Constitution of PACCMAN

What is PACCMAN?

PACCMAN stands for Pediatric Acute & Critical Care Medicine Asian Network.

Governance of PACCMAN

PACCMAN will be governed by the PACCMAN Committee, which consist of the PACCMAN Executive Committee and Scientific Committee, for a 3-year term.

PACCMAN EXCO

The PACCMAN Executive Committee (EXCO) is formed to manage the PACCMAN clinical research network. PACCMAN EXCO will provide overall direction and governance of the network, overseeing resources and budgeting, and is responsible for managing and resolving major operational and political issues/risks.

The EXCO is also responsible for all communications with media including providing final authorization for materials that go on to the public section of the website, posters and public presentations.

What constitutes the PACCMAN EXCO?

The PACCMAN EXCO will comprise of the following:

- 1 Chairman
- 1 Deputy-Chairman
- 3 Members

The Executive Committee Chair and Co-Chair will be recognized disease experts in the Asia Pacific with established publication records and expertise in the conduct of multi-site trials. The Chair

and Co-Chair may or may not also function as the Study Principal Investigator (PI) and Co-PI for particular studies. Both Chair and Co-Chair will be elected every 3 years by voting. Only Co-Chair who have completed 1 term of service will be eligible to be elected as Chair. Both Chair and Co-Chair may stand for re-election for a maximum of 2 terms of service to allow rotation and renewal of EXCO members.

PACCMAN Scientific Committee

The PACCMAN Executive Committee will be served a Scientific Committee (SC).

The SC will comprise of the following:

- Critical Care Chairman
- Acute Care Chairman
- 2 members

This committee determines the scope of research projects to ensure relevance to the overall aims, determines feasibility of research projects and coordinates related projects and programs. The SC will not be directly involved in individual studies but may be consulted by the Primary Investigators (PIs) for assistance/advise. They will also oversee reviews, provides written critiques, and gives final approval for all journal article submissions from the study. Once a manuscript is submitted, correspondences are between the corresponding author and the journal. Final versions of the manuscript, if revisions are required, must go through and receive approval from the SC.

The SC will also assist with enforcement of timelines for analysis and publication of data. If any first author cannot complete the manuscript submission within 1 year following the end of data collection/closure of data collection and cleaning, then first authorship will be re-evaluated and potentially reassigned by the SC.

Network Membership

Network members may be clinicians, allied health members or scientific staff who may propose or participate in any clinical trial conducted by PACCMAN. If the study is initiated by a single member, that member assumes the role of the Lead PI. If the study is initiated by more than one member, these members form the Lead Team. The Lead PI/Team proposes the rules of authorship to the SC and EXCO before study initiation. The general guidance is that for multisite studies, the Lead PI and Co-PI, the biostatistician, data manager, project manager, and all site PIs are co-authors. Site Co-PIs will be included whenever the position is earned and is feasible given publication limitations.

The Lead PI/Team would oversee and make decisions pertaining to all operational aspects of running the study, e.g. issues pertaining to data management, study monitoring and regulatory considerations. While any member of PACCMAN may propose a new study, the Lead PI who has proposed the study would be expected to secure the required funding to conduct the study. In the absence of such funding, PACCMAN has no obligation to proceed with the trial.

For each proposed study, other members may opt in or opt out of the study. Each participating member assumes the role of a Site-PI and is responsible for seeking ethics approval, ensuring responsible conduct, accuracy of data and other operational aspects of the study at their respective center.

Secondary analyses from such studies can be assigned to Site PIs/ Co-PIs or proposed by Site PIs/ Co-PIs. In these cases, the Site PI and Co-PI can become senior authors. These publications continue to include the biostatistician and other data center (i.e. SCRI) personnel involved in study management if they have made substantive scientific contributions to the manuscripts. The SC (or the EXCO – depending on the Network and Study) will review, approve and recommend author slots for additional (unplanned) secondary analyses.

All members are invited to attend the General Meeting or Scientific Meetings of PACCMAN. However, the PACCMAN is not a closed group. PACCMAN meetings may be open to interested parties, such as subject matter experts, to participate as observers and contribute, where

possible, and on a space availability basis. Attendance by industry members should be cleared by the PACCMAN EXCO.

PACCMAN membership is not exclusive. Members can still join other networks on the condition that members inform the EXCO, copying the PACCMAN secretariat.

Responsibilities of Members

1. To commit to attendance in a majority of PACCMAN meetings, where possible
2. To abide by the specific professional and ethical requirements in conducting clinical research
3. To participate and actively engage, where possible, with approved trials within the group's remit
4. To review and consider participating in each PACCMAN study protocol proposed by PACCMAN members and others
5. Participating member is responsible for obtaining the necessary funding for the trial at his/her site.
6. Participating member is responsible for seeking ethics approval, ensuring responsible conduct, accuracy of data and other operational aspects of the study at their respective center
7. Participating member is responsible for obtaining the necessary approval to share the research data and images for the purpose of the study, and the approval to transfer data to the database and image archival facilities of the Study Coordination Centre, and to transfer ownership of the research data to the Study Coordination Centre for clinical trials
8. Agreement to treat any confidential information disclosed to PACCMAN Members with due care to prevent its disclosure or unauthorized use
9. All members should at least participant in 1 study over a 3-year time period to remain as an active member. PACCMAN EXCO reserved the rights to terminate the membership of inactive members.
10. To contribute to the success of the group

Voting Rights of Members

Members of each site shall elect 1 site representative (up to 2 representatives if the site has a lot of members) to help coordinate projects and programs for the site. The site representative should have significant contribution of patients and possibly contributions to study protocol, and other inputs to the study/network. Each site will have 1 voting rights for any decision making processes in PACCMAN, e.g. during EXCO election. The site representative shall coordinate and discuss with the site members before casting the vote on behalf of the site.

Membership Application

To join PACCMAN, interested candidate will have to complete and submit an application form to the PACCMAN secretariat. The application will be reviewed by the EXCO and subjected to their approval.

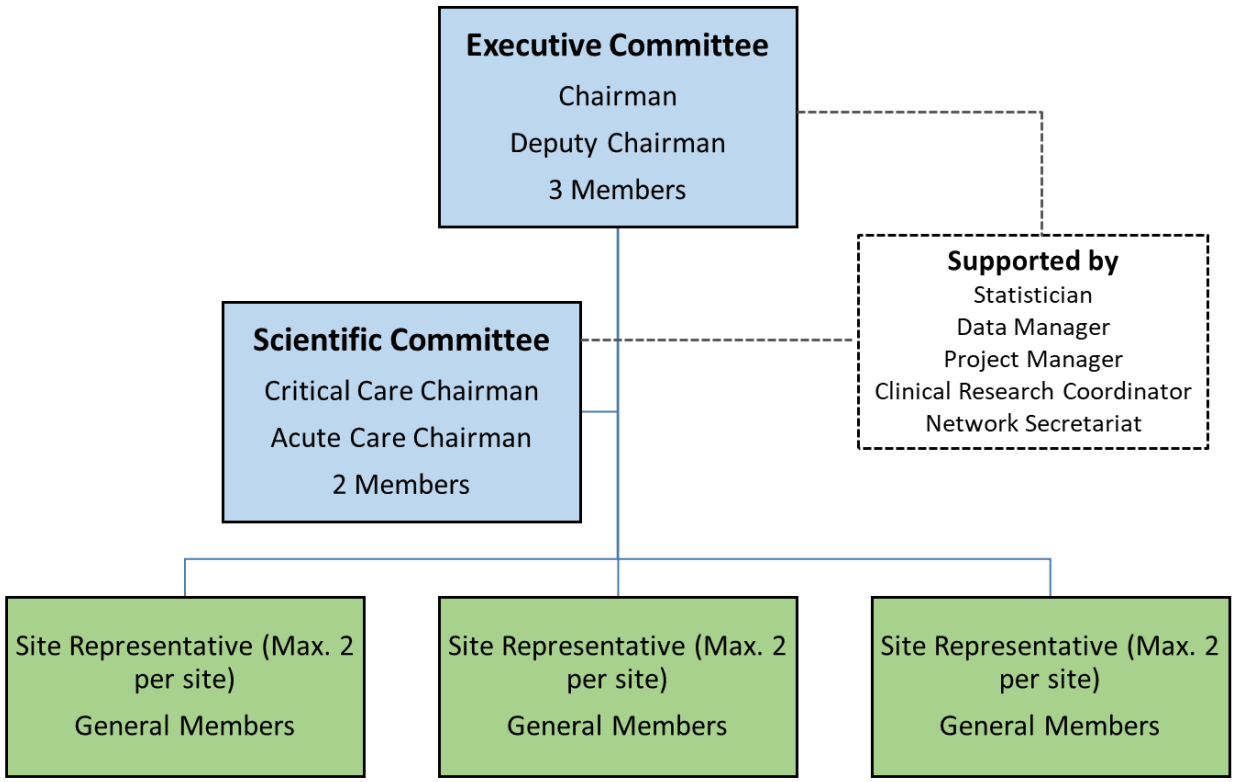
Members join voluntarily. By joining, all members agree to uphold the Responsibilities of Members, as well as the PACCMAN principles, policies and procedures.

Membership Termination

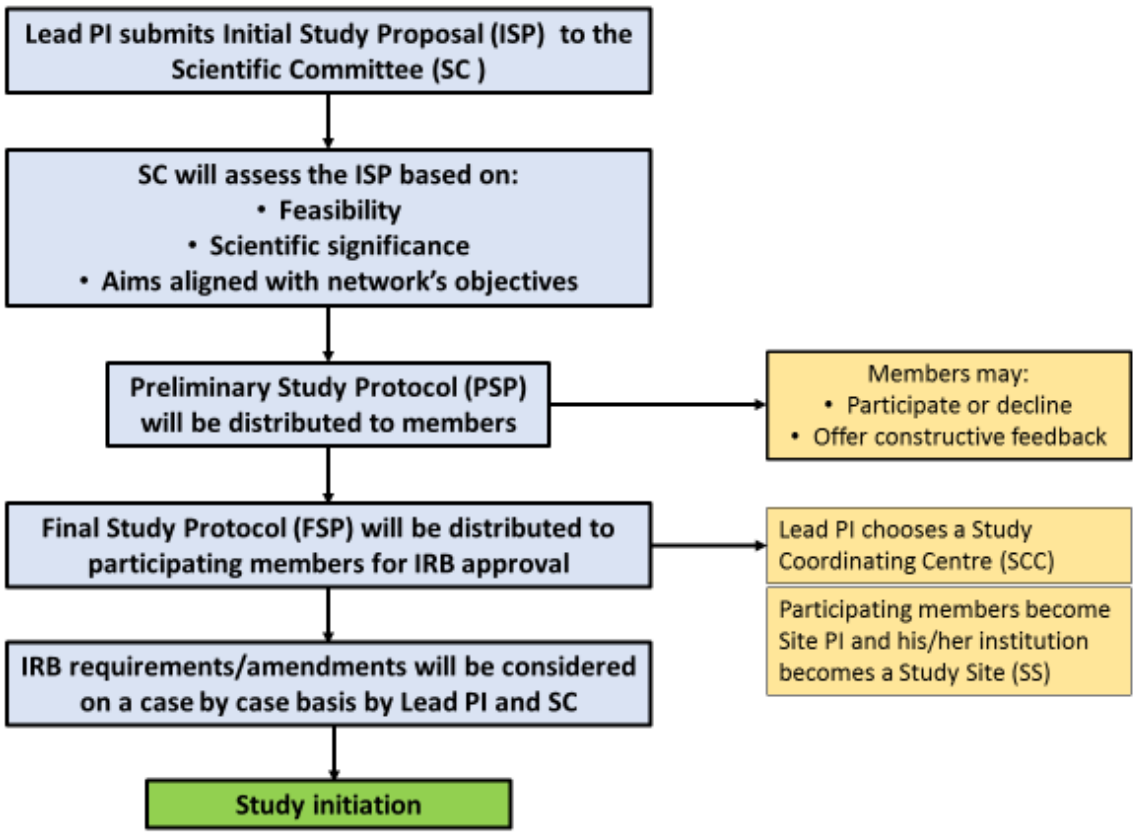
PACCMAN EXCO reserved the rights to terminate the membership of inactive and non-contributing PACCMAN members.

PACCMAN members may terminate their membership by written notice of its intention to do so to the PACCMAN EXCO, copying the PACCMAN secretariat.

Organization Chart



Study Proposal



Any member, as individual (Lead PI) or in group (Lead Team) may propose and submit new study proposals, known as Initial Study Proposal (ISP) to the PACCMAN Secretariat. The ISP will be submitted for SC perusal and feedback.

The SC will decide on the feasibility of the ISP. If the ISP is feasible, the SC have 1 month to submit their proposed amendments to the LPI/Team through the PACCMAN Secretariat. Thereafter, the LPI/Team has 1 month to finalise and submit the preliminary study protocol (PSP) to the PACCMAN Secretariat.

The PACCMAN Secretariat is responsible for receiving and disseminating the PSP to all members for their perusal and feedback.

Interested members have 1 month to submit their proposed amendments to the LPI/Team through the PACCMAN Secretariat. Thereafter, the LPI/Team has 1 month to finalise and submit

the final study protocol (FSP) to the PACCMAN Secretariat. The PACCMAN Secretariat is responsible for disseminating the FSP.

The LPI/Team now assumes the responsibility of forming the Study Coordinating Centre (SCC). The SCC may utilise the services of his/her institution, or an academic/commercial CRO. The LPI/Team is responsible for the SCC.

Each member may choose to participate in the study or decline. Participating members are responsible for submitting the FSP for their IRB approval. Members are responsible for informing the SCC feedback provided by and amendments required by his/her IRB. He is also responsible for providing reasonable institutional information required by the protocol to the SCC.

The SCC collates protocol amendments required by each IRB, and refer to the LPI/Team for decision. The LPI/Team decides on protocol amendment if necessary.

Once approved by the IRB, the participating member is responsible for submitting the documentary proof of the IRB approval to the SCC. The participating member now assumes the role of SPI, and his/her institution is registered a Study Site (SS).

The SCC is responsible for site training, registration and initiation. If required, for example, for registered clinical trials, the SCC is responsible for appointing a Study Monitor / Study Monitors. By participating in the trial, each SPI is responsible for obtaining the permission from his/her institution to allow site inspection by the study monitor.

Data Ownership

Only de-identified data will be contributed to PACCMAN. Each site will have to retain their own identification list. The data contributed to PACCMAN belongs to the Network, with SCRI/ host of the database as the default custodian of these data. Members of PACCMAN whose institution have contributed to the Network data will continue to own their portion of source data and they are free to use them in a way they deem appropriate as long as they do not conflict with the PACCMAN main study. Any use of data drawn from PACCMAN beyond that contributed by one's

own institution would require an approval from the PACCMAN Scientific Committee, EXCO and the respective contributing sites.

The participating member is responsible for long-term (on or off-site archival) storage of the study data according to the requirements of clinical trial registry, typically 10 years.

Data Ownership after Membership Termination

Upon membership termination, the individual will no longer contribute data to PACCMAN. However, data contributed to PACCMAN before the membership termination should still be available to the Network and the terms mentioned above should still apply to the data.

Authorship and Acknowledgement Rules

Priority and eligibility for authorship will be given to those investigators at sites that have contributed data. Site PIs and Coordinators who have not contributed data will, in general, not be considered co-authors. Exceptions can be granted for special circumstances at the request of the first or senior author of each manuscript, and should be discussed and approved by the PACCMAN Scientific Committee.

First, second, third and senior authorship will be assigned to individuals who have done the most amount of work (i.e. development and organization of protocol or tool, recruited many subjects, etc.), and who have contributed intellectually to that specific manuscript. These, for the most part, are individuals who have been working on the project over the past 2-3 years, and who have been involved from the inception of the project. Priority to young investigators as first, second and third authors, when possible and appropriate.

We will attempt to appropriately attribute academic credit, with emphasis on acknowledgement of all involved (usually with most input from first and senior authors as to order). All site investigators will be recognized as part of "PACCMAN" in all PACCMAN publications by the byline

"PACCMAN Investigators" (Note: this usually allows all investigators to be cited in PubMed as co-authors).

Local collaborators at sites who are not site PI's or co-PI's will generally be acknowledged in an appendix of site participants appropriate to that manuscript (this will include acknowledgement of key research coordinators, key local investigators or organizers of research at each institution).

Individuals who have left PACCMAN will still be included in the authorship if their data contributed before membership termination are used in the manuscript.