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

Scientific and operational support

Preamble
ANZMUSC will be using some of our NHMRC funding to provide complimentary scientific and operational support to its members. These services will be provided by staff from the George Institute for Global Health which has a very strong track record in completing clinical trials to the highest standards. The services include project management, clinical operations, data management and statistics. A full list of the services is provided in the support request form.

The scheme provides (i) support for research proposal development for a new trial or (ii) support for an existing ANZMUSC trial. In both cases this is meant to provide brief time-limited support, typically less than one week of staff time. In the case of existing trials it is not meant to back-fill an existing trial budget. An example for an idea for a new trial would be a request for advice from an experienced biostatistician on use of a stepped wedge design for an implementation trial. Examples for an existing ANZMUSC trial include advice about how to audit sites to assess trial fidelity in a multi-centre trial or how to set up a Data Safety Monitoring Board.

We will also use some funds to conduct a scoping review of ANZMUSC trials so that we can better understand what central services and training we need to provide in future years. We will be contacting the spokesperson for each trial shortly. While we are mainly conducting this review with an eye to the future we are sure that existing ANZMUSC trials that are reviewed will benefit from the advice of an experienced project manager. This service will also be provided to ANZMUSC trials at no cost.

Lastly we are also able to direct you to the George Institute if you wanted ongoing support on a cost-recovery basis. This would be charged to the trial and not covered by ANZMUSC.

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. participate in scoping review of ANZMUSC trials 2. research proposal development (e.g sample size estimation for a stepped wedge trial) 3. one-off complimentary support for existing ANZMUSC trial (e.g advice about setting up a DSMB) 4. ongoing service to support existing ANZMUSC trial (e.g performing the statistical analysis of a trial) NB: 1 – 3 are free (conditional on availability of ANZMUSC funds),4 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

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    - 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
    - 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

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1. VOLUNTEER TO PARTICIPATE IN SCOPING REVIEW OF ANZMUSC TRIALS

ANZMUSC is aiming to develop core capacity that will underpin all research projects (e.g. a common set of standard case report forms, training in GCP, operational advice at trial set-up).

In 2018 we want to undertake a scoping review of ANZMUSC trials so that we can better understand what central services and training we need to provide in future years. The goal is to ensure ANZMUSC trials are conducted to the highest possible scientific standards and also that operational services are provided in a highly efficient manner.

While we are mainly conducting this review with an eye to the future we are sure that existing ANZMUSC trials that are reviewed will benefit from the advice of an experienced project manager. **This service will be provided to ANZMUSC trials at no cost.**

Please complete the box below if you want to volunteer.

Status of trial	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 enrolled the first participant 12 months ago and we have recruited about 10% of the sample.

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2. 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 exerienced 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 llike 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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3. 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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4. 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 of this service.