Policy Guidelines for Research Endorsement
May 2022

Document Review

Timeframe for review: Every three years, or earlier if required
Document authorisation: GMA Steering Committee
Document implementation: GMA Scientific Advisory Committee and GMA Operations Committee
Document maintenance: GMA Operations Committee

Revision History

Version Date	Pages revised	Brief Explanation of Revision
15 March 2022	All	Initial draft
6 May 2022	2,4, 5	Added logo; update for funding sources; conflict of interest; endorsement process for core methods

1. Purpose

The Growing Minds Australia (GMA) Steering Committee (GMA SC) works with the GMA Scientific Advisory Committee (GMA SAC), and Community Engagement Advisory Committee (GMA CEAC), to oversee GMA's research activities, providing strategic direction with regards to the co-ordination, facilitation, endorsement, and monitoring of collaborative child and youth mental health research, and to establish the Growing Minds Australia Clinical Trials Network (GMACTN).

The purpose of this document is to outline the process and criteria to be used by the GMA SAC in determining whether or not a research proposal is suitable for endorsement by GMA. This process will ensure that endorsement is synonymous with a consistently high standard of study design, conduct, analysis, publication, and dissemination, with optimal research capacity and study feasibility. Maintenance of high quality ensures that GMA endorsement of a research study and its outputs is considered as 'gold standard'. This document applies to both applicants and GMA members acting on behalf of GMA. It outlines the prerequisites, review process, and conditions of endorsement for clinical and non-clinical studies approved by GMA. Endorsement is contingent upon the research study steering committee fulfilling and maintaining these terms as outlined below.

2. Endorsement and submission of external grant applications

Investigators may not indicate in an external grant application that the study is endorsed by GMA unless formal written endorsement has been provided by the GMA SAC. Indication in a grant application of submission (or intention to submit) for GMA endorsement requires the final approval and sign-off from the GMA SAC.

3. Conditions for endorsement

A new study proposal is developed by a group of individuals who form the study steering / management committee. The research project/study must be clinical research (not necessarily a clinical trial), or a project using routinely collected mental health data primarily related to child and youth mental health. Study designs where the sole component is a survey will not be considered. Programs of research proposing more than one individual study will not be endorsed collectively. Each component of a proposed program must be submitted separately for endorsement.

Unless exceptional circumstances exist, the GMA SAC will only endorse studies prospectively, that is before they commence recruitment or data request/extraction/linkage at Australasian sites. Presentation of studies at an early stage of development is strongly encouraged.

Achieving co-funding is preferred for any GMA endorsed research study. Co-funding sources are generally limited to MRFF Eligible Organisations at the discretion of the GMA SAC and GMA SC (see MRFF website here: https://www.nhmrc.gov.au/funding/manage-your-funding/mrff-eligible-organisations)

3.1 Clinical research study proposals

For clinical research study proposals, it is recommended that applicants utilise the guidelines outlined in the Standard Protocol Items: Recommendations for International Trials (SPIRIT) 2013 Statement. Specifically, the following criteria should be apparent within the study protocol:

Introduction

- Background and rationale, describing theory and/or justification for undertaking the trial
- Specific research questions, objectives, and/or any prespecified hypotheses
- Trial design, including type of trial, allocation ratio, and framework

Methods

Participants, interventions, and outcomes

- Study settings, including references to where a list of study sites can be obtained
- Eligibility criteria (inclusion and exclusion) for participants and study centres (if applicable)
- Intervention(s), including criteria for discontinuing or modifying interventions (if applicable), and any relevant concomitant care and interventions that are permitted or prohibited during the trial
- Primary, secondary, and other outcomes including the specific measurement variable(s), analysis metric, aggregation method, and time point for each outcome (explanation of clinical relevance of chosen outcome is strongly recommended)
- Participant timeline (schematic diagram is highly recommended)
- Sample size, including recruitment strategy for achieving adequate enrolment to reach target sample size

Methods

Assignment of interventions (for controlled trials)

- Sequence generation method, and list of any factors for stratification
- Allocation concealment mechanism
- Blinding (if applicable), including circumstances under which unblinding is permissible and the procedure for revealing a participant's allocated intervention during the trial

Data collection, management, and analysis

- Data collection methods, including any related process(es) to promote data quality, a description of study instruments and the reliability and validity of study instruments (if known)
- Data management
- Data Linkage plans where relevant

• Statistical methods for analysing primary, secondary, and other outcomes, any additional analyses, and any methods to handle missing data

Monitoring

• Data monitoring, including composition of data monitoring committee or an explanation of why such a committee is not needed, and description of who will have access to any interim results and make the final decision to terminate the project

• Harms, including management plans for solicited and spontaneously reported adverse events and other unintended effects

• Auditing procedures and frequency, and whether the process will be independent from project investigator(s) and/or sponsor(s)

Ethics and dissemination

• Research ethics approval

• Protocol amendments, including plans for communicating any important protocol modifications

• Consent or assent

• Patient confidentiality

• Declarations of interest

• Access to data, and data linkage including disclosure of any confidentiality agreements that limit such access for investigators

• Ancillary and post-trial care provisions (if any)

• Dissemination policy with regards to participants, healthcare professionals, the public, and other relevant groups

3.2 Research study proposals

For research study proposals that involve the use of routinely-collected health data, it is recommended that the guidelines outlined in the Reporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement 2 are followed. Specifically, the following criteria should be apparent within the study protocol.

Introduction

• Background and rationale, describing the justification for undertaking the project

• Specific objectives and/or any prespecified hypotheses

Methods

Participants, interventions, and outcomes

• Study design and setting, including the setting, locations, and any relevant dates (including periods of recruitment, exposure, follow-up, and data collection)

• Participants, including methods of study population selection. Where codes or algorithms will be used to identify subjects, any validation studies of such codes or algorithms should be referenced.

If the project will involve linkage of databases, a flow diagram or other schematic representation is recommended to demonstrate the data linkage process and the number of anticipated individuals with linked data at each stage

• Variables, including a complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers. If these cannot be reported, an explanation should be provided

• Statistical methods, including those used to control for confounders, examination of any subgroups and interactions, and those that will address missing data. If applicable, an explanation of how loss to follow-up (for Cohort studies) or how matching of cases and controls (for Case-control studies) will be addressed

Data collection, management, and analysis

• Data sources and methods of assessment for each variable of interest

• Any efforts to address potential sources of bias should be described
• Explanation of how the study size was determined
• Explanation of how quantitative variables will be handled in the analysis including (if applicable) which groupings will be chosen and why
• Data linkage plans where relevant

Monitoring

• Data access and cleaning methods, including the extent to which investigators will have access to the database population used to create the study population
• Linkage and methods of linkage quality evaluation, including a statement of whether the project will include personal-level, institutional level, or other data linkage across two or more databases

Ethics and dissemination

• Research ethics approval
• Protocol amendments, including plans for communicating any important protocol modifications
• Consent or assent
• Patient confidentiality
• Declarations of interest
• Access to data, and data linkage including disclosure of any confidentiality agreements that limit such access for investigators
• Dissemination policy with regards to participants, healthcare professionals, the public, and other relevant groups.

4. Endorsement process

Applications are invited with a structured application form made available for each endorsement process. Proposals will be endorsed on a weighted adjudication of criteria made specific for each round of endorsement activity. In general endorsement can be expected to require the address of:

- Scientific merit;
- Evidence that amount of funding applied for is used to seed advancement with further funding;
- Evidence of collaboration including early-mid career researcher strategy;
- Demonstration that study accords with the mission, vision and values of GMA and its Terms of Reference;
- Inclusion of health economics;
- Inclusion of stakeholder consultation/community engagement process;
- Evidence of the extent this study avoids duplication with existing studies;
- Coverage of feasibility for the study;
- A plan detailing how collaboration and stakeholder consultation will overcome the barriers that have traditionally limited trial size and quality in the area.

The specific criteria to be addressed are outlined in the GMA Application for Endorsement Form. Applications for endorsement must be made using this form.

If the study is proposed to be performed in conjunction with a different clinical trials network (such as MAGNET), this must be made clear in the application.

Review Process Detail

• The GMA SAC chairs will supervise the review of each submitted study. Members of GMA SAC who have an established conflict of interest will not be involved in either the supervision or the conduct of a review of an endorsement application. If the Chair is conflicted, the GMA SAC will appoint an external delegate as specified in the Terms of Reference.

• Competing studies endorsed by the same network may compromise trial recruitment and risk the reputation of the network and therefore the CTN brand, in particular for studies where co-enrolment is not possible. This may include the same diagnosis being studied, or overlap in eligibility criteria. Competing studies run by the same network may jeopardise potential funding opportunities and coherence among network members. Growing Minds Australia on principle will prioritise its awarding of funding by:

- Requesting that the investigators provide evidence of feasibility (for example, site investigators indicating that they support the study or plan to recruit to the study).
- Explicating for each round where required a clear process for prioritisation of competing studies, for example, priority for already funded studies or a temporal sequence of endorsement.

• Applications for endorsement will undergo an initial review by the Executive Officer based on eligibility/inclusion criteria. Suitable applications will then be reviewed by the GMA Core Methods teams (Health economics; Translation; Community Engagement teams), to assess the proposed plans for incorporating health economics, translation, and community engagement, and to provide recommendations for these plans as needed. Applications will be further assessed by a minimum of three members of the GMA-CTN determined to be free from conflicts of interest, with external reviewers sought when conflicts of interest cannot be resolved internally.

• All reviewers will be asked to comment on the scientific merit, significance, and feasibility of the proposed study. This includes but is not limited to investigator(s) track record in the area of clinical and/or epidemiological research; the ability of the proposed study to enhance the development of child and youth mental health research; the ability of the proposed study to generate results that are of importance at least to a national level (ideally international); the ability of the proposed study to generate novel data and information as opposed to replicating previous or ongoing research studies. Assessments will be made based on the prescribed Application for Endorsement Form.

• The Chairs of GMA SAC will coordinate the reviews. A majority vote of non-conflicted voting members of GMA SAC will be used to determine the outcome where conflicting reviews exist. In instances where there is not one (1) non-conflicted member of the GMA SAC, external reviewers will be sought.

• Endorsement or non-endorsement of a trial will be reported to the GMA Steering Committee, who may request a review of the decision. All Steering Committee members involved in this process shall be subject to the same conflict policy as outlined above.

• Applicants will be notified of the outcome in a timely manner. Review of any decision (appeal) will be made in accordance with GMA review and appeals processes. Notification will include the conditions of endorsement (Section 5) and require an acceptance of these conditions by the applicant for endorsement to be effective.

5. Conditions of endorsement

Once endorsed by GMA, the following conditions apply for the duration of the study and for all prospective aspects of the study following, including any sub-studies. The chair of the study advisory committee will be responsible for ensuring that these conditions are fulfilled:

- 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.

- The study advisory committee will nominate a member, usually the Chair, who is responsible for liaison with the GMA SAC, and it is the responsibility of the study steering committee to update GMA SAC with respect to any major design or administration changes that occur after endorsement is conferred.

- The study steering committee should meet and maintain records of their meetings (for example, minutes or action points) with sufficient frequency to ensure good governance of the study. The records of steering committee meetings will be made available to GMA SAC if requested.

- A study progress report will be submitted to GMA SAC yearly upon request. In this instance, receipt of annual research ethics reports will suffice as a study progress report. The GMA Administration Officer should receive study updates.

- GMA SAC reserves the right to withdraw endorsement at any stage should the study not progress adequately, or if irresolvable conflicts of interest arise.

- Manuscripts arising from the study will comply with the GMA Publication Policy, and will be reviewed prior to submission to peer-reviewed publications, with a view only to brand assurance.

6. Management of conflicts of interest during the review process

The GMA SAC is committed to providing a fair and transparent process of review for all endorsement applications. A member of GMA SAC is regarded as conflicted with respect to an endorsement application if that person is a member of the study steering committee or a proposed or confirmed principal investigator for that study. Members of GMA SAC who are conflicted will not participate in the assessment and evaluation of endorsement applications. Individuals who are invited to review studies and manuscripts on behalf of the Scientific Advisory Committee must not be involved in the design or conduct of the study.