



BYLAWS

of the

North Carolina Regulatory Affairs Forum

as amended 06 January 2010

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Article I. Name

The name of this organization shall be the North Carolina Regulatory Affairs Forum (NCRAF).

Article II. Type of Organization

NCRAF shall be a nonprofit corporation in perpetuity under the laws of the State of North Carolina. The officers of NCRAF shall serve as directors of the corporation, and shall file and maintain Articles of Incorporation with the Department of the Secretary of State of North Carolina.

Article III. Purpose

The purpose of NCRAF is to provide a local forum for the exchange of information regarding regulatory affairs activities as they apply to organizations in research, development, or manufacture of drugs, biologics, or medical devices. NCRAF is dedicated to providing education and support for the continuing professional development of individuals who have an interest in regulatory affairs.

Article IV. Membership

Individuals shall become members of NCRAF upon payment of annual membership dues. All individuals, and particularly individuals currently working, or with experience, in regulatory affairs, may become members. Only NCRAF members in good standing shall be entitled to vote for the election of officers and to hold office as officers or standing committee chairpersons.

Article V. Membership Dues

Section 1. Annual Dues

Membership dues for each year shall be paid annually in the amount set periodically by the Executive Committee. Membership dues are nonrefundable and are applied to the individual named in the membership application only.

Section 2. Lifetime Dues

The Executive Committee may establish optional lifetime membership dues as an alternative to annual dues.

Article VI - Executive Committee

The Executive Committee shall consist of the officers, the chairpersons of the standing committees, and the Past-President. The President of NCRAF shall chair the Executive Committee.



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The Executive Committee shall be the governing body of the organization:

- It will establish by quorum vote those organizational policies and procedures it deems necessary to control the activities of the organization. These policies and procedures will be binding upon the organization until such time that a duly elected Executive Committee rescinds or modifies by quorum vote the previously established policies or procedures.
- It will establish by quorum vote an annual budget no later than January 31 of each year. It may revise the budget by quorum vote at any time during the year. It will approve in advance and by quorum vote any expenditures that are not provided for in the budget, any expenditures that exceed the amount allocated in the budget, and any proposed actions that have the potential to reduce the revenues included in the budget.
- It will review and approve in advance and by quorum vote all contracts and other agreements in which NCRAF is identified as a party and will identify the individuals authorized to sign the contracts and other agreements upon Executive Committee approval.
- It will review and approve in advance and by quorum vote any use of NCRAF's name in association with a program or other activity.

The Executive Committee shall set the amount of membership dues as provided under Article V, above, and shall establish fees and assessments for special purposes and events as needed.

Article VII - Officers

The officers of NCRAF shall be a President; a President-Elect; a Vice President, Programs; a Vice President, Communications; a Recording Secretary; and a Treasurer. All officers shall be NCRAF members in good standing.

Section 1 - Duties of Officers

The duties of the officers shall be as follows:

A. President

The President shall preside at all meetings of NCRAF and of its Executive Committee; shall supervise the affairs of the organization; shall, with the concurrence of a majority of the officers currently serving, appoint the chairpersons of those standing committees for which chairpersons are not elected; shall serve as an ex officio voting member of each of the standing committees; and shall have all executive powers normal to this office, except as otherwise provided in these bylaws.

B. President-Elect

The President-Elect shall assist the President in all duties of that office; shall, in the absence of the President, serve as Acting President with all of the authority and responsibilities of the President; and shall succeed to the office of President upon completion of the President's term of office or upon the incapacity or resignation of the President.



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C. Vice President, Programs

The Vice President, Programs shall chair the Programs Committee and shall, in the absence of both the President and the President-Elect, serve as Acting President with all of the authority and responsibilities of the President.

D. Vice President, Communications

The Vice President, Communications shall chair the Communications Committee.

E. Recording Secretary

The Recording Secretary shall keep minutes of all meetings of NCRAF and of its Executive Committee, shall keep the nonfinancial records of the organization, other than those that are the responsibility of the Vice President, Communications; shall preserve the records of the organization and see that they are transmitted to succeeding officers; and shall have authority and duties appropriate to this office, except as otherwise provided in these bylaws.

F. Treasurer

The Treasurer shall conduct the financial transactions and keep the financial records of the organization; shall report on the financial status of the organization at its meetings, at meetings of the Executive Committee, or when so requested by the President; and shall have authority and duties appropriate to this office, except as otherwise provided in these bylaws.

Section 2 - Election of Officers

Officers shall be nominated and elected by the membership.

Section 3 - Terms of Office

The term of office for the President, President-Elect, and Past President will be one year, beginning on January 1 and ending on December 31 of the year in which they assume office.

The terms of office for the Secretary, Treasurer, and Vice Presidents will be two years, beginning on January 1 of the year of their election and ending on December 31 of the year following the year in which they assumed office. The terms of office for the Secretary and VP Communications will begin in odd-numbered years; the terms of office for the Treasurer and VP Programs will begin in even-numbered years.

The President-Elect, upon completion of their term of office or upon a vacancy in the office of President, shall succeed to the office of President. In the event of a vacancy in the office of President-Elect, the remainder of any vacant term may be filled by appointment by the Executive Committee with the concurrence of the President. A President-Elect thus appointed by the Executive Committee shall not automatically succeed to President without a vote of the membership. In the event of vacancies in any office other than President or President-Elect, the remainder of any vacant term may be filled by appointment by the President with the concurrence of the Executive Committee.



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Article VIII - Standing Committees

Chairpersons and members of standing committees shall be NCRAF members in good standing. The duties of the standing committees shall be as follows:

Section 1 – Programs Committee

The Programs Committee shall be chaired by the Vice President, Programs. Members are appointed by the chairperson.

The Programs Committee shall, in consultation with the Executive Committee, establish topics and identify speakers for programs to be presented at NCRAF membership meetings. The committee shall make arrangements for facilities and refreshments for membership meetings, shall prepare meeting announcements for distribution to the membership, and coordinate meeting registration.

The Professional Liaison is a member of the Programs Committee and shall initiate contact with FDA on behalf of members (e.g., to propose presentation topics and invite FDA speakers for NCRAF meetings, etc.). The liaison shall also be the initial point of contact to foster relationships and at the direction of the Vice President, Programs coordinate joint meetings with other local professional organizations that have similar missions. The liaison shall apprise the Programs Committee of professional development opportunities available through local organizations.

Section 2 – Communications Committee

The Communications Committee shall be chaired by the Vice President, Communications. The NCRAF newsletter editor, the NCRAF webmaster, and the NCRAF Advertisement Coordinator shall be members of the Communications Committee. Members are appointed by the chairperson.

The External Liaison is a member of the Communications Committee. The External Liaison serves as the point of contact between NCRAF and other organizations for the purpose of collaboration and information-sharing. The External Liaison maintains a database of other professional organizations that are active in North Carolina and that have interests and activities that overlap with those of NCRAF. The External Liaison proactively communicates with these organizations regarding their events and activities and notifies the Communications Committee of upcoming events sponsored by other organizations that are likely to be of particular interest to NCRAF members.

The Communications Committee shall keep the membership records of the organization; shall distribute meeting announcements, newsletters, and other official publications of the organization authorized by the Executive Committee; shall assure that the NCRAF website contains current information; and shall coordinate advertisement postings in the newsletter and on the website.

Section 3 – Education and Training Committee

The chairperson(s) of the Education and Training Committee shall be appointed by the President in consultation with the Executive Committee. Members are appointed by the chairperson(s). The Education and Training Committee shall coordinate member training focused on preparation for professional certification examinations. The Committee shall identify topics and speakers, determine the meeting schedule, arrange for facilities, and prepare course announcements for distribution to the membership. In addition, the Committee shall consult with the Executive Committee to confirm the current membership status and payment of training fees for each participant.



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Section 4 – Nominating Committee

The chairperson of the Nominating Committee shall be the President of NCRAF. The President-Elect and Past-President will also serve on the Nominating Committee. The Nominating Committee shall coordinate votes by the membership to elect officers or amend the bylaws. The Committee shall resolve any questions regarding the voting eligibility of any member or the acceptability of any ballot, tally the votes, and report the results to the Executive Committee and the membership. For the election of officers, the Nominating Committee shall solicit nominations for officers from the membership of the organization, shall review the nominations for eligibility, and shall present a slate of no more than three candidates for each office to the membership at least one month prior to the Annual Meeting each year.

Article IX - Special Committees

Special committees may be appointed by the President or by the Executive Committee whenever necessary to carry out the purposes of NCRAF.

Article X - Meetings

Section 1 - General Membership

A. Meetings

It is the intention that NCRAF hold a minimum of six general membership meetings per year, at least one meeting per quarter. The Annual Meeting of the Membership shall be held during the first quarter of each year, at which time the elected officers shall be introduced to the membership and shall assume their responsibilities. Special meetings may be called at any time by the President or by the Executive Committee.

Section 2 - Executive Committee

A. Meetings

The Executive Committee shall meet at least bimonthly and at such other times as necessary to meet its responsibilities. These meetings shall be called by the President or by the President-Elect, or, if unusual circumstances warrant, by any other member of the Executive Committee. Notification of Executive Committee meetings shall be made by the person calling the meeting.

B. Quorum

A majority of the Executive Committee members currently serving shall constitute a quorum. A quorum is necessary for all major Executive Committee decisions (e.g., significant expenditures or policy changes, Executive Committee member replacement, interpretation of NCRAF Bylaws, etc.).

Section 3 - Standing Committees

A. Meetings

Standing Committees shall meet at such times as necessary to meet their responsibilities. Meetings of each Standing Committee shall be called by the chairperson of that committee or by the President of NCRAF.



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B. Quorum

The chairperson or the chairperson and one other member of any Standing Committee shall constitute a quorum.

Article XI - Election of Officers

Officers shall be nominated and elected by NCRAF members in good standing in a manner consistent with the following:

Section 1 - Nominations

The Nominating Committee shall solicit nominations for officers from the membership of the organization, shall review the nominations for eligibility, and shall present a slate of candidates for each office (the goal should be at least two candidates for each office) to the membership at least one month prior to the Annual Business Meeting each year.

Section 2 - Elections

The Nominating Committee shall be in charge of all elections, and votes shall be tallied by the Nominating Committee. Officers shall be elected by a plurality of the votes cast by secret ballot, prior to the Annual Business Meeting. Questions regarding the voting eligibility of any member or the acceptability of any ballot shall be resolved by the Nominating Committee. The results of the election shall be announced to the membership at the Annual Business Meeting by the Chairperson of the Nominating Committee, or, in the chairperson's absence, by the presiding officer. Installation of officers shall take place at the Annual Business Meeting.

Article XII - Amendments to These Bylaws

Proposals for amendments to these bylaws may be made at any time, and shall be presented to the Executive Committee in writing. If the Executive Committee finds a proposed amendment to be consistent with the objectives of and in the best interests of the organization, it shall send the proposal to the Nominating Committee for presentation to the voting members by paper or electronic means. This written communication shall be sent to the member's address that is on file in the NCRAF contact information. Approval shall be by majority vote, by secret ballot. The Nominating Committee shall oversee voting on proposed amendments and shall resolve any questions regarding the voting eligibility of any member or the acceptability of any ballot. Amendments so adopted shall become effective upon announcement by the Nominating Committee of the results of the balloting.

Adopted by the membership 06 January 2010