

Australian and New Zealand College of Anaesthetists

Faculty of Pain Medicine

Novice Investigator Grant Application Guide 2021

ADVICE AND INSTRUCTIONS TO APPLICANTS

To be used in conjunction with Novice Investigator Grant Application Form

CLOSING DATE: 5 PM AEDT April 1, 2020

Email applications to: ANZCA Research Administration Coordinator research@anzca.edu.au



IMPORTANT POINTS FOR COMPLETING ANZCA GRANT APPLICATIONS

- It is a major goal of the college to encourage and foster novice researchers. The Research Committee invites early application by novice investigators. Applications must be received by **January 14** each year. A mentor from the Research Committee, or an experienced investigator appointed by the committee, will be assigned who will assess the application and provide feedback before final submission by the deadline. This committee member will not participate as a reviewer or spokesperson for the application.
- Please read the ANZCA Research Grant Policy before completing the application form (http://www.anzca.edu.au/fellows/Research/anzca-research-information.html)
- An ANZCA REGKEY must be obtained and included in the header of the application form. Double-click
 on the header to add your REGKEY. Contact Susan Collins (email: research@anzca.edu.au) to obtain
 your REGKEY.
- Do not include or copy the cover sheet. Start your application with the page headed "In Confidence".
- Eligibility: Ensure chief investigator A is a fellow or registered trainee of ANZCA or FPM.
- Eligibility: Ensure all chief investigators are novice investigators (as per the definition on page 3).
- Eligibility No single prior grant exceeds \$10,000.
- Ensure all chief investigators do not exceed the two active grants or applications maximum.
- Ensure the research plan is no more than 7 pages, including references with a font size no smaller than 10 point. The minimum margin is 2cm.
- Ensure the budget is in line with the maximum amount allowed.
- Rows may be added to tables where this is allowed in these guidelines (e.g. list of chief investigators, list of current research grants). Do not exceed prescribed word/page counts. Text that exceeds prescribed word counts will not be considered.
- Ensure that each page is numbered consecutively in the application.
- A written quotation for equipment costing \$A10,000 or more, as requested in the budget section, must be attached to each copy of the application.
- The application must be submitted <u>electronically via email</u> to <u>research@anzca.edu.au</u>. Only files of 6MB or less will be accepted. The electronic copy may include the signature pages within the application form or these may be sent via email as a separate document with scanned or electronic signatures.
- Electronic copies must be in PDF format (converted word files only, not scanned documents) or
 Microsoft word format. Note for older versions on Microsoft Word please install the official update
 from https://www.microsoft.com/en-au/download/details.aspx?id=7. This update will allow
 Microsoft office 2007 save documents to .PDF format.
- The complete application must be received by the Research and Administration Coordinator by 5PM AEDT on the closing date for applications. Late applications WILL NOT BE ACCEPTED.
- Incomplete applications or those that do not follow these guidelines WILL NOT BE ACCEPTED.
- ANZCA cannot amend an application once it has been submitted.



A. CONDITIONS OF ANZCA NOVICE INVESTIGATOR GRANTS

1 General

ANZCA Novice Investigator grants support research projects conducted by novice investigators. A novice investigator grant application is for a novice investigator who: 1) may have been awarded previous grant funding as a principle investigator provided no single grant has exceeded \$10K, 2) has not published more than 5 research papers in the 5 years prior to the year of application, 3) does not have an experienced investigator as a <u>co-investigator</u> on the proposed grant. The salary and position of the novice investigator (chief investigator A [CIA]) should be reasonably assured for the duration of the grant.

2 Payment

Sums awarded will be paid upon request after **January 1** each year for the duration of the grant. All payments will be made in Australian dollars, upon receipt of a fully correct tax invoice from the administering institution.

3 Conditions of professional research personnel

The conditions for professional research personnel shall be those of the institution in which the work is carried out or as the college may determine in particular circumstances. This includes annual leave and sick leave. However, the college does not provide for long service leave.

4 Alterations in research program budget

The CIA is expected to adhere to the approved research program or budget, and to notify any absences other than for short periods (e.g. three to four weeks). Full details of any proposed major alterations to either program or budget, or of any absences during the course of the grant, should be submitted in advance by the CIA to the Research Administration Coordinator for approval by the chair of the Research Committee (or his or her delegate).

5 Reporting requirements

Eligibility to apply for future funding will be contingent on complying with the reporting requirements of the ANZCA Grant Agreement Terms and Conditions. Unless otherwise specified, grants are awarded for the period of two calendar years following the year of the grant decision. The CIA may request in writing a time-only extension or roll-over of funds if the project is not completed at the end of the two-year period.

5.1 Progress report

The CIA is required to forward a progress report on the approved form to the college, by **September 1** in each year of the award. This form can be found on the ANZCA website. If a progress report is not received by the due date, any funding for multi-year projects may be withheld and/or any future funding requested in subsequent years by the CIA may not be considered.

5.2 Final report

The CIA is required to forward a final report on the approved form to the college, within three months following the completion of the project. This form can be found on the ANZCA website. The final report must include a statement of expenditure charged to the grant. Any unexpended balance of the grant should be returned to the college and must not be used on other projects.

6 Publications and presentations

The college requires that its contribution be acknowledged in all publications and presentations of the research project, for example "This study was supported by a grant from the ANZCA Research Foundation, Australian and New Zealand College of Anaesthetists" and that a presentation relating to the project be made at a major college meeting. A hard copy or pdf of the reprint should be sent to the Research and Administration Coordinator. If the protocol is registered with a journal or other relevant organisation, the college must receive a copy of the registration certificate

7 Patents

Any discovery arising out of work supported by the college must not be the subject of application for patent except with the written approval of the college and the agreement of the institution in which the work is carried out.



8 Audit of research projects

In accordance with the ANZCA Academic Integrity Policy, available on the website, ANZCA reserves the right to conduct a random audit of ANZCA-funded research through the administering institution's research office.

9 Termination of grant

A grant may be terminated if the conditions of the grant are not observed. A grant will terminate, unless other arrangements satisfactory to the college are made, if the CIA leaves the institution before the expiry of the grant. In such an eventuality, the recipient and the head of the department are expected to notify the college CEO. When a grant terminates any unexpended balance must be returned to the college.

B. GENERAL INFORMATION FOR APPLICANTS

1 Introduction

The future of research in our specialties depends on the transformation of novices into established researchers. The main source of support for the development of novice investigators is through the ANZCA scholarship scheme as part of a project grant which supports salaries of fellows and trainees undertaking higher degrees. Novice investigators are strongly encouraged to consider undertaking a higher degree and applying for a scholarship.

The college also wishes to support novice investigators undertaking their initial research projects. Novice investigators sometimes have difficulty obtaining grants in open competition with experienced investigators. For this reason, the college has established the ANZCA Novice Investigator grants. The novice investigator(s) will be the chief investigator(s) of the grant application and will undertake most of the research personally, under the supervision of experienced colleagues.

2 Novice investigator grants

Novice investigator grants are awarded to support of scientific investigations proposed by fellows and registered trainees of ANZCA or FPM and their research collaborators (scientists, students etc). The policy in relation to chief investigators is:

- The "chief investigator A" (i.e. the first-named investigator [CIA]) must be a fellow or registered trainee of ANZCA or FPM, be financial and in good standing with ANZCA.
- All chief investigators must be novice investigators. A novice investigator is defined as an investigator who
 1) may have been awarded previous grant funding as a principle investigator provided no single grant has exceeded \$10K, 2) has not published more than 5 research papers in the five years prior to the year of application.
- For novice investigator grants, other chief investigators may include fellows or registered trainees of ANZCA or FPM, other medical practitioners, healthcare professionals, scientists, research students, professional research personnel etc.

An experienced investigator must be named as the supervisor of the novice applicant(s). This investigator is capable of supervising the research, and is a fellow of ANZCA or FPM or another suitable supervisor with qualifications acceptable to the Research Committee. Novice investigators without access to appropriate supervisors may seek the advice of the chair of the ANZCA Research Committee.

An individual may only be named as a chief investigator or professional research person on a **maximum of two applications and/or applications** in any one year. This maximum will include any grant which was approved for multi-year funding in previous grant rounds and is still current – a multi-year grant will count as one active grant in each year that it is paid. This provision includes Project Grants, Novice Investigator Grants, the Simulation/Education Grant and the Academic Enhancement Grant. It does NOT include the Douglas Joseph and Lennard Travers Professorships, which may be considered and awarded in addition to two active grants or applications. If, however, an applicant wishes an unsuccessful professorship application to be considered for a project grant and has indicated this by ticking the box on the professorship application form then when this occurs it will count as one of the two allowed active grants or applications for that round. Fellows and registered trainees must be financial and in good standing with ANZCA or FPM.



Applicants should note that an application should only be made in one of the three main grant categories. Should a submission of the same application be made in two grant categories, the applicant may be contacted and requested to identify which one of the submissions they want to be considered.

Funding is available for research either wholly or partly conducted overseas by fellows and registered trainees under the following conditions:

- 1. A fellow must have a certified ongoing appointment in Australia, New Zealand, Hong Kong, Malaysia or Singapore.
- 2. A trainee must return to Australia, New Zealand, Hong Kong, Malaysia or Singapore to complete their training program or return to a guaranteed specialist appointment.
- 3. The researcher who is conducting research overseas must be a chief investigator.
- 4. The research proposed would normally be completed during the tenure of the grant.
- 5. The applicant must demonstrate in the application how the project will benefit research in Australia, New Zealand, Hong Kong, Malaysia and/or Singapore.

The investigation will have objectives of mutual interest to ANZCA, the recipient institution, and the investigator. Whilst the grants may specify financial support for individual professional research personnel, the institutions are responsible for administration of the grant.

The maximum amount available for a novice investigator grant is **\$A20,000** for one year. For administrative purposes, grants are awarded for the period of two calendar years following the year of the grant decision. The aim of the grant is to support research that is personally conducted by the novice investigator(s). That is, novice investigators are expected to be the main people who make preparations to commence the research, recruit the patients (if applicable), collect the data, establish a database, analyse the data, prepare the manuscript for publication and any other necessary activities, with the assistance of supervisors and other coinvestigators. Applicants are strongly encouraged to budget for research equipment, consumables, statistical advice and the like, and are strongly discouraged from budgeting for research nurse assistance. Full justification of the budget is required in the application.

Awards of grants will be announced by October of each year. No payment of the grant will be made until written communication accepting the offer and agreeing to the conditions, and a fully correct tax invoice, are received by the college, and all necessary clearances have been obtained. Funding is made available after 1 January in the following year. Liaison between ANZCA and other major funding bodies, both government and private, has been established to preclude duplication of support for identical proposals, as far as possible.

3 Procedure for evaluation of grant applications

The procedure for the evaluation of ANZCA grant applications is modelled on the NHMRC review process. Each application is assessed by three reviewers, one of whom is a spokesperson appointed from the Research Committee, who have been carefully chosen for their expertise in relation to the particular grant application.

To assess the scientific merit of the project and to determine the ability of the investigators to carry out the research, reviewers are requested to (i) rate the grant application and (ii) provide a written report.

Applications are rated on a seven-point scale (ranging from "outstanding" through to "poor") along a set of six research criteria (track record, scientific merit, originality, design/methods, feasibility and international competitiveness).

The written report addresses the scientific merit of the application (originality of hypothesis, substantiation of objective, soundness of research plan and methodology, and feasibility of the project), the track record of the applicant and the budget, and raises questions on areas of the research which require clarification, including problems and limitations likely to be encountered. The written report is forwarded to the applicant for comment. The applicant response is limited to three pages only with a minimum 12pt font and 1.5cm margin. Pages in excess of the three page limit will not be considered. Applicants may make minor amendments to their protocol provided these do not constitute substantive revisions to the entire protocol and study design. These amendments should be noted in the three page applicant response and does not require an amended copy of the protocol or study design to be resubmitted with the three page applicant response. If major changes are made, they will not be considered and the applicant will be advised that their



study should be resubmitted as a new project in the following year's grant round. If the applicant responses are not received by the due date, they will not be considered in the ranking of the application.

The Research Committee then meets and considers all the materials, as presented by the spokesperson. At this time, the spokesperson will highlight and comment on discrepancies between reviewers' numerical rankings and any inadequacies or inconsistencies in the reviewers written reports that should be considered. Such reports are then considered further by committee members before a final ranking is determined. Using a blinded voting system, each member allocates a score out of seven to the grant. The committee support officer tallies these scores and the final ranking of each grant application is determined. The Research Committee determines a rating score as a cut-off point, below which funding is not available. Those applications that are close to the cut-off score are considered in more detail. Applications identified to receive a grant are then further considered to determine the level of funding to be awarded.

Applicants will be notified of the outcome of their applications by October following the Research Committee meeting. Successful grant applicants will be expected to participate in reviewing ANZCA grant applications in future years as a condition of accepting the grant.

4 Confidentiality

Applications for grants are received by ANZCA on an "IN CONFIDENCE" basis. This means that the application document will not be released other than in compliance with any waiver or consent given by the applicant.

5 Applications to philanthropic trusts and foundations for research grants

Through the ANZCA Research Foundation, submissions will be made to the philanthropic sector from successful and highly ranked grant applications awarded through the ANZCA peer-reviewed grant process. It should be noted that approved grant funding through the peer-review process is not dependent on an application to the philanthropic sector. Final confirmation of ANZCA funding is subject to completion of any external funding applications for this project that are in progress. The aim of the foundation submitting applications to the philanthropic sector is to continue to increase the pool of available funds for future ANZCA research projects. If an ANZCA grant application is deemed a suitable match to the specific interests of a particular trust or foundation, approval of the CIA will be sought for a submission to be made. The CIA's input and advice would be sought during the application process. Acceptance of philanthropic trust or foundation support will usually require acknowledgement of that support in publication or presentation of research. This is in addition to the requirement to acknowledge any support provided by ANZCA.



C. INSTRUCTIONS TO APPLICANTS FOR COMPLETING FORM

1 Scientific project title

The scientific title will be used to identify the application at all times and should accurately describe the nature of the project. Use no more than 120 characters, including spaces. Additional characters will not be recorded.

2 (a) Chief investigators

Chief investigator A (CIA) **MUST** be a fellow or registered trainee of ANZCA or FPM. The CIA will be regarded as the contact person for the application and will, in all instances, be assumed to be acting on behalf of, and with the concurrence of, all chief investigators named in this section. An individual may only be named as a chief investigator or professional research person on a **maximum of two applications** in any one year. This maximum will include any grant which was approved for multi-year funding in previous grant rounds and is still current — a multi-year grant will count as one active grant in each year that it is paid. This provision includes Project Grants, Novice Investigator Grants, the Simulation/Education Grant, the Academic Enhancement Grant. It does NOT include the Douglas Joseph and Lennard Travers Professorships, which may be considered and awarded in addition to two active grants or applications. If, however, an applicant wishes an unsuccessful professorship application to be considered for a project grant and has indicated this by ticking the box on the professorship application form then when this occurs it will count as one of the two allowed active grants or applications for that round. Fellows and registered trainees must be financial and in good standing with ANZCA or FPM. (Add additional rows if necessary).

2 (b) Supervisor

An experienced investigator must be named as the supervisor of the novice applicant(s).

2 (c) Associate investigators

Associate investigators may be fellows, trainees, students or professional research personnel, who assist with the research or bring a particular skill (e.g. statistics, assays) to the team. They may or may not be fully conversant with all aspects of the work. Associate investigators do not receive salary support from ANZCA. It should be understood that associate investigators are generally intended to support the CI in specific aspects of the project. (Add additional rows if necessary).

3 Administering institution

The full name and full address of the institution responsible for administering the grant must appear here (e.g. Royal Prince Alfred Hospital, Missenden Road, Camperdown NSW 2030). While there may be instances where a research project is carried out in more than one location, there can be only one administering institution for each grant.

4 Institution(s) where research will be carried out

The name(s) of the department and name(s) and address(es) of the institution(s) where the proposed research will actually be undertaken is (are) required (e.g. Department of Anaesthesia, Royal Melbourne Hospital VIC 3050). (Add more rows if necessary).

5 Area of research

Specify anaesthesia (01), intensive care medicine (02), pain medicine (03), perioperative medicine (04) or other (05).

6 Keywords

Select up to five keywords or phrases from the list at the end of this guide. If appropriate words are not found in the list, applicants may add their own keywords in this section. The keywords will be used to identify suitable reviewers.

7 Lay description of research

Provide a brief description of the department and/or chief investigator(s), the achievements of the department and/or chief investigator(s), and the proposed research and its significance [suitable for a media release]. No more than one page is allowed. Please provide a lay title.



8 Grant synopsis

This information is used primarily to assign the application for review. This one page synopsis should describe the project and include a description of the aims, significance, context, objectives, methods and likely benefits of the research plan to the research group and the specialty.

<u>Requested non-reviewers:</u> Applicants preferring particular reviewers NOT to be approached to assess their application should attach a letter containing details of up to two non-requested non-reviewers. This letter should be attached to the original application only. These requests will be considered by the ANZCA Research Committee.

9 Research plan

Describe your research project in this section. Do not use more than seven pages in total, including references. Note that the minimum page margin is 2cm and the minimum font size is 10pt. Any additional pages will be removed prior to review.

You *must* use the headings listed below to describe your research.

- **9.1 Aims and significance:** Use this space exclusively to describe the broad aims and potential significance of the research. Hypotheses to be tested **must** be clearly stated.
- **9.2 Background:** Describe the significance of the broad area of research, the objectives of the research and the background including scientific aspects.
- **9.3 Methods:** Include details of the experimental design of the project and statistical methods to be used. Include sample size estimations.
- **9.4 Feasibility:** You must provide evidence that the proposed study can proceed in a timely fashion (i.e. recruitment of participants is assured, instruments have been developed and piloted).
- **9.5 References:** References should be provided within the <u>seven-page</u> count. Do not attach copies of any references. Include the title of the paper when citing references to other work.

Explanatory appendices are not permissible, nor is it appropriate to use such phrases as "refer to last year's application".

10 Professional research personnel

Professional research personnel may include nurses, scientists, research assistants and the like. Full-time students, fellows and trainees may not be included as professional research personnel.

Where appropriate, request for professional salaries should be in accordance with the official salary scales (such as NHMRC or nursing scales). Personnel should be named where known. Where the personnel are unknown the required salary should be determined on the basis of the appropriate scale. Requests for new senior research officer positions only must provide a curriculum vitae with the application. Include provision for payroll tax, workers' compensation insurance, superannuation or other institutional legal liabilities. Nursing awards may also be appropriate for calculating salaries.

Add more rows to any of the tables in this section if necessary and repeat for each named professional research person.

11 Budget items

Please note that applications for more than the maximum amount will be returned.

The budget must be constructed in Australian dollars. The maximum amount available for the novice investigator grant is \$A20,000 for one year only. Please note that institutional infrastructure costs are not paid by the college and should not be included as a budget item.

All items, listed in the space provided, are to be classified under these headings:

11.1 Personnel: Chief investigators and associate investigators may not receive salary from novice investigator grants. Requests for professional research personnel salaries including initial, promotion



and renewal requests, should be in accordance with the official NHMRC or MRC designations and salary scales, or appropriate nursing awards. Include provision for payroll tax, workers' compensation insurance, superannuation or other institutional legal liabilities and on-costs. **NOTE** that novice investigators are encouraged to undertake the research personally and so requests for salary support should be not be made or be very limited. See also item 5.

- 11.2 Equipment: Equipment requests should not include the type of apparatus normally provided from institutional funds (such as equipment used in the normal course of patient care); requests should cover only those items individually costing over \$A800, which are essential to the project. Where the cost of a specific item of equipment, plus related accessories, is in excess of \$A10,000, a firm written quotation based on current prices, not incorporating any component for customs duty, must be submitted. Applicants should ensure that the institution is prepared to meet all service costs in relation to equipment awarded.
- **11.3 Maintenance:** Enter those items not included within other categories, i.e. such items as equipment costing less than \$A800, consumables (under major headings), printed materials, microfilms, survey or field expenses and computing charges.
- 11.4 Other items: Include all other budget items here. Funding for travel or accommodation related to the presentation of study findings will not normally be funded.
 ANZCA will consider requests for funding for computer programming and preparation, and storage of data, but will not normally provide funds for the hire of computer time on a computer within the applicant's institution. Requests for funds for programming, preparation and data storage or the hire of external computer time must be fully justified. Funds for purchase of computer equipment and hire of computer personnel should be itemised under "Equipment" and "Personnel" respectively.
- 11.5 Justification of budget: It is important to note that realistic budgetary details for the whole period are provided, as no supplementary requests will be granted. A genuine assessment is therefore required for funding of the grant. Amounts requested should reflect the real needs of the project

12 Chief investigators

The Chief investigator(s) is (are) pivotal to the concept, design and conduct of the research, analysis of the data and/or preparation of the manuscripts. The chief investigator(s) is (are) fully conversant with all aspects of the research. Chief investigators **DO NOT** receive salary support from novice investigator grants.

Complete item 12 for each named chief investigator on this application. Start each chief investigator on a new page. Add rows to any of the items if necessary.

- **12.1 Contact details:** Please ensure that the details provided are complete and accurate, as this information will be used to communicate with the applicants.
- **12.2** Academic qualifications/awards: Provide details of academic qualifications including university degrees, specialist college diplomas, research or other awards or honours, the institution or body awarding the qualification and the year it was awarded.
- **12.3** *Current appointments*: List all current positions with the location (institution). Any changes during the lifetime of the grant relating require notification to ANZCA.
- 12.4 Previous appointments: Please list relevant previous positions held.
- **12.5** Anticipated absences during grant period: Should an investigator be absent during the project grant for a period in excess of two months, specify period of absence and give reason.

13 Supervisor

The supervisor assists, mentors and supervises the chief investigator(s). The supervisor may also participate more fully in the conduct of the research. Supervisors **DO NOT** receive salary support from novice investigator grants.



- **13.1 Contact details:** Please ensure that the details provided are complete and accurate, as this information will be used to communicate with the applicants.
- **13.2** Academic qualifications/awards: Provide details of academic qualifications including university degrees, specialist college diplomas, research or other awards or honours, the institution or body awarding the qualification and the year it was awarded.
- **13.3** *Current appointments*: List all current positions with the location (institution). Any changes during the lifetime of the grant relating require notification to ANZCA.
- **13.4** *Previous appointments:* Please list relevant previous positions held.
- **13.5** Anticipated absences during grant period: Should an investigator be absent during the project for a period in excess of two months, specify period of absence and give reason.
- **13.6 Details of supervision:** Include the contribution to the protocol and grant application, and the anticipated supervision and contribution to the conduct of the research.

14 Research support

The information sought on past, present and future support will assist ANZCA in determining the relationship between various projects and the personnel involved in them, including their time commitment. For this reason, applicants should list ALL projects for which their name is recorded as a chief investigator in each category. However, novice investigator applicants should note that <u>no single</u> grant awarded to them as a principle investigator should have exceeded \$10K.

In each category, indicate the year of application, funding body, title of grant, chief investigators, time commitment of each named investigator to each grant, period of support and funds for each year. In the column headed Publications, please identify separately, by number, each publication listed by a chief investigator which has resulted directly from each project (i.e. CIA-4: the 4th publication in the list of chief investigator A publications). Do not include the same publication more than once; include only original papers published or accepted for publication in refereed journals. Add more rows to each table if necessary.

- **14.1** Current/previous grant support: Include details of all currently/previously held grants, including those that have been awarded but have not yet commenced.
- **14.2** Requested grants: Include this application and any other grant requests relating to this program of research, as well as requests related to other research. Failure to disclose full information will result in the application being removed from any further consideration by ANZCA. If you apply to another funding agency after submitting this application, you must immediately notify ANZCA in writing.

15 Track record

15.1 Publications of chief investigators

List, and number consecutively, papers published, in press or finally accepted for publication in refereed journals, by any of the chief investigators (CIA, CIB, CIC, CID etc) in the five years prior to the year of application and in the year of application. The listing must indicate titles of papers, sequence of authors as shown in the paper, first and last pages, name, volume and date of journal; for recent papers not yet published, the date of final acceptance by the journal's editor is required. Quality as well as quantity of publications will be considered in the assessment of grant applications. Papers in refereed journals in which the chief investigator was not co-author, but which resulted from previous grants, should be listed at the end of that chief investigator's publications under the title 'Non-chief investigator papers' (e.g. papers with scientists or PhDs supported by the grant but in which the chief investigator was not an author). Documentary evidence of final acceptance by editors must be made available to ANZCA. Do not include abstracts or papers in preparation or submitted for publication but not yet finally accepted.

Asterisk (*) a maximum of five publications per chief investigator, which are considered to best reflect research contributions to date. Please include the citation index for these five papers and the impact factor of the journal in which they were published.



15.2 Other items for consideration

The chief investigators may list other items for track record consideration. For participation in multi-centre trials, the chief investigator must be the named principal site investigator. The name of the trial, the chief investigator(s) of the trial and the number of patients enrolled at the time of application must be included. For ongoing study in statistics/epidemiology/research methods, please state the institution, name and duration of the course. Other items may include membership of research ethics committees or grant committees, supervision of research students and the like. A maximum of one page for all investigators combined is permitted.

16 Clearance requirements

The Research Committee strongly encourages investigators to apply for ethics committee approval and submit the approvals to the College by **September 1**. If a grant is awarded, funding will not be released until all relevant clearances for the initial project have been received by ANZCA. ANZCA reserves the right to request full ethics committee submissions and correspondence as part of the granting process. In addition, ANZCA requires that clinical trials are pre-registered with the appropriate agency (e.g. NHMRC).

16.1 Research involving humans

- (i) Approval of the institutional ethics committee should be sought for ALL projects in humans. In the case of audit or routine testing, the ethics committee may not require a formal application, but will provide a covering letter that must be submitted to the college. Human research, in this context, includes research involving any human tissue, no matter what the source, and also includes research in which there is any intervention (physical or psychological) in the normal lives of humans. Projects supported by ANZCA are expected to conform with the general principles outlined in the NHMRC National statement on ethical conduct in human research (2007 updated 2018). (see NHMRC website).
- (ii) Under the various privacy laws, any form of experimentation involving humans (including epidemiological research) which uses personal information that is obtained from a national or state department or agency must be considered by a Human Research Ethics Committee (HREC).
- (iii) All projects involving the administration to humans of drugs, chemical agents or vaccines need to be considered by the relevant institutional Human Research Ethics Committee (HREC) to assess the appropriateness of their use. Clearance by the IEC is not only required for projects involving the use of imported substances, but also for projects involving the experimental use of locally produced therapeutic substances. ANZCA funds will not be provided unless appropriate clearance for the use of such substances is given. In the case of multi-centred trials, approval must be obtained from the HREC of each institution involved. In the case of drugs that are not approved for use in Australia, New Zealand, Hong Kong, Malaysia and/or Singapore, approval of the appropriate authority must be obtained before funds can be released.
- (iv) The official letter or statement of approval from the ethics committee must be forwarded to ANZCA no later than **September 1** each year, or before a tax invoice for funds is sent to the College.
- (v) ANZCA should have access, if required, to all information relating to ethical decisions arising from an application and the institutional response to the application. Provisional clearances will not be accepted.
- (vi) Under item 16.4, please summarise all the ethical implications of your research program. Do not use more than one page. Include the issues of privacy, and male-female ratios, and the cultural implications of your research (i.e. as they relate to aboriginal populations). Please refer to the NHMRC National statement on ethical conduct in human research 2007 (updated 2018). Note that it is not sufficient to state that "the NHMRC National statement on ethical conduct in human research will be observed". The research plan must include sufficient detail to enable the project to be fully assessed with respect to ethical issues by an independent ethics committee.



16.2 Research involving animals

- (i) Projects supported by ANZCA are expected to conform with the provisions and principles of the NHMRC *Australian code for the care and use of animals for scientific purposes 8th (Ed) 2013* or the New Zealand equivalent.
- (ii) ANZCA requires a statement from the relevant institutional animal experimentation ethics committee that any project involving animal experimentation has been reviewed and is approved by the Committee as complying with the code of practice. It is the applicant's responsibility to ensure that a copy of his or her project application is referred to the relevant institutional animal ethics committee; it also his or her responsibility to ensure that the completed approval form is forwarded to ANZCA, no later than **September 1** each year, or before the tax invoice for funds is sent to ANZCA.
- (iii) ANZCA should have access, if required, to all information relating to ethical decisions arising from an application and the institutional response to that application. Please identify the institutional animal ethics committee to which the application has been or will be referred. Provisional clearances will not be accepted.
- (iv) Applicants whose projects involve inbred strains of animals must take action to confirm that the genetic authenticity of the colony has been checked at appropriate intervals.
- (v) Ideally the health status of animals should be known and the colony regularly monitored for pathogens which may influence results in the investigator's particular area of research.
- (vi) Under item 16.5, please summarise all the ethical implications of your research program. Do not use more than one page. Include the issues related to the care and welfare of animals. Please refer to the NHMRC Australian code for the care and use of animals for scientific purposes 8th (Ed) 2013. Note that it is not sufficient to state that "the Australian code for the care and use of animals for scientific purposes will be observed". The research plan must include sufficient detail to enable the project to be fully assessed with respect to ethical issues by an independent animal ethics committee. Applications involving animals must contain adequate information to allow assessment of the ethical implications of experiments, particularly where significant pain and/or distress may be caused, where death is likely to occur, or where experiments in Category 4 are to be carried out.

16.3 Other clearances

- 16.3.1 Genetic manipulation of organisms: Applicants proposing to undertake research involving genetically modified organisms (GMO) must ensure that all the requirements of the Gene Technology Act 2000 and the Gene Technology Regulations 2014 have been met. Information on the Act and Regulations can be found on the Office of the Gene Technology Regulator website (www.ogtr.gov.au). Applicants should seek advice from their institutional biosafety committee (or equivalent) on the level of authorisation required for any GMO research. Clearances from an institutional biosafety committee (or equivalent) must be forwarded to ANZCA prior to release of grant monies.
- 16.3.2 Use of carcinogenic or highly toxic chemicals: Applicants whose projects involve the use and disposal of potent carcinogenic or other highly toxic chemicals must adhere to the National Occupational Health and Safety Commission guidelines, National Code of Practice for the Preparation of Material Safety Data Sheets 2nd edition. Further information is available from the Safe Work Australian website or equivalent. Such applicants must seek clearance to be forwarded to ANZCA prior to release of grant monies.
- 16.4 Conflict of Interest: Applicants are NOT required to complete the questionnaire but rather are requested to read and understand the ANZCA Conflict of Interest Policy (available at: http://www.anzca.edu.au/documents/conflict-of-interest-policy.pdf declare any conflicts, and state how such conflicts will be managed.



17 Certification by chief investigators, head of department and of institution

The application is invalid without the signature(s) of all the chief investigator(s). Grants will only be considered for support if the head of department/head of research committee certifies that the facilities available are appropriate to meet the needs of the application (e.g. adequately staffed and equipped laboratories/workshops, secretarial assistance, library resources, research/maintenance support including equipment maintenance, animal housing facilities etc).

When applicants are not formally attached to institutions, they should indicate whether they have access to appropriate facilities to undertake the research proposed.

ANZCA accepts as the head of institutions: the registrars of universities, the directors of independent institutes, and the managers/secretaries or medical superintendents of hospitals.

The head of the institution should note that Statements of Compliance with the NHMRC Australian code for the care and use of animals for scientific purposes 8th (Ed) 2013 and the NHMRC Statement on ethical conduct in human research 2007 (updated 2018) are required to be completed and submitted to ANZCA on request. The head of the institution is also required to certify that the institution has established administrative processes for assuring sound scientific practice in accordance with the NHMRC Australian code for the responsible conduct of research.

Checklist

Complete checklist and add to original application.



APPENDIX: KEY WORDS AND PHRASES FOR USE IN ANZCA GRANT APPLICATIONS

These key words are phrases are modified from those used by the journal Anesthesiology. If the key word or phrase that describes your work is not listed here, please list in the key word section of your application.

STEMS Key words/phrases

ACID-BASE CHEMISTRY

ADDICTION AND DRUG ABUSE Alcohol and alcoholism

AIRWAY and AIRWAY MANAGEMENT Airway and ETT assessment

Cervical spine movement

Endotracheal tubes

LMA, ILMA and other supraglottic airways

Laryngeal and pharyngeal function and anatomy

Aspiration

Laryngoscopy, direct

Laryngoscopy, flexible and rigid fiberoptic Lightwands and other Indirect methods

Lung isolation devices

Tracheostomy and cricothyroidotomy

AMBULATORY CARE Anaesthesia ventilators ANAESTHESIA MACHINES and CIRCUITS

Circuits and vaporizers

CO₂ absorbants and humidification

Waste gases and scavenging

ANAESTHETICS, GASES Nitrous oxide

Xenon

ANAESTHETICS, INHALATION Halothane, enflurane and isoflurane

> Desflurane Sevoflurane Non-Immobilizers

Other inhalation anaesthetics

Anaesthetic metabolism and degradation Carbon monoxide

Compound A and fluoride

MAC

Uptake and Distribution

ANAESTHETICS, INTRAVENOUS Barbiturates

Benzodiazepines (and antagonists)

Etomidate

Ketamine (and related drugs)

Butyrophenones

Alpha2 agonists (as sedatives)

Propofol

Computer controlled infusions

Opioids (as anaesthetic supplements)



ANAESTHETICS, LOCAL Bupivacaine, lignocaine or mepivacaine

Levobupivacaine

Ropivacaine

Encapsulated agents
Other local anaesthetics

Cardiotoxicity

Seizures

AUTONOMIC NERVOUS SYSTEM Baroreflexes

Catecholamines
Heart rate variability
Microneurography

Parasympathetic nervous system Sympathetic nervous system

AWARENESS and RECALL BLOOD COAGULATION

Enoxaparin and LMWH Heparin and protamine

Hirudin Fibrinolytics

Coagulation testing

DIC and other coagulopathies Platelets and platelet function Aminocaproic and tranexamic acid

Aprotinin

Recombinant factor VIIa

BLOOD TRANSFUSION, CONSERVATION and

SUBSTITUTES

Acute normovolemic hemodilution Cell saver and other salvage methods

Controlled hypotension

Haemoglobin-based oxygen carriers

Perfluorocarbons

CANCER and MALIGNANCY

Mutation and mutagenesis

CARDIOVASCULAR FUNCTION, DISEASE AND

MANAGEMENT

Cardiac electrophysiology and conduction

Cardiac rhythm and dysrhythmias

Cardiac smooth muscle and myocyte function (in

vitro)

Cardiopulmonary bypass

Circulatory arrest

Circulatory physiology and hemodynamics Congenital heart disease and surgery

Coronary circulation, myocardial ischemia and

infarction

Cardiac revascularization surgery (CABG etc) Myocardial preconditioning and protection

Reperfusion injury

Valvular heart disease and surgery

Ventricular function

Hypertension



Pacing, pacemakers and defibrillators

CARDIOVASCULAR DRUGS ACE inhibitors

Alpha2 agonists (CV Actions)

Angiotensin receptor blockers Beta-Adrenergic blockers

Beta-Agonists

Calcium channel blockers Other antiarrythmics

Norepinephrine and epinephrine (vasopressors)

Dopamine Dobutamine Fenoldepam

Phosphodiesterase inhibitors Amrinone and milrinone

Nitroprusside and nitroglycerin

Other vasopressors

Vasopressin Statins

CELL BIOLOGY AND PHYSIOLOGY Apoptosis

ATP and electron transport Calcium and calcium signaling Calcium dinding proteins

Gene expression Mitochondria

CHEMISTRY, BIOPHYSICS AND PHYSICS

COMPLICATIONS

Drug related Equipment related Procedure related

Compartment syndromes

Other

CRITICAL CARE Burns

Trauma care

DERMATOLOGY

ECONOMICS, OR MANAGEMENT and MANPOWER

EDUCATION

Trainee evaluation

Simulators

EMBOLI and EMBOLIC DISORDERS Amniotic fluid emboli

Fat and particulate emboli Pulmonary thromboembolism Venous and arterial gas emboli

ENDOCRINOLOGY Diabetes mellitus and insulin

Oestrogen

Pheochromocytoma



Renin and angiotensin

Atrial and brain natriuretic peptides

EPIDURAL and **SPINAL** Dural-puncture headache and blood patch

> Neurologic symptoms and injury Balance, posture and position sense

EQUIPMENT, TECHNOLOGY AND BIOENGINEERING

ETHICS

Animal care

Brain death and organ harvest Do Not Resuscitate orders Human studies and consent

EYE Eye injuries and blindness

Eye surgery

Intraocular pressure

FLUIDS, ELECTROLYTES and PLASMA SUBSTITUTES Hetastarch and pentastarch

Hypertonic saline

Osmolality and oncotic pressure

Serum sodium, potassium and other electrolytes

Lipid and intralipid

GASTROINTESTINAL PHYSIOLOGY and

PATHOPHYSIOLOGY

Gastric reflux and emptying

Intestinal motility Intestinal permeability Splanchnic circulation

GENDER

GENETICS and GENETIC DISORDERS

Sickle cell disease Genetic testing

Gene therapy

GERIATRICS

HISTORY and HUMOR

IMAGING

CT scanning

Magnetic Resonance Imaging and fMRI

PET scanning Ultrasound Xray

IMMUNOLOGY, INFLAMMATION and INFECTION

Allergy and snaphylaxis

Latex allergy

Histamine and antihistamines Steroid therapy (systemic)

Antibiotics

Systemic inflammatory response/disease

Cytokines and interleukins **Tumour Necrosis Factor**

Endotoxin and lipopolysaccarides Free radicals and scavengers

Leukocytes, lymphocytes and macrophages

Phagocytosis



Wound infection

Infection control (hand washing, antiseptics etc)

IONS AND ION CHANNELS Calcium and calcium channels

Potassium and potassium channels Sodium and sodium channels

Ion transport

KIDNEY and BLADDER PATHOPHYSIOLOGY Bladder function and urinary retention

Renal function testing Renal failure and dialysis

LIVER PHYSIOLOGY and PATHOPHYSIOLOGY Liver blood flow

Liver function tests

MALIGNANT HYPERTHERMIA Diagnostic testing

Genetics and genotyping

METABOLISM and NUTRITION Glucose and carbohydrate metabolism

Whole body metabolic rate

Obesity

Protein metabolism

MONITORING (CARDIORESPIRATORY)

Arterial catheters and pressure measurement

Blood volume, systemic Systolic pressure variation Cardiac output measurement Central venous catheterization

Doppler, other Doppler, precordial

Echocardiography, transoesophageal

Echocardiography, other Electrocardiography Expired gas analysis Gastric tonometry Oximetry, pulse

Oximetry, mixed venous

Oximetry, other

Pulmonary artery catheterization

MONITORING (CNS)

BIS and similar techniques

Electroencephalography (EEG) Evoked potentials, auditory Evoked potentials, motor Evoked potentials, other

Evoked potentials, somatosensory

Oximetry, jugular venous Oximetry, transcranial Transcranial Doppler



Depth of Anaesthesia Assessment

Antiemetics NAUSEA and VOMITING

NERVE BLOCKS Brachial and cervical plexus blocks

> Celiac plexus block Lower extremity blocks

Intravenous regional anaesthesia

Other regional techniques Nerve localization methods

Nerve injury and other complications Neostigmine and anticholinesterases

Neuromuscular junction Neuromuscular monitoring Nondepolarizing agents

Succinylcholine Myaesthenia Gravis

NEUROPHYSIOLOGY, BRAIN Blood brain barrier

Cerebral blood flow and volume

Cerebral oedema and intracranial hypertension

Cerebral ischemia and anoxia

Cerebral metabolism

Cerebral protection and preconditioning

Clinical neuroanaesthesia

Clinical neurology and neurologic examination

Head injury

Hippocampus and hppocampal electrophysiology Intracranial pressure and intracranial hypertension

Neuronal electrophysiology, other

NEUROPHYSIOLOGY, SPINAL CORD Dorsal root ganglia

Spinal cord electrophysiology

Spinal cord injury Spinal cord ischemia Spinal cord anatomy

Spinal cord protection and preconditioning

NEUROPHYSIOLOGY, PERIPHERAL NERVE Peripheral nerve injuries

Growth factors

Nerve conduction and EMG

Peripheral nerve electrophysiology

NEUROTRANSMISSION, TRANSMITTERS AND

RECEPTORS

Acetylcholine and receptors Adenosine and receptors

Adrenergic agents and receptors Cannabis and cannabinoid Receptors Capsaicin and thermal receptors

Dopamine and receptors



GABA and receptors Glutamate and receptors Glycine and receptors

Neurokinins and receptors

Nitric oxide and nitric oxide Synthase

Opioids and opioid receptors

Serotonin and serotonergic receptors Neurotransmitter release and reuptake

NEUROTRANSMISSION and SIGNAL TRANSDUCTION G-proteins

cAMP and cGMP Protein kinases

OBSTETRICAL ANESTHESIA

Caesarean section

Eclampsia and preeclampsia

Foetal monitoring and pathophysiology

Labour and delivery

Uterine and placental function

Uterine smooth muscle

OXYGEN and OXYGEN TRANSPORT

Hypoxia

Hemodilution (physiology)
Tissue oxygen tension (PtO2)

Hyperbaric oxygen

PAIN MANAGEMENT, CLINICAL

Acupuncture and accupressure

Chronic pain

Epidural and other steroid injections

Neuropathic pain and CRP Stellate ganglion blocks Lumbar sympathectomy Pain assessment techniques Patient controlled analgesia

Postoperative pain Headache (NOT PLPH)

Herpes zoster

Intraarticular analgesia

Intrapleural and intraperitoneal local snaesthetics

Phantom limb pain

Preemptive analgesia (clinical)
TENS and related methods
Spinal cord stimulation

Epiduroscopy

Radiofrequency lesions and neurolysis

PAIN-RELATED PHARMACOLOGY

Alpha 2 Agonists (analgesics) Aspirin and Acetominophen

Baclofen

COX2 antagonists

Gabapentin



Neostigmine

NMDA antagonists

NSAIDs Opioids

Opioid antagonists
Opioid tolerance

Tramadol Nitric oxide

PAIN PHYSIOLOGY, EXPERIMENTAL Incisional pain

Neuropathic pain Inflammatory pain

Pain assessment techniques

Pain mechanisms, central Pain mechanisms, peripheral Pain mechanisms, spinal

Pain models

Preemptive analgesia (experimental)

Visceral pain

PATIENT SAFETY and MEDICOLEGAL ISSUES Closed claims studies

Electrical and fire safety Medicolegal matters

PAEDIATRIC ANESTHESIA and PAEDIATRICS Neonatology

PHARMACOKINETICS and PHARMACODYNAMICS Pharmacogenetics

PHARMACOLOGY (GENERAL) Chronopharmacology/Chronobiology

Drug interactions Drug metabolism Cytochromes P450

Drug toxicity

Liposomes and microcapsule delivery systems

Osmotic pumps Stereoisomers

Transcutaneous delivery systems Transmucosal delivery systems

PHYSICIAN SAFETY

POSITIONING Antidepressants
POSTOPERATIVE CARE Anxiety and anxiolysis

PREOPERATIVE ASSESSMENT and CARE Psychologic, psychometric and behavioural

PROSTAGLANDINS and RELATED COMPOUNDS Testing

PSYCHOLOGY, PSYCHIATRY and BEHAVIOR Electroconvulsive Therapy (ECT)

RESPIRATORY DISORDERS and MANAGEMENT ARDS and lung injury

Aspiration pneumonia
Asthma and bronchospasm



Barotrauma

COPD

Extracorporeal membrane oxygenation

High frequency ventilation Mechanical ventilation Nitric oxide inhalation

Pneumonia and lung infections

PEEP and CPAP
Pulmonary oedema

Pulmonary function testing

Smoking

RESPIRATORY PHYSIOLOGY Alveolar macrophage function

Control of respiration

Gas exchange

Pulmonary blood flow Respiratory mechanics

Surfactant

Tracheal and bronchial smooth muscle

Ventilation-perfusion matching

RISK, OUTCOME and QUALITY MANAGEMENT Patient safety and satisfaction

Quality assurance and management

Morbidity and mortality Perioperative risk factors Automated record keeping

SEIZURES and ANTICONVULSANTS SHOCK AND RESUSCITATION

Cardiac arrest and CPR Sepsis and septic shock

Haemorrhagic and hypovolemic shock

SKELETAL MUSCLE

SLEEP and SLEEP DISORDERS

Circadian rhythm Sleep apnoea Sleep deprivation

STUDY DESIGN AND TECHNIQUES, LABORATORY Autoradiography

Brain slices

Histopathology and histochemistry

Cultured cells and tissues Laser Doppler Flowmetry

Microdialysis
Patch clamping

PCR

Receptor binding
Recombinant methods

Transgenic and knockout animals

Isobolographic analysis

Analytic chemistry (chromatography etc)

Molecular modeling



STUDY DESIGN AND TECHNIQUES, CLINICAL Clinical trial

Epidemiology

Mathematical modeling

Metaanalysis Statistics Survey

SURGERY, MISCELLANEOUS Laparoscopy

Neurosurgery Oral surgery

Orthopaedic surgery

Joint Replacement surgery

Otolaryngology Plastic surgery

Aortic aneurysm (abdominal and thoracic)

Carotid endarterectomy

Thoracic anaesthesia and surgery

Vascular surgery

Other surgical procedures

TEMPERATURE REGULATION and MANAGEMENT Hypothermia

Hyperthermia and fever

Shivering

TRANSPLANTATION Heart transplantation

Liver transplantation Lung transplantation Immunosuppressants

VASCULAR PHYSIOLOGY Rheology and viscosity

Endothelium Endothelin

Leukocyte adhesion

Nitric oxide, nitric oxide synthase and EDRF

Selectins

Vascular smooth muscle Vascular growth factors Vascular electrophysiology

Microcirculation