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

ANZMUSC Scientific and Operational Support Request (red font is example, please replace with your specific request)

Chief investigator (name, email and phone)	Prof. John Smith, j.smith@wus.org.au, 0305 678 567
Contact person (name, email and phone)	Prof. John Smith, j.smith@wus.org.au, 0305 678 567
Study title	ANZAC (Australian and New Zealand Anterior Cruciate surgery trial)
Type of support requested (underline one)	1. research proposal development (e.g sample size estimation for a stepped wedge trial) 2. one-off complimentary support for existing ANZMUSC trial (e.g advice about setting up a DSMB) 3. ongoing service to support existing ANZMUSC trial (e.g performing the statistical analysis of a trial) *NB: 1 – 2 are free (conditional on availability of ANZMUSC funds), 3 is billed on a cost-recovery basis*

A list of possible scientific and operational support services is provided below;

Project management

- Development of project plans, templates and tools
- Development of monitoring processes
- Budget management
- Project reporting processes
- Project Committee management
- Assist with protocol development
- Source and manage study intervention

Clinical operations

- Site feasibility
- Site selection
- Site initiation
- Site management
- Site monitoring
- Project essential documents

Data Management

- Determine appropriate database platform
- Data Management Plan
- Set up project specific database screens
- Program edit checks for all studies
- Implement randomisation function on all studies
- Implement inventory management function as required
- Provide status reporting for each project
- Ongoing data review
- Coding of required data
- Finalise data for database lock

Statistics

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- Protocol review
- Randomisation
- Assistance with database and CRF setup
- DSMB/interim analyses
- Statistical analysis plan
- Programming and validation
- Preparation of reports and peer-reviewed publications

1. REQUEST FOR COMPLIMENTARY SUPPORT FOR RESEARCH PROPOSAL DEVELOPMENT

NB: this is meant to provide brief time-limited support, typically less than one week of staff time.

Type of operational and scientific support requested	Advice from an experienced biostatistician on design of a trial to implement the RCGP OA clinical practice guideline across GP clinics in Victoria. We were thinking of a stepped wedge design but we have not done a trial like this before.

(1) Please list the confirmed investigators

Investigator	**Role**	**Skills/experience**

(2) Please write a paragraph describing project. Include a couple of sentences to explain how the proposal is consistent with ANZMUSC endorsement criteria.

ANZMUSC endorsement criteria	
1	Must satisfy an ANZMUSC research priority (reflecting important disease burden and an important evidence or evidence-practice gap).
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. “
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 (>1 site of recruitment and investigators from >1 institute); to encourage collaboration, increase power and increase implementation of findings. Single site studies of sufficient size and quality may be considered for endorsement if sufficient justification is provided.
7	At least 1 member of the investigative team must be a registered full member of the ANZMUSC Clinical Trials Group.
General comments: (<150 words)	

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2. REQUEST FOR COMPLIMENTARY ONE-OFF SUPPORT FOR EXISTING ANZMUSC TRIAL

NB: this is meant to provide brief time-limited support, typically less than one week of staff time. It is not meant to back-fill an existing trial budget. The requests should relate to more complex issues or issues that could not reasonably have been foreseen at trial commencement.

Type of operational and scientific support requested	ANZAC is a placebo-controlled trial of anterior cruciate ligament repair with two year follow-up. The lead site is in Adelaide and there are 8 sites across Australia and New Zealand. The trial is due to commence in 2-3 months time. The trial has already been approved by ANZMUSC and has NHMRC project grant funding. We have not yet registered the trial or published a protocol. As this is our first placebo surgical trial we would like an experienced project manager to review our trial protocol and SOPs to ensure that the trial complies with regulatory and best practice standards. We would like also specific advice about whether we should convene a Data Safety Monitoring Board and if so how we would go about this. As this is a multi-centre trial we would also like to ask advice about auditing sites to assess trial fidelity. Lastly we would like to know what level of GCP training our treating surgeons should complete.

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3. REQUEST FOR ONGOING SUPPORT FOR EXISTING ANZMUSC TRIAL

NB: this will provide ongoing support on a cost-recovery basis.

Type of operational and scientific support requested	ANZAC is a placebo-controlled trial of anterior cruciate ligament repair with two year follow-up. The lead site is in Adelaide and there are 8 sites across Australia and New Zealand. The trial completed follow-up early this year, the data have been double checked and cleaned and the database locked. We would like to engage an experienced biostatistician to review the statistical analysis plan and conduct the statistical analyses. Originally this was going to be done by a colleague in the department but they have moved overseas and are too busy in their new job. We confirm that we have funds to meet the cost