Australian Clinical Trials Alliance

Authorship and Publication Policy: Guidance for CTNs

September 2019

ACTA gratefully acknowledges operational funding from the Australian Government's Medical Research Future Fund

TABLE OF CONTENTS

PURPOSE OF THIS DOCUMENT

This document will assist clinical trials networks (CTNs) in establishing authorship and publication guidelines.

THE ROLE OF ACTA IN DEVELOPING TERMS OF REFERENCE

The Australian Clinical Trials Alliance (ACTA) is providing advice to assist CTNs in developing authorship and publication guidelines. The generic advice provided by ACTA should be considered and applied by each CTN, taking into account the specific network and trial requirements.

USE OF THIS DOCUMENT

ACTA encourages the use of all materials listed on its website (www.clinicaltrialsalliance.org.au) in the pursuit of improving the clinical trials enterprise. ACTA requests that the following acknowledgement is included in any CTN authorship and publication guidelines that are developed and documented using knowledge gained from this document.

> "[Name of CTN] acknowledges the contribution of ACTA to the development of authorship and publication guidelines within our network (reference: *Australian Clinical Trials Alliance Authorship and Publication Policy: Guidance for CTNs 2019*)".

DISCLAIMER

The information in this document is for general guidance only. ACTA does not make any representations or warranties (expressed or implied) as to the accuracy, currency or authenticity of the information provided.

ABBREVIATIONS

ACTA	Australian Clinical Trials Alliance
CPI	Coordinating Principal Investigator
CTN	Clinical Trial Network
ICMJE	International Committee of Medical Journal Editors
JAMA	Journal of American Medical Association
NHMRC	National Health and Medical Research Council
NSC	Network Steering Committee also known as CTN Executive
PI	Principal Investigator
TMC	Trial Management Committee
TSC	Trial Steering Committee

RATIONALE FOR DEVELOPING AN OVERARCHING AUTHORSHIP GUIDELINE AND PUBLICATION POLICY FOR THE NETWORK

Large, international, multi-centre, clinical trials often involve a large number of investigators and research groups, both locally and internationally, who are involved in the concept, design, conduct, acquisition and analysis of the data. Patient recruitment and high-quality follow-up are done by site investigators and trial coordinators at established sites affiliated with the Clinical Trials Network (CTN). This commitment from site investigators and trial coordinators ensures that the trial is completed on time and within budget, contributing to the overall success of the clinical trial.

It is important that all individuals who make a substantial and meaningful contribution to the clinical trial and intellectual content of the work are appropriately recognised and acknowledged for their contribution in the final publications. Authorship is critical to help build the track record of individuals for a range of reasons (e.g., employment, grant applications and awards). It has financial, academic and social implications for the individual[1], so it is critical that decisions pertaining to authorship are transparent to promote coherence of the network. Since authorship on a manuscript does not always convey the precise contribution the individual made to the work, many journals and CTNs are now adopting authorship guidelines to ensure that the individual is accountable for the work and has contributed appropriately to the work. To this end, guidelines for authorship and publications must outline a fair and transparent process for members of the Network.

This document has been developed as a guidance document for CTNs to use when creating their overarching authorship and publication policy. It outlines various options that a network may consider when establishing guidelines for their CTN. This document also outlines options that the Principal Investigator (PI) may adopt when establishing an authorship plan for specific trials conducted/endorsed by the Network, which is developed and set in place before the study commences.

1 DEVELOPMENT OF AN OVERARCHING AUTHORSHIP AND PUBLICATION STRATEGY FOR THE NETWORK

The development of an overarching authorship and publication guideline or policy for the CTN may be overseen and endorsed by the Network Steering Committee (NSC) or CTN Executive. The policy should set out criteria for authorship on manuscripts and how the network will acknowledge collaborators of the work. It should also include guidance on how the CTN/group of the trial investigators are to be appropriately listed in the by-line of publications. Adherence to the authorship and publication policy may be a condition of endorsement for investigators of CTN-endorsed trials. This is important to develop as it contributes to the track record and brand of the CTN. (Refer to the ACTA endorsement policy.)

1.1 PUBLICATION STRATEGY

The publication strategy should list processes around drafting, review and publication of the manuscript as well as timeframes. This may include timeframes for the presentation of the main results and at which forum the investigators are aiming to present the results.

The publication strategy should also outline who is involved in the drafting and review of the main manuscript, and which other individuals or trial committees may be involved in providing feedback on the results. It is expected that all listed authors in the main paper will provide feedback within the set timeframe. There should also be an agreed method for distribution which may be done by the corresponding author. The CTN Executive should decide which committee or body is responsible for authorship, and therefore who is ultimately responsible for the final approval to submit the manuscript to the journal editors. Options for authorship oversight could be the writing committee, trial steering committee, PI or the CTN Executive.

1.2 OPTIONS FOR PRESENTATION OF THE MAIN TRIAL RESULTS

Investigators may opt to premiere the main trial results at a significant meeting in their Network or through a webinar which allows for all individuals involved in the work to hear the results. With enough lead time, a manuscript can be embargoed with the publishing journal until the exact time of the premiere of the results. The lead investigator may also organise media releases to coincide with the publication and presentation of the main trial results (see Section 1.5).

To acknowledge and respect the contribution of individuals involved in the study, the Principal Investigator may organise for the results to be released 24 hours before the premiere. This may be done by organising confidentiality agreements.

1.3 COMMUNICATIONS PLAN

As part of the Publication Strategy, trial investigators can draw up a communication plan on how the results will be disseminated and to whom. If the results are presented before the manuscript is published, guidelines should be developed around the use of social media and photography of slides during the presentation, in particular, if this is likely to generate media attention. The communications plan may also outline which groups or individuals will learn the trial results before the main presentation and publication, and which individuals and groups will learn about the results during the main premiere of the results.

1.4 PRESENTATIONS AND THE USE OF THE CTN BRAND

CTNs may consider guidelines around the use of the CTN brand when presenting results, including for poster and oral presentations. These may include:

- The use of the CTN logo and adherence to style guides
- The listing of other details: Social media (Facebook, Twitter handle, etc.).

1.5 MEDIA RELEASES

All media releases related to the trial should be approved the body responsible for authorship before the media release. The PI should liaise with relevant parties, for example, sites, affiliated university, research institute, parent organisations, and pharmaceutical companies to coordinate media releases.

2 DEVELOPMENT OF A TRIAL-SPECIFIC AUTHORSHIP PLAN

There are different scenarios that authorship guidelines may address when developing a trial-specific authorship plan:

1) The publication of the protocol and statistical analyses plan prior to the closure of the trial
2) The primary analyses or the main results of the clinical trial
3) Secondary outcomes or analyses of the clinical trials
4) Sub-studies of the main clinical trial
5) Secondary use of the data or data linkage studies.

A trial-specific authorship plan may address authorship criteria for manuscripts resulting from the above scenarios. The plan may assign responsibilities for drafting, reviewing and submitting the manuscript, as well as stating the relevant timeframes for each activity. Nonetheless, it is worth noting that some journals may have specific criteria around authorship that may need to be adhered to.

2.1 CONSIDERATIONS FOR AUTHORSHIP CRITERIA FOR THE PRIMARY ANALYSES OR MAIN RESULTS OF THE TRIAL

An authorship plan for each individual trial, particularly addressing the main manuscript publishing the primary outcomes of the trial should be drafted and endorsed before the trial starts.

The development of an authorship plan for the specific trial is usually overseen by the PI, however, all lead investigators involved in the study design should be given the opportunity to review the plan and provide input before the trial starts. The plan should be routinely reviewed at steering committee meetings/trial management meetings to ensure that it is up-to-date.

2.1.1 NATIONAL RECOMMENDATIONS

The National Health and Medical Research Council (NHMRC) have published a guide on authorship[1] supporting the Australian Code for Responsible Research Conduct. These guidelines recognise an author as someone who has made a significant intellectual or scholarly contribution to the study. These guidelines also recommend that institutes conducting research have fair and transparent policies around the assignment and attribution of authorship, including how disputes will be handled. Contributors who do not meet authorship criteria can be acknowledged in the manuscript in accordance with these guidelines[1].

2.1.2 INTERNATIONAL RECOMMENDATIONS

Many CTNs adopt the 'Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals'[1], developed by the International Committee of Medical Journal Editors (ICMJE), either as a general guideline or incorporated into each trial-specific authorship plan. These recommendations aim to ensure that all listed authors have meaningful and substantive contributions to the work, and take public responsibility for their contribution to the work. The ICMJE recommendations also detail requirements for written sections of the manuscript, helping to ensure that the work that is published is accurate, clear and reproducible.

2.1.3 SITE INVESTIGATORS, COLLABORATORS AND SUB-COMMITTEES

The running of clinical trials usually involves a number of people and teams in the design, conduct, analysis and oversight of the trial. These individuals and teams may include:

- The Writing Committee (the individuals who have contributed to the drafting and reviewing of the manuscript)
- Trial Steering Committee (TSC) (the individuals who were involved in the design of the study, protocol development, database design and analyses plan, and responsible for the overall conduct of the trial)
- Trial Management Committee (TMC) (the individuals involved in the day-to-day running of the trial)
- Coordinating Principal Investigator (CPI) (the individual who is the main study lead)
- Statistical Committee (the individuals involved in the statistical plan and statistical analyses of the study)
- Site investigators (individuals responsible for the conduct of the trial at the site)
- Site coordinators (individuals usually involved in patient recruitment and follow-up at the site)
- Trial managers (individuals who are responsible for the project management of the trial)
- Trial safety and other oversight committees (for example, endpoint adjudication committee, data quality committee, operations committee).

The authorship plan may address what eligibility criteria for authorship on the main publication or online supplement/ appendix, or how these contributors will be acknowledged in the manuscript. Exceptional circumstances may arise where the authorship oversight body may consider (usually by majority vote) a group or individual who warrants authorship on the main publication. The CTN Executive may consider how to set up transparent processes when considering authorship that is not pre-defined in the guidelines.

2.1.4 AUTHORSHIP AND ACKNOWLEDGEMENT CRITERIA FOR SITE INVESTIGATORS AND COORDINATORS

The trial-specific authorship plan may include pre-defined inclusion criteria for site investigators and coordinators who are involved in patient recruitment and follow-up. For example, the plan could outline how many patients each site must recruit for the site investigator to be listed as a contributor in the manuscript, and how the sites and individuals will be listed in the paper (either main paper or online supplement/appendix). Alternatively, the authorship plan may state that investigators from the percentage of the highest recruiting sites will qualify for authorship on the manuscript. This plan should be made available to all potential sites, collaborators and sub-committees involved in the trial before the trial starts. The PI may opt to enter into a signed authorship agreement with site investigators and collaborators to ensure that expectations about authorship are managed. People who do not meet the authorship criteria may be recognised in the Acknowledgements section (see below).

2.1.5 AUTHORSHIP ORDER

Authorship order is usually determined by the individual's overall contribution to the study. Usually, the PI will be first author or senior author in the publication depending on the journal. It is usually at the discretion of the authorship oversight body to evaluate the contribution by individuals and list the names in an appropriate order. It is important that a transparent process for authorship criteria, order and appearance in the manu

script is pre-defined in the guidelines.

A strategy may need to be considered for authors who are deemed to have contributed at equal levels to the published works. Possibilities include listing in alphabetical order, or if two publications result from the findings to switch the order of the authors.

The planned authorship list and order may be extended or altered according to a majority vote of the TMC/TSC. This should be agreed in writing with the relevant committee and then communicated to study collaborators.

2.2 PUBLICATION PROCESS

Timely publication of the main trial results is critical to preserve the public standing of the CTN brand. The CTN may consider the following options to allow for accountability of the trial investigators to publish the work (regardless if it is a negative trial):

- The establishment of a writing committee to oversee the drafting and reviewing of the manuscript
- Assigning responsibility and oversight for authorship to an appropriate committee. Throughout this document, we refer to this committee as the authorship oversight body.
- Assigning a member of the Trial Steering Committee/Governance Committee to facilitate and oversee the publication process.

2.2.1 WRITING COMMITTEE

The writing committee usually consists of members involved in the design and implementation of the clinical trial and involves members that have experience in the preparation of manuscripts in high-impact journals. CTNs may consider having an emerging researcher on the writing committee to help draft the manuscript.

2.2.2 CORRESPONDING AUTHOR

The corresponding author is the primary correspondent with the editorial office to which proofs and revised manuscripts will be sent. The corresponding author usually has experience with drafting manuscripts and liaising with journal editors. The corresponding author is often the PI of the study.

2.2.3 TIMEFRAMES FOR PUBLICATION OF THE MAIN TRIAL RESULTS

The CTN may decide on a timeframe by when the publication process should be completed to ensure there is no delay in the write up of results. Timeframes are more critical for high impact work where it is important that the results are translated to practice as soon as reasonably possible. However, it is also important that all work, including negative trials, are published in a timely manner.

2.3 SECONDARY ANALYSES AND SUB-STUDIES OF THE MAIN CLINICAL TRIAL

Many subsequent publications are likely to arise from the primary results/main manuscript. These include sub-studies and secondary analyses. Permission to undertake a sub-study or use the dataset for secondary analyses is usually sought from the PI on behalf of the TSC/TMC. The lead investigator would usually provide oversight of the subsequent study and therefore is likely to be an author. A specific authorship plan could be tailored for sub-studies and secondary analyses. Often the sub-study/secondary analyses PI would be the primary author. Usually, the main results are published before any publication of sub-studies and secondary analyses, and always before any sub-studies or secondary analyses that allow trial results to be inferred, but this will be trial-specific (taking into account trial duration).

2.4 AUTHORSHIP PLAN TEMPLATE

The authorship template may include the following details:

- Name of the trial
- Principal Investigator
- Lead author and other authors in the order that they are intended to appear in the manuscript
- The targeted journals listed in the order in which the authors plan to submit the manuscript
- Plan and timelines for manuscript drafting, reviewing and submission
- The Writing Committee (list the individuals)
- Corresponding author (liaison between the journal editors and the writing committee)
- Planned presentation of main results and secondary analyses.

2.5 DISPUTE RESOLUTION

The CTN should have a fair and transparent process regarding decisions on authorship, ensuring agreement among authors and a process for resolving disputes. Grievance adjudicators should be free from conflict of interest and not part of the manuscript authorship team. They must either possess the responsibility to override earlier decisions on authorship, or report to another body or committee that has been delegated this responsibility. A person also needs to be nominated who will communicate decisions to the complainant and the authorship team. Typically, the CTN Chair is involved in these decisions.

3 SUMMARY OF NATIONAL AND INTERNATIONAL GUIDELINES FOR AUTHORSHIP CRITERIA AND BY-LINING AUTHORSHIP

This section summarises the national recommendations that have been developed by the NHMRC[1], and international standards developed by the ICMJE[2] and Journal of the American Medical Association (JAMA)[3]. These standards have been employed by many trial networks where all authors listed in the manuscript must meet minimum requirements in terms of criteria, responsibility and contribution to the intellectual content of the work. Journals may have their criteria for authorship that all authors must meet and sign off in order to have the manuscript published with that journal. These standards are summarised below and may be employed by CTNs, in particular, where there are no pre-defined authorship guidelines.

3.1 NATIONAL RECOMMENDATIONS BY THE NHMRC

The NHMRC[1] recommends that authorship criteria must include at least one of the following criteria, but ideally two or more:

- Conception and design of the project or output
- Acquisition of research data where the acquisition has required significant intellectual judgement, planning, design and input
- Contribution of knowledge, where justified, including indigenous knowledge
- Analysis or interpretation of the research output or critically revising it so as to contribute to its interpretation.

The guidelines recommend that authors should be accountable for their contribution, and those who are unwilling to be accountable should not be included in the research output.

The guidelines also recommend that authorship should not be assigned solely on the following:

- Acquisition of funding, data, materials, infrastructure or access to equipment
- Proving routine technical support, advice or assistance
- The position or profession of the individual, for example, the author's supervisor or head of department ('gift authorship')
- Whether the contribution was paid or voluntary
- The status of the individual who has not made a significant intellectual or scholarly contribution, to lift the esteem of the research ('guest authorship').

For more information, refer to the NHMRC guide[1].

3.2 INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS AUTHORSHIP RECOMMENDATIONS

The ICMJE recommends[2] that authorship is based on the following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and
- Drafting the work or revising it critically for important intellectual content; and
- Final approval of the version to be published; and
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Authors should be aware of the contribution to the work of the other authors and have confidence in the integrity of the work. All individuals/investigators/collaborators who meet the first criterion should be given the opportunity to draft and review the manuscript, and should not be automatically disqualified from the authorship if they are not given the opportunity to do so. Timeframes should apply for the review and feedback process. The ICMJE also recommends that individuals who are conducting the work ensure that colleagues meet all the criteria for authorship, as it is not the responsibility of the journal. For more information, see ICMJE recommendations[2].

3.3 JOURNAL OF THE AMERICAL MEDICAL ASSOCIATION (JAMA) RECOMMENDATIONS NETWORK OF AUTHORSHIP RECOMMENDATIONS

JAMA Network Journals[3] has also published authorship criteria as follows:

All authors should meet all of four of the following criteria listed in A, B, C and D.

A) The author agrees to all of the following

- The work is original and valid, and the content or similar content described in the manuscript is not considered for publication elsewhere (except where disclosed as an attachment with copies of the related manuscript).
- The author is accountable for the validity and rigour of the work to ensure that questions relating to the integrity and accuracy of the work are resolved.
- The author will provide access to the data if requested, or cooperate fully in providing access to the data on which the manuscript is based, to the editor for examination.
- Where there is more than one author, the author agrees to let the corresponding author serve as the primary correspondent with the editorial office to review the proofs and edits.

B) The author gives final approval of the manuscript.

C) The author has contributed sufficiently to either all or part of the content, including from each of the following categories 1 to 3:

1. A. Conception and design, and/or
   B. Data acquisition, analysis or interpretation of data
2. A. Drafting the manuscript, and/or
   B. Critically reviewing the manuscript for important intellectual content
3. The author has made a substantial contribution to one or more of the following:
   A. Statistical analysis
   B. Obtaining funding
   C. Administrative, general or technical support
   D. Supervision
   E. Other (specify)

For more information, refer to the Fontanarosa et al., 2017[3].

3.4 GROUP AUTHORSHIP

It is becoming more common for some journals to use the name of the network or groups in the authorship by-line instead of listing the individuals in the main manuscript. Listing a group is known as corporate authorship. Criteria qualifying individuals to be included in this "group" authorship may need to be established. Individuals who qualify for group authorship may have their names listed in the online supplement or appendix. If the names are appropriately indexed in PubMed, the individual will be searchable/citable as an 'author'.

3.4.1 BY-LINING AUTHOR AND GROUP AUTHORSHIP IN THE MANUSCRIPT

All authors listed in the by-line should meet the pre-defined authorship criteria. All authors should complete the author and disclosure forms and indicate their specific contributions to the work, affiliations and any conflicts of interest. Where there is no limit to the number, all authors should be listed as long as the authorship criteria are met. Where there are too many names to be listed, the Group or Network name should be listed in the by-line, and the authors can be listed by name together with their affiliation and any conflicts of interest in the Acknowledgements section. This approach will allow the author to be listed in PubMed, together with the Group name. All non-author collaborators can be listed in the Acknowledgements section. If appropriately set up, all author members of the Group and non-author collaborators will be listed in PubMed.

There are several variations of how authorship could be listed:

3.4.1.1 Individual Authors "for" a Research Group (i.e., not all members of the Group are authors)

Individuals who are authors are listed in the by-line, followed by the name of the research group. Not all of the research group are authors, and others can be listed as collaborators in the acknowledgement section. The by-line would appear as "Authors A, B, C, ... for the Research Group".

3.4.1.2 Listed investigators and the X Study Investigators

Individual Authors "and" a Research Group (i.e., all members of the Group are authors). Individuals who are authors are listed in the by-line, followed by the name of the research group. All members of the research group are authors and can be listed in the acknowledgement section. The by-line would appear as "Authors A, B, C, ... and the Research Group".

3.4.1.3 Research Group (i.e., all members of the research Group are authors)

No individual authors named in the by-line. The article does not have any individual authors listed but only the name of the research group. The by-line would appear as "The Research Group".

The section below outlines options for authorship or acknowledgement that may be adopted by CTNs for groups or individuals.

3.5 INSTITUTION/SITE CONTRIBUTOR LIST

Hospital site leads and other collaborators may also be listed as an author (in the main paper/online supplement/appendix) if they meet minimum recruitment requirements for authorship (see Section 2.1.3). The site contributors list could also be tiered, for example, sites recruiting more than 100 patients may choose to list up to three people at the discretion of the lead site investigator (e.g., list the site investigator and two trial coordinators or a co-investigator at the site). How the names appear in the online supplement/appendix should also be stipulated in the authorship plan from the outset of the trial. Where another craft group has been significantly involved in the study, additional contributors may be nominated at each site, however, this should be defined in the guidelines.

3.6 LISTING OF NAMES AND CONTRIBUTOR LISTS IN THE ONLINE SUPPLEMENT/APPENDIX

The authorship plan should outline how the sites will be grouped and how members will be listed. For example, the sites may be grouped by country in alphabetical order, and the site investigator will be listed first followed by other investigators/ trial coordinators listed either alphabetically/or in order of their level of contribution.

The authorship plan should include minimum requirements to be listed as a collaborator and groups. The pre-defined inclusion criteria, and how groups are categorised and names and orders of members in each group should be outlined in the authorship plan and conveyed to sites and groups prior to the trial starting.

3.7 NON-AUTHOR SUB-COMMITTEES

Other contributors who are not authors but have contributed can be listed in accordance with the journal's policies. Identification of members of the sub-committees such as the Data Safety Monitoring Board, the statistical committee or writing committee may be listed in alphabetical order following the chair of the committee.

3.8 MINOR COLLABORATIONS ACKNOWLEDGEMENT

If sites have not met the criteria to list individuals at the site, a statement such as the following could be used to acknowledge the contribution from these sites, "The authors and the trial steering committee would like to thank clinicians, researchers and research coordinators at the following contributing sites …" and list them in alphabetical order.

Acquisition of funding, collection of data, a representative of a research consortium or general supervision of a research group, alone, may not justify authorship. However, minor collaborators can be recognised in the acknowledgment section of the manuscript. Wording can vary. For example, the authors wish to acknowledge "X" for providing advice on the study design.

3.9 FUNDING ACKNOWLEDGEMENT

Funding acknowledgements may be listed in the funding acknowledgement section of the manuscript, but in some journals may be in the acknowledgment section of the manuscript. Funding acknowledgements may be listed alphabetically according to country, or according to the amount of funding that was received. The journal editors may have set requirements for acknowledging funders.

3.10 ACKNOWLEDGEMENT OF THE CTN FOR THEIR INVOLVEMENT IN INTERNATIONALLY-LED CLINICAL TRIALS, OR VICE VERSA

International clinical trials groups will usually have their own authorship and publication guidance that local CTNs are likely to have to adhere to when agreeing to the partnership. The CTN should negotiate and agree on how they will be acknowledged and listed as an author before they start the trial, through a signed agreement.

The CTN endorsement policy may also outline as a condition of endorsement that the CTN group name is listed in the by-line if the trial has been endorsed by the CTN.

CTN investigators should be mindful of the ramifications of data fraud in particularly where they are not aware of the integrity and contribution by the other authors.

4 CTN-ENDORSED TRIALS PUBLICATION POLICY

The CTN may elect to link an authorship policy as a condition of trial endorsement, which may stipulate the inclusion of the network name in the by-line as an affiliation. Examples are:

- 'The X Study Investigators "for" the "X" Clinical Trials Network'
- 'Listed investigators, "and" the X Study Investigators "for" the "X" Clinical Trials Network', or
- 'Listed individuals, the X Study Investigators, the X Institution "for" the "X" Clinical Trials Network'.

In multi-network studies, it is suggested that sites and investigators affiliated with the CTN be clearly identified. This will ensure the network is citable on all PubMed searches.

5 ACKNOWLEDGEMENTS

We acknowledge the contributions of ACTA CTN members and members of ACTA's Efficient and Effective CTNs Reference Group in the preparation, development and review of this document.

We would specifically like to thank the Australian and New Zealand Intensive Care Research Centre (ANZIC-RC), Australian and New Zealand College of Anaesthetists Clinical Trials Network (ANZCA CTN), Paediatric Research in Emergency Departments International Collaborative (PREDICT), CTANZ, AGITIG networks in sharing their policies that have been considered to develop this document:

- Australian and New Zealand Intensive Care Research Centre Terms of Reference – October 2017. https://www.monash.edu/_data/assets/pdf_file/0005/1098428/2017-10-05-ANZIC-RC-Terms-of-Ref.pdf Accessed 10 July 2019.
- ANZCA Clinical Trials Network. http://www.anzca.edu.au/ctn Accessed 10 July 2019.

6 REFERENCES

1. National Health and Medical Research Council. (2019). *Authorship: A guide supporting the Australian Code for Australian Code for the Responsible Conduct of Research*. https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018#block-views-block-file-attachments-content-block-1 Accessed 18 September 2019.
2. International Committee of Medical Journal Editors. (December, 2018). *Recommendations for the conduct, reporting editing, and publication of scholarly work in medical journals*. http://www.icmje.org Accessed 10 July 2019.
3. Fontantanarosa, P., Bauchner, H., and Flanagin, A. (2017). Authorship and Team Science. *JAMA, 26*;318(24):2433–2437. doi: 10.1001/jama.2017.19341.

Australian
Clinical
Trials
Alliance

www.clinicaltrialsalliance.org.au

ACTA gratefully acknowledges operational funding from the Australian Government's Medical Research Future Fund