



Research Endorsement Guidelines

About these guidelines

These Research Endorsement Guidelines apply to those involved in allergy research, who seek to submit a study for endorsement by the National Allergy Centre of Excellence (NACE).

The NACE, supported by the Australian Government, is a national collaboration of drug, food, insect and respiratory allergy researchers. Hosted at the Murdoch Children's Research Institute in Melbourne, the NACE is building the tools and resources needed to accelerate allergy research to save lives, improve health and reduce the burden of allergic disease.

NACE is conducting a number of strategic projects across its four Pillars as part of its key deliverables for the Australian Government, referred to herein as 'NACE projects'.

In addition to its own projects, the NACE – as Australia's peak allergy research body – will look to consider endorsement of research from the wider NACE membership.

Through the endorsement of research, the NACE aims to:

- Encourage collaboration across the NACE membership
- Promote the development of research that focuses on the key issues in allergy
- Advocate for a high standard of research design, conduct, analysis and reporting
- Strengthen the reputation of the NACE for delivering and endorsing high quality research
- Enhance the attractiveness of completed studies to journal editors

- Enhance the possibility of success and competitiveness when applying for grants.

Purpose

The purpose of the Endorsement Guidelines is to set out the process and requirements for NACE endorsement and the ongoing responsibilities of the investigators of endorsed research.

Applicants

- Members of the NACE Streams
- External and international collaborators – at least one member of the research team must be a NACE member
- Higher degree students – their primary supervisor must be a NACE member

Authority and responsibility

These Guidelines are issued under the authority of the Director of the NACE. The Director and Allergy Research Hub Coordinator are responsible for the content and review of this guideline.

Endorsement Guidelines

1. Eligibility for NACE endorsement

To be eligible for NACE endorsement, the study must meet the following criteria:

- Meet the requirements of the *National Statement on Ethical Conduct in Human Research*.
- Align with the NACE vision, mission and values and be related to drug, food, insect or respiratory allergic disease.
- Demonstrate a commitment to meeting study regulatory requirements, including, where appropriate, one or more of the following: *the NHMRC Australian Code for the Responsible Conduct for Research (2018)*; *ICH Guideline for Good Clinical Practice*; *the Australian Clinical Trial Handbook*; SPIRIT guidelines for protocol development, CONSORT and equivalent statements for reporting of trial results.
- Demonstrate scientific quality and include sufficient preliminary evidence to support the proposed research, this may include the results of systematic reviews, surveys and/or observational studies of current practices. A sufficient sample size to demonstrate plausible effect and sound statistical methods must also be shown, where applicable.
- Demonstrate evidence of feasibility, including funding sources.
- Align with core NACE research – the study will not be endorsed if it potentially compromises another NACE project. If there is a concern, there needs to be an agreed plan between the relevant parties to ensure that it is managed.
- Potential for implementation of the results into clinical practice or policy including an implementation plan.
- Demonstrate planned or current ongoing consumer involvement in the study.

2. Application process for endorsement

All studies must be submitted to the NACE Executive Committee, plus relevant Stream Advisory Group Co-chairs and CAG members as required for review and approval. Endorsement will only be considered if the project meets the Eligibility Criteria and the NACE conditions for endorsement.

i. What should be included in the application for endorsement?

- NACE Application for Endorsement form (Appendix 1)
- A cover letter explaining the reason you are seeking NACE endorsement
- Protocol or any other relevant documents to support the application

The above process needs to be completed for:

- Studies that have been developed with other external groups and networks
- New project ideas

For new project ideas, it is the preference of the NACE to be notified early in the development phase to enable collaboration throughout the study.

All applications will be overseen by the NACE Management Office and the NACE Executive Committee. All related documentation will be securely managed and confidentiality maintained.

ii. Where do I submit the application?

- Submit to the NACE Management Team at: nace@mcri.edu.au or phone 03 9936 7522
- Applications will be accepted on a rolling basis, from February 1 through to December 1. This specific time period will ensure that the NACE is able to deliver timely reviews and responses to applications.

iii. What is the review process?

The NACE Executive Committee will review all submitted applications and may call upon the services of other NACE Stream Advisory Group Co-chairs and CAG members for content expertise as relevant. Only those applications with the majority vote will be approved for endorsement. All reviewers will be required to complete a NACE Confidentiality Undertaking. Those who have an established Conflict of Interest (CoI) will not be involved in the review or decision-making (voting) process of a submission.

iv. How will I be informed of the decision on my application for NACE endorsement?

You will be emailed the outcome from the NACE Management Office approximately three weeks after the meeting at which your application was

discussed. In some instances, the NACE may request additional information as part of the review process before making a final decision.

For endorsed projects, the NACE Endorsement Letter will outline the conditions that must be upheld for the endorsement to be ongoing. Successful applicants are required to sign the letter and return it to the NACE Management Office. This document serves as a permanent record of the endorsement agreement between both parties.

If a project has not been endorsed you may submit an appeal in writing to the NACE Management Office, who will coordinate the necessary actions between you and the NACE Executive Committee.

3. Conditions of endorsement

The conditions outlined below apply for the duration of any study endorsed. It is the responsibility of the Investigator to ensure these conditions are fulfilled.

- Investigators oversee and carry out the endorsed study in compliance with appropriate regulatory requirements – this includes ethics committees.
- NACE policies and processes are adhered to – Publication Guidelines, Conflict of Interest and reporting obligations.

i. Reporting to the NACE

The Principal Investigator (PI) or Study Coordinator (SC) of the study is expected to give progress reports to the NACE at two timepoints annually – six months and 12 months post the endorsement date.

Six monthly report

An informal update via email sent to nace@mcri.edu.au. The email subject line should clearly indicate the study name and reporting timeframe e.g. ABC study – 6 monthly report.

If there are any queries, the relevant parties will contact the PI/SC.

12 month (annual) report

A formal progress report is to be submitted and sent to nace@mcri.edu.au. A copy of the HREC Progress Report (annual) for the study will meet the NACE reporting requirements.

Progress updates may also be required for general communications on the NACE website and to the Department of Health. This would be facilitated by the NACE Communications Manager.

Endorsed projects will be listed on the NACE website as part of the [Allergy Studies Directory](#). A temporary embargo process will be adhered to by the NACE Management Office if requested and appropriate, but it is expected that endorsed studies will be listed on the NACE website and information accessible to clinicians, researchers and the public.

ii. Consumer engagement

The NACE recognises meaningful consumer involvement provides the opportunity for different lived experiences and perspectives to shape and inform decisions on research activities. The NACE aims to have the inclusion of consumer opinion in research across the project cycle – i.e. design, implementation, evaluation, reporting and advocacy.

Consumer engagement is encouraged for NACE endorsed projects and may be facilitated via access to the NACE [Consumer Engagement Register](#). Contact the NACE Management Office for inquiries at nace@mcri.edu.au or phone 03 9936 7522

iii. Acknowledgements and publications

All NACE endorsed studies will be required to have the NACE recognised in the acknowledgements section of any journal publications or conference oral or poster presentations.

The approved text is:

The [study name] is endorsed by the National Allergy Centre of Excellence (NACE). The NACE is Australia's peak allergy research body supported by the Australian Government and hosted at the Murdoch Children's Research Institute.

Please refer to the NACE Publication Guidelines for guidance on the recording of affiliations and acknowledgements related to the NACE.

Any use of the NACE logo or other branding material must first be approved by the NACE Communications Manager.

4. Managing competing studies

The NACE will not endorse a study if it compromises another core NACE project.

The NACE Executive Committee will consult with you if your application appears to compete with an already endorsed study. In this situation a clearly documented plan on how the proposed study and any overlaps would be managed will be required for NACE endorsement.

5. Withdrawal of endorsement

The NACE reserves the right to withdraw its endorsement. This may be for any of the following reasons:

- Research misconduct
- Failure to gain ethics approval
- Failure to gain funding
- Failure to recruit at a sufficient rate, where applicable
- Failure to adhere to the conditions of endorsement as outlined by the NACE

The NACE will consult with you if the withdrawal of endorsement is under consideration.

6. Endorsement of submissions to public inquiries

The NACE Research Endorsement Guidelines may also be extended to endorse submissions to relevant public inquiries by NACE members. Draft submissions should be emailed as early as possible to

nace@mcri.edu.au with supporting information regarding the purpose of the submission and how it aligns with the NACE vision, mission and values.

The review and approval of submissions for endorsement will be the responsibility of the NACE Executive Committee and relevant Stream Advisory Group Co-chairs and CAG members (as required). Any use of the NACE logo or other branding material must first be approved by the NACE Communications Manager.

7. References

Australian clinical trial handbook – *Guidance on conducting clinical trials in Australia using ‘unapproved’ Therapeutic goods (2021)*

National Health and Medical Research Council, *Australian Code for the Responsible Conduct of Research (2018)*

Australian Clinical Trials Alliance (ACTA) – *Trial Endorsement and Review: Guidance for CTNs (2019)*

ICH Guideline for Good Clinical Practice (2018)

NACE Publication Guidelines (2023)

National Statement on Ethical Conduct in Human Research (2023)

Paediatric Research in Emergency Departments International Collaborative (PREDICT), *Project Endorsement Process (2023)*

Version	Changes	Date approved	Next review date
1.0	Original version	15 Dec 2023	15 Nov 2025
1.1	Donor acknowledgment update, annual reporting requirements	13 Feb 2024	13 Feb 2026