NHMRC Clinical Trials and Cohort Studies (CTCS) Grant Information Session

15 July 2022

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[press record!]
NHMRC CTCS Info Session Overview

• What is the NHMRC CTCS Grants Scheme?

• Assessment Criteria
  – Significance (40%)
  – Research Quality (40%)
  – Team Quality & Capability (20%)

• Completing your Application
  – Profile & CV
  – Grant Proposal
  – Budget

• Research Innovation and Commercialisation Processes and Resources
  – Critical Dates
  – Application Process
  – What does RIC offer in Application Review?

• Questions at the end, so put them in the chat!
NHMRC CTCS Grant Scheme

- The CTCS Grant scheme has a funding allocation from the Medical Research Endowment Account (MREA) of $75 million (approximately 10% of MREA).
- The objective of the CTCS Grant scheme is to support high-quality clinical trials and cohort studies that address important gaps in knowledge, leading to relevant and implementable findings for the benefit of human health.
- The expected outcomes of the CTCS Grant scheme are improvements in health and well-being, health care practice or policy, as a result of:
  - High-quality clinical trials that provide reliable evidence of the effects of health-related interventions on health outcomes (or appropriate surrogates),
  - High-quality cohort studies that provide reliable evidence on the relation of important risk factors and other exposures to health-related outcomes, and/or
  - High quality retrospective cohort studies that provide reliable evidence on the relation of important risk factors and other exposures to health-related outcomes.
- Grants can be 1 to 5 years duration, with no cap on application budget.
# NHMRC CTCS Past Round Statistics

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<tr>
<th></th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
</tr>
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<tbody>
<tr>
<td>Total number of applications received</td>
<td>571</td>
<td>436</td>
<td>293</td>
</tr>
<tr>
<td>Total number of applications applying for NHMRC funding</td>
<td>570*</td>
<td>436</td>
<td>291</td>
</tr>
<tr>
<td>Number of grants awarded</td>
<td>31</td>
<td>30</td>
<td>33</td>
</tr>
<tr>
<td>% of applications awarded</td>
<td>5.4%</td>
<td>6.9%</td>
<td>11.3%</td>
</tr>
<tr>
<td>Mean budget for awarded grants</td>
<td>$2,404,324</td>
<td>$2,474,105</td>
<td>$2,283,378</td>
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*Excludes one application that did not request NHMRC funding. Includes one application that was withdrawn.
CTCS Grants Submitting an Application

• Submitted through Sapphire: **Register your/CI/Al Sapphire accounts ASAP!**
• **CIA** must be based in Australia for at least 80% of the funding period
• At time of acceptance, CIA must be Australian or NZ citizen, permanent resident, or have an appropriate work place visa in place
• Up to 10 Chief Investigators and up to 10 Associate Investigators per application
• Budget: salaries, DRCs, Equipment
  – Each requested item must be fully justified
  – Budget requests for equipment require a quote
• There are no limits on the number of applications a CI may submit
• Number of applications is not affected by any other NHMRC grants applied for or held
• Applicants must not submit the same application to both the Ideas and CTCS schemes in the same round (Ideas closed in May 2022) – otherwise, both applications will be ruled ineligible
NHMRC CTCS Grant Assessment Process

- NHMRC assigns applications and peer reviewers to panels of up to 15 members. Each application will be assigned up to 3 peer reviewers.
- Applications are allocated to a panel primarily based on the applicant’s nominated peer review areas. Allocation may also be informed by the proposed field of research and other key words entered into Sapphire.
- Peer reviewers provide independent scores and peer reviewers’ scores will be used to create ranked lists of applications from which will be used to shortlist applications that will proceed to the grant review panel.
- The least competitive applications within the provisional ranked list of applications for each panel will form a Not For Further Consideration (NFFC) list – these applicants will be notified in early Dec 2022. Applications not on the NFFC list will proceed to full panel review.
- After the panel meetings, application scores from all panels are used to create a ranked list. This final ranked list will be used to prepare funding recommendations to NHMRC’s Research Committee and Council for advice to the CEO, who will then make recommendations to the Minister for Health.
Key changes to this round

Changes to publication assessment in track record

- **E. Chief Investigator Capability and Achievement** section of Grant Proposal will no longer include top 5 publications from past 5 years, and full list of applicant publications from the past 5 years will no longer be provided to peer reviewers for their assessment.

- This has been replaced with a Top 10 publications list from the last 10 years: each CI has 200 characters per publication to provide the reference for that publication, and then 2000 characters to provide an overall explanation of why these 10 publications have been selected, outlining the quality of the publications and their contribution to science as it relates to the proposed research.

- Focus on “quality over quantity”
- NHMRC will consider preprints in track record assessment

Updates to Category Descriptors and Assessment Criteria

- Revised Clinical Trials and Cohort Studies Grants 2022 Category Descriptors (Appendix B) and Section 6 (The Assessment Criteria)
- Assessment of Research Quality now includes consideration of budget scope & scale
- Assessment of Significance now includes consideration of community involvement
Assessment Criteria

Significance (40%)
• Significance for this grant opportunity is the extent to which the research findings will substantially advance knowledge to improve the prevention, diagnosis or treatment of medical conditions, or to improve health and wellbeing.

Research Quality (40%)
• Research quality for this grant opportunity encompasses the quality and feasibility of the proposed research, incorporating theoretical concepts, hypothesis, research design and robustness.
• Applicants are able to describe the impacts of COVID19 on their research, and if appropriate, can address expected future impacts as part of their risk management strategy within their grant proposal.

Team Quality & Capability (20%)
• This criterion is used to assess whether the CI team named in your application has the appropriate mix of research skills and experience to undertake the clinical trial and/or cohort study and achieve the stated objectives of the proposed research.
Significance (40%)

**Score 7 Category Descriptors**

The proposed clinical trial and/or cohort study:

- will comprehensively and convincingly address the objective of this grant opportunity and will deliver against the desired outcomes
- is informed by an exemplary analysis or review of existing and ongoing studies in the field
- is developed with extremely broad and meaningful community involvement, meaning the proposal is extremely feasible
- [New this year] has consumer representation that is fully integrated into all aspects of the planning, conduct, publication and translation of the project
- if successful, will have very significant research impacts

**Indigenous Criteria**

**Sustainability and transferability**

- The outcomes of the study will definitely lead to major and effective health gains for Aboriginal and Torres Strait Islander peoples, beyond the life of the project
- The outcomes of the study will have a very high impact on health services delivery or other community priorities.

**Benefit**

- Study outcomes will have a very significant health benefit for Aboriginal and Torres Strait Islander peoples.
Research Quality (40%)

**Score 7 Category Descriptors**
The proposed clinical trial and/or cohort study:

• has a near flawless design and research methodologies appropriate to the research question
• is comparable with the best international research in the field
• is highly feasible with all of the required techniques and resources established
• **[New this year] has a proposed budget that very accurately matches the scope and scale of the proposed project with no budgeting concerns, and is highly feasible, sustainable and highly appropriate to undertake all components of work.**
• includes highly effective milestones and performance indicators
• was developed with outstanding risk management strategies that include a thorough barriers and enablers analysis to ensure successful implementation.

**Indigenous Criteria**

**Community Engagement**
The proposal has a research plan that:

• has outstanding levels of community engagement, ensuring that the proposal is highly feasible
• demonstrates how the research and potential outcomes are a priority for the community to an outstanding degree.
Team Quality & Capability (20%)

Score 7 Category Descriptors
Relative to opportunity, the Chief Investigators (CIs):
• have a high level of expertise and experience in all aspects of the proposed research
• have a very high level of influence and strong networks to contribute to the proposed research
• have over the last 5 years, a combined record of research achievement that is outstanding by international standards commensurate with their field of research (research achievement, quality and productivity)
• have outstanding national and international reputations in clinical trial or cohort study methodology and relevant research fields
• may include junior members who are strong contributors to overall team capability

Indigenous Criteria

Building capability
• The team has an outstanding track record in working with communities and building capability among Aboriginal and Torres Strait Islander people
• The proposal will build outstanding capability among Aboriginal and Torres Strait Islander people.
Completing your Application – Profile & CV

See section 4 – 5 of Appendix C for full details

If anyone in your research team doesn’t have a Sapphire account, register your/CI/AI Sapphire accounts ASAP!

Mandatory Sections of ‘My Profile’ indicated by red asterisk in Sapphire (*) – CIs cannot be added to the research team unless they have completed all mandatory sections:

– About My Profile
– Personal information
– Academic Information
– Peer Review Information
– Unavailability Calendar
– Contributions to NHMRC

Specific Requirements for the Clinical Trials and Cohort Studies 2022 grant opportunity – the following sections will be imported from applicant profiles into the submitted application:

– Career Disruptions within the last 5 years
– Relative to Opportunity within the last 5 years
– Publications
Completing your Application - Grant Proposal

- Use the template!

GRANT PROPOSAL – CLINICAL TRIALS AND COHORT STUDIES GRANTS 2022

A. Research proposal (maximum nine A4 pages)

B. References (maximum two A4 pages)

C. Milestones and Performance Indicators (maximum two A4 pages)

D. Team Quality and Capability (maximum one A4 page)

E. CI Capability and Achievement (maximum two A4 pages per CI)

F. Cancer Australia PdCCRS (if applicable) (maximum one A4 page)
Completing your Application - Grant Proposal

Read through Appendix C. Guide to Applicants, section 6.8 Grant Proposal thoroughly

A. Research Proposal: 9 pages (relevant to ‘Research Quality’ – 40% – and ‘Significance’ – 40%)

- “High-quality clinical trials and cohort studies that address important gaps in knowledge, leading to relevant and implementable findings for the benefit of human health.”
- Demonstrate the quality and feasibility of your proposed research
- Demonstrate the extent to which the research findings will substantially advance knowledge to improve the prevention, diagnosis or treatment of medical conditions, or to improve health and wellbeing (see Category Descriptors).
- All scientific information relating to your application must be contained here and must provide sufficient detailed information to enable the research plan to be thoroughly assessed.
- Should address the following (we strongly advise using these as clear headings throughout section A):
  - Aims
  - Background
  - Research Plan: methods and techniques to be used. Give consideration to crucial design elements that enhance the reproducibility of research findings
  - Timeline
  - Identified Risks: describe the risks and how you will manage/mitigate them, including potential risks that the Covid-19 pandemic may pose to the project. We suggest using a table that describes each risk, the risk rating, and how the risk will be monitored, managed, and mitigated. Link these to your project management/governance structures to further demonstrate the project feasibility.
  - Outcomes and Significance: while these should be described throughout the proposal, a final section providing an overall summary of the expected outcomes and impact at the end of section A helps provide a clear indication of Significance to peer reviewers.
Completing your Application - Grant Proposal

C. Milestones and Performance Indicators: 2 pages (relevant to ‘Research Quality’ – 40%)

- Table of milestones and performance indicators with corresponding dates.
- Approach should be specific to proposed research and provide for effective monitoring of progress at 12-month intervals.
- If relevant, include:
  - Recruitment targets
  - Application for and receipt of ethics approval
  - Dissemination of key findings
- You should also:
  - Describe your approach to managing the project: what is your methodology? Will there be a steering group?
  - Justify the approach taken e.g. has it been successfully used in the past?
- Performance indicators should be clear and detailed enough to demonstrate their usefulness
- Where applicable, end points of each milestone should be measurable. How this will be done should be clearly explained.
- For ease of reference and to account for unexpected changes to timeline after award, refer to milestones in terms of Year 1, Year 2, etc. rather than 2023, 2024, etc.
Completing your Application - Grant Proposal

D. Team Quality and Capability: 1 page

(‘Team Quality and Capability’ – 20%)

• Provide a summary of the research team’s quality and capability.

• Detail the following:
  – expertise and productivity of team members relevant to the proposed project
  – their influence in this specific field of research
  – how the team will work together to achieve the project aims
  – how junior members are contributing to the proposed research and the overall team quality and capability.

• Demonstrate the importance of the team as a whole by:
  – describing the impacts of previous work from collaborations within the research team
  – focusing more on how the team will work as a whole, rather than listing the individual achievements of each CI
  – explaining how the team as a whole addresses all the necessary needs of the project
Completing your Application - Grant Proposal

E. Chief Investigator Capability and Achievement: 2 pages per CI  
(‘Team Quality and Capability’ – 20%)

• Chief Investigators should use this section to highlight their research achievements:
  – Overall track record in the last 5 years - identify aspects of each CI’s track record in addition to their top 10 publications listed in the Sapphire application (no need to include the top 10 here).

• To demonstrate each CI’s Overall Track Record in the last 5 years, detail their:
  – Career summary including qualifications, employment and appointment history
  – Contributions to the relevant fields of research and the impact of those contributions (e.g. policy, methodologies), including the translation of research into health, commercial outcomes, such as patents, including whether licensed (when, to whom and whether current) (see NHMRC’s Guide to Evaluating Industry-Relevant Experience at https://nhmrc.gov.au/about-us/publications/guide-evaluating-industry-relevantexperience)
  – Relevant collaborations and their significant achievements
  – Community engagement and involvement
  – International standing including invitations to speak and committee memberships
  – Peer review (e.g. for granting bodies, journals/editorial roles)
  – Professional activities (e.g. committees, conference organization/participation)
  – Supervision and mentoring: also consider highlighting key achievements of supervised/mentored students
  – Current grants held
Completing your Application - Budget

• For detailed information on what can and cannot be requested as part of your budget, as well as how to complete your budget, read:
  – What the grant money can be used for (pp.10-11 of the guidelines)
  – NHMRC Direct research cost guidelines (download from NHMRC site)
  – Personnel and Salary Support packages (available from NHMRC site)
  – Appendix C: 6.9 Budget Proposal – Third Party Research Facilities and 6.10 Direct Research Costs (pp. 51-53 of the guidelines)

• Funds must be spent on costs directly incurred in the grant activity described in the proposal:
  – Salaries
  – Other Research Costs (ORCs)
  – Equipment
  – Third Party Facilities

• Fully justify every element of your budget!
  – From the Research Quality (40%) Score 7 Category Descriptors: “has a proposed budget that very accurately matches the scope and scale of the proposed project with no budgeting concerns, and is highly feasible, sustainable and highly appropriate to undertake all components of work.”
  – Describe the purpose and link each item (salary or ORCs) to aims & experiments
  – Salaries: justify role requirements, skills/experience, time fraction, how role will interact with team
  – ORCs: provide detailed breakdowns of costs. Justify the amounts – how did you reach these totals?
Completing your Application - Budget

• For more complete advice, see our Dos and Don’ts of NHMRC Budgets Info Session
  – Salaries, Other Research Costs, Equipment
  – What you can and can’t ask for
  – How to fully justify all aspects of your budget to ensure best chance of full budget being awarded
  – Recording and slides available on the RIC NHMRC Ideas Grants page

How to complete your budget in Sapphire - Salaries

• Describe position function
  – NHMRC terms for PSP descriptions e.g. Junior graduate research assistant (PSP2), Experienced postdoctoral researcher (PSP4)
  – Describe role e.g. relate to specific experiments/ expertise or specific aims
• Select appropriate PSP and time fraction for the requirements of the project
• Provide full justification for each role
  – Role requirements
  – Skill/research level
  – Time fraction
  – Align role with research aims
  – Indicate how each requested role will interact with the research team e.g. who will supervise, which lab will the work in
  – Justify changes across project (e.g. Reduction of time fraction in later years)

Position function

<table>
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<tr>
<th>Percentage</th>
<th>Salary package</th>
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<tbody>
<tr>
<td></td>
<td></td>
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<tr>
<td><strong>Year 1</strong></td>
<td><strong>Year 2</strong></td>
</tr>
<tr>
<td>66%</td>
<td>100%</td>
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<tr>
<td></td>
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<tr>
<td>Subtotal</td>
<td>$62,479.56</td>
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<tr>
<td></td>
<td>$94,666.00</td>
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<tr>
<td>Reason for salary</td>
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</table>

CIB is an NHMRC Dementia Fellow supervised by CIA. She is an expert in molecular pharmacology of GPCRs, trained by world leading GPCR expert Prof ... A biomarker for CIB will be responsible for managing the critical pharmacological assays listed in aims 1-3 of the proposal, conducting these experiments, overseeing staff and students and managing tissue sourcing and ex vivo experiments with the AL. CIB’s current salary funding will expire in April 2022. Thus we request 66% of her salary in Y1, and 100% of her salary for Y2-4. CIB will commit 100% of her NHMRC time to this project.
Other Common Questions
Clinical Trial or Cohort Study? (or Ideas!)

Not sure? Ask us!

**Clinical Trial**
- Provide reliable evidence of effects of health-related *interventions* on health outcomes (or appropriate surrogates)
  - Human participants, prospectively assigned to one or more interventions
  - Anticipated effects of intervention(s) on participants to be behavioural and/or health-related outcome

**Cohort Study**
- Provide reliable evidence on the relation of *important risk factors and other exposures* to health-related outcomes
  - Aims to evaluate associations between one or more factors in the cohort and a behavioural and/or health-related outcome
  - *Prospective cohort study*: human participants, prospectively followed over a defined period of time
  - *Retrospective cohort study*: collect/examine retrospective data, may involve elements of data linkage work

**Ideas Grant**
- Anything that is not a clinical trial or cohort study should be submitted in the 2023 NHMRC Ideas Grant round
Top 10 Publications

Top 10 Publications section not appearing in Sapphire?
• The top 10 publications section doesn’t appear in the Sapphire application form until a CI is nominated in the 'Research Team' and this appears in a separate tab to the 'Research Team' section once CIs are added to the 'Research Team' section.

How to complete the Top 10 Publications section
• The section allows 200 characters per publication to provide the reference for that publication, with one section of 2000 characters to provide an overall explanation of why the publications have been selected, outlining the quality of the publications and their contribution to science as it relates to the proposed research.
• It is advised that applicants do not include top 10 publications within the 2-page track record section for each CI in the Grant Proposal.
Cancer Australia PdCCRS Scheme (Category A)

• Can seek funding from Cancer Australia as a Funding Partner in Category A
  – Limit of 1-3 years, with a maximum of $200,000 for 1 year, $400,000 for 2 years, $600,000 for 3 years
  – If NHMRC proposal exceeds duration or budget limits, CIA must provide a revised scope and budget
  – Same CIA and Research Team

• 2 additional documents required:
  – 1-page modified research proposal included in Section F of the Grant Proposal
  – PdCCRS Questions form (available from GrantConnect)

Submitting CA supplementary documents

• Must meet Minimum Data for CTCS - **5pm Wed 27 July 2022**
• For full review, provide with CTCS application - **10am Mon 1 August 2022**
• Fully completed NHMRC CTCS application must be submitted by NHMRC close date – due to RIC by **10am Mon 22 August 2022**
  – This applies even if not requesting NHMRC funding
• Final documents must be provided to RIC via nhmrc-project@unimelb.edu.au:
  – Finalised **CA PdCCRS questions document** due to RIC by **10am Mon 29 August 2022**
Research, Innovation and Commercialisation Processes and Resources
2022 CTCS Grants Critical Dates

- **Open:** Wednesday 29 June 2022

- **RIC Hosted Scheme Information Session:** 11am Friday 15 July 2022  
  - We are here!

- **Minimum Data:** 5pm Wednesday 27 July 2022

- **RIC Review of Draft applications date:** 10am Monday 1 August 2022

- **RIC Final applications due date:** 10am Monday 22 August 2022

- **NHMRC Close Date:** Wednesday 24 August 2022

- **NHMRC Peer Review:** October 2022 – February 2023
2022 CTCS Grants Critical Dates

• Minimum Data (on Sapphire) due – **5pm Wed 27 July 2022**. Failure to meet this deadline will result in the application not proceeding.
  – Administering Institution
  – Aboriginal/Torres Strait Islander Research (yes/no)
  – Project Synopsis
  – Privacy agreement
  – Research Classification (all fields)
  – Chief Investigator A (complete CIA Name and Role) – **you must have a registered Sapphire account. Do this at least 1 week in advance!**

• Internal review by RIC due date – **10am Mon 1 August 2022**
  – Submit by email to nhmrc-project@unimelb.edu.au:
    • Draft Grant Proposal PDF

• Final submission due to RIC – **10am Mon 22 August 2022**
  **No later than this! Earlier submission is recommended**
  Include Authority to Submit form

***Please note that we have observed delays within Sapphire where the approvals tab to submit applications is taking ~15 minutes to load, as such there is a risk to the timely submission of your application if it is received after the RIC Final Submission Deadline. To minimise any delays or issues with the submission of your application we advise adhering to the RIC final submission deadline for this scheme.***
How to apply – step by step

1. Submit an NOI to RIC – ASAP (even if not 100% sure you are applying)
2. Complete/update Sapphire Profile and CV
   – If you or your research team (including CIs & AIs) do not have a Sapphire account, register for an account ASAP
3. Review key guideline documents
4. Complete draft application in Sapphire and prepare your grant proposal PDF.
5. Email application to RIC for review
6. Finalise the application
7. Certify the application in Sapphire
8. Email UOM Authority to Submit form to RIC
9. RIC to submit the application to NHMRC

https://sites.research.unimelb.edu.au/research-funding/nhmrc/clinical-trials-and-cohort-studies-grants
What does RIC offer in Application Review?

**What we do as part of our review process**

- Review all sections in Sapphire and Grant Proposal PDF
- Check eligibility
  - Can you apply for this grant? If not, what do you need to do to be eligible?
- Check compliance
  - Have all the fields been completed? Have any sections been missed?
  - Have the application rules and requirements been adhered to?
  - Does evidence meet NHMRC requirements?
- Identify how the application can be improved to best address the Assessment Criteria
  - How can the responses be better structured?
  - How can the responses and relevance to Assessment Criteria be made clearer?
  - What elements of the Assessment Criteria have not been strongly or clearly addressed?
  - What other aspects could use refinement?

**What we don’t do**

- Review scientific content: talk to colleagues in your lab, your department and your faculty!
- Proofreading: we will highlight if there are major typos that affect understanding, but full spelling & grammar checking and restructuring of sentences or sections will be left to applicants
Resources

• RIC CTCS Grant scheme webpage
  https://sites.research.unimelb.edu.au/research-funding/nhmrc/clinical-trials-and-cohort-studies-grants

• NHMRC CTCS Grant scheme webpage

• Grant Connect Webpage for scheme guidelines – GO5665 (Requires Login)
  https://www.grants.gov.au/Go/Show?GoUuid=8afb9292-766d-4a52-8c72-c664eaaf955f

• UoM Grants Library
  https://staff.unimelb.edu.au/research/grants/successful-applications-library

• NHMRC Ideas Budget presentation
  https://research.unimelb.edu.au/support/funding/nhmrc/ideas-grants
Contact us:

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Question Time