

Standard Operating Procedure

6.15 Authorship

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Introduction / Background

In accordance with the Australian Code of the Responsible Conduct of Research¹, all PaCCSC/CST/ITCC research teams have a written policy on the criteria for authorship for research output. Minimum criteria for authorship are to be in accord with the International Committee of Medical Journal Editors (ICMJE)², and the Australian Code of the Responsible Conduct of Research¹.

Objective

This SOP defines and describes how authorship will be determined within PaCCSC/CST/ITCC to ensure that publications adhere to international authorship guidelines.

Scope

This SOP applies to all staff and members involved in clinical research conducted by PaCCSC/CST /ITCC irrespective of individual organisational employment, role or position.

Ownership and Responsibility

Responsibilities of the Executive Author

- To ensure that the authorship team maintains the highest standards of research integrity
- To define the types of presentation of research output
- To negotiate authorship team responsibilities for each conference presentation
- To negotiate the authorship order and inclusion for all manuscripts and presentations
- To oversee the preparation of manuscripts, abstracts and presentations including accountability for content
- To oversee the record keeping regarding the research output including circulating drafts, integrating changes, production of the final version and making the ultimate decision regarding submission to the publishing company
- To prepare and maintain record-keeping regarding the authorship statement
- To develop timeline and ensure adherence to same

Responsibilities of the PaCCSC/CST National Manager

- To disseminate authorship information
- To facilitate conflict resolution regarding authorship
- To oversee publication timelines as drawn by the Executive Author
- To send reminders to the Executive Author regarding pending planned publications
- To follow up with Executive Authors following the closure of studies to progress timely publication of results

Procedure

1. Authorship

An 'author' is considered by PaCCSC/CST/ITCC as someone who has made a substantive intellectual contribution to the published study².

- Authorship is substantial participation, where all the following conditions are met:
 - Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data^{2,3,4};
 - Drafting of the article or critical revision for important intellectual content^{1,2,4};
 - Final approval of the version to be published^{3,4}; and
 - Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content².
- There may be instances where a contributor does not meet the above criteria; however, the individual(s) is clearly accepted by all the other authors as an appropriate member of the authorship team. In this case, the selective contribution needs to be clearly identified and accepted by all members of the authorship team.
- Where authorship of multicentre trials is attributed to a group, all members of the group who are named as authors should fully meet the above criteria².
- One co-author will be nominated as Executive Author for the whole research output and will take responsibility for record-keeping regarding the research output^{3,4-8}.
- A signed authorship statement must be generated for each manuscript that acknowledges each author's contribution in writing. Such contributions may also be requested by the journal^{3,4-9}.
- A person who meets the criteria for authorship must not be included or excluded as an author without their written permission. This permission should include a brief description of their contribution to the work.

2. Authorship teams

Since some projects are likely to have a large volume of research output leading to multiple manuscripts, a plan is required for negotiating responsibility for various components of the research output for each individual project. Collaborating researchers agree on authorship at the protocol design stage and review their decisions periodically. The authorship team members and resulting published output from each study is recorded in a specific publications plan for each individual study in conjunction with the study's dissemination plan.

A component of research output is defined as the intellectual product of a defined methodology, data collection and analysis subset of the overall study. Occasionally, similar research output may be considered by several authorship teams who approach the content with a different intellectual focus resulting in different manuscripts for publication.

Individual authorship is, where possible, supported within a team framework. As such, authors are encouraged to work in authorship teams focused on various types of research output.

An Executive Author leads each team. The Executive Author functions as the Guarantor as advocated by editors of BMJ, Lancet and JAMA; and members of the authorship team function as Contributors⁵⁻⁸. Different authorship teams may be comprised of exactly the same members, or membership can shift, and teams reframed to accommodate the type of research output, interest of the team members, contributions, etc.

Individuals who are not the Coordinating Principal Investigator but who contribute significantly to a component of research output may be members of the respective authorship team (e.g. principal investigators, sub-investigators, study site coordinators, or data managers).

Responsibilities of the **Executive Author** (Guarantor) include (but are not limited to):

- Ensuring that the authorship team maintains the highest standards of research integrity⁵⁻⁸;
- Defining the types of presentation of the research output (e.g. conference presentations, manuscripts);
- Negotiating with the authorship team to determine responsibility for each conference presentation;
- Negotiating with the authorship team regarding authorship order and inclusion within all manuscripts and presentations;
- Oversight of the preparation of manuscripts, abstracts and presentations including accountability for content⁵⁻⁸;
- Oversight of the record keeping regarding the research output including circulating drafts, integrating changes, production of the final version and making the ultimate decision regarding submission to the publishing company, including^{3,4}:
 - Corresponding with all named authors regarding submissions and responses from the publishing company as named in the list/plan and ensuring they are aware of the process to be followed as per this SOP;
 - Responding immediately to reviewers' comments that only require minor amendments (i.e. small changes, formatting etc.); or circulating reviewer's comments to the authorship team where substantial amendments are required (i.e. rewrites of text) for response within **10 days**. For substantial amendments and where discussion is required amongst the authorship team in order to reach a consensus, the Executive Author must conduct a teleconference with the authorship team to address and resolve comments in a timely manner prior to submission. All members of the authorship team are expected to contribute at this stage as there will be no further opportunity provided;

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- Collating authorship team responses to substantial amendments and simultaneously resubmitting the next version to the publishing company and to the authorship team;
 - Communicating with the authorship team regarding the receipt of acceptance or rejection of a manuscript; and
 - Provision of 'authors copy' of manuscript for uploading to 'Open Access' repository where paper is not available 'Free Online'.
- Preparation and record-keeping regarding the authorship statement⁹; and
 - Timeline development and adherence.

Members of the authorship team indicate their contribution to the project in preparation for the authorship statement. PaCCSC/CST/ITCC, via the National Manager, disseminates authorship information on a quarterly basis in line with the work instruction accompanying this SOP.

To qualify for authorship, contributors must meet the criteria outlined in Section 1 above. If expertise is contributed for one specific reason but the person is not part of the study team, he/she is acknowledged but is not included as an author.

The following contributions **do not** justify including a person as an author¹:

- Recruiting study subjects to a study
- Department head or other positions of authority
- Personal friendship with the author(s)
- Providing technical contributions only
- Providing routine assistance to the work being published
- Acquiring funding for the work being published
- General supervision of the research team undertaking the work
- Providing already published data or materials gained from a third party, but with no other intellectual input

Publication of studies strive to include all researchers who have made a substantial contribution to the research output and meet the criteria listed in section 1 above, and to avoid disseminating any research findings that do not appropriately indicate participants or acknowledge their work. PaCCSC/CST members can expect that all authors work to ensure the integrity of the published work and avoid any aspects of fraud¹⁻⁹.

Those who contribute and participate in the study, but do not meet the criteria as outlined, are credited in the Acknowledgements section of the publication manuscript. Indications for Acknowledgement include meeting only one of the authorship criteria⁵. Written consent is obtained from all individuals who are named in the Acknowledgements section of the manuscript.

3. Authorship order

The rules for authorship order continue to change. Hence, the question of authorship order is considered with flexibility and pragmatism in academic medicine. Generally, the Executive Author is first author. The order of the remaining members of the authorship team is negotiated from within the team⁵⁻⁸.

The Journal of the American Medical Association (JAMA) and British Medical Journal (BMJ) propose that each author indicate his/her percent contribution to each part of the research output, and that the authorship order reflects the relative contribution. This is one suggested method that the authorship team can consider^{5,7,8}. Critical considerations include first author, corresponding author, last author, and group authorship:

First Author

Generally, the highest impact authorship position¹⁰. The Executive Author is usually the first author, however this is still clearly negotiated and articulated within the team. If there is a dispute as to the appropriate first author, the relative percent contribution to the research output, analysis and manuscript is considered. The first author is the person who contributed most to the work, including writing the first draft of the manuscript. Also, when negotiating first authorship key options such as corresponding author and last author are also considered.

Last Author

The position of last author is also negotiated with the team and specifically with the Executive Author and the person selected as the first author. If there is a dispute as to the appropriate last author, the relative percent contribution is considered as well as the authorship tradition of placing more senior authors last who provided the team with expert experience, conceptual advice and guidance¹⁰. In general, the person who is the second highest contributor to the research output and manuscript can decide if he/she would like the second author or last author position.

Corresponding Author

This is the person listed to receive all correspondence from the journal on behalf of the authorship team (reviewers' comments, publication proofs, etc.) and all correspondence from readers after publication. Some researchers consider this position like the last author position; however, journal editors view it as similar in status to an administrative role¹⁰. In general, the corresponding author is either the first or last author as negotiated by the team.

4. Contributors listed in acknowledgements

All contributors who do not meet the criteria for authorship in section 1 are listed in the acknowledgements section. Those listed are asked to declare whether they provided assistance with study design, data collection, data analysis, or manuscript preparation. Financial and material support are also acknowledged.

Groups of persons who have contributed materially to papers but whose contributions do not justify authorship may be listed under such headings as 'clinical investigators' or 'participating investigators', and their function or contribution is described. Written permission from these people is required to be acknowledged in the manuscript.

5. Presentations

Any presentations of results (final, interim or sub-studies) require approval from the authorship team, and are subject to the same procedures and authorship rules as publications.

6. Ownership and Use of Data

The data is ultimately owned by ITCC/PaCCSC/CST and the sites, and is managed by the PaCCSC/CST National Manager (*refer* SOP 5.5.10 Data Ownership and Utilisation). Individual study sites maintain ownership of their own data to use as they wish provided that they do not pre-empt the major study findings by publication or presentation. Publications and presentations of site-specific data are acceptable provided they seek approval from the authorship team for the study in question and are required to:

Comply with this SOP for Authorship;

Accept that whole-of-study presentations and publications take precedence and site-specific outputs must not inhibit any planned whole-of-study output. Where there is any overlap approval by the relevant Scientific Advisory Committee would form part of the overall approval relating to the output of a particular study.

Where access and use of ITCC data is requested by an external person, the request is considered by the relevant Scientific Advisory Committee, after having been reviewed in light of the publication schedule. This enables consideration of conflict with other planned analyses and publication. Requests for and the use of ITCC data by external individuals/organisations are managed as per SOP 5.5.10 Data Ownership and Utilisation.

7. Data Analysis and Interpretation

On completion of a study, data is compiled by the ITCC and provided to the biostatistician for analysis. Initial results are discussed by the authorship team and presented by a member or members of the authorship team to all contributing sites. The presentation of the results at this stage is **strictly confidential**. These presentations may use electronic means of presenting the information and they may take place during regular scheduled meetings of the relevant Scientific Advisory Committee

8. Reporting of Data

The ITCC recommends that all reporting of randomised controlled trials is in accordance with the CONSORT Statement (<http://www.consort-statement.org/>) and the Jadad randomisation scoring instrument¹³. Both these documents aim to improve the quality of reporting of randomised controlled trials. They offer a standard way for researchers to report studies. The CONSORT checklist includes items, based on evidence, that need to be addressed in the report; the flow diagram provides readers with a clear picture of the progress of all participants in the study, from the time they are randomised until the end of their involvement. The intent is to make the experimental process clearer, flawed or not, so that users of the data can more appropriately evaluate its validity for their purposes. The Jadad instrument has three questions assessing randomisation, blinding and dropouts/withdrawal rates from the study.

The first draft of the study report must be drafted within six months of the close to recruitment and submitted for publication within 12 months of close to recruitment. The draft is written by the Executive Author and then shared initially with the authorship team. The introduction and methods sections are drafted from the study protocol. The format of the report follows the ICH GCP guidelines for reporting¹³. The source of funding, acknowledgements listing, and reference section can be included at this point.

9. Conflict Resolution

The Australian Code for the Responsible Conduct of Research suggests that all groups of researchers establish procedures to resolve conflicts arising through disputes about authorship¹.

In the event that there is a dispute or concern about authorship or the journal order to be considered for publication, the conflict is resolved with the help of the relevant Scientific Committee.

If it becomes evident that an Executive Author or contributor needs or wants to be removed from an authorship team (e.g. inability to meet deadlines or participate in team discussions, membership in multiple other teams), the person can write to the Executive Author or PaCCSC/CST National Manager to indicate that they wish to withdraw from the team. Otherwise, the person can only be removed from the authorship team through a recommendation of the relevant Scientific Advisory Committee.

An important component of authorship is the preparation of abstracts, presentations, and manuscripts, and getting the product out in a timely manner. The Executive Author is responsible for time management. Provided that the analysed results have been provided by the data analysis team:

- If the research output is not prepared by **four months** after the goal date, then the Executive Author will receive an initial reminder from the PaCCSC/CST National Manager that the product is pending.
- If the product is still not ready **one month** later, a second reminder is issued.
- If the product is still not ready **one month** after the second reminder, the National Manager submits a notice to the relevant Scientific Advisory Committee who makes a decision regarding possible replacement of the Executive Author and re-organisation of the authorship team.

10. Reference Collection

Any articles or references collected for individual clinical studies are:

- Obtained in hard copy.
- Numbered according to an agreed electronic library file.
- Copied and placed in the project file in the coordinating site. These references then remain permanently attached to the other documents used in preparation of any manuscripts.

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- Inserted into the electronic bibliography. The format is determined at the commencement of the study protocol.
- The electronic reference file accompanies the electronic circulation of the manuscript.

Where the reference is cited within the project submission documents or draft manuscripts, the relevant section of the reference is highlighted. These papers are placed in a folder accompanying the manuscript.

Where the reference is not cited but may be used in the future or provides some useful background, the article is kept in another folder.

Related SOPs

- 6.0 Protocol Development
- 5.5.1 Electronic Data Handling
- 5.5.10 Data Ownership and Utilisation
- 6.15.1 Dissemination of Study Results

Related documents

- CONSORT Checklist
- Template 24: Dissemination Plan
- Guidance 12: Publication Planning

References

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Additional references

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History			
Version	Date	Author	Reason
1.1	10/01/2006	A Abernethy	New procedure
1.2	25/02/2007	S Whicker	Administrative update
1.3	18/07/2007	B Fazekas	Update prior to MAB review
1.4	18/04/2008	B Fazekas T Shelby-James	Revision following MAB review
1.5	16/09/2010	B Fazekas T Shelby-James	Periodic update
2.0	3/02/2011	B Fazekas	Changes ratified by MAB
2.1	27/09/2012	L Devilee	Revisions following discussions at TMC, Scientific Committee and Management Advisory Committee 2012 and development of work instruction and publications sub-committee Terms of Reference
3.0	6/08/2013	L Devilee	Revisions following first meeting of the publications sub-committee. Presentation of changes to the Scientific Committee and final approval by MAB 26 th August 2013.
3.1	6/01/2014	L Devilee	Revisions following meeting of the publications sub-committee on 8 th November 2013 and 4 th March 2014, and approval by MAB 21 st March 2014.
3.2	3/01/2015	C Hope	Periodic review
3.3	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
3.4	02/08/2018	L Brown	Review requested by Scientific Committee to include suggested timeframes.
3.5	26/02/2020	V Yenson S Kent	Periodic Review
3.6	29/2/2022	L Brown	Periodic Review

Approval		
Version	Approval Name	Approval Signature
3.6	M Agar	