

Bylaws

Alliance for Clinical Trials in Oncology (Alliance)

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1. Membership

Members of the Alliance will be institutions meeting all requirements for membership, which include accrual, data quality and timeliness, adherence to Alliance policies and procedures, and participation in Alliance scientific activities.

Institutional membership of the Alliance shall be structured in two levels representing the magnitude of accrual to Alliance trials provided by the member institution. Main members shall be institutions meeting a level of accrual that is equal to or greater than 15 patient enrollments to treatment and cancer control interventional studies per year, credited to the Alliance. Affiliate members are institutions that by themselves do not meet the requirements for membership, but are granted membership by virtue of a formal association with a Main member institution. Affiliate members shall be institutions whose 3-year average accrual is greater than or equal to 5 patient enrollments per year. The Membership Committee may also recommend one or more additional levels of membership, according to the needs of the Alliance, and with approval by the Board of Directors. The level of accrual required for membership status for all levels of membership shall be proposed by the Membership Committee and approved by the Board of Directors. This accrual level shall be determined by a three year rolling average, and evaluated yearly.

The Membership Committee may also recommend accrual credit for ancillary non-treatment studies and non-treatment substudies, cancer care delivery research studies and genomic screening studies to the Executive Committee for approval. Ancillary accruals would be added to the number of patient enrollments for evaluation of membership performance and institutional accrual ranking.

Each member institution shall have a Principal Investigator, who is primarily responsible for any and all activities related to Alliance at the institution. Each Main member institution shall also have a Co-Principal Investigator, who shall assume responsibility in place of the Principal Investigator if for any reason the Principal Investigator is unable to perform duties required for Alliance institutional membership.

2. Membership Committee

The Membership Committee shall review existing policies and best practices, and shall recommend to the Board of Directors for its approval a set of requirements for new institutional membership and for maintenance of membership. The Membership Committee shall meet at a frequency of not less than twice yearly. During these meetings, the Membership Committee shall review the current policies for evaluation of institutional members for overall responsiveness to the needs of the Alliance. The committee shall receive and evaluate new applications for membership, and shall also receive and review recommendations concerning activities of current members from the Institutional Performance Evaluation Committee. Based

upon these reviews, the Membership Committee shall make recommendations to the Board of Directors concerning policies and procedures for institutional membership, and also concerning the status of applicant institutions and current member institutions. Decisions made by the Membership Committee shall be by simple majority vote.

3. Qualifications for Prospective Institutional Members

Each member institution shall have a developed and functioning structure of an Alliance -oriented clinical research program with an Office for Human Research Protections (OHRP)-approved Federalwide Assurance (FWA) and an OHRP-registered institutional review board (IRB). The member shall also meet other requirements such as are established by the Board of Directors, based upon recommendations from the Membership Committee.

The prospective Principal Investigator of the applicant institution shall provide the Membership Committee with the information required for the evaluation of new membership applications. Prospective member institutions consisting of more than one hospital or institute must provide all the required information for each of their affiliated hospitals or institutes, and this information shall become part of the application for membership in the Alliance. The composite qualifications of all these affiliated and contributor institutions shall be used to evaluate the qualifications of the applicant institution.

4. Qualifications Required for the Addition of Contributor Hospitals or Institutes to Become an Affiliate Member

Qualifications for Affiliate membership shall be supplied by the Principal Investigator of the sponsoring Main member institution to the Membership Committee, assuring the committee that the qualifications of the proposed Affiliate member shall satisfy the maintenance of overall institutional membership quality as defined by the current institutional review requirements of Alliance. Where a Main member institution is comprised of several affiliated hospitals or medical centers that have agreed to form a network and come under the administration and coordination of the Principal Investigator, the Principal Investigator assumes full responsibility for the effective operation of Alliance functions at these hospitals or medical centers.

5. Procedure for Evaluation of New Institutional Membership Applications

The Membership Committee shall review and evaluate the application of proposed new member institutions. The evaluation criteria will be those developed by the Membership Committee and approved by the Board of Directors. Based upon these criteria, the Membership Committee shall recommend approval or disapproval to the Board of Directors. This recommendation must be forwarded to the Board of Directors within three months of receipt of the application and at least 30 days prior to a Board meeting. The Board of Directors shall make the final decision concerning all membership applications. A two-thirds supporting vote is required for approval of the applicant institution for provisionary (new) institution member status. Under exceptional circumstances immediate, Main institutional membership may be granted by the Board of

Directors by a two-thirds majority supporting vote. Affiliate applications may be approved or disapproved by the Membership Committee for activation, and do not require approval by the Board of Directors.

6. Procedure for Promotion of Provisionary (New) Institutional Membership to Main Institutional Membership

Provisionary (new) members shall be reviewed yearly by the Membership Committee and their contributions to Alliance activities shall be evaluated according to criteria developed by the Membership Committee and approved by the Board of Directors. The Membership Committee shall make one of the following recommendations to the Board of Directors:

- a. That the provisional member be elevated to the status of Main membership, or
- b. That the provisional member be continued as provisional for another year, or
- c. That the provisional member be dropped from further consideration for Alliance membership.

A provisional member that is not accepted as a Main member institution after three years of provisional status is dropped from further consideration for membership. Such institutions may re-apply for membership following a 3-year interval.

7. Procedure for Continuing Membership Status

Each institutional member shall be re-evaluated for performance in Alliance activities by the Membership Committee at least once a year. An in-depth review of each member shall be made by the Institutional Performance Evaluation Committee annually. This evaluation will involve data submitted to the Institutional Performance Evaluation Committee from multiple sources, including the Statistics and Data Management Center (accrual data) and the Audit Committee (data quality, timeliness, and adherence to regulatory requirements). The results of this evaluation shall be forwarded to the Membership Committee who shall review and make recommendations to the Board of Directors. Based on this evaluation, one of the following recommendations shall be made by the Membership Committee to the Board of Directors:

- a. Continue institutional membership
- b. Change to probationary status due to issues related to accrual, data quality or other membership requirements
- c. Change in membership category (e.g. Main member to Affiliate)
- d. Expulsion from the Alliance

The Membership Committee shall communicate its recommendation to the institutions so evaluated at a date no later than 30 days prior to the scheduled Board of Directors meeting. The latter may appeal the recommendation to the Board of Directors before a final decision is rendered. The Board of Directors shall make the final decision and a simple majority shall indicate final approval of recommendations for "continuing institutional membership," or for "change to probationary status." A two-thirds vote is required for expulsion of a member from

the Alliance. Institutions who are expelled from Alliance may re-apply for membership no sooner than three years after the date of expulsion.

8. Procedures Following Placement of a Member Institution on Probation

Members failing to meet accrual criteria, or other criteria specified by the Membership Committee to maintain membership, will continue their present membership level for a one year probationary period. Main members on probation for institutional performance will forfeit their vote on the Board of Directors until successful removal from probationary status. Additional sanctions may be recommended by the Membership Committee for approval by the Board.

Member institutions will have one year to improve their performance. At the end of this probationary period, the institution will be re-evaluated by the Membership Committee, with input from the Institutional Performance Evaluation Committee, the Audit Committee, and other sources as deemed necessary. This evaluation will result in one of the following recommendations from the Membership Committee to the Board of Directors:

- a. Lifting of probationary status due to satisfactory resolution of all membership issues
- b. Extension of probationary status for a maximum of one additional year
- c. Change in institutional membership level (e.g. from Main member to Affiliate member due to insufficient accrual to maintain current membership level, based upon a 3-year rolling average), with lifting of probationary status if all other membership requirements have been satisfied
- d. Expulsion from Alliance.

Institutions who do not resolve issues responsible for probationary status within one year following an extension of probationary status, and who cannot successfully resolve such issues by changing to another membership level will be expelled from Alliance. The Membership Committee shall communicate the recommendation to the institutions so evaluated at a date no later than 30 days prior to the scheduled Board of Directors meeting. The latter may appeal the recommendation to the Board of Directors before a final decision is rendered. The Board of Directors shall make the final decision and a simple majority shall indicate final approval of recommendations for lifting of probationary status or one year extension of probationary status. A two-thirds vote is required for a change in institutional membership level or expulsion of a member from the Alliance. Institutions who are expelled from Alliance may re-apply for membership no sooner than three years after the date of expulsion.

9. Board of Directors: Selection of Main Member Institution Representatives

Each Main member institution that ranks among the top 40 institutions in total Alliance accrual by three-year rolling average shall designate one individual, who may be either the PI or a designated representative, who shall sit on the Board of Directors and have voting privileges. The remaining Main member institutions shall elect at-large individuals to sit on the Board of Directors for a three-year term and have voting privileges. The number of these individuals shall not exceed 20% of the total number of voting Board members (i.e., 10 elected

representatives). PIs or designees of provisional or probationary Main member institutions shall not sit on the Board of Directors, but may attend open sessions of Board meetings. The Principal Investigators of the remaining Main member institutions shall nominate and elect their own representatives to the Board of Directors. To assist in this matter, the Group Chair shall name a nominating committee, and the election shall be by secret ballot.

10. Programs

Established Programs of the Alliance shall include the Central Protocol Operations Program, the Statistics and Data Management Program, the Cancer Control, Prevention and Health Outcomes Research Program, the Translational Research Program, and the American College of Surgeons Clinical Cancer Research Program. Principal Investigators for each Program shall be nominated by the Group Chair and approved by simple majority vote of the Board of Directors. In the event that a Program Principal Investigator is unable to execute their duties, the Group Chair will name an interim Program Principal Investigator, who shall serve until a new Program Principal Investigator is nominated by the Group Chair and approved by the Board of Directors.

11. Administrative Committees

Administrative Committees of the Alliance shall include the following which are specified in the Constitution: Executive, Membership, Institution Performance Evaluation, Audit, Conflict of Interest, Constitution and Bylaws, Data and Safety Monitoring Board, Ethics, and Study Concept Review Committees. Additional Administrative Committees specified in these Bylaws are Patient Communication, Information Systems, Karyotype Review, Pharmacy, and Publications.

12. Scientific Committees

Scientific Committees of the Alliance shall include the following:

A. Modality Committees

Modality committees of the Alliance shall include the following: Clinical Research Professionals, Imaging, Oncology Nursing, Patient Advocate, Pathology, Radiation Oncology, and Transplant. Chairs of all modality committees shall be *ex officio* members of the Board of Directors, but shall have no vote.

B. Discipline Committees

Discipline committees of the Alliance shall include the following: Health Disparities, Cancer in the Elderly, Community Oncology, Health Outcomes, Experimental Therapeutics, Leukemia Correlative Sciences, Pharmacogenomics and Population Pharmacology, Prevention, Solid Tumor Correlative Science, and Symptom Intervention.

C. Disease Committees

Disease committees of the Alliance shall include the following: Breast, Gastrointestinal, Genitourinary, Leukemia, Lymphoma, Myeloma, Neuro-Oncology, and Respiratory.

13. Protocol Authorship Policy

It is acknowledged that studies conducted by Alliance involve contribution from multiple disciplines and modalities, with a number of individuals serving significant leadership roles. In recognition of this, authorship of Alliance protocols shall include, at a minimum, a Chair responsible for overall conduct of the study, a Study Statistician, and a Co-Chair who is the Chair of the relevant Disease Committee. At least one member of the protocol leadership team in the role of Chair or Co-Chair shall be a community oncologist. Various other modality and discipline Co-Chairs shall be included as deemed appropriate by the overall Study Chair. Any areas of disagreement will be adjudicated by the Executive Committee based upon recommendations from the Publications Committee.

14. Publication Policies

The Publications Committee shall review existing policies and best practices concerning authorship of scientific publications, and shall recommend to the Executive Committee for its approval a set of requirements for authorship of Alliance publications. These requirements shall be in the form of a guidance policy for Alliance publications and shall address rules governing authorship and disclosure of conflict of interest for Alliance publications. The Chair and Vice Chair of the Publications Committee shall include one individual who is a scientific leader and one who is a community oncology leader. The Publication Committee shall include as members include representatives from the Central Protocol Operations Program and the Statistics and Data Management Program, as well as other members as deemed appropriate.

The Publications Committee shall meet at a frequency of not less than once yearly. As needed, the Publications Committee shall also adjudicate in a timely manner any issues related to publication of Alliance manuscripts, and make recommendations concerning these matters to be acted upon by the Executive Committee.