MACQUARIE University

NHMRC Clinical Trials and Cohorts Studies Grants Funding Scheme

5 March 2020

Sapphire

Please note this application will be submitted via the NHMRC's new Grant Management System Sapphire. If you had an active RGMS account your CV and Profile email was migrated into Sapphire on 12 February 2020. To login to Sapphire:

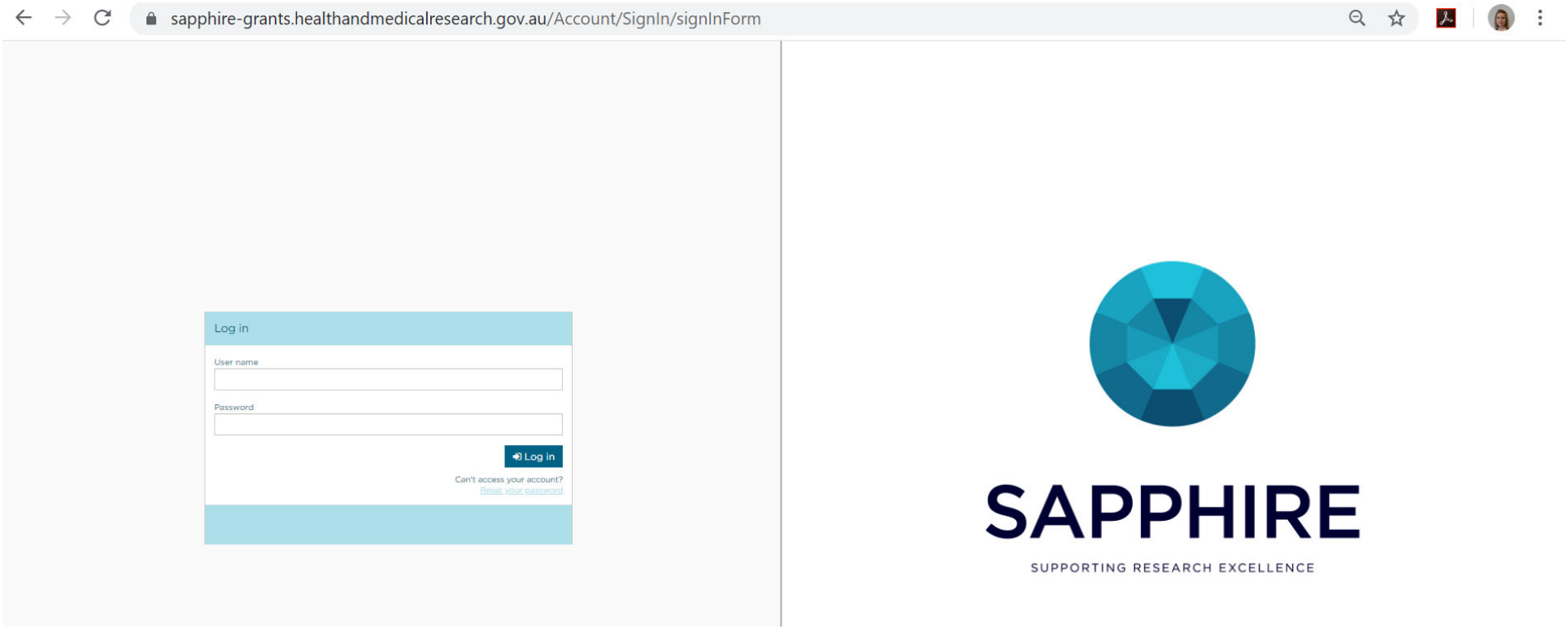
1. If you have an existing RGMS account, a Sapphire account has been created for you. Click here to Activate your account.

2. If you did not have an RGMS account, you will need to register for a Sapphire account. Click here to Register for an account.

Tutorial and training modules for Sapphire can be found here.

Sapphire

https://sapphire-grants.healthandmedicalresearch.gov.au/Account/SignIn/signInForm



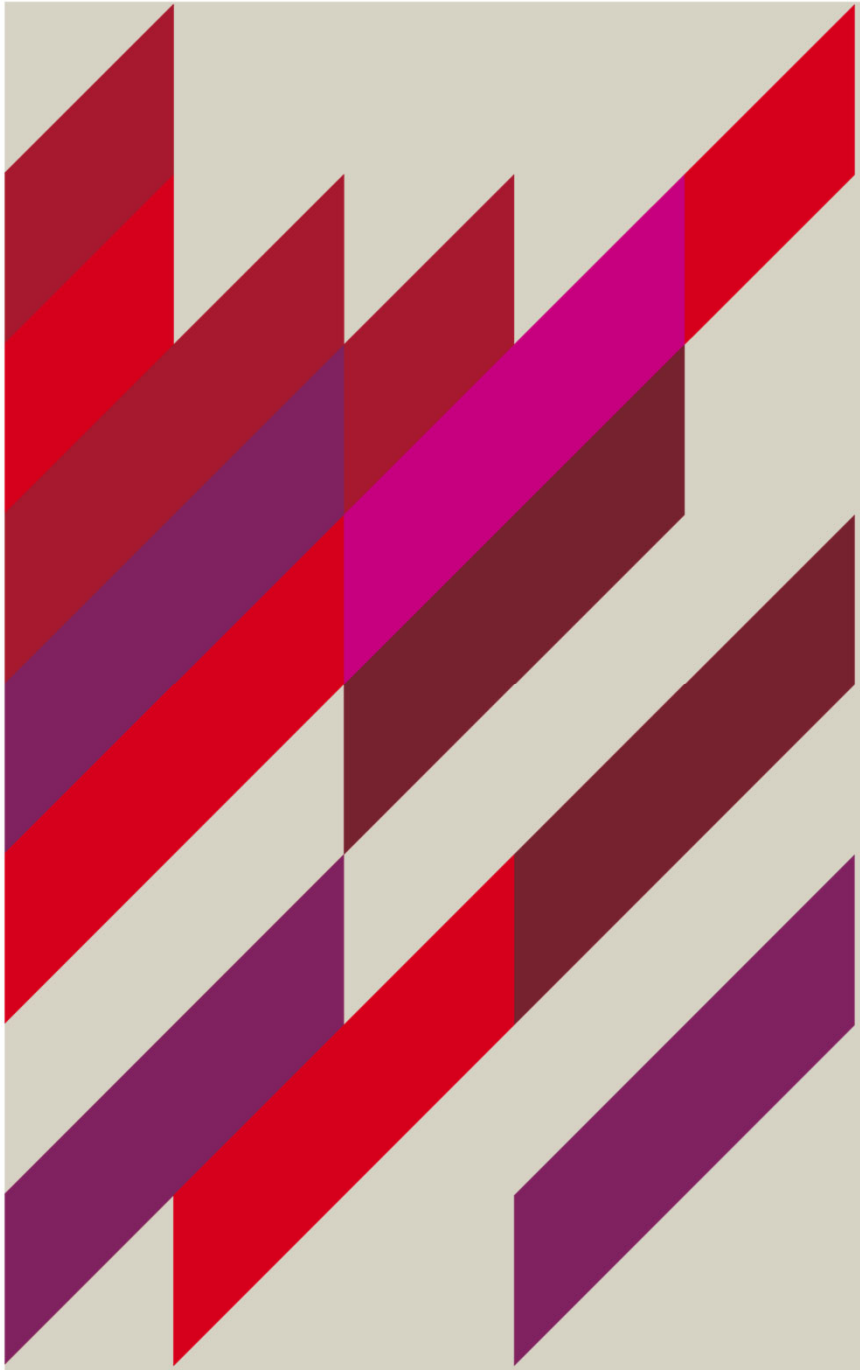
Changes in Sapphire

- No CI and AI certification emails/forms – inbuilt into Sapphire, as you invite CI and AI's to join the application

- Sapphire is a shared document
  - One person in the document at one time
  - You can assign other CI's to edit the application

- No hidden menus

- Clear markers for minimum data sections



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NHMRC CTCS Grant Application

The Scheme

About CTCS Grants

- The objective of the CTCS 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 are:

- High-quality clinical trials that provide reliable evidence of the effects of health-related interventions on health outcomes (or appropriate surrogates), and/or
- High-quality cohort studies that provide reliable evidence on the relations of important risk factors and other exposures to health-related outcomes.

What is not CTCS Grants

- laboratory-based research, including research based on animal models or other pre-clinical studies
- studies designed to understand biological or behavioural processes/mechanisms
- studies investigating the pathophysiology of diseases
- proof of concept studies of new discoveries/treatments
- studies involving data repurposing activities only
- studies involving data mining activities only
- studies exploring new scientific principles, and
- studies developing or testing new methodologies or the mechanism of action of interventions.

NHMRC Documents

Grant Opportunity Documents - GO3714

Clinical Trials and Cohort Studies 2020 Grants

GO ID: GO3714

The files below make up the document set for this grant opportunity.

To open the files, click on the file name. Some web browsers require you to click the right mouse button. You will then see a list of options; choose either 'Save Target As' or 'Save Link As...'

CTCS Grants 2020 Grant Guidelines

CTCS Grants 2020 Grant Guidelines.pdf 951 KB

CTCS Grants 2020 Grant Proposal

CTCS Grants 2020 Grant Proposal.doc 28 KB

CTCS Grants 2020 FAQs

CTCS Grants 2020 FAQs.pdf 174 KB

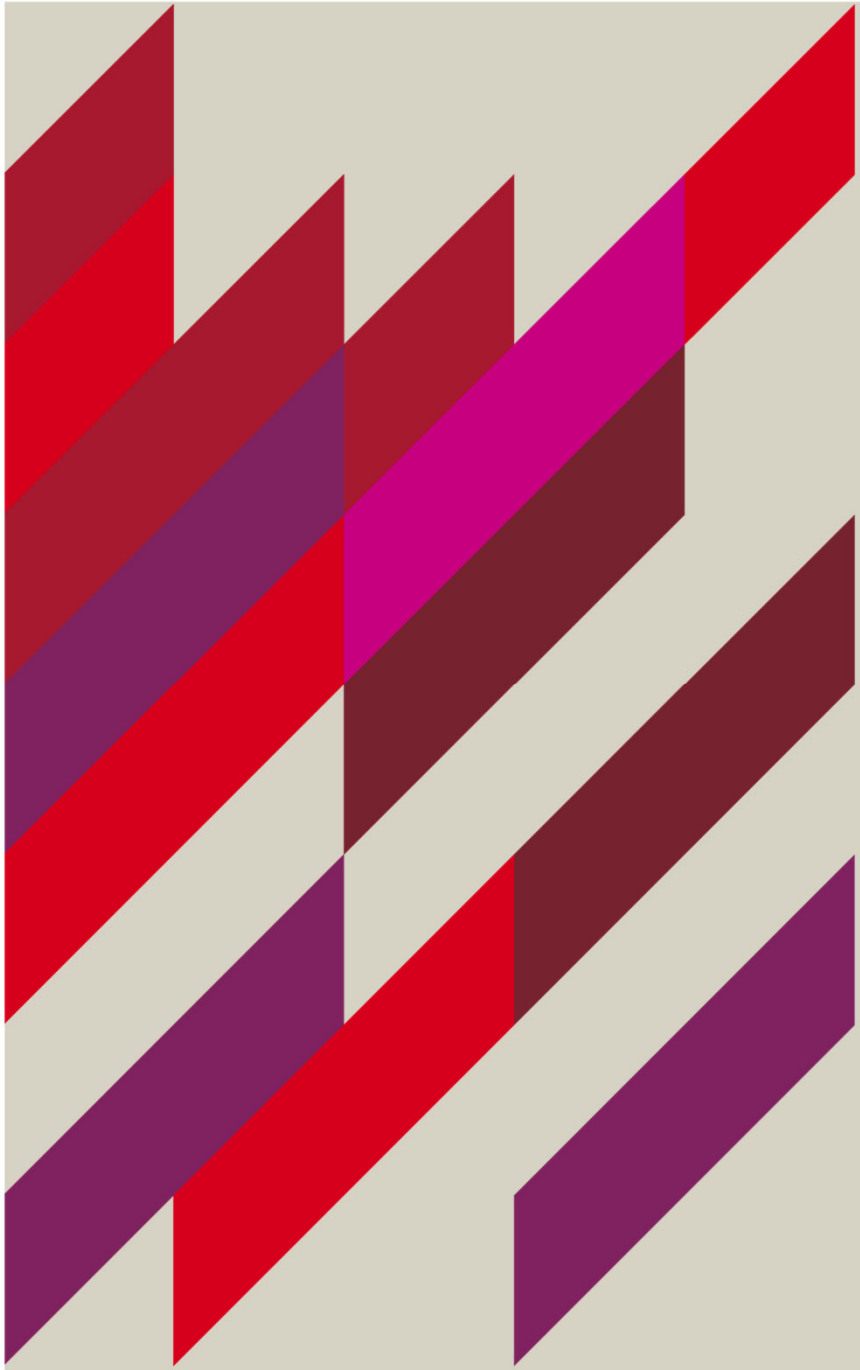
www.grants.gov.au

2021 CTCS Grant Dates

Activity	Deadline
Applications Open (Sapphire)	Wednesday 4 March 2020
MQ Minimum Data Deadline ***All Sapphire sections MUST be complete by 9am on this date***	9am Tuesday 31 March 2020.
MQ Submission Date ***All complete applications must be submitted internally by this date (Grant Proposal and Sapphire snapshots attached and submitted through Pure)***	9am Wednesday 1 April 2020
MQ will submit applications to NHMRC	29 April 2020
Outcomes	November/December 2020
Commence Ideas Grant	1 January 2021

Eligibility

- At the time of acceptance and for the duration of the grant, the CIA must be an Australian or New Zealand citizen, or a permanent resident of Australia.



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NHMRC CTCS Grant Application

MQ Process
Application Structure

The Application Process

- Discuss your CTCS Grant research idea and team with MQ staff (E.g. supervisor, HoD, Faculty Research Office). To confirm it is a CT or CS.
- Begin working on full application
- Complete all of Sapphire by 9am on Tuesday 31 March
- Submit full application, via PURE, by the MQ internal deadline (1 April 2020)
- Submit application via Sapphire to the NHMRC (29 April 2020)

Change in MQ Process and Why

- All Sapphire sections **MUST be complete by 9am on Tuesday 31 March 2020** and applicants **must remain logged out of Sapphire until they receive an email from the Proposals Team to confirm their minimum data** and each section is complete. NOTE: No extensions will be given on this process

- **The word version of your grant proposal (complete full draft) and all Sapphire snapshots (all sections completed) must be submitted via PURE (click 'Send to Internal Approval')** by the Macquarie University submission date of **Wednesday 1 April 2020 (9am)** for strategic, eligibility and compliance checks and submission to the NHRMC by Research Services. You will also need to follow this step again for your second compliance check, due date for this check will be given to you by the Proposals Team when your first compliance feedback is provided.

Note these two steps have be put in place to prevent researchers having to submit their grant to RAO via Sapphire, thus locking their application until checks are complete. Sapphire is set-up as a shared document, in which only one person can be logged into an application at a time (this was not the case in RGMS).

Sapphire: CV and Profile (last 5 years)

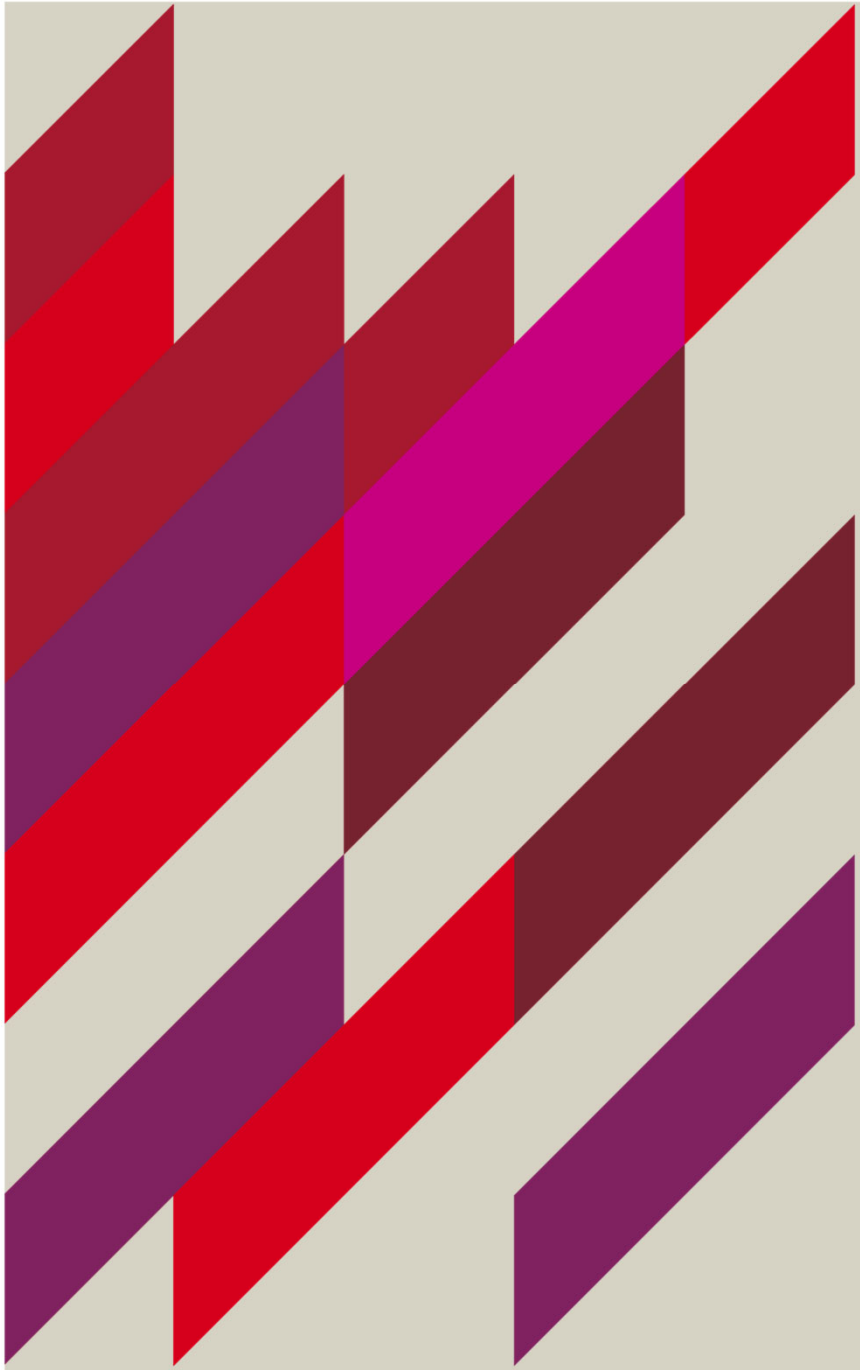
- Relative to Opportunity
- Career Disruption
- Publications

Sapphire: Application

- Synopsis
- Plain English Summary
- Participating Institutions
- Research Classification
- Burden of Disease
- Research Team
- Ethics
- Proposed Budget
- Research Proposal

Grant Proposal

Component	Page Limit
Research Proposal	9 Pages
References	2 Pages
Milestones and Performance Indicators	2 Page
Team Quality and Capability	1 Page
Chief Investigator Capability and Achievement	2 Pages per CI
Indigenous Research Excellence Criteria (if applicable)	2 Pages
Cancer Australia PdCCRS (if applicable)	1 Page



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NHMRC Ideas Grant Assessment

NHMRC Process Assessment Criteria

Assessment Criteria

- **Significance (40%)**
  - Proposal
- **Research Quality (40%)**
  - Proposal
- **Team Quality and Capability (20%)**
  - CI publications
  - CI two page capability and achievement
  - Team Quality 1 page

Assessment Criteria Scoring

Score	Performance Indicator
7	Exceptional
6	Outstanding
5	Excellent
4	Very Good
3	Good
2	Satisfactory
1	Weak or Limited

Assessment Criteria Scoring

Significance (40%)

SCORE						
7	**6**	**5**	**4**	**3**	**2**	**1**
The proposed clinical trial and/or cohort study: • will comprehensively and convincingly address the objective of this grant opportunity and will deliver against the desired outcomes • is informed by an exemplary analysis or review of existing and ongoing studies in the field • was developed with broad and meaningful involvement of research end-users to ensure it meets their needs • if successful, will have very significant research impacts.	The proposed clinical trial and/or cohort study: • will strongly address the objective of this grant opportunity and will deliver against desired outcomes • is informed by a thorough analysis or review of existing and ongoing studies in the field • was developed with meaningful involvement of research end-users to ensure it meets their needs • if successful, will have significant research impacts.	The proposed clinical trial and/or cohort study: • will address the objective of this grant opportunity with only minor concerns and deliver relevant desired outcomes • is informed by a good analysis or review of relevant existing and ongoing studies in the field, with only minor concerns with respect to the analysis • had research end-user involvement in a number of key aspects of the design • if successful, will have appreciable research impacts.	The proposed clinical trial and/or cohort study: • will partially address the objective of the grant opportunity and deliver desired outcomes of some relevance • there are several minor concerns about the analysis or review of existing and ongoing studies which informs the research • had research end-user involvement in a number of aspects of the design • if successful, may have moderate research impacts.	The proposed clinical trial and/or cohort study: • will not convincingly address the objective of this grant opportunity or is unclear in its approach to doing so • there are significant or major concerns about the analysis or review of existing and ongoing studies which informs the research • had limited research end-user involvement in the design • if successful, it is unlikely to have anything other than minor research impact.	The proposed clinical trial and/or cohort study: • will not address the objective of this grant opportunity or is unclear in its approach to doing so • is informed by a very limited analysis or review of existing and ongoing studies in the field • had minimal research end-user involvement in limited aspects of the design.	The proposed clinical trial and/or cohort study: • will not address any of the objectives of this grant opportunity • is informed by a poor analysis or review of existing and ongoing studies in the field and therefore will not translate into outcomes that improve treatment of a medical condition or improve health outcomes.

Assessment Criteria Scoring

Research Quality (40%)

SCORE						
7	**6**	**5**	**4**	**3**	**2**	**1**
The proposed clinical trial and/or cohort study: • has a near flawless design and research methodologies appropriate to the research question • is comparable with the best international research in the field • is highly feasible with all of the required techniques and resources established • includes highly appropriate research end-user involvement • includes highly effective milestones and performance indicators.	The proposed clinical trial and/or cohort study: • has a strong, well defined and coherent design and research methodologies appropriate to the research question • is comparable with strong proposals in the field internationally • is feasible with required techniques and resources established • includes appropriate research end-user involvement • includes effective milestones and performance indicators.	The proposed clinical trial and/or cohort study: • is generally clear in its research methodology, logical and appropriate to the research question • raises only very few minor concerns with respect to the study design • is feasible in almost all areas: required techniques and resources established or nearly established • may not be highly competitive with similar research proposals internationally • includes some appropriate research end-user involvement • raises a few very minor concerns about the appropriateness of milestones and performance indicators.	The proposed clinical trial and/or cohort study: • is generally solid in design and is appropriate to the research question, but may not always be clear in its intent and focus • raises several minor concerns regarding the study design and research methodologies • raises doubts about feasibility in a number of areas • is not likely to be competitive with similar research proposals internationally • includes constructive research end-user involvement but with limited scope • raises minor concerns about the appropriateness of milestones and performance indicators.	The proposed clinical trial and/or cohort study: • is somewhat unclear in its design • is not appropriate to the research question or contains some major design or methodological flaws • raises major concerns about the feasibility and thus the likelihood of successful completion • includes minimal, tokenistic research end-user involvement • raises significant concerns about the appropriateness of milestones and performance indicators.	The proposed clinical trial and/or cohort study: • is unclear in its design • contains several major flaws in study design and research methodologies • raises several major concerns about the feasibility and thus the likelihood of successful completion.	The proposed clinical trial and/or cohort study: • has a poorly developed research proposal which does not seem to be feasible and is unlikely to be successfully completed.

Assessment Criteria Scoring

Team Quality and Capability (20%)

SCORE						
7	**6**	**5**	**4**	**3**	**2**	**1**
Relative to opportunity, the Chief Investigators (CIs): • have a high level of expertise and experience in all aspects of the proposed research • have 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.	Relative to opportunity, the CIs: • have expertise and experience that is highly relevant to the proposed research • have over the last 5 years, a combined record of research achievement that is excellent by international standards commensurate with their field of research (research achievement, quality and productivity) • have excellent national and/or international reputations in clinical trial or cohort study methodology and relevant research fields • may include junior members who contribute to overall team capability.	Relative to opportunity: • there are only minor concerns about the CIs' level of expertise and experience required to undertake the proposed research • the CIs have over the last 5 years, a combined record of research achievement that is well above average by international standards commensurate with their field of research (research achievement, quality and productivity) • the CIs have very good national and/or international reputations in clinical trial or cohort study methodology and relevant research fields • the CIs may include junior members who have the potential to add to the team capability.	Relative to opportunity: • there are significant concerns about the CIs' level of expertise and experience required to undertake the proposed research • the CIs have over the last 5 years, a combined record of research achievement that is average by international standards commensurate with their field of research (research achievement, quality and productivity) • the CIs have good national and/or international reputations in clinical trial or cohort study methodology and the relevant research fields • the CIs may include junior members who have the potential to add to the team capability, but there is little evidence of a mentoring framework.	Relative to opportunity, the CIs: • have made contributions to the field of research but there are significant concerns regarding the depth and breadth of relevant expertise of the team • have over the last 5 years, a combined record of research achievement (research achievement, quality and productivity), that places them at an average level for their peers/cohort • have made limited progress towards research achievements warranting national or international recognition.	Relative to opportunity, the CIs: • are deficient in some areas of expertise required to successfully complete the proposed research • have published only a few works in relevant fields of research • are not well recognised nationally or internationally for their achievements in the relevant research fields.	Relative to opportunity, the CIs: • are deficient in the relevant expertise required to successfully complete the proposed research • are not productive to any significant extent in relevant fields of research • are not well recognised nationally or internationally for their achievements in the relevant research fields.

CTCS Grants

Total number of applications received	571
Total number of applications applying for NHMRC funding	570
Number of grants awarded	31
Percentage of applications awarded	5.4%
Mean budget for awarded grants	$2,404,324

Trial or Study Type	Applications	Grants Awarded	Funded Rate	Proportion of Grants Awarded	Total Value	Mean Budget of Awarded Grants
Clinical Trials	421	23	5.5%	74.2%	$58,556,219	$2,545,922.57
Cohort Studies	148	8	5.4%	25.8%	$15,977,825	$1,997,228.17
Withdrawn	1	0	0.0%	0.0%	$0.00	$0.00

CTCS Grants - 2019

- Total applications requested approx. $1.013 billion
- $70 million available funding
- Broad Research Areas
  - Basic Science (1%)
  - Clinical Medicine and Science (66%)
  - Public Health (19%)
  - Health Services Research (14%)

Selected Successful Clinical Trial Example

- **Metformin Aneurysm Trial**
  Rupture of the main abdominal artery leads to approx. 200,000 deaths per year world-wide. Based on substantial laboratory and observational data this trial tests the efficacy of a novel medication in limiting important artery weakening-related clinical events.

- **The Staphylococcus aureus Network Adaptive Platform Trial**
  There are an estimated 5000 episodes per year of bloodstream infections due to Staphylococcus aureus (golden staph) in Australia and an associated mortality of 20%. Despite this, there is little clinical trials evidence to guide best management. The Staphylococcus aureus Network Adaptive Platform trial (SNAP) will be a novel, large scale, international clinical trial that will both establish best practice evidence and optimise care for patients during the conduct of the trial.

Selected Successful Cohort Study Example

- **Antecedents of Renal Disease in Aboriginal Children and young adults study – ARDAC**
  Chronic disease is the main reason Aboriginal people have poorer health outcomes compared to other Australians. The Antecedents of Renal Disease in Aboriginal Children (ARDAC) Study will generate critical new knowledge about when and how chronic kidney disease develops and progresses in Aboriginal people in the transition period from childhood to adulthood, and inform the development of sustainable, culturally appropriate interventions to reverse this trajectory.

Selected Successful Cohort Study Example

- **Understanding the impact of language ability on the transition from late adolescence to early adulthood: the Early Language in Victoria Study**

  Very little is known about the number of children who leave school with poor language skills and the extent to which these difficulties impact on them. In this landmark study we will look at the relationship between language, and associated literacy and numeracy, and important issues affecting young people (such as mental health, quality of life and employment) as they make the critical transition from high school.

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Research Support

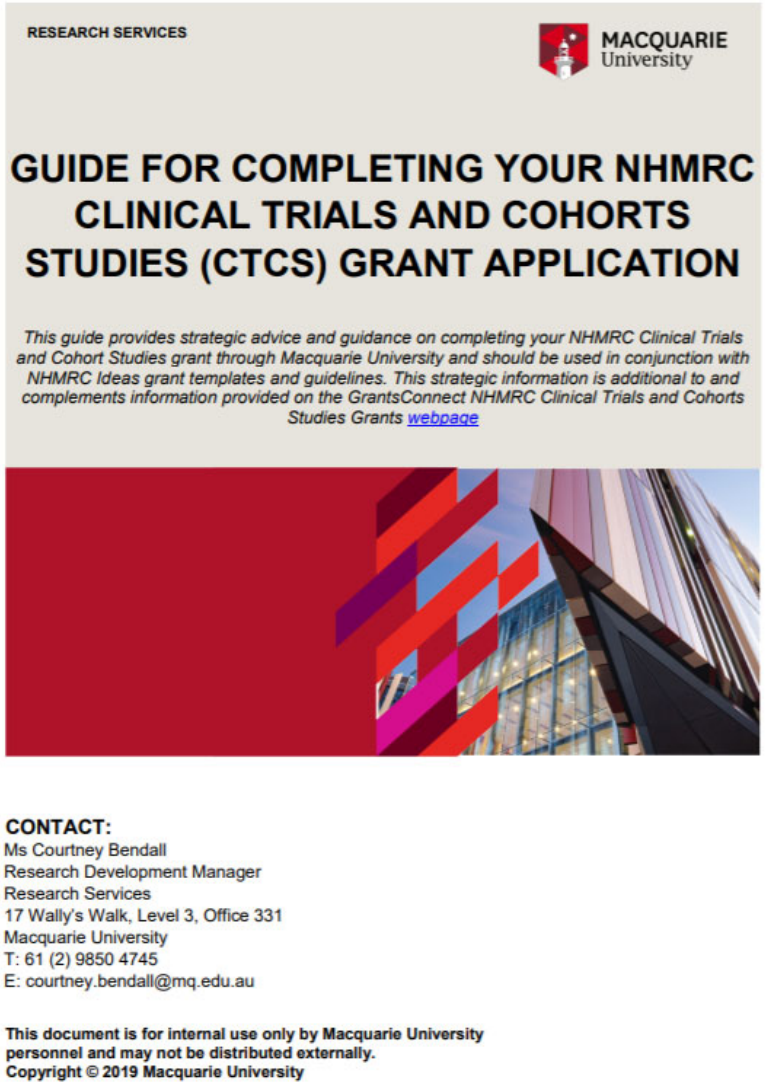
Advice Toolkit
Workshops
Faculty Contacts
Research Services Staff
Online Successful Grants Library

Advice Toolkit

Version 1 available from:

https://truth.mq.edu.au/share/id/mqu4hnaj

Version 2 will be available on Friday 6 March



RESEARCH SERVICES

MACQUARIE University

GUIDE FOR COMPLETING YOUR NHMRC CLINICAL TRIALS AND COHORTS STUDIES (CTCS) GRANT APPLICATION

This guide provides strategic advice and guidance on completing your NHMRC Clinical Trials and Cohort Studies grant through Macquarie University and should be used in conjunction with NHMRC Ideas grant templates and guidelines. This strategic information is additional to and complements information provided on the GrantsConnect NHMRC Clinical Trials and Cohorts Studies Grants webpage

CONTACT:
Ms Courtney Bendall
Research Development Manager
Research Services
17 Wally's Walk, Level 3, Office 331
Macquarie University
T: 61 (2) 9850 4745
E: courtney.bendall@mq.edu.au

Upcoming Workshop

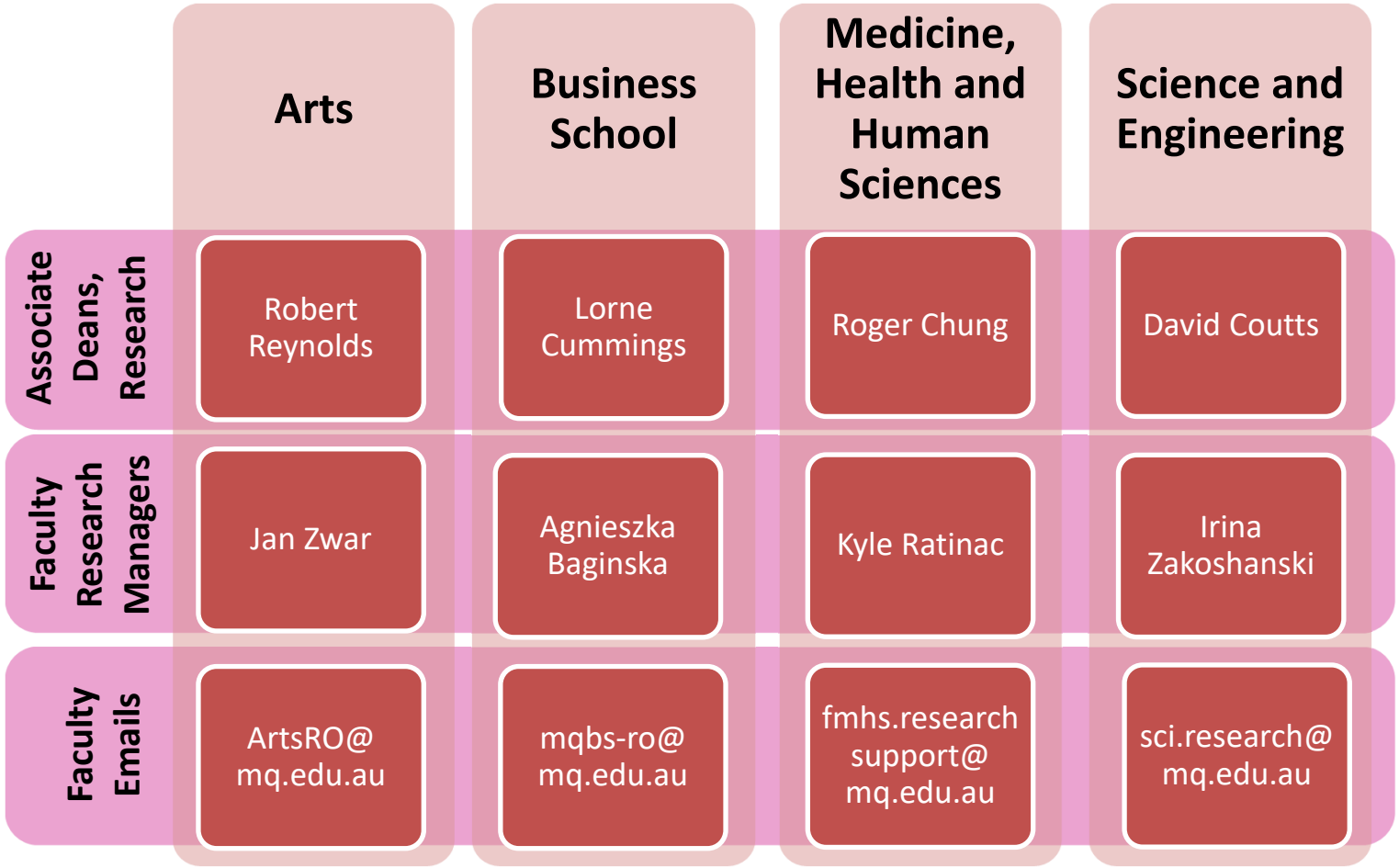
1. Building Your Budget: CTCS and Ideas Grants
   Thurs 26 March 2020, 12:30 – 13:30
   Room 801, Level 8, 12 Wally's Walk

Faculty Initiatives

- **Faculty of Medicine, Health and Human Sciences**
  - EOI disciplinary review
  - Writing Retreat
  - Strategic review by FRO and Courtney Bendall

- **Faculty of Science and Engineering**
  - Strategic review by FRO and Courtney Bendall

Faculty Contacts



	Arts	Business School	Medicine, Health and Human Sciences	Science and Engineering
Associate Deans, Research	Robert Reynolds	Lorne Cummings	Roger Chung	David Coutts
Faculty Research Managers	Jan Zwar	Agnieszka Baginska	Kyle Ratinac	Irina Zakoshanski
Faculty Emails	ArtsRO@mq.edu.au	mqbs-ro@mq.edu.au	fmhs.researchsupport@mq.edu.au	sci.research@mq.edu.au

Research Services Support

- **Research Services (Level 3, 17 Wally's Walk, East Entrance)**
  Courtney Bendall
  Research Development Manager
  Ph: x4745
  E: courtney.Bendall@mq.edu.au

- **MQ CTCS Grants website**
  https://www.mq.edu.au/research/research-funding-and-grant-opportunities/fellowship-and-grant-opportunities/nhmrc/nhmrc-clinical-trials-and-cohorts-studies-grants

- **Successful Grants Library**
  https://www.mq.edu.au/research/research-funding-and-grant-opportunities/training-and-support/successful-grants-library

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Thank you

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