Australian Government

National Health and Medical Research Council

NHMRC

Centres of Research Excellence 2024 Peer Review Guidelines

Opening date:	**18 October 2023**
Closing date and time:	17.00 ACT local time on 29 November 2023
Commonwealth policy entity:	National Health and Medical Research Council (NHMRC)
Sapphire assistance and enquiries:	NHMRC Research Help Centre Phone: 1800 500 983 (+61 2 6217 9451 for international callers) Email: help@nhmrc.gov.au Note: NHMRC's Research Help Centre aims to provide a reply to all requests for general assistance within two working days. This timeframe may be delayed during peak periods or for more detailed requests for assistance.
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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 Centres of Research Excellence (CRE) 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:

- *Centres of Research Excellence 2024 grant guidelines*, available on GrantConnect, which set out the rules, objectives and other considerations relevant to NHMRC funding.

- *Policy on the Disclosure of Interests requirements for prospective and appointed NHMRC committee members* (Section 39 Committees). This Policy outlines peer reviewers' responsibilities to ensure all disclosures of interests are addressed in a rigorous and transparent way throughout the period of a peer reviewer's participation in NHMRC Committees.

2. Key changes

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

Peer reviewers must follow these updated processes:

- In track record assessment, peer reviewers must consider COVID-19 related circumstances, as outlined by applicants, as part of career disruptions or other relative to opportunity considerations under the provisions of NHMRC's *Relative to Opportunity Policy*.

- Peer reviewers should note that applicants have been advised that they may include information on any potential significant and long-term impacts of the COVID-19 pandemic on their proposed research, and proposals for managing such risks, as part of their research risk management plan within the grant proposal.

- Peer reviewers are not to let the potential impacts of the COVID-19 pandemic on the proposed research affect the assessment of the research proposal of an application (e.g. the feasibility of accessing certain patient or population groups with social distancing restrictions in place).

- Peer reviewers must note that changes to the research proposal of a funded application, necessitated by the impacts of the COVID-19 pandemic (e.g. the commencement of a project needs to be delayed by six months until COVID-19 restrictions are eased) will be considered through NHMRC's Postaward management and grant variations processes. Such considerations do not form part of the peer review assessment of the proposal, particularly given that the long term impacts of the pandemic are still unknown.

Peer reviewers should note the following significant changes for the CRE 2024 grant opportunity:

- The funding allocation to the CRE scheme has increased and the funding distribution across CRE streams has changed. As a result the number of applications anticipated to be discussed at each CRE stream peer review panel meeting has changed (section 4.3.7.1).

- Funding is available for CRE in Basic Science Research grants. CRE in Basic Science Research applications will be assessed by a CRE in Basic Science Research peer review panel.

- Funding is available for dementia research with a basic science research focus through the CRE in Basic Science Research application stream. Applications which nominate for consideration for dementia-specific research funding will be assessed by the Basic Science Research peer review panel (section 4.3.4).

- Assessment criteria and score descriptors have been amended to incorporate assessment of CRE in Basic Science Research stream applications (Appendices C and D).

3. Principles, conduct and obligations during peer review

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

3.1. NHMRC's Principles of Peer Review

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

- **Fairness.** Peer review processes are fair and seen to be fair by all.

- **Transparency.** Applies to all stages of peer review.

- **Independence.** Peer reviewers provide independent advice. There is also independent oversight of peer review processes by independent Chairs, Peer Review Mentors and Observers, where relevant.

- **Appropriateness and balance.** There is appropriate experience, expertise and representation of peer reviewers assessing applications.

- **Research community participation.** Persons holding taxpayer-funded grants should willingly make themselves available to participate in peer review processes, whenever possible, in accordance with the obligations in the Funding Agreement.

- **Confidentiality.** Participants respect that confidentiality is important to the fairness and robustness of peer review.

- **Impartiality.** Peer review is objective and impartial, with appropriate processes in place to manage disclosures of interest.

- **Quality and excellence.** NHMRC will continue to introduce evidence-based improvements into its processes to achieve the highest quality decision-making through peer review.

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

3.2.   The Australian Code for the Responsible Conduct of Research

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

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

3.3.   Use of Generative Artificial Intelligence in Peer Review

Information provided to generative artificial intelligence (such as natural language processing models and artificial intelligence technology tools) becomes part of a public database and may be accessed by third parties.

Peer reviewers must not input any part of a grant application, or any information from a grant application, into a natural language processing and/or artificial intelligence technology system to assist them in the assessment of applications.

Use of generative artificial intelligence may compromise the integrity of NHMRC's peer review process and be in breach of its Principles of Peer Review, the *Australian Code for the Responsible Conduct of Research* and the confidentiality undertaking of peer reviewers.

3.4.   Disclosures of Interest

3.4.1.   What is an interest?

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

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

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

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

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

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

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

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

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

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

An outline of potential CoI situations and guidance is provided for peer reviewers at Appendix B.

3.4.3. Disclosure of Interests in the Peer Review Process

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

3.4.4. 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.

3.5. 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.

3.6. 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. CRE peer review process

4.1. Overview of the CRE peer review process

Date	Activity
29 November 2023	Deadline for CRE application submission
December 2023	Application eligibility review and confirmation
January 2024	Peer reviewers disclose interests and suitability against applications
January 2024	Assessments against the *Indigenous Research Excellence Criteria* obtained
February 2024	Applications allocated to peer reviewers
February/March 2024	Peer reviewers review applications and submit scores and comments against CRE assessment criteria for each allocated application
April 2024	Least competitive applications deemed 'Not For Further Consideration' (NFFC)
April 2024	Allocation of applications to spokespersons. Peer reviewers notified whether they are required to attend the panel meeting.
April 2024	Panel members review applications for discussion at panel meeting
1-8 May 2024*	Panel meetings
August 2024*	Outcomes announced

* Dates are indicative and subject to change.

Further information on the steps outlined in this process is provided in section 4.3.

4.2. Roles and responsibilities

The roles and responsibilities of those participating in the CRE peer review process are identified in the following sections.

4.2.1. Chair

The Chair's role is to ensure NHMRC's procedures are adhered to and that fair and equitable consideration is given to every application being discussed at the panel meeting.

Chairs do not assess applications but manage the process of peer review in accordance with this Guide.

Prior to the panel meeting Chairs need to:

- familiarise themselves with this document and other material as identified by NHMRC staff
- identify and advise NHMRC of all interests they have with applications assigned to their panel
- familiarise themselves with ALL the applications assigned to their panel, excluding those for which they have been determined to have a high CoI
- assist peer reviewers with their duties and in understanding what is expected of them.

During the panel meeting, Chairs will:

- take appropriate action for each CoI

- introduce each application and announce the Primary and Secondary Spokesperson's initial assessment scores

- keep discussions on time and focused

- ensure NHMRC procedures are followed

- promote good engagement by peer reviewers in all discussions

- ensure that all peer reviewers consider 'relative to opportunity', including career disruptions, when discussing applications

- ensure that any discussion and assessment is based on the CRE assessment criteria and associated score descriptors (Appendices C and D).

- ensure the panel consistently considers the assessment against the *Indigenous Research Excellence Criteria* for applications with an Aboriginal and Torres Strait Islander health focus

- ensure peer reviewers are satisfied with the consistency and appropriateness of discussions for each application

- record and notify NHMRC of any requests for clarification or advice

- approve Meeting Attendance Record sheets.

Chairs may need to:

- fulfil the duties and responsibilities of a peer reviewer where required (e.g. to meet quorum requirements of the panel when assessing particular applications) – in such an instance a substitute Chair will be identified for relevant applications.

4.2.2. Assistant Chair

Prior to the panel meeting Assistant Chairs need to:

- familiarise themselves with this document and other material as identified by NHMRC staff

- identify and advise NHMRC of all interests they may have with applications to be reviewed by the panel

- familiarise themselves with all applications being considered by the panel.

During the panel meeting Assistant Chairs will:

- note the strengths and weaknesses of the application while discussion by the panel is underway

- act as Chair for applications where the Chair is unavailable or has a CoI.

Assistant Chairs may need to:

- fulfil the duties and responsibilities of a panel member where required (e.g. to meet quorum requirements of the panel when assessing particular applications) – in such an instance a substitute Assistant Chair will be identified for relevant applications.

4.2.3. 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 them/their panel

- provide a fair and impartial assessment against the CRE assessment criteria and associated score descriptors (Appendices C and D) in a timely manner, for each non-conflicted application assigned

- assess track record by taking into consideration research achievements 'relative to opportunity', including any career disruptions, where applicable

- consider the assessment against the *Indigenous Research Excellence Criteria* (<u>Appendix E</u>) provided for applications confirmed to have an Aboriginal and Torres Strait Islander health focus

- provide a brief summary of their assessment against each criterion in line with the associated score descriptors.

During the panel meeting, peer reviewers will:

- disclose interests they have with other peer reviewers

- prepare for and participate in the discussion for each application where they do not have a high CoI

- provide a score against the CRE assessment criteria and associated score descriptors for all applications where they do not have a high CoI.

4.2.4. Primary Spokesperson (1SP)

Prior to the panel meeting:

- prepare speaking notes to present the application at the panel meeting focusing on its key strengths and weaknesses

At the panel meeting:

- lead the discussion using prepared notes, considering research achievements 'relative to opportunity', including any career disruptions, and the assessment provided against the *Indigenous Research Excellence Criteria*, where applicable

- provide and announce final scores against the CRE assessment criteria based on discussions

- provide a summary of the panel's assessment against each criterion in line with the score descriptors for provision to the applicant.

4.2.5. Secondary Spokesperson (2SP)

Prior to the panel meeting:

- prepare speaking notes to present the application at the panel meeting focusing on its key strengths and weaknesses.

At the panel meeting:

- add to the 1SP comments using prepared notes

- provide and announce final scores against the CRE assessment criteria based on panel discussions.

4.2.6. NHMRC Staff

Under direction from the CEO, NHMRC staff will be responsible for overall administration of the peer review process and for the conduct of specific activities.

Prior to the panel meeting, NHMRC staff will:

- invite individuals to participate in the CRE 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 peer reviewers to the appropriate panel and applications to the appropriate peer reviewers based on peer reviewers' declaration of interests and suitability.

At the panel meeting NHMRC staff will:

- support the operation of Sapphire

- assist the Chair in running the discussions

- fulfil the role of Chair/Assistant Chair where required (e.g. where the Chair/Assistant Chair is deemed to have a high conflict of interest with an application)

- implement appropriate management plans for peer reviewers with 'high' interests or conflicts with applications and ensure that all participants (including community observers) are aware of disclosed interests

- ensure that all peer reviewers are provided with the necessary information to review each application, and assist and advise on the peer review process as required

- maintain scoring records for each application

- act as the first point of contact for peer reviewers and community observers

- seek feedback from participants in the peer review process on improvements for future processes.

4.2.7.   Indigenous health research peer reviewers

Indigenous health research peer reviewers will review how well each application addresses NHMRC's *Indigenous Research Excellence Criteria* (Appendix E) where applicable.

Indigenous health research peer reviewers will not participate in scoring. They will act as external experts and provide guiding comments to the peer reviewers relating to the *Indigenous Research Excellence Criteria*.

4.2.8.   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

- 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 CRE applications

All CRE applications are assessed against the CRE assessment criteria and the associated score descriptors at Appendices C and D. Applications that are accepted by NHMRC as relating to the improvement of Aboriginal and Torres Strait Islander health (see section 4.3.1) are also assessed against the *Indigenous Research Excellence Criteria* as set out at Appendix E.

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

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

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

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

4.3.2.   Receipt and initial processing of applications

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

4.3.3.   Disclosure of interests and peer reviewer suitability

Peer reviewers will be provided with a summary of each application and disclose their interests within Sapphire, in accordance with the guidelines provided at section 3.4 and Appendix B.

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

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

4.3.4.   Establishment of panels and assignment of applications to peer reviewers

Considering CoIs and peer reviewer suitability, NHMRC staff will assign peer reviewers to a Basic Science Research, Clinical Research, Health Services Research or Public Health Research stream panel. Each application will be assigned 4 peer reviewers in the Initial Assessment stage.

Applications are allocated to the CRE stream panel selected by the applicant. Applications submitted to the CRE in Basic Science Research stream which nominate to be considered for dementia-specific research funding will be assessed by the Basic Science Research panel.

4.3.5.   Briefing

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

4.3.6.   Assessment of applications

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

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

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

arrangements.

Four independent assessments will be sought for each application. Peer reviewers' scores will be used to create provisional ranked lists of applications for each panel which will be used to shortlist the applications proceeding to panel discussion. 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 3 decimal places, will take account of the weighting of each criterion.

Some peer reviewers will remain on the panel based on the required expertise for the applications proceeding to panel discussion. The remaining peer reviewers will not be required to participate beyond this part of the peer review process.

The 1SP for applications discussed at panel meetings is required to provide a brief summary of the panel's assessment against each criterion in line with the score descriptors. This feedback will be provided to the applicant. Peer Reviewers must remain fair and impartial when providing the panel's feedback to applicants (for further guidance see section 4.3.10).

4.3.6.1.   Relative to opportunity and career disruption

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

4.3.6.2.   Mitigating bias in peer review

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

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

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

NHMRC is committed to its vision of a gender diverse and inclusive health and medical research workforce to take advantage of the full range of talent needed to build a healthy Australia. Fostering gender equity in peer review is a strategic objective underpinned by *NHMRC's Gender Equity Strategy*.

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

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

By completing the test, peer reviewers gain a better understanding and increased awareness of how unconscious attitudes may affect their decisions, which prepares them to carry out their duties to the high standards of fairness and rigour expected by NHMRC. Peer reviewers should continue to follow

all peer review principles and processes outlined in these guidelines, ensuring that each application is accurately reviewed against the assessment criteria (Appendix C). NHMRC does not have access to, nor does it seek, peer reviewers' information and results for the IAT for gender and science in the peer review process.

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

Use of gender-neutral language

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

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

- avoid the use of gendered pronouns such as he/she or her/his, and instead use gender-neutral alternatives such as CIA/CIB, CI last-name or plural pronouns (they/their) when referring to applicants.

- avoid the use of first names, and

- use gender-neutral nouns where appropriate e.g. parental leave rather than maternity/paternity leave.

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

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

4.3.6.3. Industry-relevant experience

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

4.3.6.4. Assessment of the publication component of an applicant's track record

Peer reviewers are to consider 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 considers 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. Journal-based metrics, if included by an applicant, should not be taken into consideration in the assessment of publications.

Instead, peer reviewers are to focus on the creativity and innovation of ideas, rigour of experimental design, appropriate use of statistical methods, reproducibility of results, analytical strength of interpretations and significance of outcomes, all of which serve as surrogates for measuring research quality of a publication, irrespective of the field of research.

ONHMRC also encourages the use of research quality guidelines such as the Hong Kong Principles

for assessing researchers[1], which recommends focussing on responsible research practices, transparent reporting, open science, diversity of research and recognition of all contributions to research as hallmarks of publication quality.

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

4.3.6.5.   Enhancing reproducibility and applicability of research outcomes

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

- scientific premise of the proposed research (that is, 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

- sex and gender elements of the research to maximise impact and any other considerations relevant to the field of research necessary to assess the rigour of the proposed design.

4.3.6.6.   Research Integrity Issues

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

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

4.3.6.7.   Contact between peer reviewers and applicants

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

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[1] https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.3000737

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 CRE panel meetings will occur via videoconference.

Each panel will meet for up to 2 days (depending on the number of applications per panel).

4.3.7.1. Discussion of applications at panel meeting

The least competitive applications within the provisional ranked list of applications for each panel will form a Not For Further Consideration (NFFC) list. Applications not on the NFFC list will proceed to panel discussion.

It is expected that the number of applications to proceed to discussion at each panel meeting will be twice the number of applications anticipated to be funded.

For the CRE in Basic Science Research panel meeting, it is expected that at least 2 of the applications to be discussed at the panel will be the top ranked applications to have nominated for consideration for dementia-specific research funding.

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

- NHMRC has not received a score and an assessment for all criteria from at least 3 peer reviewers

- if a peer reviewer has a high CoI after the initial assessment has been undertaken

- if it relates to an NHMRC strategic priority, as determined by NHMRC, and achieves an overall score of 4.001 or higher.

NHMRC may at its discretion also identify applications for discussion at panel meetings.

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 score descriptors.

Peer reviewers are expected to read all applications proceeding to panel discussion for which they do not have a high CoI. All peer reviewers are expected to contribute to discussion and provide scores for each application.

Each application is assigned a 1SP and 2SP. Where possible, spokespersons are assigned from the 4 peer reviewers initially assigned to that application.

The process for the panel meeting is as follows:

Declaration of inter-relationships

Suggested time limit: 20 minutes

When panel members (including the Chair, Assistant Chair and secretariat) meet 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 temporarily blocked from the videoconference by the secretariat (the videoconference connection will remain active).

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

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

Once highly conflicted members have been temporarily blocked from the videoconference by the secretariat (those with a low CoI remain in the meeting), the Chair will announce the category of funding the application relates to, identify the 1SP and 2SP and announce the Spokesperson scores for each of the 5 assessment criteria.

1SP and 2SP to comment on the application

Suggested time limit: 5 minutes (1SP) and 4 minutes (2SP)

The 1SP will:

- discuss the application's strengths and weaknesses against the assessment criteria, referring to the score descriptors

The 2SP will:

- add anything not addressed by the 1SP, or explain why they disagree with the 1SP, if applicable.

Full panel discussion

Suggested time limit: 7 minutes

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

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

The 1SP will write a brief summary of the panel's assessment against each criterion in line with the score descriptors (Appendix D) and in keeping with the guidance provided at section 4.3.10. The 1SP

will be able to enter the summary into Sapphire following the conclusion of the panel meeting.

Scoring by panel members

Suggested time limit: 3 minutes

Following the panel's discussion, the Chair will ask the 1SP and 2SP to confirm their 5 criterion scores noting that these may have changed 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's criterion scores. If so, the panel member must declare this and provide a brief justification, which will be recorded by the secretariat. The intent of this process is to encourage full discussion of applications rather than encourage individual peer reviewers to regress their scores to the panel mean or 1SP scores.

All panel members in the videoconference, excluding the Chair and Assistant Chair, must independently score the application in Sapphire. All scoring panel members will provide scores against the 5 assessment criteria using the seven-point scale outlined in the Centres of Research Excellence 2024 score descriptors (Appendix D), as a reference. While the score 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.

Panel members should not aim to achieve a consensus score, nor take into consideration the potential overall ranking or funding outcome of an application. At the completion of scoring, the panel secretariat will announce the average criterion and overall score. The average criterion and the overall score will be determined by including each panel member's score for each of the assessment criteria. The overall score, as calculated arithmetically to 3 decimal places, will take account of the weighting of each criterion.

4.3.7.3. Panel Reconciliation

At the end of deliberations, a reconciliation of the review process will take place. This reconciliation gives panel members a final opportunity to raise any concerns regarding the consistency of the review of applications throughout the meeting.

Where a panel member believes an application may have been reviewed in an inconsistent manner, they should raise the matter with the panel Chair. The panel secretariat will ensure that members with high CoIs leave the meeting before any details of the application and the circumstances of concern are outlined to the panel.

If the majority of the panel decide that an application needs to be reassessed, the application will be reopened for discussion and rescored by the panel.

4.3.8. Quorum

A panel meeting quorum is regarded as 50% 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% (e.g. 7 in the case of 13 members).

NHMRC will endeavour to identify, prior to panel meetings, those applications that do not have a scoring quorum and obtain a suitably qualified member to participate in panel discussion and to score that application. However, in situations where a number of members have a high CoI with an application and a suitably qualified member(s) cannot be sourced, the scoring quorum cannot be less than one-third of the panel members present at the meeting.

4.3.9. Principles for setting conditions of funding for NHMRC grants

Setting a condition of funding (CoF) on a grant through the peer review process is, and should be, a rare event. When this does occur, the panel 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.

4.3.10. Providing feedback on applications

When conducting assessments, peer reviewers are required to provide constructive qualitative feedback to applicants that focus on the strengths and weaknesses of the application. For applications discussed at panel in the 2024 CRE grant opportunity, the 1SP will write a brief summary of the panel's assessment against each assessment criterion in line with the score descriptors (Appendix D).

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 score descriptors** (Appendices C and D).

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

Avoid comments that:	Instead:
- Make specific comparisons between applications/applicants - Are discourteous, derogatory, unprofessional or use emotive or overly expressive (positive or negative) language - Employ an overly negative or critical tone (i.e. instead of "the applicant failed to", use "it would improve the application if") - Use overly expressive language and words that convey emotion (e.g. "disappointingly", "unfortunately", "failed to") - Represent your personal views or attitudes towards a statement written by the applicant/s - Focus on the faults or shortcomings of the application or applicant/s - Refer to your ability/suitability to review the application - Employ a negative or critical tone - Refer to issues that are out of the applicant's/reviewer's control (e.g. "This	- Highlight the key elements of the application that influenced your scores - Consider the strengths and weaknesses of the application against each assessment criterion - Use score descriptors associated with the assessment criteria and ensure they are addressed - Focus on the information that is provided in the application - Provide constructive feedback that reflects your scores - Provide neutral statements - Write with an objective tone - Provide specific advice or references to relevant bodies of work you think the applicant/s may have overlooked.

application deserves to be funded")	
• Provide broad statements which suggest the application is worthy or not worthy of funding	
• Minimise accomplishments or claims made by the applicant/s	
• Use dismissive language or statements that discount or belittle an application or applicant/s	
• Use stylistic choices that convey the feelings of the reviewer such as rhetorical questions, speculation or punctuation such as exclamation marks.	
• Use universal language (e.g. "any expert knows")	
• Question issues of eligibility or integrity of the application or applicant/s. This should be raised with NHMRC separately.	

4.3.11.   Documentation

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

4.3.12.   Funding Recommendation

After the panel meetings, the final overall score for each application is used to create a ranked list for each CRE stream. These final ranked lists 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 and Aged Care.

4.3.13.   Notification of Outcomes

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

Feedback will be provided to all applicants in the form of an Application Assessment Summary. 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. Applications discussed at panel meetings will also receive a written summary of the panel's assessment against each assessment criterion in line with the score descriptors.

Appendix A - Understanding the Principles of Peer Review

Fairness

- Peer review processes are designed to ensure that peer review is fair and seen to be fair by all involved.

- Peer reviewers have an obligation to ensure that each application is judged consistently and objectively on its own merits, against published assessment criteria. Peer reviewers must not introduce irrelevant issues into the assessment of an application.

- Peer reviewers must only address information provided in the application based on its relevance to the assessment criteria. Any information or issues relating to the applicant(s) outside of the application must not be considered in the peer reviewers assessment. Applications will be subject to scrutiny and evaluation by individuals who have appropriate knowledge of the fields covered in the application.

- Peer reviewers should ensure that their assessments are accurate and that all statements are capable of being verified.

- Complaints processes are outlined on the NHMRC website. All complaints to NHMRC relating to the peer review process are dealt with independently and impartially.

Transparency

- NHMRC will publish key dates, all relevant material for applicants and peer reviewers, and grant announcements on its website and/or via GrantConnect.

- NHMRC publicly recognises the contribution of participants in the peer review process, through publishing their names on the NHMRC website.[2]

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

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

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.

- Any information or documents made available to peer reviewers in the peer review process are confidential and must not be used other than to fulfil their role.

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

Impartiality

- Peer reviewers must disclose all interests and matters that may, or may be perceived to, affect objectivity in considering particular applications.

- Peer reviewers must disclose relationships with other members of the panel, and interests with applications being reviewed, including:

    - research collaborations

    - student, teacher or mentoring relationships

    - employment arrangements

    - any other relationship that may, or may be seen to, undermine fair and impartial judgement.

- Disclosures of interest are managed to ensure that no one with a high conflict is involved in the assessment of relevant applications.

Quality and Excellence

- NHMRC will continue to introduce evidence-based improvements into its peer review processes.

- Any significant change will be developed in consultation with the research community and may involve piloting new processes.

- NHMRC will strive to introduce new technologies that are demonstrated to maximise the benefits of peer review and improve the efficiency and effectiveness of the process while minimising individual workloads.

- NHMRC will undertake post-scheme assessment of all its schemes with feedback from the sector.

- NHMRC will provide advice, training and feedback for peer reviewers new to NHMRC peer review.

- Where NHMRC finds peer reviewers to be substandard in their performance, NHMRC may provide such feedback directly to the peer reviewer or their institution.

Appendix B - Guidance for Declaring and Assessing Disclosures of Interest

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

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

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

- **Impartiality:** The benefits of peer reviewers' expert advice needs to be balanced with the risk of real or perceived interests affecting an impartial review.

- **Significance:** Not all interests are equal. The type of interest needs to be considered in terms of its significance and time when it occurred.

- **Integrity through disclosure:** Peer review rests on the integrity of peer reviewers to disclose any interests and contribute to transparently managing any real or perceived conflicts in a rigorous way. The peer review system cannot be effective without trusting peer reviewers' integrity.

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

- the interest's significance

- its impact on the impartiality of the reviewer, and

- maintaining the integrity of the peer review process.

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

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

HIGH Conflict of Interest

Associated with Application and/or Chief Investigator (CI) and/or Primary Supervisor

- ✓ Peer reviewer is a CI/Associate Investigator/Primary Supervisor on the application under review.

- ✓ Peer reviewer has had discussions/significant input into the study design or research proposal of this application.

Collaborations

- ✓ Peer reviewer is actively collaborating or has collaborated with the CI or Primary Supervisor in the last 3 calendar years on publications (co-authorship), pending grant applications and/or existing grants.

Working relationships

- ✓ Peer reviewer and a CI or Primary Supervisor currently work or are negotiating future employment in the same:

  - research field at an independent Medical Research Institute.

  - Department or School of a university.

  - Department of a hospital.

- ✓ Peer reviewer is in a position of influence within the same organisation as a CI/Primary Supervisor, or has a pecuniary interest in the organisation (either perceived or real) e.g. Dean of Faculty or School/Institute Directors.

- ✓ Peer reviewer and a CI/Primary Supervisor 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/Primary Supervisor are both on the same governing board within their organisation.

Professional relationships and interests

- ✓ Peer reviewer or a peer reviewer's employer is directly affiliated or associated with an organisation(s) that may have, or may be perceived to have, a vested interest in the research. For example, a pharmaceutical company, which has provided drugs for testing, has a vested interest in the outcome.

Social relationship and / or interests

- ✓ The peer reviewer or a peer reviewer's immediate family member has a personal or social relationship with a CI/Primary Supervisor on the application.

Teaching or supervisory relationship

- ✓ Peer reviewer has taught or supervised a CI for either undergraduate or postgraduate studies within the last 3 years.

- ✓ Peer reviewer and a CI/Primary Supervisor co-supervise an undergraduate or postgraduate student and collaborate with each other on the student's research.

Direct financial interest in the application

✓ Peer reviewer has the potential for financial gain if the application is successful, such as benefits from: payments from resulting patents, supply of goods and services, access to facilities, and provision of cells/animals as part of the collaboration.

✓ Peer reviewer receives research funding or other support from a company and the research proposal may involve collaboration/association with that company.

✓ Peer reviewer receives research funding or other support from a company and the research proposal may affect the company.

Other interests or situations

✓ Peer reviewer had or has an ongoing scientific disagreement and/or dispute with a CI. This may still be ruled as a high conflict if the events in question occurred beyond the last 3 years.

✓ There are other interests or situations not covered above that could influence/or be perceived to influence the peer review process. In these instances, sufficient details must be provided to allow NHMRC to make a ruling.

LOW Conflict of Interest

Collaborations

- ✓ Peer reviewer and a CI on the application have collaborated more than 3 years ago.

- ✓ Within the last 3 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 10 CIs (e.g. large collaborative research centres and network grants).

- ✓ A colleague is planning future collaborations with a CI.

- ✓ Peer reviewer and a named AI on the application are actively collaborating or have previously collaborated within the last 3 years.

- ✓ Without financial gain or exchange, a peer reviewer and a member of the research team have shared cells/animals/reagents/specialist expertise (biostatistician) etc. but have no other connection to each other.

- ✓ Collaboration between a peer reviewer's colleague/research group and a CI on the application, where the peer reviewer did not participate or have a perceived interest (e.g. direct leadership or responsibility for the researchers involved in the collaboration) in the collaboration, or vice versa.

- ✓ Peer reviewer is considering, planning or has planned a future collaboration with a CI on the application but has no current collaborations, including joint publications/applications under development.

- ✓ Peer reviewer and CI have previously proposed or planned a collaboration that did not progress.

Working relationships

- ✓ Peer reviewer and a CI currently work or are negotiating future employment in:

  - the same institution but have no direct association or collaboration.

  - the same Faculty or College of a university but in different Schools or Departments and do not know each other.

- ✓ Peer reviewer and a CI work for 2 organisations that are affiliated but there is no direct association/collaboration.

- ✓ Peer reviewer and a CI are on the same committee/board, but otherwise have no working or social relationships that constitute a high conflict and the peer reviewer or their affiliated organisation would not benefit from, or be affected by, the outcome of the application (i.e. do not have a vested interest in the proposed research). For example, the peer reviewer and CI are both on an external government advisory committee.

Professional relationships and interests

- ✓ Peer reviewer and CI's organisations are affiliated but there is no direct association/collaboration between the CI and peer reviewer and there is no other link that would constitute a high conflict.

Social relationship and/or interests

- ✓ Peer reviewer's partner or immediate family member has a known personal/social (non-work) or perceived relationship with a CI on the application, but the peer reviewer themselves does not have any link with the CI that would be perceived or constitute a

high conflict.

Teaching or supervisory relationship

- ✓ Peer reviewer taught or supervised the CI for either undergraduate or postgraduate studies, co-supervised a CI or the peer reviewer's research was supervised by a CI, more than 3 years ago.

- ✓ Peer reviewer and a CI are co-supervisors of an undergraduate or postgraduate student, but they are not collaborating with each other on the student's research (e.g. where one of the supervisors may provide additional expert input or guidance to the student's project or thesis).

Financial interest in the application

- ✓ Peer reviewer has an associated patent pending, supplied goods and services, improved access to facilities, or provided cells/animals etc. to a named CI for either undergraduate or postgraduate studies.

- ✓ Peer reviewer has intellectual property that is being commercialised by an affiliated institution. Peer reviewer has previously provided and/or received cells/animals to/from a CI on the application, but has no other financial interests directly relating to this application that would constitute a high conflict.

Other interests or situations

- ✓ Peer reviewer may be, or may be perceived to be, biased in their review of the application. For example, peer reviewer is a lobbyist on an issue related to the application.

Appendix C - Centres of Research Excellence 2024 Assessment Criteria

Applications for CRE grants are assessed by peers against the assessment criteria listed below (weighted equally) using the score descriptors as a guide. In addressing the assessment criteria, applicants should consider how the proposal addresses the associated points as described below.

Criterion One

Generate new knowledge that leads to a paradigm shift in understanding of a basic science outcome and/or a practice shift leading to improved health or health systems outcomes (20%)

- Clarity of research objectives and theoretical concepts

- Research design(s) and/or proposed methodology/ies are robust and appropriate to the broader strategy of the proposed Centre

- Aims and concepts of the research are innovative or pioneering

- Has the potential to generate significant new findings and advance knowledge in the field

- Feasibility of the proposed research.

Criterion Two

Promote effective transfer of research outcomes into knowledge gain, health policy and/or practice (20%)

- Significance and impact for human health and/or basic science

- Quality of the plan for research translation* and maximising impact, including interaction with commercial groups where appropriate

- Plans for promoting the Centre's activities to the wider community

- Involvement of consumers and the community in the planning, implementation and uptake of the research program e.g. priority-setting; design and development; governance; communication and/or implementation as appropriate to the intended outcomes of the research.

Criterion Three

Develop the health and medical research workforce by providing opportunities to advance the training of new researchers, particularly those with capability for independent research and future leadership roles (20%)

- Strategy to generate new researcher capability through training, mentoring and encouraging further career development

- Strategy to build workforce capacity and capability, including fostering the science of implementation where appropriate

- Clarity of opportunities for integrating new researchers into the teams.

Criterion Four

Facilitate collaboration (20%)

Outline past and/or proposed collaborative arrangements within the Chief Investigator team and address how the team will ensure the cohesive running of the research during its funding period, including but not limited to:

- likely effectiveness of working collaborations and intellectual exchange

- the relationship with other groups in the particular fields of research

- integration and cohesiveness of the team

- roles and responsibilities within the team

- benefits of the proposed Centre beyond the sum of its individual components or previously funded Centre.

Criterion Five

Record of research and translation achievement – relative to opportunity (20%)

- The previous research and/or translation experience of Chief Investigators (CIs) demonstrates that the team has the appropriate mix of research skills and experience to deliver the proposal.

- Record of achievement encompasses the national and international standing of the CIs based upon their research and/or translation achievements, relative to opportunity, including but not limited to:
  - research outputs, such as: publications that illustrate innovation and significance of past accomplishments; outcome and impact of previous research achievements including effects on health care practices or policy and knowledge uptake
  - contribution to field of research, such as: requests to lead discipline thinking through prestigious review invitations, keynote, plenary or named Lectureships; editorial appointments; leadership positions in scientific or professional societies; specialist and high level health policy committee appointments; commercial involvement
  - evidence of research translation, such as: influence on the next stage of research, new research or research re-design; public policy; health-related systems and practice; commercialisation of research discoveries.

* NHMRC's Research Translation Strategy 2022-2025 describes research translation as activities that use the results of research to inform, for example, the next stage of research, new research or research re-design, public policy, health-related systems and practice, or support the commercialisation of research discoveries, for the improvement of individual and population health. All types of research knowledge are valuable and can be translated (e.g. biomedical, clinical, public health and health services research).

The Research Translation Strategy acknowledges that translation is complex and is sometimes referred to as a 'translation pathway' from research through to implementation into policy and practice. Translation can occur at any stage and can follow many different pathways; strategies and activities may need to be modified repeatedly along this pathway. For Basic Science Research stream applications, in addition to informing next steps or new research, applications should address how the interface between the basic science and clinical practice, public health and/or health services is likely to lead to translational outcomes even if these are long term and not within scope for this grant.

Appendix D - Centres of Research Excellence 2024 Score Descriptors

The following descriptors are used as a guide to scoring an application against each of the assessment criteria. Note that all criteria have equal weighting. Applications with an overall score equal to or below 3.500 are not fundable. Applications with an overall score above 3.500 are potentially fundable, subject to the availability of funds.

While the score 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 score descriptors are a guide to a "best fit" outcome. Peer reviewers will consistently refer to the score descriptors to ensure thorough, equitable and transparent assessment of applications.

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.

Criterion 1. Generate new knowledge that leads to a paradigm shift in understanding of a basic science outcome and/or a practice shift leading to improved health or health systems outcomes (20%)

- Clarity of research objectives and theoretical concepts
- Research design(s) and/or proposed methodology/ies are robust and appropriate to the broader strategy of the proposed Centre
- Aims and concepts of the research are innovative or pioneering
- Has the potential to generate significant new findings and advance knowledge in the field
- Feasibility of the proposed research

Score	Performance Indicator	Score Descriptors
7	Exceptional	The proposal: • has objectives that are well-defined, highly coherent and strongly developed • is exemplary in design and state of the art in concept • is highly innovative throughout and introduces advances in concept • if successful, will have impact internationally and relevance across several fields • is highly feasible.
6	Outstanding	The proposal: • has objectives that are clear and logical • is well-designed and conceptually sophisticated • is innovative and introduces some advances in concept • if successful will have impact internationally • is highly feasible.
5	Excellent	The proposal: • has clear objectives • is well-designed, but with minor flaws • contains innovative ideas and minor advances in concept • if successful will have impact nationally • is feasible, but with some areas that are less certain.
4	Very Good	The proposal: • has sound objectives • has satisfactory experimental design in general, but some areas that are weaker • has some innovative features • if successful will have impact nationally within a field • may be feasible but there are clear areas of concern.

3	Good	The proposal: - has some sound objectives but others that are problematic - contains some study design problems or flaws - has relatively little novelty or innovation - if successful will advance knowledge incrementally - has parts that are feasible and others that are likely not.
2	Satisfactory	The proposal: - has objectives which require further development - has major flaws in design and/or concepts - is derivative and lacking in innovation - if successful will lead to marginal advancement of knowledge - contains a research plan which is generally not feasible.
1	Weak or Limited	The proposal: - has no clear objectives - is inappropriate in design and concepts - is unlikely to lead to any significant knowledge gain - lacks innovation or significance - raises major concerns about the feasibility of the research plan.

Criterion 2. Promote effective transfer of research outcomes into knowledge gain, health policy and/or practice (20%)

- Significance and impact for human health and/or basic science
- Quality of the plan for research translation* and maximising impact, including interaction with commercial groups where appropriate
- Plans for promoting the Centre's activities to the wider community
- Involvement of consumers and the community in the planning, implementation and uptake of the research program e.g. priority-setting; design and development; governance; communication and/or implementation as appropriate to the intended outcomes of the research

Score	Performance Indicator	Score Descriptors
7	Exceptional	The proposal: • addresses an issue of utmost importance to human health or to basic science with a high likelihood of impacting on human health • will translate into fundamental outcomes in the science and/or practice of clinical medicine or public health, or fundamental changes in health policy or the next stage of research, new research or research re-design • will lead to published research and other outputs that will be highly influential in promoting change in research direction or health policy and/or practice • has exceptional involvement of consumers and the community in key project phases as appropriate to the intended outcomes of the research.
6	Outstanding	The proposal: • addresses an issue of major importance to human health or to basic science with significant potential to impact on human health • is highly likely to translate into fundamental outcomes in the science and/or practice of clinical medicine or public health, or fundamental changes in health policy or the next stage of research, new research or research re-design • will lead to published research and other outputs that should be very influential in promoting change in research direction or health policy and/or practice • has extensive involvement of consumers and the community in key phases of the project as appropriate to the intended outcomes of the research.
5	Excellent	The proposal: • addresses an issue of considerable importance to human health or to basic science with the potential to impact on human health • is likely to translate into fundamental outcomes in the science and/or practice of clinical medicine or public health, or fundamental changes in health policy or the next stage of research, new research or research re-design • will lead to published research and other outputs influential in promoting change in research direction or health policy and/or practice • has relatively extensive involvement of consumers and the community in key phases of the project as appropriate to the intended outcomes of the research.

4	Very Good	The proposal: • addresses an issue of some importance to human health or to basic science with the potential to impact on human health • has potential to translate into fundamental outcomes in the science and/or practice of clinical medicine or public health, or fundamental changes in health policy or the next stage of research, new research or research re-design • will lead to published research and other outputs which may be influential in promoting change in research direction or health policy and/or practice • has some involvement of consumers and the community in key phases of the project as appropriate to the intended outcomes of the research.
3	Good	The proposal: • addresses an issue of some concern to human health or to basic science with the theoretical potential to impact on human health • has potential to translate into outcomes in the science and/or practice of clinical medicine or public health, or changes in health policy or the next stage of research, new research or research re-design • will lead to published research or other outputs which may be influential in promoting change in research direction or health policy and/or practice • has some involvement of consumers and the community in the project.
2	Satisfactory	The proposal: • addresses an issue of only marginal concern to human health or to basic science with the plausible but unclear potential to impact on human health • is unlikely to translate into outcomes in the science and/or practice of clinical medicine or public health, or changes in health policy or the next stage of research, new research or research re-design • will lead to published research or other outputs that are unlikely to be influential in promoting change in research direction or health policy and/or practice • has little involvement of consumers and the community.
1	Weak or Limited	The proposal: • does not address an issue of concern to human health or to basic science with any likely impact on human health • will not translate into outcomes in the science and/or practice of clinical medicine or public health, or changes in health policy or the next stage of research, new research or research re-design • will lead to published research or other outputs that will not be influential in promoting change in research direction or health policy and/or practice • has virtually no involvement of consumers and the community.

* NHMRC's Research Translation Strategy 2022-2025 describes research translation as activities that use the results of research to inform, for example, the next stage of research, new research or research re-design, public policy, health-related systems and practice, or support the commercialisation of research discoveries, for the improvement of individual and population health. All types of research knowledge are valuable and can be translated (e.g. biomedical, clinical, public health and health services research).

The Research Translation Strategy acknowledges that translation is complex and is sometimes referred to as a 'translation pathway' from research through to implementation into policy and practice. Translation can occur at any stage and can follow many different pathways; strategies and activities may need to be modified repeatedly along this pathway. For Basic Science Research stream applications, in addition to informing next steps or new research, applications should address how the interface between the basic science and clinical practice, public health and/or health services is likely to lead to translational outcomes even if these are long term and not within scope for this grant.

	Criterion 3. Develop the health and medical research workforce by providing opportunities to advance the training of new researchers, particularly those with capability for independent research and future leadership roles (20%)	
	● Strategy to generate new researcher capability through training, mentoring and encouraging further career development ● Strategy to build workforce capacity and capability, including fostering the science of implementation where appropriate ● Clarity of opportunities for integrating new researchers into the teams	

Score	Performance Indicator	Score Descriptors
7	Exceptional	The proposal: ● includes an exceptional strategy to generate new researcher capability, including clear pathways for career development and future leadership roles ● includes an exceptional strategy to build workforce capacity and capability ● will comprehensively integrate new researchers into teams with extensive mentoring and development opportunities.
6	Outstanding	The proposal: ● includes a strongly developed and well-articulated strategy to generate new researcher capability, including pathways for career development ● includes a strongly developed and well-articulated strategy to build workforce capacity and capability ● will integrate new researchers into teams with some mentoring and development opportunities.
5	Excellent	The proposal: ● includes a persuasive strategy to generate new researcher capability, including some pathways for career development ● includes a persuasive strategy to build workforce capacity and capability ● will integrate new researchers into teams with limited mentoring and development opportunities described.
4	Very Good	The proposal ● includes a sound strategy to generate new researcher capability, however pathways for career development are not well defined ● includes a sound strategy to build workforce capacity and capability ● should integrate new researchers into teams however mentoring and development opportunities are unclear.
3	Good	The proposal: ● includes a strategy that should generate new researcher capability, however pathways for career development are unclear ● includes a strategy that should build workforce capacity and capability ● includes few opportunities to integrate new researchers into teams.
2	Satisfactory	The proposal: ● includes a weak strategy to generate new researcher capability, and there are minimal career development options ● includes a weak strategy to build workforce capacity and capability ● has few viable opportunities to integrate new researchers into teams.
1	Weak or Limited	The proposal: ● does not articulate a viable strategy to generate new researcher capability, or career development options ● does not articulate a viable strategy to build workforce capacity and capability ● has few, if any, opportunities to integrate new researchers into teams.

Criterion 4. Facilitate collaboration (20%)

Outline past and/or proposed collaborative arrangements within the Chief Investigator team and address how the team will ensure the cohesive running of the research during its funding period, including but not limited to:
- likely effectiveness of working collaborations and intellectual exchange
- the relationship with other groups in the particular fields of research
- integration and cohesiveness of the team
- roles and responsibilities within the team
- benefits of the proposed Centre beyond the sum of its individual components or previously funded Centre.

Score	Performance Indicator	Score Descriptors
7	Exceptional	The proposal: ● would be highly effective in promoting working collaborations and intellectual exchange ● has very strong relationships with other researchers ● has an exceptional degree of team integration and cohesiveness ● clearly articulates the roles and responsibilities within the team for achieving the objectives of the project ● clearly outlines the exceptional value-add to be gained from the proposed collaborative Centre.
6	Outstanding	The proposal: ● would be highly effective in promoting working collaborations and intellectual exchange ● has strong relationships with other researchers ● has a very high degree of team integration and cohesiveness ● articulates the roles and responsibilities within the team for achieving the objectives of the project ● clearly outlines the significant value-add to be gained from the proposed collaborative Centre.
5	Excellent	The proposal: ● would be effective in promoting working collaborations and intellectual exchange ● has good relationships with other researchers ● has a high degree of team integration and cohesiveness ● articulates the roles and responsibilities for most of the team for achieving the objectives of the project ● clearly outlines some value-add to be gained from the proposed collaborative Centre.
4	Very Good	The proposal: ● would be reasonably effective in promoting working collaborations and intellectual exchange ● has positive relationships with other researchers ● has a good degree of team integration and cohesiveness ● articulates the roles and responsibilities of some of the team for achieving the objectives of the project ● outlines some value-add to be gained from the proposed collaborative Centre.

3	Good	The proposal: • would have some effectiveness in promoting working collaborations and intellectual exchange • has some viable relationships with other researchers, although weak • has some degree of team integration and cohesiveness • requires further clarification of the roles and responsibilities within the team for achieving the objectives of the project • requires further clarification on the value-add to be gained from the proposed collaborative Centre.
2	Satisfactory	The proposal: • may be effective in promoting working collaborations and intellectual exchange • has little evidence of relationships with other researchers • has minimal team integration and cohesiveness • requires further clarification of the roles and responsibilities within the team for achieving the objectives of the project • does not persuasively describe the value-add to be gained from the proposed collaborative Centre.
1	Weak or Limited	The proposal: • raises doubts about its effectiveness in promoting working collaborations and intellectual exchange • has no evidence of relationships with other researchers • has little or no evidence of team integration and cohesiveness • does not define the roles and responsibilities of team members for achieving the objectives of the project • does not describe the value-add to be gained from the proposed collaborative Centre.

	Criterion 5. Record of research and translation achievement – relative to opportunity (20%)	
<td colspan="3"> - The previous research and/or translation experience of Chief Investigators (CIs) demonstrates that the team has the appropriate mix of research skills and experience to deliver the proposal. - Record of achievement encompasses the national and international standing of the CIs based upon their research and/or translation achievements, relative to opportunity, including but not limited to: - research outputs, such as: most recent significant publications; publications that illustrate innovation and significance of past accomplishments; outcome and impact of previous research achievements including effects on health care practices or policy and knowledge uptake - contribution to field of research, such as: requests to lead discipline thinking through prestigious review invitations, keynote, plenary or named Lectureships; editorial appointments; leadership positions in scientific or professional societies; specialist and high level health policy committee appointments; commercial involvement - evidence of research translation, such as: influence on the next stage of research, new research or research re-design; public policy; health-related systems and practice; commercialisation of research discoveries. </td>		

Score	Performance Indicator	Score Descriptors
7	Exceptional	Relative to opportunity, the CI team: - possess the optimal breadth of research skills and experience relevant for successful delivery of the proposal - are the most outstanding researchers in the country for their peers/cohort with a very strong record of research and translation outputs - have strong international reputations or are well on the way to developing them, and hold leadership positions in their field - are at the forefront of promoting knowledge translation in their field.
6	Outstanding	Relative to opportunity, the CI team: - possess the breadth of research skills and experience relevant for successful delivery of the proposal - have a record of research outputs that places them in the top 10-20% of peers/cohort - have growing international reputations and established positions of leadership, or are emerging leaders, in their field - are highly recognised for their contributions to promoting knowledge translation in their field.
5	Excellent	Relative to opportunity, the CI team: - have a strong breadth of research skills and experience and any gaps relevant to the proposal are minor - have a record of research outputs that places them well above average for their peers/cohort - have strong national reputations and are emerging leaders in their field - are well recognised for their contributions to promoting knowledge translation in their field.
4	Very Good	Relative to opportunity, the CI team: - have limited research skills and experience in some of the areas necessary for successful delivery of the proposal - have an above average record of research outputs - have existing or emerging national reputations - have made valued contributions to promoting knowledge translation in their field.

3	Good	Relative to opportunity, the CI team: • are deficient in some areas of expertise required for successful delivery of the proposal • have a moderate record of research outputs • have emerging national reputations • have made contributions to promoting knowledge translation in their field.
2	Satisfactory	Relative to opportunity, the CI team: • are underpowered in expertise relevant to the proposal • have a weak record of research outputs and have been less productive than might reasonably be expected • have emerging national reputations in a niche area • have made limited contributions to promoting knowledge translation in their field.
1	Weak or Limited	Relative to opportunity, the CI team: • are heavily underpowered in expertise relevant to the proposal • are not productive to any significant extent in relevant fields • have yet to establish national reputations • have not made contributions to promoting knowledge translation in their field.

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:

  o 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:

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 e.g. by providing expert research services for fees. Publications of such work might be precluded or delayed according to contract arrangements. The specialised nature of this research might also restrict publication to specialised journals only, as opposed to generalist journals.

Relevant industry outputs

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