Policy Name: Committees and their Function in Alliance	Policy Number: 4.1
Section: Committees – 4	Date Revised: January 1, 2018

4 Committees

4.1 Committees and their function in Alliance

The Alliance has scientific (disease, modality, and discipline) and administrative committees. These committees are responsible for the scientific, administrative oversight and quality assurance activities of the Alliance.

4.1.1 Disease committees

The Alliance disease committees are responsible for developing and conducting the scientific agenda of the Alliance. They collaborate closely with the modality and discipline committees and many of the Alliance studies are multimodality studies that address more than one research hypothesis.

4.1.2 Discipline committees

The Alliance discipline committees, working in conjunction with the disease committees or on their own, are responsible for studies that focus on new methodologies for treating cancer or minimizing the burden of cancer for individuals and their family members. These committees also develop studies addressing the fundamental biology of cancer, cancer risk assessment and prevention.

4.1.3 Modality committees

The Alliance modality committees develop educational programs and/or provide quality control services and serve as a scientific resource for other committees.

4.1.4 Administrative committees

The Alliance administrative committees are responsible for the administrative and quality assurance activities of the Alliance.

Policy Name: How to Form a Committee	Policy Number: 4.2
Section: Committees – 4	Date Revised: January 1, 2018

4.2 How to form a committee

The proposal to form a new scientific committee is brought before the Executive Committee for review and approval. The approval and formation of a new committee are also brought to the attention of the chair of the Constitution Committee, since changes to the Alliance Constitution or Bylaws may be required.

The group chair may form administrative, ad hoc committees, and working groups; the Executive Committee must approve these committees and the chairs of newly formed committees.

Policy Name: Committee Membership	Policy Number: 4.3
Section: Committees – 4	Date Revised: January 1, 2018

4.3 Committee membership

The group chair, with the approval of the Executive Committee, names the committee chair and the committee chair selects the committee members. Members are encouraged to bring their ideas to the committee chair for consideration and let the committee chair know of their interest in being on the committee. Committee membership is rotated at appropriate intervals.

Policy Name: Roles and Responsibilities in Committees	Policy Number: 4.4
Section: Committees – 4	Date Revised: January 1, 2018

4.4 Roles and responsibilities in committees

4.4.1 Committee chair nomination and approval

Committee chairs are either proposed by the group chair or, for those committees within Alliance programs, are nominated by the appropriate program director. All chair appointments are approved by the Alliance Executive Committee. The chair is chosen and their performance is evaluated on the basis of the leadership they can provide to the area of committee responsibility.

4.4.2 Committee chair responsibilities

It is the responsibility of the committee chair to coordinate the activities of the committee and to ensure that the work of the committee is performed in a timely manner.

4.4.2.1 Administration

Committee membership: The committee chair names the members of the committee. The number of members may not exceed the number designated by the group chair. The committee chair is responsible for rotating members off of the committee and adding new ones as needed.

The committee chair nominates the vice chair of the committee to the group chair for the group chair's review and approval. The committee chair also nominates subcommittee chairs, if applicable, to the group chair for the group chair's review and approval.

Committee liaisons: The committee chair names liaisons to the committee from other committees after discussion with the other committee chair.

Group and committee meetings: The committee chair or designee prepares agendas for committee and group meetings.

The committee chair also identifies invitees to the meetings and requests support for travel, as appropriate.

The committee chair may schedule conference calls as often as needed to accomplish the work of the committee.

Policy Name: Roles and Responsibilities in Committees	Policy Number: 4.4
Section: Committees – 4	Date Revised: January 1, 2018

Conflict of interest: The committee chair, vice chair, study chair and study co-chair (of studies that have not been published, current and pending studies) are required to complete a conflict of interest disclosure form at least annually (see Alliance Policies and Procedures, section 3.5 Conflict of Interest).

Scientific misconduct: Each participant in the Alliance is expected to review and comply with the section on individual scientific misconduct in the Alliance Policies and Procedures (see section 3.4 Individual Scientific Misconduct).

The committee chair and all investigators are expected to comply with federal guidelines regarding human subjects training requirements.

Annual progress reports: The committee chair prepares an annual progress report for the committee for inclusion in the annual grant progress report that the Alliance must submit to NCI.

Competing renewal report: The committee chair prepares a committee report whenever the Alliance submits a competing renewal application.

4.4.2.2 Protocol development and management

The committee chair assigns study chairs and evaluates study chair performance on an ongoing basis.

The committee chair supervises the protocol process from concept development through publication of results. This includes overseeing the development and review of concepts, submitting concepts to the Study Concept Review Committee, providing input throughout the protocol development process, and reviewing publications including interim agenda reports, abstracts and manuscripts. Committee chairs are responsible for mentoring study chairs and guiding them through the protocol development process, including forms development. The committee chair acts as a mediator if other members of the study team cannot reach resolution on significant issues that arise during the life cycle of a protocol. Committee chairs also participate in the development of protocol amendments as required.

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The committee chair reviews study accrual on an ongoing basis and consults with the study team to develop appropriate action plans for studies that are accruing at a slower pace than anticipated.

The committee chair attends DSMB meetings for studies within the committee.

The committee chair participates in study team conference calls as appropriate.

The committee chairs may be contacted by investigators, oncology nurses and clinical research associates when the study chair is unavailable, with questions pertaining to a specific study (e.g., clarification of eligibility, treatment issues). Nobody, including the committee chair, may grant waivers of eligibility criteria,.

The committee chair regularly communicates with the data managers. The committee chair may be called on to answer protocol questions in the absence of the study chair.

The committee chair regularly communicates with the statisticians responsible for the committee regarding protocol development, monitoring of ongoing studies and analysis/publication of results.

4.4.2.3 Publications

The committee chair, along with the committee's primary statistician, works with study chairs to complete manuscripts in a timely manner. If the study chair is not able to write a manuscript in a timely manner, then the committee chair discusses with the group chair reassignment of that study to another individual who will be able to write the manuscript.

The committee chair reviews the committee's statistical study summaries before they are distributed to the Alliance.

The committee chair reviews the committee's abstracts/manuscripts/presentations prior to public distribution.

The committee chair works with his/her counterpart in other network groups to ensure that intergroup studies have a representative from each group that participated in the study.

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4.4.2.4 Intergroup collaborations

If appropriate, the committee chair discusses collaboration with his/her counterpart in other national groups.

The committee chair may also explore collaborations with international groups in conjunction with the CPOP office. International groups must comply with the federal regulations of the United States in addition to their own country's regulations.

4.4.2.5 Finances

Travel to Alliance meetings: Committees that do not have a separate grant have travel funds available in the Office of the Group Chair from various grants and other sources to support travel to the committee meetings. Travel expense reimbursement policies and frequently asked questions may be found on the <u>Alliance website</u> in the "Meetings" section.

Funding to support research projects: The committee chair works with the committee members and interested participants in the Alliance demonstrating interest in applying for additional funding. If the project appears feasible, the committee chair asks the person who is responsible for the project to discuss the project with the executive officer and the primary statistician so that appropriate budgets, supporting the efforts of the Alliance operations offices, will be included in the application.

If funding is requested to support a research project, the group chair, appropriate committee chair(s), executive officer, and group statistician are copied on correspondence regarding this project.

Details concerning the proposed funding are included with the concept when it is submitted to the SCRC for review. Some concepts are not approved if no new funds are brought in to finance them. Information about the potential sources of support—federal or non-federal—should appear on the cover sheet that accompanies the concept.

The proposal is submitted to the CPOP office for review of the scientific plan and budgetary requests prior to submitting an application to the NCI or other granting agencies. If the proposal is submitted to a non-federal source, the Alliance Foundation reviews

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it prior to the submission. Applications to non-profit organizations are submitted from the Alliance Foundation.

All negotiations with industry collaborators are handled by the CPOP office staff, not by the investigator or committee chair who proposed the project. The Alliance and the party arrange the details of the drug/device provision directly to group members.

4.4.3 Committee vice chairs

The committee vice chairs assists the committee chair in carrying out the responsibilities of the committee and assumes responsibility for the committee when the committee chair is absent. The committee chair nominates candidates for committee vice chairs, who are approved by the Executive Committee.

4.4.4 Subcommittee chairs/cadre leaders

The cadre leader is appointed by the committee chair with the approval of the group chair. The cadre leader coordinates the activities of a subcommittee.

4.4.5 Committee members

Committee members, based on their expertise and interest in that particular area, are appointed by the committee chair with input from the vice chairs and from modality/discipline committee leaders. Principal investigators may nominate Alliance members to the committee for consideration by the committee chair, but only the committee chair appoints the committee members.

Patient advocates are assigned to other committees (besides the Patient Advocate Committee) and advise committees on various aspects of clinical research, providing the patient perspective.

Policy Name: Electing Executive Committee Members	Policy Number: 4.5
Section: Committees – 4	Date Revised: January 1, 2018

4.5 Electing Executive Committee members

The group chair appoints a nominating committee consisting of at least three individuals, no more than one of whom may be from any single member institution. The nominating committee, after consultation with the chairs of the appropriate modality committee and the cancer control committee, proposes a candidate(s) for vacant positions on the Executive Committee. In addition, individual institutional members may make nominations at the time of the election by the Board of Directors. Each position on the Executive Committee is filled by a separate election. Each election is conducted by closed ballot. In the event of a plurality, only the top two candidates are entered into a runoff election.

Each elected representative to the Executive Committee serves a three-year term and may only be elected for three consecutive terms, but is eligible for re-election following a term out of office. The terms of office of the elected members of the Executive Committee overlap to provide continuity of committee activities. See the Alliance Constitution for additional details.