AUSTRALASIAN GASTRO-INTESTINAL TRIALS GROUP

Publication Policy

A. General Principles

1. The aim of the Publication Policy is to ensure appropriate dissemination of AGITG clinical research programme results to the scientific community and the population at large.

   1.1. Study results are categorised as:

   - Reports of primary outcomes;
   - Reports of secondary outcomes;
   - Reports of tertiary outcomes; and
   - Reports of sub-studies.

   1.2. The Publication Policy applies to the following types of output:

   - Manuscripts,
   - Conference presentations,
   - Abstracts,
   - Posters,
   - Media releases, and
   - Consensus reviews.

2. Publication of AGITG study data without adhering to this policy is not permitted without prior written consent of the Chair of the AGITG Scientific Advisory Committee (SAC).

3. In line with contractual arrangements, AGITG requires an opportunity to **review and approve <u>all</u>** publications (see A.1.2) **<u>prior</u>** to submission to a Journal or Conference.

4. AGITG will be acknowledged in **<u>all</u>** publications in the relevant Sections as per below:

   - Title,
   - Support, and
   - Acknowledgements.

5. The Coordinating Centre and relevant funding bodies will be acknowledged in **all** publications.

6. The AGITG Board of Directors is responsible for approving the Publication Policy.

7. The SAC will ensure compliance with this Publication Policy via internal reports detailing a list of all publications and presentations.

8. AGITG will maintain a current index of all publications notified to the AGITG, CTC Publications Officer and Operations Executive Committee (OEC). The index will be published on the AGITG website.

9. A trial-specific publication plan will be developed in liaison with the Study Chair, Trial Management Committee (TMC) and Coordinating Centre to define the approval process, authorship, and timelines.

B. Study Chair and TMC

1. Ensure timely production of a scientific manuscript at the completion of the trial. If there is a significant delay in the writing of the manuscript, alternate strategies will be explored.

    1.1. **Timeframe for publication** – there is an expectation that the study data is published **within 12 months** of study closure. However if this milestone is not achievable, the Study Chair will provide the final analysis as a Study Report to the OEC and/or AGITG. The Study Report will be publicly available on the AGITG website as well as the University of Sydney repository for trials coordinated by CTC.

    1.2. **Studies that are published** – a lay summary of the publication relating to primary outcomes will be provided by the Study Chair to AGITG. The summary will be made available on the AGITG website following Consumer Advisory Panel (CAP) review and feedback.

2. Prepare a trial-specific publication plan in liaison with the Coordinating Centre to address:

    2.1. Authorship, including allocation of authors for various planned publications for the study.

    2.2. Process for approving publications.

    2.3. A priority list of journals for manuscript submission.

C. Authorship

1. Presentation of the primary results of the main study should include group authorship where possible with a list of specific contributions at the end.

2. As per the ICMJE guidelines, an 'author' is considered to be someone who has made substantive intellectual contributions to a published study. Authorship credit should be based on:

    2.1. Substantial contributions to the conception and design, or acquisition of data, or analysis and interpretation of data.

    2.2. Drafting the article or revising it critically for important intellectual content.

    2.3. Final approval of the version to be published.

    2.4. Authors should meet conditions C.1, C.2 and C.3.

3. Eligibility for authorship will be based on the following factors:

    3.1. Substantial contribution to the trial design and protocol development.

    3.2. Substantial contribution to the management and conduct of the trial.

    3.3. Substantial contribution to the analysis and interpretation of the data.

    3.4. Level of contribution of participants to the study.

4. **Study Chair** or **Co-Chair** should be the first (potentially two) author(s) on the basis that:

    - Study Chair and/or Co-Chair has ensured the success of the study.
    - Study Chair and/or Co-Chair has made significant contributions to the scientific ideas on which the study was based and to the writing of the manuscript.
    - Study Chair and/or Co-Chair is a guarantor of the study.

    4.1. In the event there are two Co-Chairs on a trial, the arrangements for authorship should be determined in consultation with the TMC as per the publication plan.

4.2. In the event there are Co-Chairs on a trial, every effort should be made to ensure there are opportunities for more than one publication and that both Co-Chairs can have a first-author publication.

4.3. A Co-Chair who is not the first author should choose whether to be second author or last author.

5. **Statistician** should be a principal author (second, third or fourth author) on the basis that:
    - A significant contribution was made to the scientific principles of the study.
    - The Statistician has been a prime contributor to the study design, determination of sample size and scientific conduct of the study (unblinding principles, analysis principles, interpretation of results, compliance, etc.)
    - The Statistician guarantees the scientific integrity of the study.

6. **AGITG-CTC Group Coordinator** should be considered as an author to reflect their contribution throughout the lifecycle of the trial (development, conduct, analysis and publication) for studies coordinated by the NHMRC CTC, if in compliance with Section C of the policy criteria.

7. **SAC Chair** should be considered as an author to reflect their contribution throughout the lifecycle of the trial (development, conduct, analysis and publication), if in compliance with Section C of the policy criteria.

8. Subsequent authors will comprise clinicians, project manager or other scientists who have made scientific or intellectual contributions to the study question or conduct and meet the journal's requirements for authorship, including members of the TMC.

9. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

10. Contributors listed in Acknowledgements:
    - Site Principal Investigators and if possible, local study coordinators, will be listed in all manuscripts either in the Acknowledgments section or as an Appendix.
    - Any person who contributes to the development, conduct, analysis and interpretation of the study or the progress of the manuscript but does not qualify for authorship should (with their permission) be acknowledged.

D. Sub-Studies

1. Sub-studies will adhere to the authorship guidelines noted in section C.

2. A separate publication plan may be required to ensure all relevant parties are recognised. The sub-study chair will generally be the first author on publications.

E. Intergroup Cooperative Studies

1. If the study is a collaborative (intergroup) trial, authorship should be agreed to in the protocol development phase.

2. The publication plan will detail involvement of collaborating parties and process for approval per the contract.

3. Authorship:

    2.1 AGITG-led intergroup studies will follow the principles detailed in section C.

    2.2 Intergroup studies where AGITG are participating but not leading, will follow the publication policy of the lead group.

2.3 The Australian Study Chair in consultation with the Australian TMC will determine authorship for Australian investigators.

4. Publications arising from:

4.1 AGITG-led intergroup studies must be approved by the TMC and other collaborators as listed in the contract.

4.2 Intergroup studies where AGITG are participating but not leading, must be approved by the collaborators noted in the contract.

5. During the development of intergroup protocols, the Publication Policy should be circulated to the Protocol Development Group to facilitate discussion.

6. Manuscripts should be provided to OEC to ensure adherence to the Publication Policy.

F. Abstracts, Conference Presentations and Posters

1. Study investigators are encouraged to develop and present abstracts based on the scientific information available from the study, with input from the TMC.

2. Authorship will follow the principles detailed in section C.

3. Prior to submission:

3.1 The Statistician will ensure that information disclosed is appropriate and will not compromise the main study.

3.2 OEC will ensure adherence to the Publication Policy.

3.3 TMC approval is to be obtained.

4. Conference posters must include:

4.1 AGITG logo, in addition to being acknowledged as per section C.

4.2 Additional logos of organisations providing study support per the contract.

5. Final abstracts and posters should be made available to the AGITG and Coordinating Centre by the first author.

G. Disputes

1. Disputes that cannot be resolved by discussion will be referred to OEC for trials coordinated by the CTC.

2. An independent sub-group of the SAC will resolve disputes for trials coordinated outside of the CTC. This committee will be chaired by SAC Chair. In cases where there is a conflict of interest, the committee will be chaired by a member nominated by the SAC Chair.

H. References

1. International Committee of Medical Journal Editors (ICMJE)

2. Australian Code for the Responsible Conduct of Research, 2018

3. Medicines Australia Code of Conduct, 2019

I. Glossary of Terms

Operations Executive:	AGITG representatives on the OEC include: SAC Chair, CEO, Clinical Research Manager, Finance Manager, Clinical Trials Assistant, and Communications Manager. NHMRC CTC representatives on the OEC include: Group Coordinator, Research Fellow(s), Clinical Trials Operations Lead, Research Development Lead, and Translational Research Lead.
Study Chair:	A person, or persons, usually clinicians, taking primary responsibility for the conception, conduct, monitoring and completion of the trial or research project.
Statistician:	The statistician taking primary responsibility for the statistical considerations of the trial. Usually the group statistician or his or her designate.
Trial Coordinator:	The person responsible for the running of the trial on a day-to-day basis. Responsibilities include randomisation, documentation, data processing, data cleaning, adverse event monitoring, quality control, liaison with site staff and preparation of reports.
Project Manager:	Used interchangeably with the term Trial Coordinator.
Principal Investigator:	Person identified at each participating institution responsible for the conduct of the trial or research project within that institution.
Reviewed:	Appraised of the content of the manuscript or abstract to ensure that the validity of the trial, the objectives of the group, and the interpretation of the data are maintained.
Commented:	Provided written feedback to the principal investigator, first author or coordinating centre to indicate that the review is complete.
Approved:	Signed off on the manuscript or abstract after review, with or without comment, and conveying this in writing to the principal investigator, first author or coordinating centre.