ANZMUSC
AUSTRALIA & NEW ZEALAND MUSCULOSKELETAL CLINICAL TRIALS NETWORK
NHMRC CENTRE OF RESEARCH EXCELLENCE

# MEMBERSHIP PACK

## ANZMUSC Executive Committee

**Professor Rachelle Buchbinder**
**Professor Ian Harris AM**
**Professor Chris Maher**
**Professor Jane Latimer**
**Professor Sally Green**
**Associate Professor Will Taylor**
**Dr Bethan Richards**
**Ms Ornella Clavisi**
**Dr Sam Whittle**

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# 1. INTRODUCTION

The Australia & New Zealand Musculoskeletal (ANZMUSC) Clinical Trials Network is a collaboration of accomplished clinical researchers, health professionals and consumers who are working to improve the evidence base of musculoskeletal health through the conduct of high quality, multicentre randomised controlled trials and related research. The ANZMUSC Clinical Trials Network was established in 2015 with an inaugural summit held in Melbourne in April 2015 attended by 100 stakeholders. At this summit, ANZMUSC's vision, mission and values were debated and agreed by consensus. ANZMUSC has broad expertise in physiotherapy, rheumatology, orthopaedic surgery and community health among others. It has the support of leading musculoskeletal consumer organisations including MOVE muscle, bone & joint health (formally Arthritis and Osteoporosis Victoria), Arthritis Australia as well as the support of policy advisors, government and insurance groups with an interest in these conditions.

## 1.1 Our Vision

To optimise musculoskeletal health through high quality, collaborative clinical research.

## 1.2 Our Mission

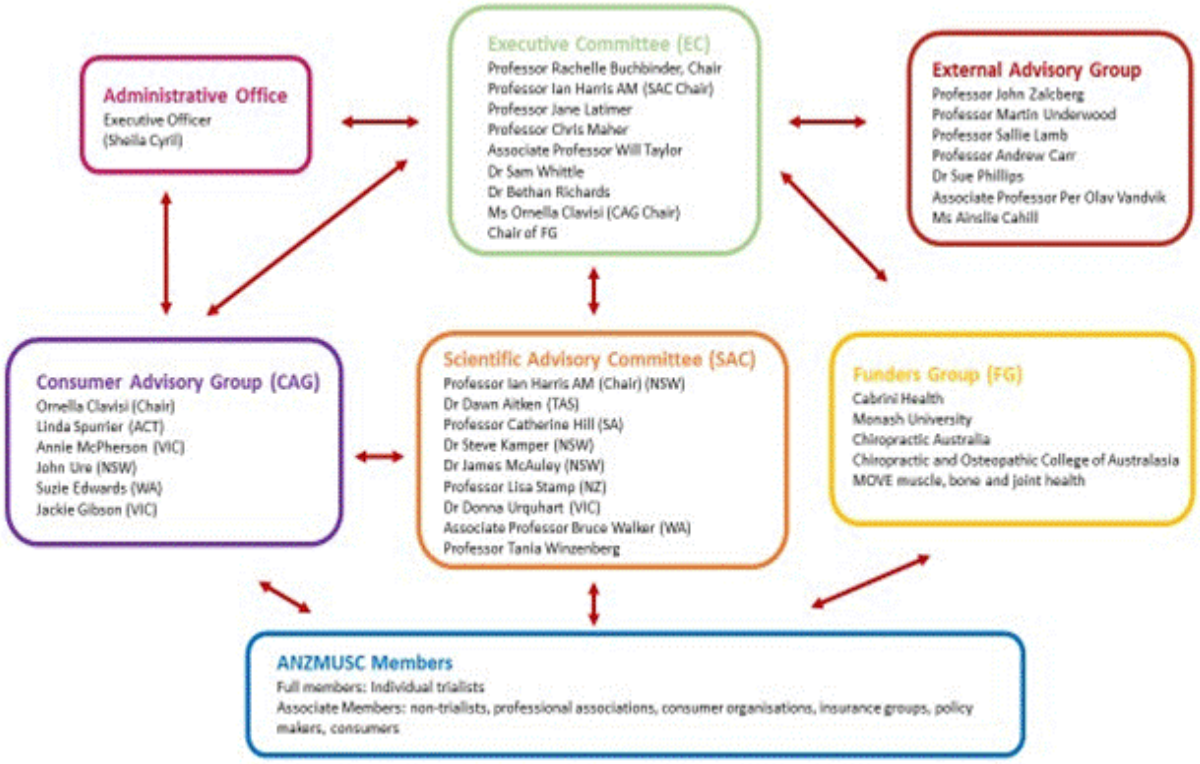
- To identify the key clinical research questions relevant to musculoskeletal health.
- To improve the scientific quality of musculoskeletal research and its translation into policy and practice.
- To facilitate and endorse clinical research based on scientific quality and potential to improve health outcomes.
- Advocate for musculoskeletal research support.
- Foster collaboration between research groups and stakeholders.
- Advance the understanding of research through mentoring and education.

## 1.3 Our Values

- Visionary
- Altruistic (generous, benevolent)
- Scientific integrity
- Transparency

- Equity
- Mutual respect
- Health consumer centred
- Ethical

## 2. ANZMUSC Governance and Structure




The ANZMUSC structure comprises various groups and committees all of which are governed by the Executive Committee. The Executive Committee (EC) also known as the working group has overall responsibility for coordinating the activities of the ANZMUSC Clinical Trials Network including the functioning of the other advisory groups. Apart from its supervisory role in the administration of ANZMUSC, the EC also finalises the scientific review process of clinical trials submitted for endorsement to the ANZMUSC Clinical Trials Network. The EC is multidisciplinary in nature with members having backgrounds in orthopaedics, rheumatology, physiotherapy, clinical epidemiology and musculoskeletal research. The EC is chaired by Prof Rachelle Buchbinder who is the Director of the Monash Department of Clinical Epidemiology at Cabrini Hospital, and Professor, Department of Epidemiology and Preventive Medicine at Monash University.

The Scientific Advisory Committee (SAC) has been established in order to provide scientific and methodological advice on proposals that have been submitted for presentation at an ANZMUSC Scientific Meeting Open Forum and to review research proposals submitted for endorsement to the ANZMUSC. The committee will be responsible for providing feedback

and opinions about the merit of proposed trials and assisting trial development. The committee will also perform other evaluations including PhD application reviews for partner organisations as needed. Similar to the EC, the SAC comprises members hailing from various disciplines including rheumatology, orthopaedics, psychology, physiotherapy, chiropractic and general practice. The SAC is chaired by Prof Ian Harris, who is Professor of Orthopaedic Surgery at the University of New South Wales. The SAC is accountable to the ANZMUSC EC and is represented on the EC by the SAC Chair.

The role of the Consumer Advisory Group (CAG) is to provide a mechanism for consumer input on ANZMUSC clinical trials by reviewing clinical trial proposals for ANZMUSC endorsement from the consumers' perspective. The CAG is also responsible for providing advice and guidance to ANZMUSC members regarding consumer research priorities and issues of importance to consumers with musculoskeletal conditions. The CAG comprises consumer representatives from all six states of Australia who bring with them a wealth of experience in musculoskeletal disorders as well as community engagement. The activities of CAG are convened by the CAG Chair Ms Ornella Clavisi, Musculoskeletal Research Manager at MOVE *muscle, bone and joint health*, the new voice of Arthritis and Osteoporosis Victoria. The CAG is accountable to the ANZMUSC EC and is represented on the EC by the CAG Chair.

The External Advisory Group is responsible for knowledge translation and capacity building to achieve the implementation of the expected clinical trial outcomes and provide expert advice on research directions. The role of the Funders group is to financially support the various activities of the ANZMUSC Clinical Trials Network.

## 3. ANZMUSC Membership Policy

There are two categories of ANZMUSC membership – Full members and Associate members. Both categories are expected to abide by ANZMUSC's vision, mission and values i.e. to *optimise musculoskeletal health through high quality, collaborative clinical research*, and agree to participate as able in ANZMUSC research activities, including the review of trial proposals and serving on committees as requested.

### 3.1 Full Members

Full membership is only open to individuals who are clinical trial researchers based in Australia or New Zealand currently active in investigator-initiated musculoskeletal clinical trials research (e.g. have a trial registered on the ANZCTR) and have published at least one peer-reviewed clinical trial. Full Members have the right to nominate candidates for election to the Board of Directors and vote at meetings of members.

### 3.2 Associate Members

Associate membership is open to individuals who are non-clinical trial researchers and those who do not fulfil the criteria for full membership (e.g. have a trial registered on the ANZCTR; published at least one peer-reviewed clinical trial). This category also includes professional organisations, consumer organisations and individual consumers, who support ANZMUSC's mission and vision and wish to be actively engaged within ANZMUSC. A detailed description of associate members can be found below.

#### 3.2.1 Professional Associations/Societies

Professional associations or societies who have members who are clinicians and/or researchers in the field of musculoskeletal health; and demonstrate an ongoing commitment to ANZMUSC's vision to *optimise musculoskeletal health through high quality, collaborative clinical research.*

### 3.2.2 Professional Individuals

Non-clinical trial researchers, early career researchers who do not yet qualify for full membership, international associates not currently working in Australia or New Zealand, health insurers and policy makers who are interested in high quality clinical trials for musculoskeletal conditions and demonstrate an ongoing commitment to ANZMUSC's vision to *optimise musculoskeletal health through high quality, collaborative clinical research*.

### 3.2.3 Consumer Organisations

Consumer organisations who actively engage with consumers living with one or more musculoskeletal conditions; who advocate for high quality research and clinical trials to improve the lives of consumers; and demonstrate an ongoing commitment to ANZMUSC's vision to *optimise musculoskeletal health through high quality, collaborative clinical research.*

### 3.2.4 Consumer (individuals)

Individual consumers who are living with one or more musculoskeletal conditions; who understand and support high quality research and clinical trials to improve the lives of consumers; and demonstrate an ongoing commitment to ANZMUSC's vision to *optimise musculoskeletal health through high quality, collaborative clinical research.*

## 3.3 Benefits of Full & Associate Membership

- Participate in, develop and or conduct world-class multi-centre investigator-initiated musculoskeletal clinical trials and other clinical research with the support of the ANZMUSC Clinical Trial Network.
- Have an active role in ensuring an effective collective voice for those suffering musculoskeletal disorders, and for the Australian and New Zealand clinicians and researchers working to optimise musculoskeletal health.
- Help to shape healthcare and research policy that directly impacts musculoskeletal research.

- A ‘seat at the table’ to ensure that your area of musculoskeletal interest is well represented providing the opportunity to influence and help drive ANZMUSC’s advocacy for the sector.
- Nominate colleagues from within your field to contribute to ANZMUSC Roundtables/Working Groups/Standing Committees to provide further opportunity to ensure that issues impacting your field of research are communicated effectively to governments and key stakeholders.
- Active promotion of the activities and achievements of you/your research group through ANZMUSC publications, member profiles on the ANZMUSC website and news listings on major publications and trial results.
- Receive policy alerts & e-newsletters, provide comments to inform ANZMUSC submissions and rapid responses, and receive invitations to member forums/events.

### 3.4 Membership fees

ANZMUSC Clinical Trial Network Membership is currently free. ANZMUSC reserves the right to charge membership fees for full members in the future. Associate members will be free of charge. Paying members will be entitled to a discounted registration fee at ANZMUSC meetings and events.

### 3.5 Member details

The contact details of both full and associate members will be entered into the ANZMUSC member database to assist members to identify potential collaborators or expertise and allow contact to be made. This database is secure and accessible only to members and regulated by a person nominated by the ANZMUSC Executive. Annual database audits are performed to ensure the input of the most updated member details and maintenance of database security. Members can email sheilacyril@cabrini.com.au to update the ANZMUSC team of any changes to their contact details or if they would like to withdraw their membership.

All members are added to the ANZMUSC mailing list for periodic updates. This is a closed email list with access restricted from the general public and commercial entities. The list is regulated by a person nominated by the ANZMUSC Executive and is audited at least once per year to maintain security.

# 4. ENDORSEMENT

## 4.1 Rationale

One of the key roles of ANZMUSC is to facilitate high quality clinical trials in the area of musculoskeletal conditions. The principal ways of doing this are to provide an advisory service for ANZMUSC members planning a trial (e.g. design & conduct of the trial, fund-raising, dissemination of results/implementation plan, engagement with stakeholders, consumer input) and to endorse high quality clinical trials that are being conducted by its members.

Endorsement means more than a 'rubber-stamp' of approval. It means any funding applications can use the ANZMUSC brand to indicate the study is of high scientific merit. It includes a process of ensuring high quality trial design and conduct but also confers a degree of 'ownership' to ANZMUSC members. Trials endorsed by ANZMUSC will need to be prospectively registered, conform to best practice guidelines (e.g. those from the equator network) and regulatory standards (e.g. ICH GCP, National Statement), require regular reporting to ANZMUSC and presentation of updates at the annual scientific meeting, and agreement to abide by the ANZMUSC authorship policy. ANZMUSC endorsement will provide benefits to both parties: ANZMUSC will gain importance in the research community to enable it to act as a peak body for musculoskeletal research and to achieve its goals. Trialists and their trials will benefit from methodological input, and ANZMUSC endorsement may assist with gaining community and professional acceptance, funding, and implementation.

## 4.2 Process of ANZMUSC Endorsement

The following process is required for all studies seeking ANZMUSC endorsement.

1. All applicants will apply to present their trial in an open forum at the ANZMUSC Annual Scientific meeting. Only proposals that fit ANZMUSC criteria will be accepted. Discussion of each proposal will be led by a reviewer appointed by the Scientific Committee, who will have reviewed the proposal beforehand.
2. If agreed to at the ANZMUSC meeting (following the open forum), the application is submitted to the Scientific Committee.

3. The application will be reviewed by 2 research reviewers and 1 consumer and a decision made by the committee whether to recommend endorsement, enable further development of the proposed trial to meet endorsement standards or reject.
4. The applicant is notified of the decision within 4 weeks of submission.
5. Projects marked for development will need to be revised and resubmitted to the committee for endorsement. This process is expected to involve interaction between the investigators and the Scientific Committee prior to resubmission in order to increase the likelihood of endorsement.
6. The final decision will be made by the Executive committee, usually on the basis of the recommendation of the Scientific Committee.

### 4.3 Criteria for ANZMUSC Endorsement

Only clinical trials in the field of musculoskeletal health will be considered. Trials that fulfil all ANZMUSC endorsement criteria will be prioritised.

1. Must satisfy an ANZMUSC research priority (reflecting important disease burden and an important evidence or evidence-practice gap). Until priority setting is complete, this will be at the discretion of the Executive Committee.
2. Must present evidence confirming that the research question is one that the clinical and/or consumer community want answered.
3. Must be of high quality (e.g. minimising risk of bias, ensuring appropriate power) and include an economic evaluation and process measures where relevant. “High quality” assessment will be at the discretion of the SAC.
4. Must be feasible (reflecting cost, logistics, track record and likely recruitment rate)
5. Must show strong potential to change practice and/or policy (reflecting academic impact, implementation, and generalisability).
6. Must be multicentre, or have the potential to become multicentre (recruitment at ≥1 site, investigators from ≥ 1 site) (to encourage collaboration, increase power and increase implementation of findings). Single site studies will be considered with justification.
7. At least 1 member of the investigative team must be a registered full member of the ANZMUSC Clinical Trials Network.

Investigators will be required to prospectively register the trial, publish the protocol and statistical analysis plan, make plans for implementation of the results and making trial data

publicly available, abide by the ANZMUSC publications policy, misconduct policy, and agree to provide annual updates at the ANZMUSC meetings. A short annual review template will be created for this purpose and annual updates may be presented by any investigator associated with the trial.

## 5. PUBLICATION POLICY

The ANZMUSC Publication Policy has been adapted from other established network groups. This policy has been developed in alignment with the endorsement principles of ANZMUSC. The purpose of endorsement by ANZMUSC is to indicate that the research question is important, the study design and methodology is of the highest scientific quality, and the results are likely to make a significant impact on practice and/or policy. Endorsement from ANZMUSC therefore comes with a set of requirements to protect the ANZMUSC brand.

- Manuscripts should comply with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals published by the International Committee of Medical Journal Editors and with guidelines for reporting of specific study types such as CONSORT and STROBE.
- Study manuscripts or theses reporting results obtained from ANZMUSC-endorsed studies (including ANZMUSC endorsed sub-studies) or from post-hoc analyses of an ANZMUSC-endorsed study, require review and endorsement by the ANZMUSC Executive prior to submission for publication or examination.
- All manuscripts that describe aspects of the conduct (e.g. protocols or statistical analysis plans) or secondary discussion papers of an ANZMUSC-endorsed study must be submitted for review and endorsed by the ANZMUSC Executive prior to submission to a journal for publication. This review may be undertaken by the Chair or Chair-delegate who will determine whether external review is required or whether the Chair or Chair-delegate should recommend endorsement to the Executive without external review.
- All other manuscripts that are proposed to be published in the name of the group study investigators or the management committee of an ANZMUSC-endorsed study (e.g. editorials or review articles) must be submitted for review and endorsed by the ANZMUSC Executive prior to submission to a journal for publication. Manuscripts proposed to be published on behalf of individuals that do not include study data do not require ANZMUSC endorsement.
- The default authorship for all ANZMUSC-endorsed study manuscripts is:
    - "The X Study Investigators and the ANZMUSC Clinical Trials Network" or

    - "Listed individuals, the X Study investigators and the ANZMUSC Clinical Trials Network" or
    - "Listed individuals, the X Study investigators, the X Institution and the ANZMUSC Clinical Trials Network". Other arrangements may be acceptable but must be approved by the ANZMUSC Executive.
- The default listing of individuals on lists of investigators or study sub-committees is the Chair followed by alphabetical order, unless prospectively agreed by the management committee and approved by the ANZMUSC Chair or Chair-delegate.
- Identification of contributors on study sub-committees, such as steering, data and safety monitoring, statistical and writing committees will be listed in accordance with the respective journal's policy. The nomination and appointment of people to these sub-committees will be determined by the study management committee. These subcommittees will comprise of a Chair and other members with the appropriate expertise.
- All hospitals/centres that participated in the study must be listed in the manuscript or on-line appendix. Individuals who contributed to the conduct of the study at each participating hospital must be listed, and where possible, as collaborators. It is usually the case that this will comprise one or more site Research Coordinator(s) and the Site Investigator(s). Variations to this requirement may be proposed by journals and may be acceptable with approval from the ANZMUSC Chair or Chair-delegate. Participating institutions will be listed alphabetically; individual(s) will be listed alphabetically within each institution, unless agreed by the Management Committee or otherwise as required by the journal.
- Manuscripts submitted to ANZMUSC for publication endorsement will be reviewed by at least two people, at least one of whom is a voting member of the ANZMUSC All other aspects of the review process for manuscripts are as described for study proposal endorsements above.
- Prior to submission to a journal, a copy of the final manuscript must be sent or made available to all participating sites. Principal Investigators should be given a reasonable period of time to voice any major concerns to the writing committee.
- The outcome of submission of an ANZMUSC-endorsed manuscript to a journal must be disclosed to the ANZMUSC Executive Office. Where submission to an alternative

journal is planned the name of the new target journal must be provided to the ANZMUSC Executive Office. If an ANZMUSC-endorsed manuscript is neither submitted for publication, nor accepted at any journal for publication, this must be disclosed to the ANZMUSC Executive Office. A copy of all ANZMUSC-endorsed manuscripts that are published must be sent to the ANZMUSC Executive Office.

- The ANZMUSC Executive reserves the right to withdraw endorsement for publication at any stage of the submission for publication process should the scientific quality of a manuscript be deemed substandard or if conflicts cannot be resolved.
- Studies not endorsed by ANZMUSC, 'non ANZMUSC' studies should not mention ANZMUSC in applications for funding. The Principal Investigator(s) own the study data. Publications and presentations of these studies must make no reference to ANZMUSC, except for acknowledgments where appropriate.

# 6. SCIENTIFIC MEETINGS

The ANZMUSC Executive Committee conducts scientific meetings each year. ANZMUSC Annual Scientific Meetings (ASM) aim to provide a forum for research related discussions and particularly the development of study proposals. Other key aspects of these conferences include educational sessions and development of position papers and operating procedures relating to intensive care research.

ANZMUSC Members are encouraged to submit study proposals or discussion papers for presentation at the ANZMUSC ASM. A closing date for submission of presentations will apply. All submissions should be sent to the ANZMUSC Executive Officer or the meeting convener. The EC will decide which submissions are accepted for presentation.

Presentation of a protocol or proposal at the ANZMUSC conference does not alone confer endorsement of the study by the ANZMUSC. The proposal needs to be submitted for review and subject to the process of endorsement as outlined in the earlier section. Studies that have been developed or completed through the ANZMUSC email list or conferences, but not officially endorsed as ANZMUSC studies, are independent of the ANZMUSC ('non-ANZMUSC' studies).

## 6.1 Review of a trial proposal submitted at the ANZMUSC ASM

Each trial proposal will have two reviewers and each reviewer will have 2-3 minutes to present their comments. The following criteria will be used to review trial proposals.

**Rationale:** Does the trial address an important disease burden and/or evidence or evidence-practice gap (i.e. size of problem, if previous trials why is another one needed)? Is the trial well justified? Do you have any suggestions for improvement?

**Aim/s:** Is the research question clear (i.e. all components of the PICO included)? Do you have any suggestions for improvement?

**Study design:** Comment on the study design including any potential sources of bias. Do you have any suggestions for improvement?

**Participants:** Were the selection criteria clear and appropriate?

**Interventions:** Are the interventions well justified and clear?

**Outcome measurement:** Comment on the baseline and outcome measures proposed and the timing of assessment. Do they include all patient-relevant outcomes? Do you have any suggestions?

**Sample size and data analysis:** Comment on the sample size calculations and analysis plan.

**Feasibility:** Comment on the trial feasibility and whether or not you think pilot data are needed. Do you think the recruitment rate is reasonable? Do you have suggestions for improvements?

**Implementation:** If the trial indicates a clinical practice or other change is desirable, do you foresee any important barriers to implementation? Does the trial have the potential to change practice and/or policy?