



TRIAL ENDORSEMENT POLICY

Version 1.0

The Australasian Nursing and Midwifery Clinical Trials Network acknowledges the contribution of ACTA to the development of trial endorsement processes within our network (Reference: Trial Endorsement and Review: Guidance for CTNs)

DOCUMENT REVIEW

Timeframe for Review: Every two years, or earlier if required.

VERSION CONTROL

Version	Date Approved	Title	Document Authorisation	Next Review
1.0	03/03/2023	Trial Endorsement Policy	Australasian Nursing and Midwifery Clinical Trials Network Executive Committee	03/03/2025

TABLE OF CONTENTS

1.	THE AUSTRALASIAN NURSING AND MIDWIFERY CLINICAL TRIALS NETWORK.....	4
2.	PURPOSE	4
3.	APPLICATION PROCESS	4
3.1.	CATEGORIES OF TRIAL ENDORSEMENT	4
3.2.	APPLICANTS	5
3.3.	THE APPLICATION	5
4.	REVIEW PROCESS.....	5
4.1.	REVIEWERS.....	5
4.2.	CONFLICT OF INTEREST	6
4.3.	CONFIDENTIALITY	6
4.4.	DEADLINES AND TIMELINES FOR THE ENDORSEMENT PROCESS	6
4.5.	COMMUNICATIONS, DISPUTE AND APPEALS PROCESS.....	6
4.6.	THE RIGHT TO RETRACT ENDORSEMENT.....	6
5.	CONDITIONS OF ENDORSEMENT.....	6
5.1.	TRIAL PUBLICATION AND AUTHORSHIP CONSIDERATIONS.....	7
5.2.	TRIAL FUNDING source CONSIDERATIONS	7
6.	REVIEW OF THE TRIAL ENDORSEMENT POLICY	7
7.	APPENDIX A: INITIAL APPLICATION FOR ENDORSEMENT FORM VIA THE AUSTRALASIAN NURSING AND MIDWIFERY CLINICAL TRIALS NETWORK WEBSITE QUALTRICS LINK	8
8.	APPENDIX B: FLOW CHART ON PROCESS FOR ANMCTN TRIAL ENDORSEMENT	11

1. THE AUSTRALASIAN NURSING AND MIDWIFERY CLINICAL TRIALS NETWORK

The Australasian Nursing and Midwifery Clinical Trials Network (ANMCTN) is a network of institutions, academic researchers and industry collaborators who have come together across Australia and New Zealand. The aim of the ANMCTN is to establish and sustain a coordinated nursing and midwifery clinical research network focused on facilitating high quality, high impact clinical research to improve patient outcomes, advance clinical care through contribution to the evidence base, and improve the efficiency of the healthcare system.

2. PURPOSE

The purpose of this document is to outline the criteria to be used by the Australasian Nursing and Midwifery Clinical Trials Network Scientific Committee in determining whether a proposed trial is suitable for endorsement. This process is to:

- Improve the track record of the delivery of nursing and midwifery led studies.
- Ensure that endorsement promotes a high standard of clinical trial design, conduct, analysis and reporting.
- Increase the competitiveness of grant applications of endorsed nursing and midwifery clinical trials and enhance the chances of success and competitiveness on grant applications.
- Strengthen the brand and reputation of the ANMCTN and its endorsed clinical trials.
- Encourage investigators to use the resources of the ANMCTN office for their clinical trials.
- Benefit investigators (especially early career investigators) through the ANMCTN track record, in competitive funding applications.

3. APPLICATION PROCESS

3.1. CATEGORIES OF TRIAL ENDORSEMENT

The ANMCTN will consider endorsement of nationally competitive scale grant applications which provides research on models of care to improve preventative health measures and/or optimise health outcomes for individuals, communities and society. These trials or studies may be multidisciplinary in nature but require nursing or midwifery to be central to the leadership, conduct and focus of the research.

The ANMCTN will consider protocols related to grant applications or published protocols which funding has been sourced for the study.

The ANMCTN will consider fellowships or other investigator-centric grants where there is a significant proportion of the proposed research program dedicated to trials or studies that meet the requirements listed in paragraph one on this section.

No ANMCTN support or resources are provided to coordinate the trial.

It is not in the remit of ANMCTN endorsement to provide a full review or deep feedback and advice on endorsement applications.

The Australasian Nursing and Midwifery Clinical Trials Network Chair of the Scientific Committee (Chair of the Scientific Committee) will decide on eligibility of trials for endorsement, considering appropriateness of research questions, methodology, public interest and competing priorities among investigators and studies.

3.2. APPLICANTS

Applications will only be considered from members of the ANMCTN who are listed as an investigator on the grant application.

External collaborators will be considered at the discretion of the Chair of the Scientific Committee, if a member of the ANMCTN is listed as the lead investigator in the protocol and where applicable, listed as an intended author on the main manuscript.

3.3. THE APPLICATION

Applications for ANMCTN endorsement must be made using the Qualtrics link on the Research - Endorsed Trials page of the ANMCTN website, refer to **Appendix A: Initial Application for Endorsement** via the ANMCTN Website Qualtrics Link.

The Chair of the Scientific Committee will undertake an initial application screening against the eligibility criteria. Applications which do not meet the required criteria will be returned to the applicants.

4. REVIEW PROCESS

The review process for trial endorsement flow chart is provided in **Appendix B: Flow Chart on Process for ANMCTN Trial Endorsement**. This process is also posted on the ANMCTN website for applicants to access if required.

Applications submitted for endorsement will be assigned to and reviewed by a minimum of two (2) members of the Australasian Nursing and Midwifery Clinical Trials Network Scientific Committee. The Chair of the Scientific Committee will source reviewers from the Scientific Committee and Executive Committee to undertake the peer review.

All reviewers will be asked to provide comments and recommendations on the scientific rigour, assessment criteria, significance and feasibility of the proposed trial application in Qualtrics.

Following individual reviews, the reviewers and the Chair of the Scientific Committee will discuss the application and determine if the application is endorsed, or if further development is required.

The Chair of the Scientific Committee will provide consolidated feedback on the application to the Executive Officer of the ANMCTN, for the Executive Officer to inform the applicant in writing, the outcome of the peer review.

There will be no charge for endorsement reviews for members of the ANMCTN.

The Chair of the Scientific Committee will report on the endorsement or non-endorsement of applications to the Executive Committee.

4.1. REVIEWERS

The Chair of the Scientific Committee will supervise the review of each submitted trial and will be responsible for assigning/sourcing appropriate reviewers, with the help of the rest of the Scientific Committee and/or Executive Committee if required.

Members of the Scientific Committee will have clinical expertise in either nursing and midwifery led trials or be members of the ANMCTN who have clinical expertise in the topic of interest, or external collaborators with clinical expertise in the topic of interest. Where applicable, the Chair of the Scientific Committee may consider review by a consumer or a consumer representative.

Reviewers will provide feedback on the application via Qualtrics which may include questions, comments and suggestions for improvements.

4.2. CONFLICT OF INTEREST

Members of the Scientific Committee who have an established conflict of interest will not be involved in either the supervision, assessment or the conduct of a review of an endorsement application.

If the Chair of the Scientific Committee is conflicted, the Scientific Committee will appoint a delegate Chair.

Individuals who are invited to review trials must not be involved in the design or conduct of the study.

4.3. CONFIDENTIALITY

Expert reviewers who are provided with the application and protocol, will treat the protocol as confidential and will not forward the protocol to peers. If there are any concerns about the application, including any conflict of interest, this should be raised in the first instance, with the Chair of the Scientific Committee.

4.4. DEADLINES AND TIMELINES FOR THE ENDORSEMENT PROCESS

The ANMCTN endorsement application form in Qualtrics, provides a field to provide application deadline and processing timeframes.

The minimum turnaround time for endorsement review is 21 days from receipt of an application through Qualtrics.

4.5. COMMUNICATIONS, DISPUTE AND APPEALS PROCESS

Applicants will be notified whether they have been successful or unsuccessful in their endorsement application in a timely manner, in writing.

Applications can be resubmitted at the discretion of the Chair of the Scientific Committee.

4.6. THE RIGHT TO RETRACT ENDORSEMENT

The ANMCTN Scientific Committee and Executive Committee reserve the right to retract endorsement. This may result from the following:

- Research misconduct.
- Failure to obtain ethics approval.
- Failure to obtain funding.
- Failure to recruit at a sufficient rate.
- Failure to adhere to the requirements of endorsement.

The Chief Investigator of each study will be contacted on a periodic basis regarding their progress.

5. CONDITIONS OF ENDORSEMENT

Investigators may not indicate in a grant application that the study is endorsed by ANMCTN unless formal written endorsement has been provided by the ANMCTN Scientific Committee.

Notification will include the conditions of endorsement and require an acceptance of the following conditions by the applicant for endorsement to be effective:

- Studies must be conducted in compliance with codes of research conduct such as the Australian Code for the Responsible Conduct of Research produced by the NHMRC.
- Clinical trials must be registered with a recognised trial registry authority, preferably the Australian and New Zealand Clinical Trials Registry.
- A study progress report will be submitted to the ANMCTN Scientific Committee yearly upon request.
- The ANMCTN reserves the right to withdraw endorsement at any stage should the study not adequately progress, if any criteria are met as listed under Section 4.6, or if irresolvable conflicts of interest arise.

5.1. TRIAL PUBLICATION AND AUTHORSHIP CONSIDERATIONS

Primary research generated from the study, is to include the following text within the acknowledgment setting of the manuscript, "*The author acknowledges the time contribution of the Australasian Nursing and Midwifery Clinical Trials Network in reviewing and endorsing the [Name of Trial] on which this manuscript is based.*".

5.2. TRIAL FUNDING SOURCE CONSIDERATIONS

The ANMCTN will consider trials endorsement for investigator-initiated trials only. Funding or in-kind contribution to support these trials may come from public funding, industry funding or a combination.

6. REVIEW OF THE TRIAL ENDORSEMENT POLICY

The ANMCTN Trial Endorsement Policy will be reviewed biannually at the first meeting of the calendar year of the Executive Committee meeting. Changes to the Trial Endorsement Policy will be tabled at an Executive Committee Meeting for endorsement.

Endorsed: 03/03/2023

The Australasian Nursing and Midwifery Clinical Trials Executive Committee

7. APPENDIX A: INITIAL APPLICATION FOR ENDORSEMENT FORM VIA THE AUSTRALASIAN NURSING AND MIDWIFERY CLINICAL TRIALS NETWORK WEBSITE QUALTRICS LINK

Australasian Nursing and Midwifery Clinical Trials Network



Trial Endorsement Review
APPLICATION FORM

The Australasian Nursing and Midwifery Clinical Trials Network (ANMCTN) was established in 2020 to bring together academic institutions to effectively facilitate and support nurse or midwife led clinical research and the translation of evidence into practice. We provide the platform to accelerate growth in nurse and midwife led trials across Australasia to help build collaboration among nursing and midwifery clinical researchers, providing opportunities for sharing resources, training and expertise, and strengthening applications for nationally competitive research funding.

The ANMCTN needs the information requested below to undertake an assessment of your application for endorsement. Please ensure you submit your application for endorsement at least 21 days before the grant submission deadline.

All information provided will be treated with the strictest confidence.

For further information please refer to the ANMCTN **Trial Endorsement Policy**.

If you have any questions regarding the completion of this form, please email us on anmctn@unisa.edu.au

APPLICANT DETAILS
Lead Investigator details
Name
Position
Department
Hospital / University / Institution
Contact Email
Contact Phone
ANMCTN Membership Status

- Institutional Founding Member
- Individual Member
- Non-Member

If the Non-Member category is ticked, the applicant will get the following message displayed.

Unfortunately applications will only be considered from members of ANMCTN who are listed as an investigator on the protocol. ANMCTN membership is free, please click [here](#) to join.

APPLICATION DETAILS

Project Title

Name of Grant Scheme

Name of Grant Funder

Please upload a copy of the Grant Guidelines - please combine all documents to one pdf prior to uploading

Please provide a list of the Assessment Criteria as outlined in the guidelines and the associated weightings.

Please use as many fields as required and ensure your weightings total 100%.

Please provide a pdf copy of your grant application - please combine all documents to one pdf prior to uploading.

Synopsis (up to 1000 characters)

Application for endorsement submission date:

Grant application due date

CERTIFY AND SUBMIT APPLICATION

The ANMCTN will aim provide feedback and/or endorsement of your application by {ReviewDueDate}.

A copy of the Australasian Nursing and Midwifery Clinical Trials Network Trial Endorsement Policy can be found *HERE*.

I certify and confirm that:

I consent, on behalf of all the parties, to this application being referred to third parties for confidential evaluation and assessment purposes.

The listed parties are responsible for the authorship and intellectual content of this application and have appropriately cited sources and acknowledged significant contributions to this application.

To the best of my knowledge, all details provided in this application form and in any supporting documents are true and complete.

I confirm that, in the event of successful endorsement, I take responsibility for compliance with all the conditions of endorsement as outlined in the Australasian Nursing and Midwifery Clinical Trials Network Trial Endorsement Policy.

Signed

Date

Thank you for submitting your application.

We will be in touch shortly.

If you have any questions regarding the completion of this form, please telephone Head Office on +61 8 8302 2698 or anmctn@unisa.edu.au

The Australasian Nursing and Midwifery Clinical Trials Network



8. APPENDIX B: FLOW CHART ON PROCESS FOR ANMCTN TRIAL ENDORSEMENT

Process for ANMCTN Trial Endorsement

