

BYLAWS of the NIAID AIDS CLINICAL TRIALS GROUP (ACTG)	
Effective:	09/27/2018
Amended:	09/21/2018, 03/08/2014, 07/19/2012, 11/20/2010
Last reviewed	09/21/2018
Originator	ACTG Executive Committee
	Page 1 of 8

ARTICLE I Name

The name of this organization shall be the AIDS Clinical Trials Group (ACTG) Network.

ARTICLE II Mission

The mission of the ACTG Network is:

To cure HIV and reduce the burden of disease due to HIV and its complications, including tuberculosis and viral hepatitis.

ARTICLE III Organization

The ACTG operates under cooperative agreements with the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID) for the Network Leadership Group, the Clinical Trials Units (CTUs) and Clinical Research Sites (CRSs) affiliated with the ACTG, and the Statistical and Data Management Center (SDMC).

The ACTG Leadership Group is composed of the Principal Investigator (PI) of the ACTG Network Leadership Group Grant, who serves as the Group Chair and the Chair of the ACTG Executive Committee; the Group Vice Chair; the International Vice Chair; the Network Laboratory PI; the Executive Committee; Scientific and Resource Committees;; the SDMC; the Leadership and Operations Center (LOC); the Network Coordinating Center (NCC); and the Specialty Laboratories.

The ACTG Leadership Steering Committee (LSC) is composed of the Network PI/Group Chair, the Group Vice Chair, the International Vice Chair, the Network Laboratory PI, the Director of the LOC, the Director of the NCC, the PI of the SDMC and the Performance Evaluation Committee (PEC) Chair.

ARTICLE IV Membership

SECTION A Voting Members of the ACTG

1. The voting members of the ACTG shall be the Network PI/Group Chair, the Group Vice Chair, the International Vice Chair, and the Network Laboratory PI; Directors of the Specialty Laboratories; the Director of the LOC; the Director of the NCC; the PI of the ACTG SDMC; and the PI or designated ACTG CRS Leader of ACTG Network-affiliated CTUs. Each voting member shall have one vote, and CTUs with more than one ACTG-affiliated CRS will have only one vote. For those CTUs that have multiple PIs, either the ACTG-affiliated PI would vote or, in the case of multiple ACTG-affiliated PIs, the PIs would caucus and cast a single consensus vote.
2. The voting members of the ACTG shall meet (in person or via teleconference) at least once per year, and a majority of its members shall constitute a quorum.

3. Voting membership shall expire at the end of a NIAID funding cycle for ACTG Network-affiliated CTUs and/or CRSs that are not refunded for the subsequent cycle.

SECTION B General Membership of the ACTG

1. The general membership of the ACTG includes all investigators and staff members of NIAID-funded ACTG Network-affiliated CTUs and their CRSs; staff of the LOC, NCC, and SDMC; ACTG consortium partners funded through the Network Leadership Group to support the ACTG; Global Community Advisory Board (GCAB) and Community Scientific Subcommittee members who participate in the functions of the ACTG; investigators not at an ACTG Network-affiliated CTU or CRS who serve as members on scientific committees and protocol teams; and non-industry representatives who serve as consultants and contribute to the ACTG research effort.
2. General membership shall expire with the cessation of a) all NIAID funding for the ACTG Network Leadership Group award, b) funding for the member's institution or group (such as CTU or CRS, SDMC, Specialty Laboratory, or ACTG subcontract), or c) membership on a scientific committee or protocol team for investigators not at an ACTG Network-affiliated CTU or CRS. The Executive Committee, by majority vote, may revoke general membership of any person or group for nonperformance, misconduct, noncompliance with ACTG policies and procedures, and/or conflict of interest.
3. Privileges of general membership shall be the ability (1) of appropriately trained clinicians and staff to enroll, follow, and monitor patients on ACTG studies; (2) of investigators to submit concept sheets for proposed studies to the ACTG and to conduct investigations outlined in approved protocols for studies within the ACTG; and (3) to be appointed to and to serve on standing ACTG committees.

SECTION C Performance Standards

All members must abide by the policies and procedures of the ACTG, including standards for the conduct of clinical trials. Failure to comply with the established performance standards set forth in ACTG policies and procedures shall result in (1) temporary discontinuation from participation in ACTG clinical trials, (2) recommendations to the NIAID to reduce the level of funding for the ACTG component in question, or (3) suspension or termination of group membership.

ARTICLE V Governing Bodies and Leadership

SECTION A The ACTG Executive Committee

1. The voting membership of the Executive Committee is composed of the Network PI/Group Chair, who serves as the Chair of the Executive Committee; the Group Vice Chair; the Network Laboratory PI; the PI of the SDMC; the International Vice Chair, the Director of the LOC; the Director of the NCC; the Director of the Data Management Center; ten ACTG-affiliated CTU PIs or CRS Leaders (at least two of whom will be from international sites) elected by a majority of the voting CTU PIs/CRS Leaders; a DAIDS Project Scientist or designee; one representative elected by the Site Management and Clinical Care Committee; the Chairs of the PEC and the Underrepresented Populations Committee (UPC); the clinician Co-Chair of the Data Management Committee; two representatives from the GCAB; and an investigator-at-large who is nominated by the

general membership of the ACTG, and who is elected by ballot by the voting members of the ACTG. The investigator at-large may be a CRS Leader who is not a CTU PI.

No two elected members from the same CTU/CRS may serve concurrently on the AEC.

The Network PI/Group Chair Elect and Vice Chair Elect shall also serve on the Executive Committee until the awarding of the new grant in the event the Network PI/Group Chair Elect and Vice Chair Elect are not Executive Committee members at the time of an election of new Network Leaders.

The outgoing Network PI/Group Chair shall serve on the Executive Committee as the Past Chair until the beginning of the subsequent grant cycle and shall serve in an advisory capacity for administrative and other Group work. Additional members may be added to the Executive Committee at the discretion of the Executive Committee and by an election process directed by the Executive Committee to meet specific leadership needs of the Group as they arise.

2. Each elected Executive Committee member, other than the Network PI/Group Chair, the Group Vice Chair and International Vice Chair, and Network Laboratory PI, shall serve a 3-year term and may not serve consecutive terms; at least 1 year must separate a member's terms on the committee.
3. The committee members' terms shall be staggered to provide continuity of committee activities.
4. A quorum of the Executive Committee shall consist of a majority of its members.
5. The Executive Committee serves as the main governing body of the ACTG Network and is responsible for the development and implementation of policy, procedural decisions, and resource allocation for the ACTG, inclusive of the following:
 - a. development, review, and approval of the scientific agenda of the ACTG;
 - b. management of ACTG financial and other resources, including, but not limited to, establishment of the schedule for the Network PI/Group Chair's fiscal reports to the Executive Committee;
 - c. allocation of resources of the Network Leadership Group award, including, but not limited to, establishment of the level at which approval by the Executive Committee is required for expenditure of funds;
 - d. development, review, approval, and monitoring of policies and procedures of the ACTG, including those for the protection of participants in ACTG research;
 - e. oversight of the selection and final approval of the membership and leadership of all ACTG Scientific and Resource Committees;
 - f. establishment of performance standards for all Network components, including the Network Leadership, the SDMC, the LOC, the NCC, the Specialty Laboratories, the Scientific and Resource Committees, and the participating CTUs and CRSs;

- g. determination of disciplinary action for Network components and members, including recommendations to the NIAID regarding funding;
 - h. development of policies and processes relevant to problem resolution, grievance and appeal, and conflict of interest;
 - i. development, conduct, and analysis of ACTG clinical trials and dissemination of research findings in compliance with all U.S. Federal regulations, NIH policies and guidance applying to the conduct of research involving human subjects, and FDA requirements for new drug or biological licenses when applicable. These include, but are not limited to, CFR Title 21, Parts 11, 50, 54, 56, 312, 314, 601; and Title 45, Part 46; Guidance for Good Clinical Practice (GCP); NIH grants policy (refer to http://grants1.nih.gov/grants/policy/nihgps_2003/index.htm); and, for all clinical research activities performed outside of the U.S., in addition to U.S. Federal regulations, compliance with all pertinent host country regulations for human subjects and/or HIV/AIDS research.
6. To implement the functions of the ACTG, the Executive Committee may form such committees, subcommittees, working groups, and advisory boards as are necessary to carry out the mission of the ACTG.
 7. During the initiation period of each new funding cycle of the ACTG, Executive Committee members will complete their terms begun under the previous cycle; and the pertinent sections of the Bylaws will become effective as their individual terms expire.

SECTION B The AIDS Clinical Trials Group Network PI/Group Chair

1. The Network PI/Group Chair shall be elected by a majority of the voting members of the ACTG. The Network PI/Group Chair may be the previous Group Vice Chair if so ratified by the voting members of the ACTG.
2. The term of office for the Network PI/Group Chair shall end at the conclusion of the middle year of the grant cycle (e.g., end of the fourth [4th] year when the cycle is 7 years). At the discretion of the voting members of the ACTG, the Network PI/Group Chair may serve a second term but may not serve more than two consecutive terms.
3. The Network PI/Group Chair shall serve as the Chair of the Executive Committee; shall receive broad mandates for policies and resource allocations from the Executive Committee; and shall be responsible for:
 - the scientific leadership, administration, management, and coordination of all Network activities;
 - developing, implementing, monitoring, and updating, in collaboration with DAIDS, the clinical research plan for the Clinical Trials Network to ensure consistency and relevance with the NIAID scientific agenda;
 - oversight and issuance of ACTG reports, statements, and progress reports;
 - review and approval of budgets, and authorization of disbursement of funds to all components of the Network Leadership Group and LOC; Network Laboratories; and Protocol Funds for distribution to ACTG-affiliated CTUs and/or CRSs;

- representing the ACTG Network on the cross-network Network Leadership Operations Group and AIDS Clinical Trials Networks Strategic Working Group, and implementation within the Network of applicable decisions and activities of these two cross-network groups;
 - provision of support for Community Partners and implementation of Community Partners recommendations, as requested by the DAIDS;
 - review of the Network's research activities and goals on a mutually agreed upon schedule (but no less than once every year) with a DAIDS Program Director or designee.
4. A special election of the voting members of the ACTG shall be held if it becomes necessary to replace the Network PI/Group Chair ahead of schedule.
 5. Removal of the Network PI/Group Chair:
 - a. A written proposal to remove the Network PI/Group Chair for cause must be submitted by a member of the Executive Committee.
 - b. A majority vote of the voting members of the Executive Committee is required to send the recommendation for removal to the voting membership of the ACTG.
 - c. Removal of the Network PI/Group Chair shall require a two-thirds vote of the ACTG voting membership and the approval of the DAIDS.

SECTION C The Group Vice Chair

1. The Group Vice Chair shall be elected by a majority of the voting members of the ACTG.
2. As in the case of the Network PI/Group Chair, the term of office for the Group Vice Chair shall end at the conclusion of the middle year of the grant cycle (e.g., end of the fourth [4th] year when the cycle is 7 years). At the discretion of the voting members of the ACTG, the Group Vice Chair may serve a second term but may not serve more than two consecutive terms.
3. The powers and the duties of the Group Vice Chair shall be to assist the Network PI/Group Chair in all of the duties of that office, to assume the powers and duties of the Network PI/Group Chair in the absence of the Group Chair, and preside at meetings of the Group and Executive Committee in the absence of the Network PI/Group Chair, and to serve as the Chair of the Scientific Agenda Steering Committee (SASC).
4. A special election of the voting members of the ACTG shall be held if it becomes necessary to replace the Group Vice Chair ahead of schedule.
5. Removal of the Vice Chair:
 - a. A written proposal to remove the Vice Chair for cause must be submitted by a member of the Executive Committee.
 - b. A majority vote of the voting members of the Executive Committee is required to send the recommendation for removal to the voting membership of the ACTG.

- c. Removal of the Group Vice Chair shall require a two-thirds vote of the ACTG voting membership and the approval of the DAIDS.

SECTION D The International Vice Chair

1. The International Vice Chair shall be elected by a majority of the voting members of the ACTG.
2. The term of office for the International Vice Chair shall end at the conclusion of the middle year of the grant cycle (e.g., end of the fourth [4th] year when the cycle is 7 years). At the discretion of the voting members of the ACTG, the International Vice Chair may serve a second term but may not serve more than two consecutive terms.
3. The International Vice Chair shall be responsible for representing the scientific interests of international investigators and sites and advising the Leadership Steering Committee and Executive Committee on all international issues.
4. A special election of the voting members shall be held if it becomes necessary to replace the International Vice Chair ahead of schedule.
5. Removal of the International Vice Chair:
 - a. A written proposal to remove the International Vice Chair for cause must be submitted by a member of the Executive Committee.
 - b. A majority vote of the voting members of the Executive Committee is required to send the recommendation for removal of the International Vice Chair to the voting membership of the ACTG.
 - c. Removal of the International Vice Chair shall require a two-thirds vote of the ACTG voting membership and the approval of the DAIDS.

SECTION E The Network Laboratory PI

1. The Network Laboratory PI shall be elected by a majority of the voting members of the Executive Committee.
2. The term of office for the Network Laboratory PI shall end at the conclusion of the middle year of the grant cycle (e.g., end of the fourth [4th] year when the cycle is 7 years). At the discretion of the voting members of the Executive Committee, the Network Laboratory PI may serve a second term but may not serve more than two consecutive terms.
3. The Network Laboratory PI shall be responsible for overall laboratory operations, set laboratory priorities based on Network research priorities, delegate responsibilities to the PIs of the individual specialty laboratories that comprise the NL structure, and advise the Leadership Steering Committee and Executive Committee on all Network laboratory-related issues.
4. A special election of the Executive Committee shall be held if it becomes necessary to replace the Laboratory PI ahead of schedule.
5. Removal of the Network Laboratory PI:

- a. A written proposal to remove the Network Laboratory PI for cause must be submitted by a member of the Executive Committee.
- b. Removal of the Laboratory PI shall require a majority vote of the voting members of the Executive Committee and the approval of the DAIDS.

ARTICLE VI Fiscal Accountability

The budgeting, administration, management, and allocation of the Network Leadership Group resources shall be the responsibility of the Network PI/Group Chair and Group Vice Chair in collaboration with the LOC. Primary resource-allocation authority shall be vested in the Executive Committee. The Network PI/Group Chair shall be responsible for this administration, authorize resource disbursement by the LOC, and be responsible for fiscal reporting. The basic mechanism for major allocations shall be that of subcontracts and subgrants; smaller expenditures shall be made through direct purchase of services to be funded. The LOC shall be responsible for ensuring compliance with all appropriate U.S. Federal regulations and with NIH and ACTG policies and procedures for all resource expenditures.

ARTICLE VII Meeting Requirements and Parliamentary Procedures

1. The full ACTG Network shall meet as a group a minimum of one time per year. Time shall be allocated for both scientific presentations and policy/administrative meetings.
2. There shall also be a minimum of one Leadership Retreat each year. The participant list and agenda will be determined each year by the Executive Committee through its Steering Committee.
3. The Group shall be governed by these Bylaws and the standing rules for this organization. The rules contained in the current edition of *Robert's Rules of Order Newly Revised* shall govern the Group in all cases to which they are applicable and in which they are not inconsistent with these Bylaws and any special rules of order the Group may adopt.

ARTICLE VIII Scientific Misconduct

The ACTG will abide by Public Health Service regulations and policies for handling misconduct in science as set forth in 42 CFR Part 50, Subpart A, and will report to the NIH at a minimum one time per year any occurrences of misconduct within the Network.

ARTICLE IX Conflict of Interest

The ACTG members will abide by the financial disclosure and conflict of interest policies and guidelines approved by the Executive Committee.

ARTICLE X Ratification of and Amendments to the Bylaws

1. With the majority of the Executive Committee voting to approve, the Bylaws shall be presented to the voting membership at least ten (10) days prior to a ratifying vote. A two-thirds vote of the voting members of the ACTG shall be required to ratify the Bylaws, and they shall take effect immediately after that ratification.
2. The Bylaws may be amended at any regularly scheduled meeting or conference call of the ACTG voting members or their designated proxies, or at a special ad hoc meeting or conference call of the ACTG voting members or their designated proxies convened for this purpose. Proposed amendments to the Bylaws shall be submitted in writing to the NCC by any voting member of the ACTG at least 30 days prior to a regularly scheduled or special ad hoc meeting or conference call of the ACTG voting members.
3. The NCC will place the proposed amendment on the agenda of the next meeting or conference call of the Executive Committee and will distribute the proposed amendment to the members of the Executive Committee prior to the meeting/call. A majority affirmative vote of the Executive Committee shall be required to send the proposed amendment to the ACTG voting members for ratification.
4. After approval of the proposed amendment by the Executive Committee, the NCC will distribute it to the ACTG voting members at least 5 working days before their next regularly scheduled or special ad hoc meeting or conference call.
5. A two-thirds vote of the ACTG voting members (or their designated proxies) present shall be required for ratification of the proposed amendment. Amendments will become effective immediately upon their ratification.

Ratified: June 22, 2008

Amended: September 21, 2018, July 1, 2016, March 8, 2014, July 19, 2012,
November 20, 2010