



# Development Grants 2023 Peer Review Guidelines

| Opening date:                      | 19 April 2023  |
|------------------------------------|--|
| Closing date and time:             | 14 June 2023 at 17:00 AEST   |
| Commonwealth policy entity:        | National Health and Medical Research Council (NHMRC)   |
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|                                    | Email: help@nhmrc.gov.au   |
|                                    | Note: NHMRC's Research Help Centre aims to provide a reply to all requests for general assistance within two working days. |
|                                    | This timeframe may be delayed during peak periods or for more detailed requests for assistance.                            |
| Development Grants enquiries:      | Phone:1800 500 983 (+61 2 6217 9451 for international callers)   |
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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 Development Grants peer review process operates, including:

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

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

This guide should be read in conjunction with the:

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

## 2. 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).

#### 2.1. NHMRC's Principles of Peer Review

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

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

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

#### 2.2. The Australian Code for the Responsible Conduct of Research

The <u>Australian Code for the Responsible Conduct of Research</u> (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 <u>Peer Review: A guide supporting the Australian Code for the Responsible Conduct of Research.</u>

#### 2.3. Disclosures of Interest

#### 2.3.1. What is an interest?

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

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

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

#### 2.3.2. What is a Conflict of Interest (Col)?

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

For NHMRC peer review purposes, interests may fall into the broad domains of:

- Involvement with the application under review
- Working relationships
- Professional relationships and associations
- Social relationships or associations

- Collaborations
- Teaching or supervisory relationships
- Financial relationships or interests
- Other relevant interests or relationships

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

Researchers frequently have a Col 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 Col situations and guidance is provided for peer reviewers at Appendix B.

#### 2.3.3. 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 (Als) on applications they will be reviewing. After appointment as a peer reviewer, but before assessing any applications, peer reviewers are required to disclose their interests in writing. While interests

must be disclosed at the beginning of the peer review process, new or previously unrecognised interests must be disclosed at any stage of the peer review process. Declarations must include details that substantiate when collaborations occurred (i.e. month and year). NHMRC will use these details to verify and determine the level of conflict. Any peer reviewer who has an interest that is determined by NHMRC to be a 'high' Col will not be able to participate in the review of that application. However, they can provide scientific advice at the request of the Chair or NHMRC.

#### 2.3.4. 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.

#### 2.4. Freedom of Information (FoI)

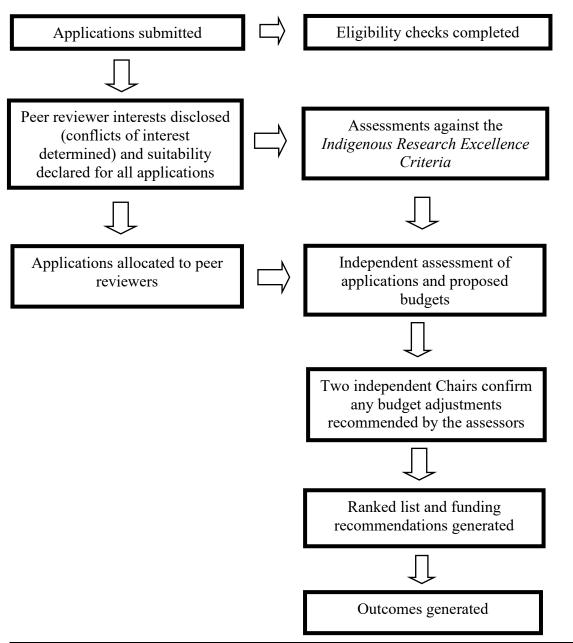
NHMRC is subject to the *Freedom of Information Act 1982* which provides a statutory right for an individual to seek access to documents. If documents that deal with peer review fall within the scope of a request, the Fol process includes consultation and exemptions. NHMRC endeavours to protect the identity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

#### 2.5. 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.

## 3. Development Grants peer review process

#### 3.1. Overview of the Development Grants peer review process



| Date                  | Activity  |  |
|-----------------------|---|--|
| 14 June 2023          | Deadline for Development Grants application submission                          |  |
| June – July 2023      | Application eligibility review and confirmation                                 |  |
| June – July 2023      | Peer reviewers disclose interests and suitability against applications          |  |
| July – August 2023    | Assessments against the Indigenous Research Excellence Criteria                 |  |
| July – August 2023    | Allocation of applications to peer reviewers                                    |  |
| August – October 2023 | Peer reviewers review applications and submit scores against Development Grants |  |
|                       | assessment criteria for each allocated application                              |  |
| December 2023         | Notification of outcomes  |  |

<sup>\*</sup>Date is indicative and subject to change.

Further information on the steps outlined in this process is provided in section 3.3 *Reviewing Development Grant applications*.

### 3.2. Roles and responsibilities

The roles and responsibilities of those participating in the Development Grants peer review process are identified in the table below.

**Development Grants Peer Review Participants Table** 

| Roles                | Responsibilities  |  |  |  |
|----------------------|---|--|--|--|
| Chair                | The Chair's role is to ensure NHMRC's procedures are adhered to and that fair and equitable consideration is given to every application being reviewed by peer reviewers.   |  |  |  |
|                      | Chairs do not assess applications but manage the process of peer review in accordance with this Guide.  |  |  |  |
|                      | Chairs need to:   |  |  |  |
|                      | <ul> <li>familiarise themselves with this document and other material as identified<br/>by NHMRC staff</li> </ul>   |  |  |  |
|                      | <ul> <li>assist peer reviewers with their duties and in understanding what is<br/>expected of them</li> </ul>   |  |  |  |
|                      | <ul> <li>mentor peer reviewers through the assessment stage of peer review, as<br/>required or requested, and</li> </ul>  |  |  |  |
|                      | <ul> <li>respond to peer reviewer enquiries on NHMRC peer review process and<br/>policy.</li> </ul>   |  |  |  |
|                      | Chairs may need to:   |  |  |  |
|                      | <ul> <li>review peer reviewer written summaries for inappropriate comments</li> <li>review any changes to the proposed budget recommended by peer reviewers, and provide advice to NHMRC on whether the recommendations are appropriate for the project, fully justified and consistent with the Peer Review Guidelines.</li> </ul> |  |  |  |
|                      |   |  |  |  |
| Peer Reviewers       | Peer reviewers need to:   |  |  |  |
|                      | <ul> <li>familiarise themselves with this Guide and other material as identified by<br/>NHMRC staff</li> </ul>  |  |  |  |
|                      | <ul> <li>identify and advise NHMRC of all interests they have with applications</li> </ul>  |  |  |  |
|                      | <ul> <li>assigned to them</li> <li>provide a fair and impartial assessment against the Development Grants assessment criteria and associated category descriptors (Appendix C/Appendices C and D) in a timely manner, for each non-conflicted application assigned</li> </ul>   |  |  |  |
|                      | <ul> <li>assess track record by taking into consideration research achievements<br/>'relative to opportunity', including any career disruptions, where<br/>applicable</li> </ul>  |  |  |  |
|                      | consider the assessment against the <i>Indigenous Research Excellence</i> Criteria (Appendix E) provided for applications confirmed to have an  Aboriginal and Torres Strait Islander health focus  |  |  |  |
|                      | provide written summaries for each application assigned to them.  |  |  |  |
| Lead Scientific Peer | The Lead Scientific Peer Reviewer needs to:   |  |  |  |
| Reviewer             | <ul> <li>familiarise themselves with this Guide and other material as identified<br/>by NHMRC staff</li> </ul>  |  |  |  |
|                      | <ul> <li>identify and advise NHMRC of all interests they have with applications assigned to them</li> </ul>   |  |  |  |
|                      | <ul> <li>provide a fair and impartial assessment against the Development<br/>Grants Scientific Merit of the Proposal assessment criterion and<br/>associated category descriptors (Appendices C and D) for each non-<br/>conflicted application assigned, in a timely manner</li> </ul>   |  |  |  |

- 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 (Appendices E and F) provided for applications with an Aboriginal and Torres Strait Islander focus
- 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
- prepare a recommendation for the Lead Commercialisation Peer Reviewer to either: leave the requested budget intact, support proposed modifications to the budget, propose further modifications to the budget, or seek advice from the Chair regarding specific budget requests.
- write a summary of their assessment of each application assigned to them

#### Lead Commercial Peer Reviewer

The Lead Commercialisation Peer Reviewer needs 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 them
- provide a fair and impartial assessment against the Development Grants Record of Commercial Achievements and Commercial Potential 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 and F) provided for applications with an Aboriginal and Torres Strait Islander focus
- support the Lead Scientific Peer Reviewer with the review 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.
- write a summary of their assessment of each application assigned to them for each assessment criteria: Record of Commercial Achievements & Commercial Potential.

#### 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.

#### NHMRC staff will:

- invite individuals to participate in the Development Grants scheme peer review process as required
- determine whether disclosed interests pose a conflict and the level of that conflict.
- act as the first point of contact for peer reviewers
- provide briefings to peer reviewers
- determine eligibility of applications
- assign applications to the appropriate peer reviewers based on peer reviewers' declaration of interests and suitability
- review peer reviewer written summaries for inappropriate comments
- ensure that all peer reviewers are provided with the necessary information to review each application, and assisting and advising on the peer review process as required
- maintain scoring records for each application

|   | <ul> <li>act as the first point of contact for peer reviewers</li> <li>seek feedback from participants in the peer review process on improvements for future processes.</li> </ul>  |
|---|---|
| Indigenous Health<br>Research Peer<br>Reviewers | Indigenous health research peer reviewers will review how well each application addresses NHMRC's <i>Indigenous Research Excellence Criteria</i> (Appendix E) where applicable.   |
|   | Indigenous health research external peer reviewers will not participate in scoring. They will act as external experts and provide guiding comments to the peer reviewers relating to the <i>Indigenous Research Excellence Criteria</i> . |

#### 3.3. Reviewing Development Grant applications

All Development Grant applications are assessed against the Development Grant Assessment Criteria and the associated Category Descriptors at <u>Appendices C and D</u>. Applications that are accepted by NHMRC as relating to the improvement of Aboriginal and Torres Strait Islander health (see section 3.3.1) are also assessed against the *Indigenous Research Excellence Criteria* as set out at Appendix E.

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

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

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

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

#### 3.3.2. Receipt and initial processing of applications

NHMRC staff will verify that Development Grants 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.

#### 3.3.3. Disclosure of interests and peer reviewer suitability

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

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

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

#### 3.3.4. Assignment of applications to peer reviewers

Taking into account CoIs and peer reviewer suitability, NHMRC staff will assign applications to peer reviewers. Each application may be assigned up to ten peer reviewers (5 Scientific and 5 Commercial).

#### 3.3.5. Briefing

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

#### 3.3.6. Assessment of applications

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

NHMRC will aim to obtain up to ten independent assessments for each application.

Peer reviewers will be able to seek clarification from independent Chairs or NHMRC staff on peer review policies and processes during the assessment phase.

Peer reviewers are required to provide a brief summary of their assessment for each application they assess, summarising the strengths and weaknesses of the application. This feedback will be provided to the applicant. Peer reviewers must remember their obligation to remain fair and impartial when providing their feedback to applicants.

To ensure they provide independent scores, peer reviewers are not to discuss applications with other peer reviewers.

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 from which funding recommendations will be based. The overall score for each application will be determined using each peer reviewer's score for each of the assessment criteria. The overall score, as calculated arithmetically to three decimal places, will take account of the weighting of each criterion.

#### 3.3.6.1. Relative to opportunity and career disruption

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

#### 3.3.6.2. Mitigating bias in peer review

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

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

To minimise or avoid bias, peer reviewers are encouraged to take action to address the unintended and systematic biases which prevent unprejudiced consideration of an application. To increase peer reviewers' awareness of the

types of cognitive biases that can occur during peer review, NHMRC recommends the San Francisco Declaration on Research Assessment (DoRA) guidance on Rethinking Research Assessment.

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

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

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

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

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

#### Use of gender-neutral language

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

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

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

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

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

3.3.6.3. Industry-relevant experience

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

3.3.6.4. Use of Impact Factors and other metrics

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

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

The San Francisco Declaration on Research Assessment (DoRA) makes recommendations for improving the

evaluation of research assessment. NHMRC is a signatory to DoRA and adheres to the recommendations outlined in DoRA for its peer review processes.

#### 3.3.6.5. Enhancing reproducibility and applicability of research outcomes

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

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

#### 3.3.6.6. Research Integrity Issues

The peer review process can sometimes identify possible research integrity issues with applications or applicants (e.g. concerns about possible plagiarism, inconsistencies in the presentation of data, inaccuracies in the presentation of track record information) or the behaviour of other peer reviewers. NHMRC has established specific processes for addressing research integrity concerns that arise in peer review. Peer reviewers must not discuss their concerns with other peer reviewers as this may jeopardise the fair assessment of an application. Instead, these issues should be raised with NHMRC separately from the peer review process. Advice about how to raise concerns and a description of how this process is managed are provided on the NHMRC website.

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

#### 3.3.6.7. Contact between peer reviewers and applicants

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

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

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

#### 3.3.7. Minimum number of assessments

The minimum number of assessments for an application is regarded as 50 percent plus one of the peer reviewers assigned to score an application. If there is an uneven number of peer reviewers assigned to an application, the minimum number of assessments is the next full number after 50 percent (e.g. six assessments in the case of ten peer reviewers).

#### 3.3.8. 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 peer reviewers or NHMRC will use the principles set out below to decide the CoF. These principles aim to achieve a consistent approach, minimise the number of conditions set and ensure conditions are unambiguous and able to be assessed.

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

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

#### The principles are:

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

#### 3.3.9. Providing feedback on applications

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

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

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

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

#### 3.3.10. Documentation

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

#### 3.3.11. Funding Recommendation

Application scores from all peer reviewers 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.

#### 3.3.12. Notification of Outcomes

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

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

### Appendix A – Understanding the Principles of Peer Review

#### **Fairness**

- Peer review processes are designed to ensure that peer review is fair and seen to be fair by all involved.
- Peer reviewers have an obligation to ensure that each application is judged consistently and objectively
  on its own merits, against published assessment criteria. Peer reviewers must not introduce irrelevant
  issues into the assessment of an application.
- Peer reviewers must only address information provided in the application based on its relevance to the assessment criteria. Any information or issues relating to the applicant(s) outside of the application must not be considered in the peer reviewers assessment. Applications will be subject to scrutiny and evaluation by individuals who have appropriate knowledge of the fields covered in the application.
- Peer reviewers should ensure that their assessments are accurate and that all statements are capable of being verified.
- Complaints processes are outlined on the <u>NHMRC website</u>. 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 <u>GrantConnect</u>.
- NHMRC publicly recognises the contribution of participants in the peer review process, through publishing their names on the NHMRC website.<sup>1</sup>

#### Independence

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

#### Appropriateness and balance

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

#### Confidentiality

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

<sup>&</sup>lt;sup>1</sup> Such information will be in a form that prevents applicants determining which particular experts were involved in the review of their application.

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

#### **Impartiality**

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

#### **Quality and Excellence**

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

# Appendix B – Guidance for Declaring and Assessing Disclosures of Interest

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

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

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

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

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

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

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

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

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

| HIGH Conflict of Interest |          |   |  |  |
|---------------------------|----------|---|--|--|
| Situation                 |          | Example   |  |  |
|                           |          | three years.  |  |  |
|                           | <b>✓</b> | There are other interests or situations not covered above that could influence/or be perceived to influence the peer review process. In these instances, sufficient details must be provided to allow NHMRC to make a ruling. |  |  |

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

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

## Appendix C – Development Grants Assessment Criteria

Applications for Development Grants 2023 are assessed by peers on the extent to which they address the assessment criteria:

- Scientific Merit of the Proposal (fitness for purpose of the science and quality of the scientific research team) – 40%
- Record of Commercial Achievements 20%
- Commercial Potential 40%

Applications will be assessed against the category descriptors at Appendix D.

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

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 – Development Grants Category Descriptors

|  | Scientific Peer Reviewers only   | Commercialisation Peer Reviewers only   |  |
|--|--|---|--|
| Category                                       | Scientific Merit of the Proposal (Fitness for purpose of the science and quality of the scientific research team) 40%  | Record of Commercial Achievements (relative to opportunity) 20%   | Commercial Potential 40%   |
| 7 Outstanding by<br>International<br>Standards | <ul> <li>The research plan:</li> <li>is well-defined, highly coherent and strongly developed</li> <li>will successfully achieve proof-of-concept</li> <li>has a near flawless design</li> <li>is without question highly feasible and thus almost certain to be successfully completed</li> <li>is consistent with the objectives of the Development Grant scheme.</li> <li>The scientific research team:</li> <li>has, overall, an outstanding record of research achievements relative to opportunity in the field of the proposed research</li> <li>brings together all of the expertise needed for success.</li> </ul> | <ul> <li>Relative to opportunity, the research team:         <ul> <li>has proven successful national and international involvement in commercialisation of research including for example, granted patents, industry consultation, licensing of IP</li> </ul> </li> <li>has had direct involvement in industry placements and/or involvement with establishing spin off companies</li> <li>has a record of commercial achievements which is outstanding by international standards</li> <li>is highly likely to achieve a very significant commercial outcome.</li> </ul> | <ul> <li>and/or impact for the potential market is extremely large</li> <li>provides a clear description of a highly feasible commercial/development pathway should the product, process or technology prove successful</li> </ul> |

|             | Scientific Peer Reviewers only  | Commercialisation Peer Reviewers only   |   |  |  |  |
|-------------|---|---|---|--|--|--|
| Category    | Scientific Merit of the Proposal (Fitness for purpose of the science and quality of the scientific research team) 40%   | Record of Commercial Achievements (relative to opportunity) 20%   | Commercial Potential 40%  |  |  |  |
| 6 Excellent | The research plan:  • is clearly defined, coherent and well developed  • is very well designed  • is feasible and highly likely to be successfully completed  • will successfully achieve proof-of-concept  • is consistent with the objectives of the Development Grant scheme.  The scientific research team:  • the leader has an excellent record of research achievements relative to opportunity, as do, on average, the other team members in the field of the proposed research  • brings together all of the expertise needed for success. | <ul> <li>Relative to opportunity, the research team:</li> <li>has significant experience in national and international commercialisation of research including approved patents, industry consultation licensing of IP, and has had direct involvement with industry</li> <li>has a record of commercial achievements which is of a high international standard</li> <li>is very likely to achieve a significant commercial outcome.</li> </ul> | <ul> <li>The commercial proposal:</li> <li>is linked to a human health issue where the size and/or impact for the potential market is very large</li> <li>provides a clear description of a feasible commercial/development pathway should the product, process or technology prove to be successful</li> <li>will be conducted in an environment with strong institutional commercial advice and development support structures, including an institutional commercialisation office or equivalent which will increase the likelihood of a commercial outcome within a foreseeable timeframe</li> <li>clearly outlines how the proposed research meets all the scheme objectives.</li> <li>The product, process or technology:</li> <li>is internationally competitive and likely to be attractive to a commercial partner</li> <li>could be linked to a strong IP position.</li> <li>Funding the project:</li> <li>would increase the probability of successful commercialisation, usually by adding substantial value to the concept and/or supporting a critical proof of concept and/or creation of a commercialisable prototype that will bring economic benefit to Australia.</li> </ul> |  |  |  |

|             | Scientific Peer Reviewers only   | Commercialisation Peer Reviewers only   |  |  |  |  |
|-------------|--|---|--|--|--|--|
| Category    | Scientific Merit of the Proposal (Fitness for purpose of the science and quality of the scientific research team) 40%  | Record of Commercial Achievements (relative to opportunity) 20%   | Commercial Potential 40%   |  |  |  |
| 5 Very Good | <ul> <li>is generally clear in its scientific plan and is logical</li> <li>raises only a few minor concerns with respect to the study design</li> <li>will likely be successfully completed and achieve proof-of-concept</li> <li>is consistent with the objectives of the Development Grant scheme.</li> <li>The scientific research team:</li> <li>members on average, have very good records of research achievements relative to opportunity in the field of the proposed research</li> <li>possesses most of the expertise needed for success.</li> </ul> | <ul> <li>Relative to opportunity, the research team:</li> <li>has been involved in national commercialisation of research including approved patents, industry consultation, licensing of intellectual property, and has had involvement in industry</li> <li>has a record of commercial achievements which is of a high or growing national standard</li> <li>has the ability to promote a strong commercial outcome.</li> </ul> | <ul> <li>The commercial proposal:</li> <li>is linked to a human health issue where the size and/or impact for the potential market is large</li> <li>provides an outline of a feasible commercial development pathway should the product, process or technology prove to be successful</li> <li>will be conducted in an environment with good access to institutional commercial development advice and support structures which will most likely increase the likelihood of a commercial outcome within a foreseeable timeframe</li> <li>adequately outlines how the proposed research meets the scheme objectives.</li> <li>The product, process or technology:</li> <li>has significant commercial potential nationally and potentially, internationally</li> <li>could be linked to a strong or strongly developing IP position.</li> <li>Funding the project</li> <li>would most likely bring economic benefit to Australia.</li> </ul> |  |  |  |

|          | Scientific Peer Reviewers only  | Commercialisation Peer Reviewers only  |  |  |  |  |
|----------|---|--|--|--|--|--|
| Category | Scientific Merit of the Proposal (Fitness for purpose of the science and quality of the scientific research team) 40%   | Record of Commercial Achievements (relative to opportunity) 20%  | Commercial Potential 40%   |  |  |  |
| 4 Good   | The research plan:  is good in terms of its objectives  contains several areas of weakness in the experimental design and feasibility  raises several concerns about successful completion  may successfully achieve proof-of-concept  is consistent with the objectives of the Development Grant scheme.  The scientific research team:  members on average, have good records of research achievements relative to opportunity in the field of the proposed research  possesses much of the expertise needed for success. | Relative to opportunity, the research team:  • has a solid record of national research commercialisation achievement including approved patents, industry consultation and licensing of IP  • has a record of commercial achievements which is of a good national standard  • has some potential to promote a viable commercial outcome. | <ul> <li>The commercial proposal:</li> <li>is linked to a human health issue where the size and/or impact for the potential market is moderate.</li> <li>provides an outline of a commercialisation pathway which could be better developed and raises only a few minor concerns.</li> <li>will be conducted in an environment with access to commercial development advice and support structures, which could increase the likelihood of a commercial outcome within a foreseeable timeframe</li> <li>outlines how the proposed research meets the scheme objectives.</li> <li>The product, process or technology:</li> <li>has some commercial potential nationally, but is very limited at an international level</li> <li>could be linked to a developing IP position.</li> <li>Funding the project:</li> <li>may bring economic benefit to Australia.</li> </ul> |  |  |  |

|            | Scientific Peer Reviewers only   | Commercialisation Peer Reviewers only   |  |  |  |  |
|------------|--|---|--|--|--|--|
| Category   | Scientific Merit of the Proposal (Fitness for purpose of the science and quality of the scientific research team) 40%  | Record of Commercial Achievements (relative to opportunity) 20%   | Commercial Potential 40%   |  |  |  |
| 3 Marginal | <ul> <li>is clearly described, but may not be successful</li> <li>contains several study design problems or flaws that will limit the successful completion of the study</li> <li>will not significantly advance current knowledge in the field</li> <li>is not likely to achieve proof-of-concept</li> <li>may not be consistent with the objectives of the Development Grant scheme.</li> </ul> The scientific research team: <ul> <li>has no expertise in most areas required for project success.</li> </ul> | <ul> <li>Relative to opportunity, the research team:</li> <li>has limited record of research commercialisation achievements including approved patents, industry consultation, licensing of IP</li> <li>does not have any significant record of commercial achievements</li> <li>has a limited ability to promote a viable commercial outcome.</li> </ul> | <ul> <li>The commercial proposal:</li> <li>is linked to a human health issue where the size and/or impact for the potential market is limited</li> <li>provides a description of a pathway to commercialisation that raises several concerns</li> <li>will be conducted in an environment with limited access to institutional commercial development advice and support structures, which is unlikely to increase the likelihood of a commercial outcome within a foreseeable timeframe</li> <li>may not meet the scheme objectives.</li> <li>The product, process or technology:</li> <li>has limited commercial potential</li> <li>could be linked to a weak IP position.</li> <li>Funding the project:</li> <li>will not bring economic benefit to Australia.</li> </ul> |  |  |  |

|                     | Scientific Peer Reviewers only   | Commercialisation Peer Reviewers only                           |   |  |  |  |
|---------------------|--|---|---|--|--|--|
| Category            | Scientific Merit of the Proposal (Fitness for purpose of the science and quality of the scientific research team) 40%  | Record of Commercial Achievements (relative to opportunity) 20% | Commercial Potential 40%  |  |  |  |
| 2<br>Unsatisfactory | <ul> <li>has poorly described or underdeveloped objectives</li> <li>contains multiple major study design problems or flaws that will limit or prohibit the successful completion of the study</li> <li>is not likely to advance current knowledge in the field</li> <li>will not likely achieve proof-of-concept</li> <li>may not be consistent with the objectives of the Development Grant scheme.</li> <li>The scientific research team:</li> <li>has no expertise in most areas required for project success.</li> </ul> | commercial achievements   | The commercial proposal:  is linked to a human health issue where the size and/or impact for the potential market is small  does not contain a clear description of a pathway to commercialisation  will not be conducted in an environment supportive of commercial development  may not meet the scheme objectives.  The product, process or technology:  has no commercial potential  could be linked to a very weak IP position.  Funding the project:  will not bring economic benefit to Australia. |  |  |  |

|          | Scientific Peer Reviewers only   | Commercialisation Peer Reviewers only   |  |  |  |  |
|----------|--|---|--|--|--|--|
| Category | Scientific Merit of the Proposal (Fitness for purpose of the science and quality of the scientific research team) 40%  | Record of Commercial Achievements (relative to opportunity) 20%   | Commercial Potential 40%   |  |  |  |
| 1 Poor   | The research plan:  • has poorly described or under developed objectives  • contains multiple major study design problems or flaws that will limit or prohibit the successful completion of the study  • will not advance current knowledge in the field  • will not achieve proof of concept  • may not be consistent with the objectives of the Development Grant scheme.  The scientific research team:  • has no expertise in most areas required for project success. | Relative to opportunity, the research team:  • has no record of research commercialisation achievements including approved patents, industry consultation, licensing of IP  • does not have any significant record of commercial achievements  • has no ability to promote a viable commercial outcome. | The commercial proposal:  is linked to a human health issue where the size and/or impact for the potential market is too small for probable commercial viability  does not contain a clear description of a pathway to commercialisation  will not be conducted in an environment supportive of commercial development  does not meet the scheme objectives.  The product, process or technology:  has no commercial potential  has a non-viable IP position.  Funding the project:  would not increase the interest of commercial partners  will not bring economic benefit to Australia. |  |  |  |

### 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 <u>Appendix C</u>.

# 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?
  - o Have relevance to other Indigenous communities?
  - o Clearly plan for and articulate a clear approach to knowledge translation and exchange?
  - o Demonstrate that the findings are likely to be taken up in health services and/or policy?
- Will the outcomes from the study make a lasting contribution to Aboriginal and Torres Strait Islander communities and their wellbeing?

#### **Building Capability**

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

# Appendix G – Guide to Evaluating Industry-Relevant Experience

#### **Principles**

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

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

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

Therefore, peer reviewers should:

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

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

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

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

## Relevant industry outputs

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

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