **Excellence through expert peer review**: The benefits of peer reviewers’ expert advice need to be balanced with the risk of real and 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 CoIs 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’ CoI, 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.

The three categories that define the NHMRC CoI outcomes are:

- **‘High’** indicates the peer reviewer or close relative or professional associate has a direct financial or other interest in an application.
- **‘Low’** indicates it may be perceived that the peer reviewer or close relative or professional associate of the peer reviewer has an interest of a financial or other interest in an application. However, the perception would not cause a reasonable person to question the peer reviewer’s impartiality if they participate in the review.
- **‘No’** indicates the peer reviewer has no link that will affect the evaluation of the application.

Once a peer reviewer notes a conflict they can detail a brief explanation of the disclosure of interest in NHMRC’s granting system to enable accurate clarification for decisions. Wherever possible, peer reviewers are encouraged to provide sufficient detail in the explanation such as date (month and year) of collaborations. Disclosures of interest where appropriate are to be documented for conflicts with both
CIs and AIs. Peer reviewers will be determined to have a high conflict of interest if they or a close relative or professional associate has had a working or collaborative relationship within the past three years (apart from the limited circumstances assessed as LOW). The written declaration of interest is retained for auditing purposes by NHMRC. The details below provide generalist examples but is not to be regarded as a prescriptive checklist.
## Expanded examples: Representative Examples of Disclosure of Interest Scenarios

### HIGH Interest

<table>
<thead>
<tr>
<th>Situation</th>
<th>Example</th>
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<tbody>
<tr>
<td><strong>Associated with Application, Chief Investigator (CI)</strong></td>
<td>☑ Peer reviewer is a CI or AI on the application under review.</td>
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<td></td>
<td>☑ Peer reviewer has had discussions/significant input into the study design or research proposal of this application.</td>
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<tr>
<td><strong>Collaborations</strong></td>
<td>☑ Peer reviewer has actively collaborated on publications within the last three years (co-authorship), pending current-round applications, existing NHMRC or other grants.</td>
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<td></td>
<td>☑ There is a direct association/collaboration between the peer reviewer and a CI that may have, or may be perceived to have, a vested interest in this research.</td>
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<tr>
<td><strong>Working relationships</strong></td>
<td>☑ Peer reviewer has the same employer, is part of the same organisation, or is negotiating for employment at the applicant’s institution, including:</td>
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<td>• in the same research field at an independent Medical Research Institute.</td>
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<td>• in the same Department or School of a university.</td>
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<td>• in the same Department of a hospital.</td>
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<tr>
<td><strong>Professional relationships and interests</strong></td>
<td>☑ Peer reviewer has a professional associate in a position of influence within an organisation, or with a pecuniary interest, e.g. Dean of Faculty or School/Institute Directors.</td>
</tr>
<tr>
<td><strong>Social relationship and / or interests</strong></td>
<td>☑ The peer reviewer, their partner or an immediate family member have a known personal/social/perceived relationship with a CI on the application.</td>
</tr>
<tr>
<td><strong>Teaching or supervisory relationship</strong></td>
<td>☑ Peer reviewer has taught or supervised the applicant for either undergraduate or postgraduate studies, co-supervised a CI, or the research was supervised by a CI within the last three years.</td>
</tr>
<tr>
<td><strong>Direct financial interest in the application</strong></td>
<td>☑ Peer reviewer has the potential for financial gains 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.</td>
</tr>
<tr>
<td></td>
<td>☑ Peer reviewer receives research funding or other support from a company and the research proposal may involve</td>
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<tr>
<td><strong>Other interests or situations</strong></td>
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</table>

collaboration/association with relevant company.
<table>
<thead>
<tr>
<th>Situation</th>
<th>Example</th>
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</thead>
<tbody>
<tr>
<td><strong>Collaborations</strong></td>
<td>✔ Peer reviewer and a CI on the application have collaborated more than three years ago.</td>
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<tr>
<td></td>
<td>✔ Within the last three years the peer reviewer has published with the CI as part of a multi-author collaborative team (i.e. &gt;10) where the peer reviewer did not have a major professional interactive role (i.e. the peer reviewers’ role was a leadership role).</td>
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<td>✔ A co-worker is planning future collaborations with a CI.</td>
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<td></td>
<td>✔ Peer reviewer and a named AI on the application are actively or have previously collaborated within the last three years.</td>
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<td></td>
<td>✔ Without financial gain or exchange, a peer reviewer and a contributor of the research team have shared cells/animals/reagents/specialist expertise (biostatistician) etc. but have no other connection to each other.</td>
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<tr>
<td></td>
<td>✔ Collaboration between a CI and the peer reviewer’s research group.</td>
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<tr>
<td></td>
<td>✔ Peer reviewer is considering/planning/or has planned a future collaboration with a CI on the application but have no current collaborations or joint applications.</td>
</tr>
<tr>
<td><strong>Working relationships</strong></td>
<td>✔ Peer reviewer has the same employer, is part of the same organisation or is negotiating employment at the applicant’s institution.</td>
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<td></td>
<td>✔ Peer reviewer and a CI work:</td>
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<td></td>
<td>• at the same institution and do not know each other.</td>
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<td></td>
<td>• in the same Faculty or College of a university but in different Schools or Departments and do not know each other.</td>
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<td></td>
<td>• in the same organisation, but the peer reviewer or applicant holds an honorary appointment.</td>
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<td></td>
<td>✔ Peer reviewer and a CI work for two organisations that are affiliated but there is/are no direct association/collaboration.</td>
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<td></td>
<td>✔ Peer reviewer and a CI are on the same scientific advisory committee, review board, exam board, trial committee, Data and Safety Monitoring Board etc., but otherwise have no association that would constitute a High decision.</td>
</tr>
<tr>
<td><strong>Professional relationships and interests</strong></td>
<td>✔ Peer reviewer’s organisation is affiliated with the CI's organisation.</td>
</tr>
<tr>
<td></td>
<td>✔ Where two 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’ decision.</td>
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<tr>
<td></td>
<td>✔ When the peer reviewer’s institution has an indirect affiliation/association with the organisation(s) that may have, or may be perceived to have, a vested interest in this research. For example, peer reviewer is employed at a large institution that does not have a direct research interest/association with the organisation(s) in question.</td>
</tr>
<tr>
<td><strong>Social relationship</strong></td>
<td>✔ Peer reviewer’s partner or an immediate family member have a known personal/social (non-work)/perceived relationship with a CI on the</td>
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<tr>
<td>and / or interests</td>
<td>application, but do not have any link with the CI that would be perceived or constitute a ‘High’ decision.</td>
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</tr>
<tr>
<td>Teaching or supervisory relationship</td>
<td>✔ Peer reviewer taught or supervised the applicant 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.</td>
</tr>
<tr>
<td>Financial interest in the application</td>
<td>✔ 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’ decision. ✔ Peer reviewer receives research funding or other support from a company, and the research proposal may impact upon the company.</td>
</tr>
<tr>
<td>Other interests or situations</td>
<td>✔ Peer reviewer is in direct scientific competition with a CI. ✔ Peer reviewer may, or may be perceived to be, biased in their review of the application. For example, peer reviewer is a lobbyist on a particular issue.</td>
</tr>
</tbody>
</table>
Appendix C – Clinical Trials and Cohort Studies Grants 2020 Assessment Criteria

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

Applications are assessed relative to opportunity, taking into consideration any career disruptions, where applicable (see Appendix G).

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 Grants 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 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?
  - Does the research question(s) meet the needs of research end-users, such as consumers, community members, policy makers and clinical practitioners?
  - If the research objectives are achieved, would the research have a significant impact on the health issue in question? This may include contributing to knowledge, health, economic and social impacts.

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:
  - Have any major pitfalls been overlooked?
o 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)?

o 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.

o Are the proposed methodological approaches appropriate? Are the participants’ intervention/exposure and comparators/controls clearly specified? Are data collection, management and statistical analyses described?

o Were relevant research end-users, such as consumers, community members, policy makers and clinical practitioners, engaged during development of the research plan? Will they be involved in the conduct of the clinical trial and/or cohort study? Will they be informed of the outcomes?

o Have barriers and enablers associated with implementation been thoroughly considered and managed?

- Is the clinical trial and/or cohort study feasible? For example:
  
o Are the required techniques established? Are the required expertise and resources available, including infrastructure, equipment and facilities?

  o Are targets for the recruitment of participants realistic? Is the sample size achievable and sufficient to detect meaningful effect differences?

  o Does the proposal include appropriate and realistic milestones and performance indicators and timeframes? Can the end-points be measured?

  o 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-compliance 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 five years? Have the CIs previously delivered high quality research outputs 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?

It is recognised that Aboriginal and/or 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 2020 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%)

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<tr>
<th>SCORE</th>
<th>The proposed clinical trial and/or cohort study:</th>
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<tr>
<td>7</td>
<td>• will comprehensively and convincingly address the objective of this grant opportunity and will deliver against the desired outcomes</td>
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<td>6</td>
<td>• is informed by an exemplary analysis or review of existing and ongoing studies in the field</td>
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<td>5</td>
<td>• was developed with broad and meaningful involvement of research end-users to ensure it meets their needs</td>
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<td>4</td>
<td>• if successful, will have very significant research impacts.</td>
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<tr>
<td>3</td>
<td>• will strongly address the objective of this grant opportunity and will deliver against desired outcomes</td>
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<tr>
<td>2</td>
<td>• is informed by a thorough analysis or review of existing and ongoing studies in the field</td>
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<tr>
<td>1</td>
<td>• was developed with meaningful involvement of research end-users to ensure it meets their needs</td>
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<td>• if successful, will have significant research impacts.</td>
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SCORE

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<td>The proposed clinical trial and/or cohort study:</td>
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<td>The proposed clinical trial and/or cohort study:</td>
<td>The proposed clinical trial and/or cohort study:</td>
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<tr>
<td>• will comprehensively and convincingly address the objective of this grant opportunity and will deliver against the desired outcomes</td>
<td>• will strongly address the objective of this grant opportunity and will deliver against desired outcomes</td>
<td>• will address the objective of this grant opportunity with only minor concerns and deliver moderate research impacts</td>
<td>• will partially address the objective of this grant opportunity and deliver desired outcomes of some relevance</td>
<td>• there are several minor concerns about the analysis or review of existing and ongoing studies which informs the research</td>
<td>• had research end-user involvement in a number of aspects of the design</td>
<td>• if successful, it is unlikely to have anything other than minor research impact.</td>
</tr>
<tr>
<td>• is informed by an exemplary analysis or review of existing and ongoing studies in the field</td>
<td>• is informed by a good analysis or review of relevant existing and ongoing studies in the field, with only minor concerns with respect to the analysis</td>
<td>• if successful, will have appreciable research impacts.</td>
<td>• will not convincingly address the objective of this grant opportunity or is unclear in its approach to doing so</td>
<td>• if successful, may have moderate research impacts.</td>
<td>• had research end-user involvement in a number of aspects of the design</td>
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</tr>
<tr>
<td>• was developed with broad and meaningful involvement of research end-users to ensure it meets their needs</td>
<td>• was developed with meaningful involvement of research end-users to ensure it meets their needs</td>
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<td></td>
<td></td>
<td>• if successful, it is unlikely to have anything other than minor research impact.</td>
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<tr>
<td>• if successful, will have very significant research impacts.</td>
<td>• if successful, will have significant research impacts.</td>
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</table>

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
• is informed by a very limited analysis or review of existing and ongoing studies in the field
• will not translate into outcomes that improve treatment of a medical condition or improve health outcomes.
## Significance of the grant outcomes: Indigenous criteria

<table>
<thead>
<tr>
<th>Sustainability and transferability</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>The outcomes of the study will have a very significant health benefit for Aboriginal and Torres Strait Islander peoples.</td>
</tr>
<tr>
<td>The outcomes of the study will have a high impact on health services delivery or other community priorities.</td>
<td>The outcomes of the study will have some health benefit for Aboriginal and Torres Strait Islander peoples.</td>
</tr>
<tr>
<td>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</td>
<td>The outcomes of the study may have some health benefit for Aboriginal and Torres Strait Islander peoples.</td>
</tr>
<tr>
<td>The outcomes of the study may lead to limited or short-term health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project</td>
<td>The outcomes of the study are likely to have a minimal health benefit for Aboriginal and Torres Strait Islander peoples.</td>
</tr>
<tr>
<td>The outcomes of the study are unlikely to lead to any health gains for Aboriginal and Torres Strait Islander peoples</td>
<td>The outcomes of the study are likely to have little or no health benefit for Aboriginal and Torres Strait Islander peoples.</td>
</tr>
<tr>
<td>The outcomes of the study are unlikely to have any impact on health services delivery or other community priorities.</td>
<td>The outcomes of the study will have no health benefit for Aboriginal and Torres Strait Islander peoples.</td>
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<tbody>
<tr>
<td>The outcomes of the study may lead to health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project</td>
<td>The outcomes of the study may have a moderate impact on health services delivery or other community priorities.</td>
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<tr>
<td>The outcomes of the study may have an impact on health services delivery or other community priorities.</td>
<td>The outcomes of the study are unlikely to have any impact on health services delivery or other community priorities.</td>
</tr>
<tr>
<td>The outcomes of the study will lead to effective health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project</td>
<td>The outcomes of the study will not have any impact on health services delivery or other community priorities.</td>
</tr>
<tr>
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<td>The outcomes of the study will not lead to any health gains for Aboriginal and Torres Strait Islander peoples.</td>
</tr>
<tr>
<td>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</td>
<td>The outcomes of the study will not have any impact on health services delivery or other community priorities.</td>
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<tr>
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<td>The outcomes of the study will not have any impact on health services delivery or other community priorities.</td>
</tr>
<tr>
<td>SCORE</td>
<td>Research Quality (40%)</td>
</tr>
<tr>
<td>-------</td>
<td>------------------------</td>
</tr>
</tbody>
</table>
| 1     | 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  
|       | • did not consider any risk management strategies. |
| 2     | The proposed clinical trial and/or cohort study:  
|       | • is unclear in its design  
|       | • contains several major flaws in study design and research methodologies  
|       | • raises several major concerns about the feasibility and thus the likelihood of successful completion  
|       | • was developed with poor risk management strategies. |
| 3     | 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  
|       | • includes minimal, tokenistic research end-user involvement  
|       | • raises significant concerns about the appropriateness of milestones and performance indicators  
|       | • was developed with some or marginal risk management strategies. |
| 4     | 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  
|       | • includes constructive research end-user involvement but with limited scope  
|       | • raises minor concerns about the appropriateness of milestones and performance indicators  
|       | • was developed with adequate risk management strategies. |
| 5     | The proposed clinical trial and/or cohort study:  
|       | • is generally clear in its research methodology, logical and appropriate to 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  
|       | • includes some appropriate research end-user involvement  
|       | • was developed with good risk management strategies that include a thorough barriers and enablers analysis to ensure successful implementation. |
| 6     | The proposed clinical trial and/or cohort study:  
|       | • has a strong, well defined and coherent design and research methodologies appropriate to the research question  
|       | • is comparable with strong proposals in the field internationally  
|       | • is feasible with required techniques and resources established  
|       | • includes appropriate research end-user involvement  
|       | • includes effective milestones and performance indicators  
|       | • was developed with very good risk management strategies that include a thorough barriers and enablers analysis to ensure successful implementation. |
| 7     | The proposed clinical trial and/or cohort study:  
|       | • has a near flawless design and research methodologies appropriate to 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  
|       | • includes highly appropriate research end-user involvement  
|       | • includes highly effective milestones and performance indicators  
|       | • was developed with outstanding risk management strategies that include a thorough barriers and enablers analysis to ensure successful implementation. |
### Research quality: Indigenous criteria

<table>
<thead>
<tr>
<th>Community Engagement</th>
<th>The proposal has a research plan that:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• has outstanding levels of community engagement, ensuring that the proposal is highly feasible</td>
</tr>
<tr>
<td></td>
<td>• demonstrates how the research and potential outcomes are a priority for the community to an outstanding degree.</td>
</tr>
</tbody>
</table>

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• has excellent levels of community engagement, ensuring that the proposal is feasible</td>
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<tr>
<td></td>
<td>• demonstrates how the research and potential outcomes are a priority for the community to an excellent degree.</td>
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<tr>
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<th>The proposal has a research plan that:</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>• has very good levels of community engagement, ensuring that the proposal is likely to be feasible</td>
</tr>
<tr>
<td></td>
<td>• clearly demonstrates how the research and potential outcomes are a priority for the community.</td>
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</table>

<table>
<thead>
<tr>
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<table>
<thead>
<tr>
<th>Community Engagement</th>
<th>The proposal:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• has limited community engagement</td>
</tr>
<tr>
<td></td>
<td>• raises several concerns whether the proposal is feasible and achievable.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Community Engagement</th>
<th>The proposal:</th>
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<tbody>
<tr>
<td></td>
<td>• has little or no community engagement</td>
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<tr>
<td></td>
<td>• is unlikely to be feasible and achievable.</td>
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</tbody>
</table>

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<thead>
<tr>
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<tbody>
<tr>
<td></td>
<td>• has no community engagement</td>
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<tr>
<td></td>
<td>• will not be feasible.</td>
</tr>
</tbody>
</table>
# Team Quality and Capability (20%)

<table>
<thead>
<tr>
<th>SCORE</th>
<th>Relative to opportunity, the CIs:</th>
<th>Relative to opportunity, the CIs:</th>
<th>Relative to opportunity, the CIs:</th>
<th>Relative to opportunity, the CIs:</th>
<th>Relative to opportunity, the CIs:</th>
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<tbody>
<tr>
<td>7</td>
<td>• have a high level of expertise and experience in all aspects of the proposed research</td>
<td>• there are only minor concerns about the CIs’ level of expertise and experience required to undertake the proposed research</td>
<td>• there are significant concerns about the CIs’ level of expertise and experience required to undertake the proposed research</td>
<td>• are deficient in the relevant expertise required to successfully complete the proposed research</td>
<td>• are deficient in the relevant expertise required to successfully complete the proposed research</td>
</tr>
<tr>
<td>6</td>
<td>• have a very high level of influence and strong networks to contribute to the proposed research</td>
<td>• have an appropriate level of influence and networks to contribute to the proposed research</td>
<td>• have some level of influence and networks to contribute to the proposed research</td>
<td>• have made contributions to the field of research but there are significant concerns regarding the depth and breadth of relevant expertise of the team</td>
<td>• have made contributions to the field of research but there are significant concerns regarding the depth and breadth of relevant expertise of the team</td>
</tr>
<tr>
<td>5</td>
<td>• have over the last 5 years, a combined record of research achievement that is outstanding by international standards commensurate with their field of research (research achievement, quality and productivity)</td>
<td>• the CIs have over the last 5 years, a combined record of research achievement that is excellent by international standards commensurate with their field of research (research achievement, quality and productivity)</td>
<td>• the CIs have over the last 5 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)</td>
<td>• the CIs have made major contributions to the field of research (research achievement, quality and productivity)</td>
<td>• the CIs have made major contributions to the field of research (research achievement, quality and productivity)</td>
</tr>
<tr>
<td>4</td>
<td>• have excellent national and/or international reputations in clinical trial or cohort study methodology and relevant research fields</td>
<td>• the CIs have very good national and/or international reputations in clinical trial or cohort study methodology and relevant research fields</td>
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</tr>
<tr>
<td>3</td>
<td>• may include junior members who are strong contributors to overall team capability.</td>
<td>• may include junior members who contribute to overall team capability.</td>
<td>• may include junior members who contribute to overall team capability.</td>
<td>• may include junior members who contribute to overall team capability.</td>
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<td>2</td>
<td>• may include junior members who are strong contributors to overall team capability.</td>
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<tr>
<td>1</td>
<td>• may include junior members who are strong contributors to overall team capability.</td>
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<td>• may include junior members who contribute to overall team capability.</td>
<td>• may include junior members who contribute to overall team capability.</td>
<td>• may include junior members who contribute to overall team capability.</td>
</tr>
</tbody>
</table>

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7: High quality and capability, with a strong potential for innovation and impact.
6: Good quality and capability, with a strong potential for innovation and impact.
5: Average quality and capability, with a moderate potential for innovation and impact.
4: Low quality and capability, with a limited potential for innovation and impact.
3: Poor quality and capability, with a low potential for innovation and impact.
2: Very poor quality and capability, with a minimal potential for innovation and impact.
1: Unable to assess due to lack of information or data.
| 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 peoples.
- The proposal will build outstanding capability among Aboriginal and Torres Strait Islander peoples.

- The team has an excellent track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples.
- The proposal will build excellent capability among Aboriginal and Torres Strait Islander peoples.

- The team has a very good track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples.
- The proposal will build very good capability among Aboriginal and Torres Strait Islander peoples.

- The team has a good track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples.
- The proposal may build good capability among Aboriginal and Torres Strait Islander peoples.

- The team has a marginal track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples.
- The proposal may build minimal capability among Aboriginal and Torres Strait Islander peoples.

- The team has an unsatisfactory track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples.
- The proposal is unlikely to build capability among Aboriginal and Torres Strait Islander peoples.

- The team has a poor track record in working with communities and building capability among Aboriginal and Torres Strait Islander peoples.
- The proposal will not build capability among Aboriginal and Torres Strait Islander peoples.
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 – NHMRC Relative to Opportunity and Career Disruption Policy

Purpose

The purpose of this document is to outline NHMRC’s Relative to Opportunity Policy with respect to peer review and eligibility to apply for Emerging Leadership Investigator Grants.

NHMRC’s objective is to support the best Australian health and medical research and the best researchers, at all career stages. NHMRC seeks to ensure that researchers with a variety of career experiences and those who have experienced pregnancy or a major illness/injury or have caring responsibilities, are not disadvantaged in applying for NHMRC grants.

Policy approach

NHMRC considers Relative to Opportunity to mean that assessment processes should accurately assess an applicant’s track record and associated productivity relative to stage of career, including considering whether productivity and contribution are commensurate with the opportunities available to the applicant. It also means that applicants with career disruptions should not be disadvantaged (in terms of years since they received their PhD) when determining their eligibility for Emerging Leadership Investigator Grants and that their Career Disruptions should be considered when their applications are being peer reviewed.

In alignment with NHMRC’s Principles of Peer Review, particularly the principles of fairness and transparency, the following additional principles further support this objective:

- **Research opportunity**: Researchers’ outputs and outcomes should reflect their opportunities to advance their career and the research they conduct.

- **Fair access**: Researchers should have access to funding support available through NHMRC grant programs consistent with their experience and career stage.

- **Career diversity**: Researchers with career paths that include time spent outside of academia should not be disadvantaged. NHMRC recognises that time spent in sectors such as industry, may enhance research outcomes for both individuals and teams.

The above principles frame NHMRC’s approach to the assessment of a researcher’s track record during expert review of grant applications and eligibility of applicants applying for Emerging Leadership Investigator Grants. NHMRC expects that those who provide expert assessment during peer review will give clear and explicit attention to these principles to identify the highest quality research and researchers to be funded. NHMRC recognises that life circumstances can be very varied and therefore it is not possible to implement a formulaic approach to applying Relative to Opportunity and Career Disruption considerations during peer review.

Relative to Opportunity considerations during peer review of applications for funding

During peer review of applications, circumstances considered under the Relative to Opportunity Policy are:

- amount of time spent as an active researcher

- available resources, including situations where research is being conducted in remote or isolated communities
• building relationships of trust with Aboriginal and Torres Strait Islander communities over long periods that can impact on track record and productivity
• clinical, administrative or teaching workload
• relocation of an applicant and his/her research laboratory or clinical practice setting or other similar circumstances that impact on research productivity
• for Aboriginal and/or Torres Strait Islander applicants, community obligations including ‘sorry business’
• the typical performance of researchers in the research field in question
• research outputs and productivity noting time employed in other sectors. For example there might be a reduction in publications when employed in sectors such as industry
• carer responsibilities (that do not come under the Career Disruption policy below).

Career Disruption considerations during peer review and eligibility to apply for Emerging Leadership Investigator Grants

A Career Disruption is defined as a prolonged interruption to an applicant’s capacity to work, due to:

• pregnancy
• major illness/injury
• carer responsibilities.

The period of career disruption may be used:

• to determine an applicant’s eligibility for an Emerging Leadership Investigator Grant
• to allow for the inclusion of additional track record information for assessment of an application
• for consideration by peer reviewers

To be considered for the purposes of eligibility and peer review, a period of Career Disruption is defined as:

• a continuous absence from work for 90 calendar days or more, and/or
• continuous, long-term, part-time employment (with defined %FTE) due to circumstances classified as Career Disruption, with the absence amounting to a total of 90 calendar days or more.4

Career Disruption and eligibility to apply for Investigator Grants

A Career Disruption can affect an applicant’s eligibility to apply for an Emerging Leadership Investigator Grant. For such grants, the 10-year time limit on the number of years post-PhD may be extended commensurate with the period of the Career Disruption.

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4 For example, an applicant who is employed at 0.8 FTE due to childcare responsibilities would need to continue this for at least 450 calendar days to achieve a Career Disruption of 90 calendar days.
Appendix H – 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

<table>
<thead>
<tr>
<th>Level of experience/output</th>
<th>IP</th>
<th>Collaboration with an industry partner</th>
<th>Established a start-up company</th>
<th>Product to market</th>
<th>Clinical trials or regulatory activities</th>
<th>Industry participation</th>
</tr>
</thead>
</table>
| **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 | - Generated regulatory standard data set  
- Successful regulatory submission to Therapeutic Goods Administration or European Conformity (CE) marking | - Phase I underway or completed  
- Protocol development  
- Patient recruitment | - Advisory or consultancy role with a national company |
| 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 |