

Policy and Procedures Guide

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PoCoG

Psycho-oncology Co-operative Research Group

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1 Mission and Aims

1.1 Mission

PoCoG's mission is to improve outcomes for people affected by cancer by developing and facilitating high quality, collaborative and clinically relevant research that focuses on interventions and services to optimise psychosocial and supportive care.

1.2 Aims

PoCoG aims to provide expert advice, resources and support to researchers and health professionals to increase collaboration and innovation in psycho-oncology research.

PoCoG:

- brings together researchers, clinicians, health care professionals and consumers to share ideas and form new collaborations and networks
- develops national research capacity and collaborations to conduct large-scale, multi-centre research of clinical relevance and importance, which would be difficult for a single team to undertake
- encourages and collaborates with cooperative cancer trials groups to include psychosocial or quality of life sub-studies in existing and planned research
- provides and promotes resources that support researchers in developing psychosocial and quality of life research.

2 PoCoG Operations

2.1 Strategic and Business Plans

The Strategic and Business plans define the purpose of PoCoG as an organisation, outline its aims and goals, and describe a plan of work and key areas of development for PoCoG both in the long and short term.

Business plan

PoCoG develops an annual business plan to correspond with each financial year. The planning process commences in early February each year. The business plan development occurs in consultation with PoCoG's Committees, staff members and other significant contributors to PoCoG's activities.

Strategic plan

PoCoG develops a strategic plan to correspond with each new Cancer Australia funding period (usually 3 years). The strategic plan informs the infrastructure funding applications and aligns with key performance objectives in the funding agreement(s) of Cancer Australia and other infrastructure funding bodies.

Progress against the current strategic and business plans

Progress is monitored six-monthly in conjunction with the preparation of regular reports required by funding bodies.

2.2 Policy and Procedures Manual

This manual outlines policy and procedures to guide the activities of PoCoG. Additions and amendments are approved as required by the PoCoG Management Team. The manual will be fully reviewed every 3 years. Specific sections may be amended in line with policy and/or procedural changes as required.

2.3 Branding and the Corporate Style Guide

PoCoG has an established corporate identity in line with The University of Sydney guidelines. PoCoG's corporate identity and rules governing branding are outlined in the PoCoG [Corporate Style Guide](#).

The use of PoCoG branding (including the logo, corporate styles etc.) is managed and monitored by the PoCoG Executive Office and requests related to PoCoG branding must be directed to the Executive Office.

2.4 Annual Report

An Annual Report highlighting the activities of the previous year is produced annually. The report provides summaries of PoCoG activities, including all ongoing and recently completed studies. Principal

Investigators of PoCoG administered and supported studies are required to provide an annual study update and these will be collated into the Annual Report by the PoCoG Office. The Annual Report is made available to all members and provided to sponsoring organisations and other bodies associated with PoCoG's work. It is also available for download from the website.

2.5 Newsletter

The PoCoG newsletter is produced and distributed via email to the PoCoG membership on a quarterly basis. It provides a brief summary of new initiatives or changes within PoCoG, as well as updates on PoCoG research and priorities.

Additional member updates and Electronic Direct Mail (EDM) may be circulated to the PoCoG membership at the discretion of the Executive Director.

Detailed policy relating to external material is available on the PoCoG website.

2.6 PoCoG Website

The aim of the PoCoG website is to provide information and documents relating to PoCoG activities, meetings and research, to members and to the broader cancer community in a timely and accessible fashion.

Web-based information and documents relating to PoCoG research, meetings and other activities are updated on an ongoing basis. It is the responsibility of the PoCoG Office to ensure that the website is up-to-date.

The style is governed by University of Sydney Guidelines, the PoCoG Corporate Style Guide and the Cancer Australia funding agreement.

3 PoCoG Chair and the PoCoG Management Team

3.1 The PoCoG Chair

3.1.1 Role

The PoCoG Chair is a leader, champion, mentor, and a representative of the group. Through their international reputation for excellence in Psycho-oncology and effective and continuing leadership, the Chair also ensures that PoCoG functions as the leading Australian Psycho-oncology research collaborative group and is recognised as an international leader in the field. The Chair oversees and acts as an adviser to the Scientific Advisory Committee (SAC) and leads the Management Team (MT). The responsibilities of the Chair include:

- Establishing the overall direction and vision for the future and collaborating with the SAC on the development of the strategy to achieve the PoCoG's goals
- Guiding the make-up of the committees and working groups to form effective leadership teams
- Ensuring alignment of these teams with the vision and strategy of PoCoG
- Representing the interests of the group nationally and internationally

3.1.2 Terms

To ensure continuity of leadership the commitment for PoCoG Chair is for six consecutive years such that a selected individual shall first serve one 2 year term as Deputy PoCoG Chair, one 2 year term as PoCoG Chair and one 2 year term as Immediate Past PoCoG Chair. The term shall commence from the time the selection results are announced.

In the absence or incapacitation of the PoCoG Chair, the Deputy Chair shall assume the PoCoG Chair's duties. In the absence or incapacitation of both PoCoG Chair and Deputy Chair, the Immediate Past PoCoG Chair together with the Executive Director will assume the PoCoG Chair's duties.

3.1.3 Process

The Chair is appointed by a selection committee headed by the incumbent Chair and the Executive Director and consisting of co-opted advisers from among current office bearers and the Australian cancer community. Expressions of interest from among current and previous PoCoG office bearers will be sought a minimum of two months prior to the Selection Committee convening.

3.2 The PoCoG Foundation Chair

3.2.1 Role

To ensure continuity of leadership, to provide oversight, and ongoing mentorship in psycho-oncology, the PoCoG Foundation Chair title is reserved exclusively for the first PoCoG Chair Professor Phyllis Butow. The PoCoG Foundation Chair provides stability and guidance, when needed, to current serving

PoCoG Chair, Management Team and Scientific Committee. The PoCoG Foundation Chair is encouraged but not required to have an active involvement in PoCoG activities.

3.2.2 Terms

The PoCoG Foundation Chair office will commence at the end of the two year term of Past PoCoG Chair and has no term limit. However, the Foundation Chair can elect to withdraw from PoCoG activities when they desire no further involvement in PoCoG activities.

3.3 The Management Team

The Management Team is responsible for overseeing the management of PoCoG, which includes financial and administrative issues, as well as liaison with other clinical trials groups and interaction with key stakeholders. The Management Team is also responsible for implementing the policies and procedures of PoCoG and operationalising the group's strategic directions. The management team has an advisory role in the strategic direction and decision-making and acts as a conduit between PoCoG governing bodies and operational staff.

The management team will consist of the senior executive staff members (Executive Director, Research Program Manager), the PoCoG Chair, PoCoG Deputy Chair, SAC Chair and SAC Deputy Chair. The terms of office of the Management Team members are defined by their terms of employment or the terms of office of their roles on PoCoG's committees.

The Management Team meets at least bi-monthly and at other times as appropriate. A quorum for approvals consists of the PoCoG Chair, the Executive Director or Officer, and either the SAC Chair or Deputy SAC Chair.

3.4 Conflict of Interest

Members are required to declare any potential conflict of interest which may have bearing on their role on the committee. Processes for declaring conflict of interest are outlined in section 10.4

4 Financial and Legal Management

4.1 Legal status

PoCoG is a Centre of the University of Sydney and as an unincorporated group operates within the university's legal, financial and administrative framework. Legal purview is provided by the University of Sydney. PoCoG uses the University of Sydney Australian Business Number ABN (ABN 15 211 513 464). For all intents and purposes the University of Sydney acts on behalf of PoCoG as the legal entity on funding agreements and other contracts.

4.2 Contractual obligations

PoCoG has contractual obligations to its sponsors. Thus, PoCoG must adhere to external policies of these organisations as specified by their funding agreements. Staff and researchers acting under the auspices of PoCoG must be aware of these obligations and act accordingly.

4.3 Privacy Policy

4.3.1 Privacy legislation

Privacy legislation that came into effect in Australia in December 2001 requires PoCoG to protect personal information provided to it in accordance with the National Privacy Principles (NPPs). The New Zealand Privacy Act 1993 (and subsequent amendments) makes similar provision in New Zealand. Information given by a member to PoCoG for its purposes cannot be passed on to a third party without the specific permission of the individual concerned. All PoCoG operations are within this context and, where relevant, within the context of similar legislation in other countries.

4.3.2 Members

PoCoG maintains a list of contact information for members. Members provide the information in the list as part of their membership of PoCoG. This information is used for PoCoG purposes only in the interests of members and is not passed on to third parties.

4.3.3 Website

The PoCoG website has a public access area and several password-controlled access areas with differential access. The Management Team may approve the provision of access to other individuals where a need has been demonstrated. In order to ensure confidentiality of this information, members of sponsoring organisations are not provided with access to the restricted access area. Information they may require in relation to sponsorship and forthcoming meetings is provided by email.

In the interest of facilitating communication and collaboration among members, PoCoG may make limited details (institutional affiliation and email addresses) and information about key interests,

available to all members via the website. This information is in a password-protected section of the website and is not available to the general public.

Members who do not wish their contact details to be available in this way may indicate this on the PoCoG membership application form.

4.3.4 Meetings

When a sponsoring company requests a list of attendees at a meeting, they are provided with a list of names and institutional affiliations. No additional information is included.

4.4 Responsibility for Financial and Legal Management

The PoCoG Chair and Executive Director are responsible for overseeing the financial management of PoCoG. The Executive Director, employed by The University of Sydney, is authorized to sign cheques, manage accounts and oversee annual budgets. It is the responsibility of the Executive Director to report to the Management Team on matters relating to the financial management of PoCoG.

Since PoCoG operates within the financial and legal framework of the University of Sydney, contracts and other legal agreements will be authorised in accordance with the University's policies, and may require a signature from a relevant university delegate.

Administration of PoCoG's infrastructure grants will be the responsibility of the Executive Director. Administration of research grants will be the responsibility of the Principal Investigators. Financial management of grants administered by PoCoG will be the responsibility of the Principal Investigator and will be managed with the assistance of the Executive Office.

PoCoG has reporting requirements to its sponsors which must be adhered to. PoCoG has a signed agreement with Cancer Australia through the University of Sydney which lays out requirements that must be observed (such as complying with the Federal Government style guide in all publications and websites).

4.5 Professional Advice and Delegation of Authority

PoCoG may need to seek professional advice from time to time. The PoCoG Chair and Executive Director are authorised to provide information as necessary to accountants, auditors, financial advisors, solicitors and other similar professionals in relation to research projects or the functioning of the group.

Other Management Team members (or, if appropriate, individual members) may similarly be authorised with respect to specific tasks for which they have been allocated responsibility. They should report on these matters to an appropriate meeting of the Management Team.

5 PoCoG Central Office Structure

5.1 PoCoG Executive Office

The PoCoG Executive Office is responsible for coordination of all aspects of the conduct of the Group's executive functions, strategic and research agenda and membership services.

The PoCoG Executive Office is constituted as follows:

- Executive Director
- Executive Officer
- Research Program Manager

The Executive Officer and Research Program Manager report to the Executive Director.

5.2 PoCoG Research Project Teams

The PoCoG Research teams implement research projects administered by PoCoG, either alone or in collaboration with other CCTGs.

The teams consist of research program managers, co-ordinators and officers/assistants (number and hours determined by funding and workload).

Research staff report to the Principal Investigators of the grant on which they are employed for content issues unless this is delegated to the Executive Director. Research staff employed on PoCoG administered studies report to the Executive Director for administrative issues. Research staff employed on PoCoG supported studies report to their local institution for administrative issues.

Visiting Fellows and Research Fellows may be appointed as relevant to a PoCoG research team.

A copy of all protocols and publications emerging from the PoCoG research team must be held by the PoCoG Office.

6 Scientific Advisory Committee

6.1 The role of the SAC

The Scientific Advisory Committee (SAC) is responsible for strategic direction, research priorities of PoCoG and scientific rigour and minimum standards of PoCoG studies. The SAC is also responsible for organisational decision-making directly relating to strategic direction.

The SAC activities include:

- Setting strategic and scientific direction and priorities and ensuring that these are in line with Cancer Australia principles and key performance indicators
- Development of PoCoG initiated research activities
- Reviewing and providing constructive feedback on proposals for PoCoG involvement in research
- Taking part in the ongoing review of PoCoG studies to ensure their scientific rigour or maintenance of minimal research quality standards

The SAC may from time to time co-opt other members to form working groups to undertake specific projects or functions.

6.2 Membership

In principle, the SAC will be multidisciplinary, include representation from across Australia and include members with expertise in qualitative and quantitative research, statistics or diverse clinical roles related to psycho-oncology.

The SAC consists of no more than 18 members and comprises:

Core SAC members:

- SAC Chair
- Deputy SAC Chair
- JCAG representative
- up to 6 ordinary members
- up to 3 Early Career Researcher members.

Additional co-opted voting members:

- PoCoG Foundation Chair
- PoCoG Chair
- PoCoG Deputy Chair

- PoCoG Immediate Past Chair
- Nominated representative of the Australian Psycho-Oncology Society (OZPOS), the Psycho-Oncology Group of COSA
- Nominated representative of Cancer Nurses Society of Australia (CNSA)
- Nominated representative of the Oncology Social Work Australia (OSWA).

In addition the following advisory (non-voting) members are regularly co-opted into specific scientific activities of PoCoG:

- Biostatistician
- A representative from the Cancer Australia Quality of Life advisory service
- A representative from the Cancer Australia Health Economics advisory service.

Staff members on the Management Team may participate in SAC meetings in advisory capacity.

Membership of the SAC is open to all PoCoG members, but not PoCoG staff members.

SAC members may choose to resign from the committee and are required to provide the Management Team with at least six weeks' notice of their resignation. Procedures for appointing new members of the SAC will then be carried out in accordance with the process described below.

Co-opted SAC member terms are in line with their individual role.

Members are required to declare any potential conflict of interest which may have bearing on their role on the committee. Processes for declaring conflict of interest are outlined in section 10.4.

6.3 Recruitment of new members

New ordinary members of the SAC will be appointed on a competitive basis via an application process. The call for expression of interest will be announced to the entire membership via the Executive Office.

Applicants must:

- Be full PoCoG members
- Be proposed and seconded by existing PoCoG members (self-nominations are permitted)
- Complete an application form which includes a brief CV.

The SAC Chair shall appoint a selection panel who will determine additional selection criteria and review the applications and select the most suitable candidate.

The SAC and the membership will be notified of the outcome of the selection process by the review panel via the Executive Office.

6.4 Terms of ordinary members

Ordinary membership of the SAC is for a term of three years with a maximum of two consecutive terms. Ex officio members of the committee are exempt from term limits. The SAC Chair and Deputy Chair are exempt from these term limits for the duration of their appointments.

Terms are staggered so that up to one third of the SAC is renewed in any one year. The turnover occurs in April each year.

If a SAC member wishes to stand for an additional term, they must re-apply through the appointment process described under “Recruitment of New Members”. Under special circumstances the SAC chair may approve reappointment for the second term without a formal application.

6.5 Meetings

The full SAC will meet at least twice per year, at least once face-to-face, and as needed via teleconference. These meetings will provide a forum for SAC members to present, discuss and develop ideas and protocols, for reporting and discussing SAC activities, and strategic planning for PoCoG.

In general only SAC members may attend SAC meetings, although invited guests or individual PoCoG members may attend for specific agenda items. Additional meetings and teleconferences of specific Working Groups may be scheduled as required.

A quorum for SAC meetings consists of six members of the Committee, with one attendee to comprise the SAC Chair, Deputy SAC Chair, or a proxy appointed from the SAC by the SAC Chair or Deputy Chair. The quorum for meetings should also include a representative of the JCAG.

If a SAC member fails to attend three consecutive meetings, the SAC Chair may ask the representative to stand down from the SAC.

6.6 The roles of SAC Chair and Deputy Chair

The SAC Chair reports to the PoCoG Chair.

The SAC Deputy Chair reports to the SAC Chair.

The SAC Chair and Deputy Chair are responsible for:

- Providing leadership and direction of SAC operations and activities
- Participating as active members of the Management Team in overseeing the management of PoCoG
- Responding to requests for advice or issues that arise outside of SAC meetings and may need SAC input
- Working with the Executive Office to develop agendas for the SAC meetings
- Working with the Executive Office to progress the SAC agenda in between meetings

- Chairing meetings of the SAC
- Reviewing research proposals by means of the PoCoG Pathways process (see section 9.2)
- Contributing to the PoCoG annual report
- Approving publications arising from SAC – initiated studies and assisting in resolving disputes concerning authorship, contents and timing of publications and presentations.

The SAC Chair will consult with other members of the SAC as appropriate.

The Deputy SAC Chair will act in place of the Chair in his/her absence and support the Chair in the above duties.

6.7 Election of the SAC Chair

The term of the SAC Chair shall be two consecutive years. After this time it is intended that the SAC Deputy Chair will become the SAC Chair in the next term of office. However this rule is not binding and comes into effect upon agreement between the SAC Chair, SAC Deputy Chair and the PoCoG Chair upon commencement of the new term.

If the SAC Deputy Chair should become unable to take on the role of Chair, a new SAC Chair will be elected from the SAC. The candidate must be a current SAC member and have at least two years' experience on the SAC, either as a currently serving member or a past member. The SAC Chair will be elected by the following means:

- Interested SAC members will submit an expression of interest form, putting forward their nomination to the Executive Office
- the Executive Office will organise the election process
- the SAC will elect a Chair from the list of candidates; the successful candidate will become the SAC Chair, subject to approval by the PoCoG Chair.

The outgoing SAC Chair shall remain on the committee as an ordinary member for one year.

6.8 Election of the SAC Deputy Chair

A new Deputy Chair will be elected from the SAC at the beginning of the term of the new Chair. The candidate must be a current PoCoG member and have some experience on the SAC, either as a currently serving member or a past member. The Deputy Chair will be elected by the following means:

- interested SAC members will submit an expression of interest form, putting forward their candidature to the Executive Office; ECR members, standing members and the outgoing Chair are not eligible
- the Executive Office will organise and hold an election process
- the SAC will elect a Deputy Chair from the list of candidates; all SAC members, including ECR members, standing members and the outgoing Chair, are eligible to vote; the successful candidate will become the Deputy Chair, subject to approval by the PoCoG Chair.

The term of the Deputy SAC Chair will align with that of the SAC Chair.

6.9 Early career SAC members

The purpose of recruiting early career PoCoG members to the SAC is to provide the opportunity for such persons to develop leadership skills by participating in PoCoG governance activities and to ensure input into SAC activities from early career members. They will also play a key role in assisting the SAC with the development and implementation of support for early career PoCoG members.

The term of office for an early career SAC member shall be three years. There will be at least two early career members at any given time. Their terms will be staggered so that the term of only one early career member end in any given year. After the end of their term early career members may apply to remain on the SAC as an ordinary member through the application process described above.

6.10 Review of the Terms of Reference of the SAC

The Terms of Reference for the Scientific Advisory Committee (SAC) document will be reviewed as required by the Scientific Advisory Committee. Changes must be approved by the PoCoG Chair.

6.11 Conflict of interest

For guidelines on declaring conflict of interest please refer to section 10.4

7 Joint Community Advisory Group

The Primary Care Collaborative Cancer Clinical Trials Group (PC4) and the Psycho-oncology Co-operative Research Group (PoCoG) are national groups working together to develop and conduct cancer research studies. The groups value the involvement of consumers in all aspects of their research programs and have established a Joint Community Advisory Group (JCAG).

7.1 Background

The purpose of the PC4 and PoCoG Joint Community Advisory Group (JCAG) is to provide a mechanism for consumer input on general research directions and priorities for both Groups.

Key activities include:

- reviewing research concepts from consumers' perspective including the relevance of the overall research question
- reviewing information sheets and consent forms of PC4 and PoCoG-supported studies
- participating in working groups as required
- facilitating two-way communication with external general consumer groups, i.e. not confined to the context of cancer.

We expect that JCAG members will also be involved in other activities including:

- facilitating links with consumers and consumer groups
- raising awareness and advocating about consumer priorities among the PoCoG and PC4 members
- advising on ways to increase public awareness of the importance of clinical trials
- advocating participation in research and clinical trials to consumers.

7.2 Structure

The JCAG shall consist of up to 12 community members and shall report to the relevant committee of both PC4 and PoCoG. The activities of the JCAG shall be facilitated by the co-chairs of JCAG and supported by the Executive Offices of the Groups as required.

7.3 Meetings

The meetings of the JCAG will be held not less than twice per year, with at least one being a face-to-face meeting (subject to funding). Teleconferencing facilities will be provided by PoCoG and PC4 to enable members to participate. Each member of the JCAG will be required to attend at least one meeting per year, either in person or via teleconference.

JCAG members may also be called upon to attend other meetings, either as a proxy for a Co-Chair or as a designated consumer advisor.

7.4 Membership

7.4.1 New members

JCAG membership will reflect a diversity of skills, experiences, demographics and location.

New members shall be required to submit an application which will detail:

- their experience with cancer
- their experience with clinical trials or studies
- their involvement with other consumer or community groups
- the reasons for wanting to join JCAG
- their curriculum vitae.

Upon appointment new members of JCAG shall be provided with access to:

- JCAG Terms of Reference (this document)
- JCAG introductory booklet
- JCAG member contact details
- recent JCAG minutes
- list of PoCoG and PC4 studies
- any other information deemed necessary.

7.4.2 Essential criteria

All members of the JCAG must be members of PC4 and PoCoG.

All members of the JCAG will be provided with opportunities to undergo training for consumer representatives. PC4 and PoCoG will endeavour to provide basic training as well as additional training activities (alone or in conjunction with other CTGs) and/or educational materials.

JCAG members are not eligible for membership of other committees of the Groups, other than as a JCAG representative.

7.4.3 Duration of appointment

Membership of the JCAG is for a term of three years. Membership may be renewed upon reapplication. Terms of the JCAG will be staggered in order to avoid the complete renewal of the subcommittee in any one year. To achieve this members will be offered renewal options of one to three years.

7.4.4 Support for JCAG Members

PC4 and PoCoG will endeavour to reimburse all travel expenses associated with members' participation on the JCAG. The PC4 and PoCoG Executive Offices will provide administrative support to JCAG members to minimise any other costs associated with JCAG participation.

7.5 JCAG Co-Chairs

The Chair position is a shared role to facilitate communication into and from the JCAG. The Co-Chairs shall be the primary spokesperson/s for the JCAG. The JCAG Co-Chairs shall be elected by members of the JCAG for a period of three years. To facilitate succession planning a Co-Chair Elect shall be installed in the position for the final year of that term.

7.5.1 Co-Chair Election Process

JCAG members self-nominate to stand for election to the position of Co-Chair:

- more than one nomination: nominees will stand for election by a secret ballot in which all JCAG members place a vote for their preferred nominee; the nominee with the most votes is endorsed by PC4 and PoCoG
- one nomination: the nominee is endorsed by PC4 and PoCoG
- no nomination: second call for self-nominations.

7.5.2 Responsibilities of JCAG Co-Chair

The JCAG Co-Chairs, with support from the Executive Offices, shall:

- coordinate the activities of the JCAG
- represent the JCAG on the Groups' committees and working groups and sub-committees as appropriate, and aligned with each Groups governance structure
- act as a representative of the JCAG at external consumer or community meetings and functions.

In the event that JCAG Co-Chairs are unable to carry out their duties at a given time (e.g. due to illness or other commitments) they can nominate a JCAG member/s to the Executive Offices as their proxy.

7.6 Role of JCAG members

PC4 and PoCoG recognise that members of the JCAG are volunteers with professional, personal and family commitments and shall endeavour to accommodate any personal circumstances to a reasonable extent. Members are eligible to apply for a leave of absence from participation requirements. New JCAG applicants are asked to consider the practical implications of committing to the JCAG and existing members are asked to be conscientious regarding their participation in JCAG activities.

JCAG members are encouraged to contribute to reviewing as many documents (concepts, protocols, Participant Information Sheets, Consent Forms, etc.) as their time permits. Documents will be circulated to all members to provide interactive feedback through email. All contributions, including 'no further

comments,' are valuable. Documents not self-selected for review will be allocated to individual members by the Executive Officers in consultation with the Co-Chairs based on participation to date, expertise and area of interest. Mandatory allocations will be restricted to a maximum of two per member per year.

When reviewing documents, JCAG members should keep in mind that the purpose of the JCAG review process is:

- to focus on the impact on the participant from a lay perspective of the proposal
- to ensure that the Participant Information Sheets and Consent Forms enable potential participants to make an informed choice whether to join the research study. Feedback on grammar and spelling is appropriate for these documents.

Generally, it is expected that JCAG would only object to approval of a study concept if it does not concord with the aims of the respective Group or if there are serious ethical flaws from the reviewer's perspective.

PC4 and PoCoG will implement organisational processes to ensure:

- there is a feedback loop from the researchers to the JCAG

7.6.1 Confidentiality and conflict of interest

JCAG members are asked to contribute to the JCAG as individuals with an interest or experience in cancer, and not as representatives of another group or organisation. JCAG members must treat all documents, be it research or governance documents, **as confidential**. JCAG members must disclose any conflict of interest in any matters being considered by the JCAG. All JCAG members shall be required to sign a Confidentiality Agreement and contact details release form.

7.6.2 Acting as a representative for the JCAG

When attending external meetings or activities on behalf of PC4 or PoCoG JCAG members are asked to reflect the groups' goals and objectives and to respect the confidentiality of both groups' documents unless disclosure has been authorised by the Executive Offices.

JCAG members are encouraged to represent the JCAG at external meetings or activities and are required to:

- inform the JCAG Co-Chair(s) and the Executive Office of this prior to the event taking place
- use approved media communications resources (PowerPoint presentation, brochures, flyers, etc.) provided by the Executive Office.

7.6.3 Breach of terms of reference and conflict resolution

Any matters of conflict or breach of terms of reference shall be referred to the Executive Officers of the Groups, who will resolve or escalate the matters internally as required.

8 Membership

PoCoG membership is open to researchers, students and health professionals with an interest in psycho-oncology research from within Australia and New Zealand. Membership is open to all disciplines associated with psycho-oncology, including (but not restricted to) Psychology, Psychiatry, Social Work, Medicine, Nursing, Allied Health, Public Health, Epidemiology and Biostatistics.

8.1 New Members

Applications for membership of PoCoG must be made via the PoCoG website by clicking the “Login/Become a member” button and completing the online form. Membership is free.

On joining, members are:

- provided with a website password via email
- automatically placed on the PoCoG membership email list
- granted access to PoCoG membership services, including:
 - website access
 - quarterly newsletters and email updates
 - limited access to membership services provided by the Executive Office and Cancer Australia advisory services
 - educational opportunities, including conferences, workshops and the information exchange scheme
 - access to research networks and interest groups.

8.2 Continuing Members

Membership does not need to be renewed annually. Members can request removal from the PoCoG membership list by contacting the Executive Office. Membership list is audited annually. Members whose email is no longer active are phoned by the Executive Officer to update contact details and confirm continued interest in PoCoG membership. Members who cannot be contacted are removed from the PoCoG membership list.

8.3 Communication with Members

The primary means of communication with members is via email, and most general announcements and provision of documents are made by this means. Members are asked to provide an e-mail address for this purpose. Announcements and documents are also made available via the PoCoG website.

8.4 Associate Members

Associate membership will be available for people with an interest in psycho-oncology who are not part of a related discipline and those living outside Australia and New Zealand.

Associate members will have access to the members-only section of the website, will receive PoCoG emails and newsletters, but will not have access to membership services that involve a financial or time commitment.

8.5 Special Interest Groups and Committees

PoCoG members may choose to form special interest groups and committees. The PoCoG office will promote special interest groups and will provide administrative support for such groups subject to funding and time availability. Special interest groups established formally under the auspices of PoCoG are required to conform to PoCoG's policies and procedures outlined in this document. In addition the groups may establish their own aims and objectives specific to the purpose of the group with approval from the Scientific Advisory Committee. Terms of Reference for special interest groups are contained in the appendix.

9 PoCoG Studies

9.1 Principles and practice

PoCoG aims to bring together researchers, clinicians, health care professionals and consumers with an interest in psycho-oncology to foster collaboration to develop large-scale, multi-centre psycho-oncology studies of clinical relevance and importance which would be difficult for any one team to mount. In light of these aims a PoCoG study should in principle:

- target a psychosocial, behavioural or supportive care issue
- be amenable to intervention resulting in improved care, in either short or long-term
- be collaborative in nature (with other Clinical Trials Groups, organisations, investigators, psycho-social clinicians)
- endeavour to address a research or clinical practice gap
- endeavour to engage populations typically underrepresented in clinical trials
- have a strong rationale and methodology
- have a Principal Investigator (PI) who is committed to obtaining funding for the study
- be conducted to the best possible standards as defined by national and international guidelines
- be industry independent.

In practice a PoCoG study is one which is administered or supported by PoCoG through its Research Support and Development Pathways process. New applications for research support may come from any PoCoG member or an external collaborator. At least one Chief Investigator must be a full PoCoG member and they will be responsible for all communications between PoCoG and the study team and adhere to reporting and other requirements.

PoCoG members should inform the Executive Office and obtain approval before entering into negotiations about formal inter-group collaborations with other groups or units on behalf of PoCoG. External requests for scientific collaborations or scientific representations will be handled by the PoCoG Management Team.

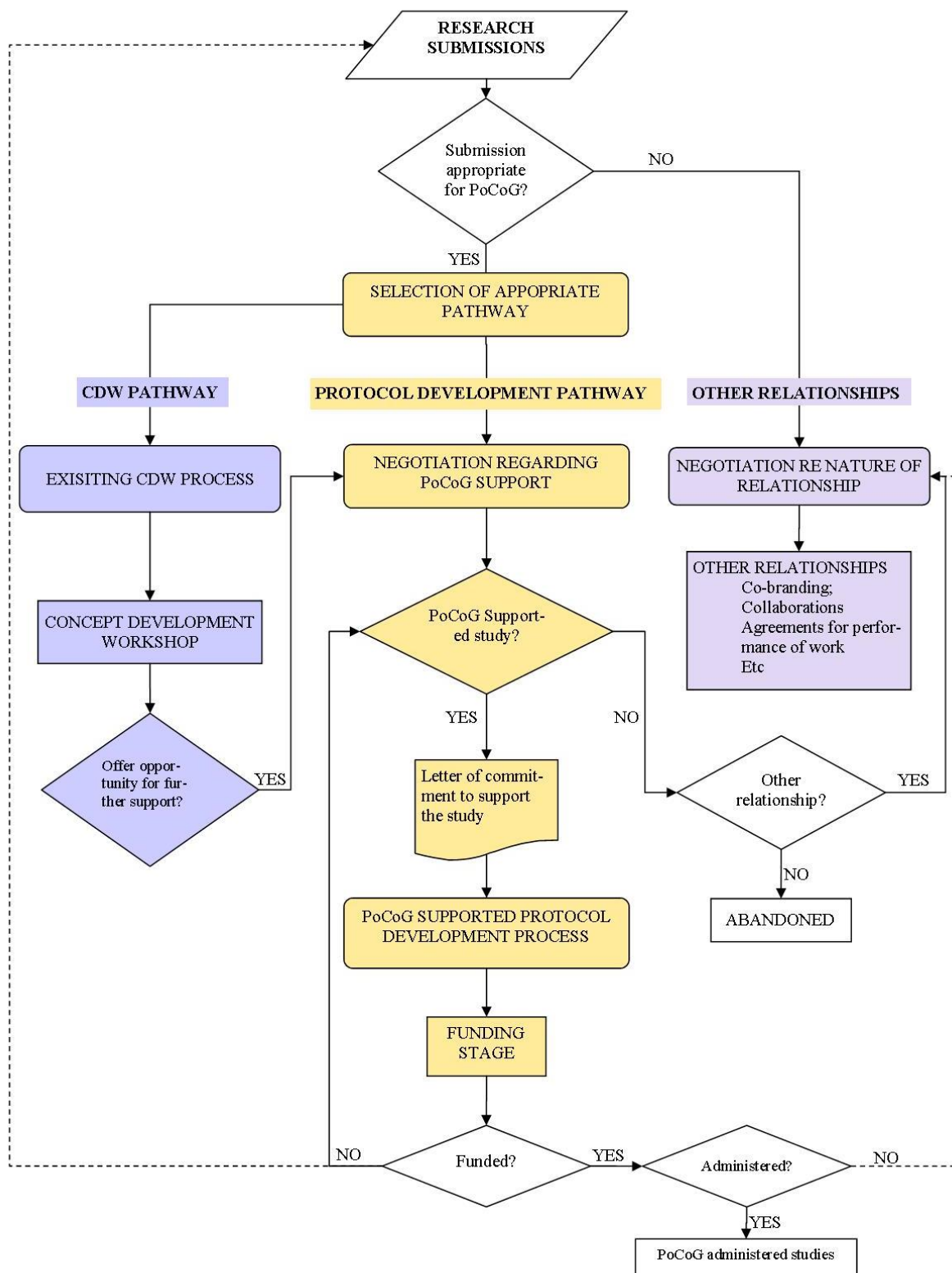
9.2 PoCoG supported studies

PoCoG considers all requests for research support from members and collaborators. Each application is considered on a case-by-case basis by the PoCoG Management Team and assessed according to preliminary criteria including:

- Meeting PoCoG objectives
- Feasibility of work to be conducted
- PoCoG's priorities and capacity to take on the work required

Based on preliminary assessment research support requests are channeled through one of three support pathways (Fig 9.1).

Figure 9.1 PoCoG Research Support and Development Pathway



9.2.1 Concept Development

This mode of support is for less developed concepts that require extensive input from Scientific Advisory Committee which acts as mentor in order to develop a study proposal that can be operationalized as a protocol.

It is assumed that any concepts developed at the PoCoG CDWs will proceed to the next stage of development pathway that supports protocol development.

9.2.2 Protocol Development

For more developed concepts or concepts developed through the CDW, investigators have the opportunity to access PoCoG's support to assist with protocol development. The level of support will be assessed and negotiated on a case-by-case basis and can range from scientific review only to support in study design, protocol development and statistical analysis plan. Protocol development support can continue up until funding stage. Further support post-funding may be negotiated. The level of support may range from access to ongoing specialist advice through to full administration of the study by PoCoG.

9.2.3 Other

Requests for support that do not involve a concept or protocol development are considered by the PoCoG management team and support is negotiated accordingly. Such relationships may include:

- Co-branding
- Collaborations
- Fee for service agreement for discrete work such as conduct of analysis or other study related activities

PoCoG supported studies are required to:

- conduct studies in accordance with federal and state legislation, national and international ethical guidelines and other relevant legislation. A list of relevant documents is available as an appendix of this document and on the PoCoG website.
- conduct research to a standard consistent with PoCoG's standard operating procedures
- undertake PoCoG reporting requirements as outlined below
- be committed to publishing the results in a timely manner
- acknowledge PoCoG on all reports and publications in accordance with the guidelines outlined below of this document
- register the study on the Australian and New Zealand Clinical Trials Registry (ANZCTR)
- include the PoCoG minimum data set in the study as outlined on the PoCoG website.

9.3 Matters of governance, reporting, authorship and intellectual property

In principle PoCoG does not wish to encroach on the investigators' intellectual property and authorship, although retains the right to be acknowledged for its involvement in the study. Matters of governance, authorship and intellectual property are described below.

9.3.1 Progress reports

It is a funding requirement of Cancer Australia, PoCoG's main funding body, that PoCoG report on its research activities, including concept development, protocol development, leveraged funding, progress of PoCoG administered and supported studies, and arising presentations and publications.

All PoCoG studies are required to submit detailed progress reports twice per year, in January and July, times which coincide with PoCoG's own reporting requirements to Cancer Australia.

9.3.2 Policy regarding publication of studies

It is the policy of PoCoG that all research studies be published. It should be the primary intention at the inception of any study to publish the results in the highest possible quality refereed journal. Small research projects and pilot studies may not find publication in major international journals. These should still be published as appropriate. For studies that close early or cannot be published for other reasons, a formal report should be presented to the SAC. Where PoCoG has participated in a collaborative research project, it is the responsibility of the PoCoG Chief Investigator to communicate these requirements to the study Principal Investigator.

9.3.3 Procedure for reporting

It will be the responsibility of the PI and CIs to ensure timely reporting of the study. The Principal Investigator or a representative should report the final accrual and final results of the study to PoCoG. In accordance with accepted standards, the manuscript should be circulated to all those who have made a contribution to the study. Final authorship on the manuscript must be determined by evidence of intellectual contribution, in terms of formulation of the protocol, comment on the results, and preparation of the final manuscripts. Reporting of studies continues for 2 years and/or until the final publication is published.

Study results may also be presented in abstract form in Australia/New Zealand and international meetings. This is of course to be encouraged, but is not to be regarded as fulfilling the requirement to publish.

A copy of all study publications should be forwarded to the PoCoG Office by the Principal Investigator.

Acknowledgment of PoCoG and its members should be included in all publications resulting from studies conducted by the group. Where a trial has been conducted jointly with another trials group, authorship and publication should be agreed on jointly with them. For multi-group trials in which PoCoG participates, it is expected that the PoCoG member involved will be a co-author and that PoCoG itself will also be acknowledged. The PoCoG member involved should also ensure that he/she reviews any abstracts or manuscripts before presentation/publication and that final versions of abstracts are made available to the PoCoG Office.

Notification of offshoot publications, involving for example a distinct subset of patients or a particular aspect of the study, should be sent to the PoCoG Office.

9.3.4 Acknowledgement of funding

All publications, resources and any other materials produced by PoCoG that promote or refer to PoCoG research, initiatives, events or activities must acknowledge the source of funding. Wording should be agreed between PoCoG and the funding organisation. In the case of jointly funded projects acknowledgements should follow approved wording for such instances and list the funders in order of the size of their contribution.

9.3.5 Authorship

Authorship credit should be based on the Vancouver statement by the International Committee of Medical Journal Editors, i.e. substantial contribution to **all three** of the following criteria:

- conception and design OR analysis and interpretation
- drafting article OR critically revising it for intellectual content
- final approval of version to be published.

In addition, a fourth criterion is included for multi centre trials:

- institutions which register/randomise a predetermined minimum proportion of the total patient numbers will be eligible to nominate an author; the designated author will be selected by the institution's Principal Investigator and in most cases would be the investigator with the highest accrual; if an institution enters a particularly large number of cases on the study, that institution will be eligible to nominate additional authors up to a maximum of three (3).

Normally, the authors of publications detailing interim and final results of the study as well as any 'overview' of the study will be:

- the study Chair or Principal Investigator
- the Study Management Committee (if there is one) or co-Principal Investigators will follow
- the statistician and relevant data manager
- then investigators who meet the authorship guidelines above who are not already listed
- then any other participants who meet the authorship guidelines above.

At least one author is required to be a member of PoCoG. All authors who are PoCoG members are required to list PoCoG as an affiliation in the following manner:

Psycho-oncology Co-operative Research Group (PoCoG), The University of Sydney, Australia

Generally speaking the order of authorship will be based on the overall contribution of the individual to the study, which will include, but not be limited to, consideration of the number of patients accrued by each institution represented. However, other considerations should be taken into account and will be decided by the Study Principal Investigator. If difficulties are encountered, the Study Principal Investigator can discuss the issues with the SAC Chair.

Every publication should include an appendix or table listing all other participants, if all participating sites do not have authorship representation.

Various offshoot publications may result from any major study. Authorship of these 'sub-studies' will again follow the general guidelines but need not have the same authorship order or number as the 'main results' publications. Reference to these authorship guidelines should be included in any future PoCoG study written protocol.

9.3.6 Meeting presentations

The Principal Investigator will inform PoCoG of any presentations of the results from PoCoG studies by means of the reporting requirements as stated in point 9.3.1 above.

9.3.7 Ownership and management of data

PoCoG expects that all its studies comply with data management principles outlined in the Australian Code for the Responsible Conduct of Research (the Code), including those pertaining to:

- Maintaining confidentiality
- Maintaining data safety
- Data retention, storage and cataloguing
- Data sharing - availability for use by other researchers (unless prevented by ethical, privacy or confidentiality matters)

Ownership of data arising from PoCoG studies is based on existing local institutional arrangements.

9.3.8 Disputes

For PoCoG administered studies, any disputes concerning authorship, contents and timing of any publication and presentation will first be dealt with by the SAC Chair. If no resolution is achieved, the matter will be referred on to the PoCoG Scientific Advisory Committee for final decisions and action. It is to be hoped that most if not all disputes are settled at the Chair level.

9.3.9 Meta-analysis

Meta-analysis is the formal evaluation of the quantitative evidence from two or more studies bearing on the same question. This most commonly involves the statistical combination of summary statistics from the various studies, but the term is sometimes also used to refer to the combination of the raw data. A common definition of the primary and secondary endpoints is essential. Data for such meta-analyses should not be released without the consent of the Principal Investigator, statistician and PoCoG Chair. Summary or raw data for meta-analysis should not be released until confirmation has been received that the final report of the PoCoG study has been accepted for publication. The Principal Investigator should ensure that he/she has the right to make reasonable amendments to the meta-analysis manuscript or to withdraw reference to the data altogether prior to submission if necessary. The Principal Investigator should determine if a PoCoG author will be included in the authorship list. The nomination of PoCoG co-authors should be discussed with the SAC Chair and will be determined by overall contribution to the conception, conduct, and analysis of the involved trial.

10 External Relationships

10.1 Relationships with Other Trials Groups

PoCoG encourages and collaborates with cooperative cancer trials groups to include psychosocial or quality of life sub-studies in existing and planned research. Collaborations may include exchange of specialist skills and expertise in administration and governance of the group as well as scientific collaborations. Guidelines for establishing research collaborations are outlined in the appendix.

10.2 Relationships with consumer groups

Consumers represent a critical stakeholder group for PoCoG and their input in guiding PoCoG activities and protocols is encouraged. Consumers are represented through appointment to the PC4 and PoCoG Joint Consumer Advisory Group. Representatives of this group provide consumer input primarily through appointment to the PoCoG Scientific Advisory Committee and by participating in the scientific review process.

In addition, PoCoG will establish relationships with and seek input from other consumer groups as appropriate in relation to PoCoG activities, meetings and protocols.

10.3 Relationships with other stakeholders

PoCoG encourages collaborative relationships and activities with other cancer organisations and stakeholders. PoCoG has a mechanism of establishing formal representation on committees and research management teams by seeking appropriate representation from its membership. Details of this mechanism are outlined in the appendix.

10.4 Conflict of Interest

10.4.1 Background

PoCoG members are frequently engaged to act on an individual basis as expert consultants/advisors for private industry or government departments. It is a well-recognised and entirely appropriate function of an expert in a particular field to be able to provide services to private and public bodies. Where such professional consultancy arrangements are in place, they should be declared if there is a potential for conflict of interest. The existence of any such arrangements should be appropriately recorded at the PoCoG SAC, Management Team and all relevant PoCoG meetings. Where such relationships exist, PoCoG members should not act on behalf of PoCoG without prior approval from the Executive Office.

PoCoG acknowledges that the pharmaceutical industry and other funding bodies make major contributions to clinical and laboratory research. While sponsorship of PoCoG research by pharmaceutical companies is likely to remain limited, consideration needs to be given to PoCoG

collaborations with other CTGs which may receive funding from pharmaceutical companies. It is important that the reputation and the independence of PoCoG be rigorously maintained. PoCoG office bearers and appointed representatives should disclose any financial arrangements so that decisions regarding the scientific and clinical work of PoCoG are free of any potential commercial or political influence.

If there is any doubt over an item it is best to include it. Such matters can also be raised with the Management Team of PoCoG or at one of the general meetings.

For more information on these and other related issues such as directorships and shareholding, private industry or government body sponsored travel, clinical trials including commissioned research projects, please refer to the ethical guidelines published by The Royal Australasian College of Physicians.

10.4.2 Procedure

PoCoG has established a mechanism for the declaration and recording of any benefits received (including cash and kind, travel support, hospitality, gifts, subsidies or research grants) received by any of the categories of PoCoG member groups listed below, so that any such benefit is not later construed as having affected the member's independence of judgement concerning PoCoG affairs.

Once each year, all chairs, committee members and PoCoG administered study Principal Investigators must provide a written declaration to the Executive Office describing any relevant arrangements that have been entered into, or have been active, over the previous 12-month period. It is required that all such arrangements that have resulted in benefits directly to the individual or a family member of AUD\$1000 or more be declared. These declarations will be considered by the Management Team and recorded in the minutes of the next meeting. It is understood that information provided by the relevant members is for the purposes of disclosing potential conflicts of interest within the group and will not be put to any other purpose.

10.4.3 Implementation and Enforcement

Where in the opinion of the Management Team, members are required to lodge a conflict of interest statement and fail to do so within a reasonable period of time; such members will become ineligible to hold any office within the group and be excluded from any discussions where a conflict of interest may arise.

11 Appendices

A Research legislation and guidelines

Multi-site Collaborative National Cancer Clinical Trials Groups are required to conduct clinical trials in accordance with federal and state legislation, national and international ethical guidelines and relevant legislation including:

- The Declaration of Helsinki (as amended)
- Privacy Act 1988
- National statement of the ethical conduct of human research (2007)
- Joint NHMRC/ AVCC statement and guidelines on research practice (1997)
- Australian Code for the Responsible Conduct of Research
- Note for guidance on good clinical practice (CPMP/ICH/135/95)
- Access to unapproved therapeutic goods in Australia
- Therapeutics Goods Act 1989
- Therapeutics Good Regulations 1990 – medicines regulations
- Therapeutics Good Regulations 2002 – medical devices regulation
- TGA Clinical Trial Exemption Scheme
- TGA Clinical Trial Notification Scheme
- Values and Ethics: Guidelines for ethical conduct in Aboriginal and Torres Strait
- Islander Health research
- Gene Technology Technical Advisory Committee Guidelines
- Research involving human embryos Act 2002
- Prohibition of cloning Act 2002
- National Occupational Health and Safety Commission Guidelines
- National Code of Practice for the Preparation of Material Safety Data Sets
- Minimum Guidelines for Health registers for Statistical and Research Purposes.

B Terms of Reference for PoCoG Interest Groups

B.1 Background

PoCoG promotes the formation of special interest groups within its membership and views them as a means of:

- increasing networking within the membership
- promoting proactive involvement of PoCoG members in activities which aim to fulfil its goals
- creating more opportunities for members to become involved in initiating, developing and participating in collaborative research projects, especially those relevant to the interest group's focus
- facilitating implementation of multi-centre research studies.

PoCoG shall endeavour to support its interest groups by providing administrative assistance wherever possible.

B.2 Structure and governance

While PoCoG wishes to promote proactivity and autonomy in its interest groups, it requires that the groups conduct their business in accordance with PoCoG's aims and objectives as well as observing its policies and procedures.

B.2.1 Aims of the interest groups

The interest groups shall determine their own aims and objectives specific to the purpose of the group. These should generally align with the aims and objectives of PoCoG's mission and aims as outlined in the PoCoG Policy and Procedures Manual and require approval by the PoCoG Scientific Advisory Committee.

B.2.2 Organisational structure

All PoCoG interest groups shall fall under the jurisdiction of the PoCoG Scientific Advisory Committee. The internal governance structure shall be determined by the group and shall be sent to the Executive Office for the purpose of record keeping.

B.2.3 Policies and procedures

All interest groups shall be required to conform to PoCoG's policies and procedures as outlined in the Policy and Procedures Manual. The groups may create additional policies and procedures pertaining to their internal group governance. These policies and any subsequent changes shall be sent to the Executive Office for the purpose of record keeping.

Succession planning must be conducted in an open, accountable and transparent manner (either via a process of election or open competition) which will ensure equitable access by all members of the group.

B.2.4 Reporting and communication with PoCoG

Groups are required to report on their activities to the PoCoG Executive Office. PoCoG Executive Office will call for updates twice per year, in January and July, in line with PoCoG's reporting requirements to Cancer Australia. Reports should include matters of governance (elections etc.) as well as any activities undertaken by the group. In addition groups shall be encouraged to submit regular updates to PoCoG Newsletter and to maintain up-to-date information on the PoCoG website.

Communication between the groups and PoCoG shall be conducted via the Executive Office where a decision will be made whether the matter requires escalation to the PoCoG Management Team or SAC. Interest groups are also encouraged to attend PoCoG Annual General Meetings the purpose of which is to inform members of previous and future activities and reviewing fiscal information for the past year as well as providing members with the opportunity to ask questions regarding operations and future directions.

B.2.5 Responsibilities of interest group leaders

The nature of leadership of the group shall be determined by the group's internal governance structure. The group leader shall be responsible for:

- ensuring that the group conducts its business in accordance with PoCoG's policies and procedures as well as the internal governance policies of the group
- liaising with the PoCoG Executive Office and with members of the group
- convening meetings
- ensuring timely reporting to the PoCoG Executive Office
- other duties as required by the groups' internal governance and policies.

B.3 Process for convening a new interest group

The process for convening a new group shall be as follows:

- a group convenor is identified (either approached by PoCoG, or self-identified as a proposer of the a new interest group)
- the group convenor prepares a brief proposal to the Scientific Advisory Committee outlining some background information as well as the aims and objectives of the group
- following approval by the SAC the convenor with assistance from the Executive Office shall prepare a "Call for Expressions of Interest" pamphlet which shall be distributed to the general membership via the web mailing list. The pamphlet may also be distributed to other interested organisations where appropriate. The pamphlet should contain information on the aims and objectives of the group, membership eligibility criteria, contact details of the Executive Office and the group convenor and instructions of how to become a member
- at the same time the group convenor shall work with the Executive Office on establishing a web page on the PoCoG website dedicated to the group
- following a suitable recruitment period the group convenor should, as soon as feasibly possible convene the first meeting of the group.

B.4 Membership

B.4.1 Recruitment of new members

New members shall be recruited by notifying general PoCoG membership as well as by other means as appropriate. The registration mechanism shall be as follows:

- if not already a member, the interested party must register on-line as a PoCoG member
- the interested member shall notify the Executive Office of their intention to join the interest group
- the Executive Office will include the membership of the interest group on the member's profile on the

PoCoG website

- the member will be provided with the Members' Email Forum Manual.

B.4.2 Essential eligibility criteria

All group members must be PoCoG members. Other essential criteria may be determined by the group convenor. Eligibility criteria must be fair and non-discriminatory.

B.4.3 Duration of membership

Membership of a PoCoG interest group shall be on-going. Membership can be terminated by notifying the group leader and the Executive Office. Request to cancel PoCoG ordinary membership shall automatically terminate membership of any PoCoG interest groups.

B.5 Meetings and activities

Interest groups shall determine the nature and frequency of their meetings and other activities. These should generally align with the aims and objectives of PoCoG's mission and aims as outlined in the PoCoG Policy and Procedures Manual. PoCoG Executive Office should be notified of any activities conducted under the auspices of PoCoG (eg using PoCoG corporate identity) prior to the event.

The use of PoCoG corporate identity must be discussed with the Executive Officer.

B.5.1 Research activities

Research studies arising from activities conducted by the group under the auspices of PoCoG shall be governed by the policies outlined in section 9 of the PoCoG Policy and Procedures Manual and must obtain support from the PoCoG Scientific Advisory Committee (SAC) via the SAC review process.

B.6 Breach of terms of reference and conflict resolution

Any matters of conflict or breach of terms of reference shall be referred to the group leader, who should escalate the matter to the Management Team if required.

Policy and Procedures version control – Changes and amendments

[illegible]