

BY-LAWS OF THE AECIC

(SPANISH ASSOCIATION OF CONTRACT RESEARCH ORGANISATIONS)

CHAPTER I NAME, AIMS, ACTIVITIES, MEMBERS, DOMICILE AND AREA OF ACTIVITY

ARTICLE 1. NAME.

The not-for-profit entity was established in Madrid in 2003 under the name ASOCIACIÓN ESPAÑOLA DE COMPAÑÍAS DE INVESTIGACIÓN CLÍNICA (SPANISH ASSOCIATION OF CONTRACT RESEARCH ORGANISATIONS), pursuant to Article 22 of the Spanish Constitution, which shall be governed by Organic Law 1/2002 of 22 March, regulating the right of association, and all other concordant regulations, and those which may be applicable at all times through the current By-Laws.

ARTICLE 2. AIMS AND OBJECTIVES OF THE ASSOCIATION.

The Association's aims are as follows:

1. To safeguard the general interests of those contract research organisations (hereinafter, CROs) which conduct their business in Spain, fostering dialogue with health and regulatory authorities and other professional and business associations, both national and international.
2. To develop and promote the use of both national and international Good Clinical Practice guidelines and other regulations, guides, standards and quality certificates, related with clinical research, as well as to ensure compliance with current legislation.
3. To represent the interests of those CROs which conduct their business in Spain before other regional, national and international associations and bodies.
4. To promote the exchange of knowledge and information relating to clinical research with the general public, among other professional and business organisations and among different partners involved in clinical research (medical societies, patient associations, the media, etc.).
5. To establish a discussion platform for topics related to clinical research, in all its aspects (quality standards, economic and legal procedures, etc.).
6. To provide legal and professional assistance and advice to members of the Association.
7. To collaborate in the development and improvement of knowledge and techniques leading to better practice in clinical research.
8. To develop a specific code of ethics, or adopt one already in use by similar professional or business associations.
9. To foster the education and training of professionals devoted to clinical research.

ARTICLE 3. ACTIVITIES.

All those activities aimed at achieving the Association's aims and objectives and which do not contravene the same.

ARTICLE 4. DOMICILE AND AREA OF ACTIVITY.

The Association is domiciled at Calle Capitán Haya, nº 1, 28020 Madrid.

The Association shall conduct its activities within the geographical limits of Spain and, where appropriate, at international level.

CHAPTER II BODIES OF THE ASSOCIATION

ARTICLE 5. GOVERNING AND REPRESENTATIVE BODIES.

The Associations' governing and representative bodies are the General Assembly and the Executive Committee, respectively.

CHAPTER III GENERAL ASSEMBLY

ARTICLE 6. NATURE.

The General Assembly is the Association's top governing body; it shall comprise all the associates. The Executive Committee may decide to allow other persons, who are not associates, to attend the Assembly as non-voting participants.

ARTICLE 7. MEETINGS.

The Assembly shall be called to meet in an ordinary sitting at least once a year to approve the expenses and budgets, on the day and at the location designated by the Executive Committee. It may also be called to meet in an extraordinary sitting, at the request of 20% of the associates, to discuss any subject or aspect related with the Association, and at the initiative of the President and/or the Executive Committee, whenever deemed appropriate.

ARTICLE 8. CALLS.

Calls for meetings of the General Assembly, both ordinary and extraordinary, shall be made in writing, specifying the location, date and time of the meeting, as well as the agenda. For the first sitting of the Assembly at least 28 working days' notice must be given for ordinary meetings and 10 working days' notice for extraordinary meetings. Where appropriate, notice may also be given of a second setting of the Assembly; a period of at least 30 minutes must be allowed between one sitting and the next.

The aforesaid periods may be reduced owing to duly substantiated grounds of urgency.

ARTICLE 9. QUORUM REQUIRED FOR OFFICIAL CONSTITUTION AND QUORUM REQUIRED FOR REACHING AGREEMENTS.

Meetings of the General Assembly, both ordinary and extraordinary, shall be **officially constituted** when at least half plus one of the associates with voting rights are present or represented and, in the second call, when at least one third of the associates with voting rights are present or represented.

Agreements may be reached by a simple majority of the votes of those associates present or represented, except in the case of the modification of the by-laws, dissolution of the Association, or the disposal or transfer of assets, for which a qualified majority of two thirds of the votes of those associates present or represented shall be required. In the event of a tie, the President, or whoever is acting as such, shall have the deciding vote.

ARTICLE 10. POWERS OF THE GENERAL ASSEMBLY.

The powers of the General Assembly are as follows:

1. To appoint the Executive Committee and the posts on the same, administrators and representatives, as well as honorary members thereof.
2. To examine and approve the annual budgets and accounts.
3. To approve, where appropriate, the management of the Executive Committee.
4. To set the annual ordinary or, where appropriate, extraordinary fees.
5. To resolve to establish a Federation of Associations or to become a member of such a body.
6. To expel members at the proposal of the Executive Committee, except in the case of non-payment, in which case expulsion shall be executed immediately.
7. To apply for public interest status.
8. To dispose of and transfer assets by means of a qualified majority.
9. To modify the By-laws (called for this purpose and with the approval of a qualified majority).
10. To dissolve the Association (called for this purpose and with the approval of a qualified majority).
11. Those members not up-to-date with the payment of their fees on the date of the meetings of the Assembly may not exercise their rights therein.
12. Resolutions not included in the agenda of the General Assembly cannot be approved.

CHAPTER IV EXECUTIVE COMMITTEE

ARTICLE 11. POWERS OF THE EXECUTIVE COMMITTEE.

The Executive Committee is the representative body which administers and represents the Association's interests in accordance with the provisions and instructions of the General Assembly. It shall consist of a President, a Secretary and, where applicable, a Vice President, a Treasurer and Executive Members, appointed by the General Assembly from among the associates, in full use of their civil rights, who are not subject to any legally established incompatibility, and who shall be selected from among the associate companies and who have submitted their candidacies for any of the posts on the Executive Committee. The term thereof shall be two years, renewable for equal periods, provided no alternative candidacy is presented for any of the posts, calling for such purposes an Extraordinary General Assembly wherein each one of the posts on the Executive Committee shall be subjected to a vote or ratification.

The President, Vice President, Secretary and Treasurer of the Executive Committee shall also be the President, Vice President, Secretary and Treasurer of the General Assembly.

All posts on the Executive Committee shall be honorary and not remunerated.

ARTICLE 12. PROCEDURES FOR THE ELECTION AND REPLACEMENT OF MEMBERS.

Election to the posts on the Executive Committee by the General Assembly shall be conducted by means of the submission of the candidacy for any of the posts on the Executive Committee, from among the applicant associate companies, of which suitable notice shall be given, 15 days in advance (*duration of the electoral period prior to the meeting of the Assembly for appointing the members of the Executive Committee*) of the holding of the corresponding meeting.

The election for each post on the Executive Committee shall be conducted by means of an individual, consecutive vote for each of the posts thereupon, starting with the President, Vice President, Secretary, Treasurer and Executive Members, with members being able to apply for one or more of the posts.

If a member of the Executive Committee is absent or ill, they may be provisionally substituted by another member of the Committee, subsequent to appointment by the majority of the members, except in the case of the President, who shall be substituted by the Vice President.

The members of the Executive Committee shall leave their posts:

1. Owing to the expiry of their term of office.
2. By express resignation.
3. By agreement of the General Assembly.

ARTICLE 13. MEETINGS AND QUORUM FOR REACHING AGREEMENTS.

The Executive Committee shall meet subsequent to a call, issued at least three days in advance of the meeting, as often as determined by its President and at the request of 50% of its members. It shall be constituted when half plus one of its members are in attendance; in order for agreements to be valid they must be adopted by a majority of votes. In the event of a tie, the President, or whoever is acting as such, shall have the deciding vote.

ARTICLE 14. POWERS OF THE EXECUTIVE COMMITTEE.

The powers of the Executive Committee are as follows:

1. To administer corporate activities and conduct the Association's financial and administrative management, agreeing to enter into the appropriate contracts and acts, notwithstanding the provisions of Article 11, section h).
2. To implement the agreements adopted by the General Assembly.
3. To prepare the annual budgets and accounts and submit them to the General Assembly for approval.
4. To prepare, where appropriate, the Internal Regulations.
5. To rule on the admission of new associates.
6. To appoint delegates for any given activity of the Association.
7. Any other power which is not the exclusive competence of the General Assembly.

ARTICLE 15. THE PRESIDENT.

The President's powers shall be as follows:

1. To be the Association's legal representative before all manner of public and private bodies.
2. To call, preside over and adjourn the sittings of the General and/or Extraordinary Assembly, as well as of the Executive Committee.
3. To conduct the deliberations and reach agreements by consensus in the aforesaid sittings.
4. To order payments and sign documents, minutes and correspondence in order to authorise them.
5. To adopt any urgent measure which may be advisable or necessary for the smooth operation of the Association or appropriate for the development of its activities, without prejudice to subsequently having to give account thereof to the Executive Committee.
6. To sign, along with the Secretary, the minutes of the General Assembly and the Executive Committee, as well as any certificates issued by the Secretary.

ARTICLE 16. THE VICE PRESIDENT.

The Vice President shall substitute the President in the absence of the latter, owing to illness or for any other reason, and shall have the same powers as the latter.

ARTICLE 17. THE SECRETARY.

1. To act as such in the meetings of the General Assembly and of the Executive Committee, recording the minutes thereof and certifying the agreements reached.
2. To keep the books, documents and seals of the Association.
3. To dispatch the correspondence in accordance with the wishes of the President.
4. To issue, along with the President, any requested certificates.
5. To establish the agenda and issue calls for meetings, in accordance with the President's wishes.
6. To receive and process requests for the admission of new members.
7. To manage the Association's administrative tasks.

ARTICLE 18. THE TREASURER.

The Treasurer's duties are as follows:

1. To manage the Association's accounting, its income and social expenses, taking an active part in all financial transactions.
2. To collect and safeguard the Association's funds.
3. To execute payment orders issued by the President.
4. To formalise the Association's annual budgets, as well as its financial statements and balance sheets.

The Treasurer shall keep all documents pertaining to financial aspects in a file which shall be available to those members who wish to examine them.

The Treasurer shall oversee all the inflows and outflows of the Association's cash. The Treasurer shall also be responsible for safeguarding and conserving the Association's assets, of which they shall keep a detailed inventory.

ARTICLE 19. EXECUTIVE MEMBERS.

Executive Members shall have the obligations inherent to their post as members of the Executive Committee, as well as those arising from the work committees or delegations which the Committee itself may entrust to them.

CHAPTER V ASSOCIATES

ARTICLE 20. REQUIREMENTS FOR ASSOCIATION.

Membership of the Association is open to any entity under Private Law which conducts its activities in Spain, on behalf of third parties, in the field of clinical research, provided that:

1. The aforesaid activity, or a similar or analogous one, is included in the corporate purpose of the applicant company.
2. There is documented evidence of the performance of clinical research services on behalf of third parties.
3. It formally requests to be admitted to the Association and accepts to adhere to and duly comply with the by-laws of the same.
4. It has paid the annual fees for the current year.

Any entity complying with the aforesaid requirements may be admitted as a full member of the Association.

The candidacies of applicant companies shall be accepted by the majority agreement of the Executive Committee, whereupon they shall be entitled to enjoy all rights as an associate until their ratification by the General Assembly.

Each member shall appoint an individual to represent it before the Association; this representative may be substituted, as often as may be necessary, by means of a written notification remitted by the associate member to the Executive Committee.

ARTICLE 21. GROUNDS FOR THE LOSS OF ASSOCIATE STATUS.

Associate status shall be lost owing to any of the following grounds:

1. Voluntary resignation, notifying the Executive Committee in writing. In such cases, membership shall be lost upon receipt of resignation by the Association; notwithstanding the foregoing, the member's financial obligations shall remain in force until the end of the calendar year.
2. Failure to comply with its financial obligations, if it fails to pay the annual fees within the six-month period following issuance of the invoice.
3. Owing to improper conduct, or to discrediting the Association or any of its associates through deeds or words which severely disrupt the acts organised by the same and the normal harmony between the associates.
4. Owing to the disappearance or loss of the associate's activity.
5. Exclusion by the Executive Committee for any breach of the articles of the By-laws of the Association or its Code of Ethics.

In the event of loss of associate status, the affected party shall, in all cases, be notified in writing of the grounds giving rise to such measure, and shall have the right to be heard, with the resolution that the General Assembly adopts in this regard having to be substantiated.

ARTICLE 22. RIGHTS OF ASSOCIATES.

Associates shall have the following rights:

1. To participate in the Association's activities and in the governing and representative bodies.
2. To exercise their right to vote and to attend the General Assembly.
3. To be informed on the make-up of the Association's governing and representative bodies, of its financial statements and the development of its activity.
4. To be heard prior to the adoption of disciplinary measures against them.
5. To contest the agreements of the Association's bodies which it deems to be contrary to the law or to the by-laws.
6. To make suggestions to members of the Executive Committee with a view to improving attainment of the Association's aims.

ARTICLE 23. DUTIES OF ASSOCIATES.

Associates shall have the following obligations:

1. To share the objectives of the Association and to collaborate in attaining the same.
2. To pay the fees, charges and any other contributions which, pursuant to the by-laws, may correspond to each associate.
3. To comply with all other obligations arising from the provisions of the by-laws.
4. To obey and comply with agreements validly adopted by the Association's governing and representative bodies.
5. To maintain due discretion and confidentiality with regard to information, which is not of a public nature, to which they may have access through their participation in the Association.

CHAPTER VI REGARDING FUNDING, ACCOUNTS AND DOCUMENTATION

ARTICLE 24. DOCUMENTARY AND ACCOUNTING OBLIGATIONS.

The Association shall maintain an up-to-date list of associates. Likewise, it shall keep accounts which give a true and fair view of the entity's equity, results and financial situation and the activities conducted. It shall also maintain an up-to-date inventory of its assets.

The minutes corresponding to the meetings of its governing and representative bodies shall be entered into a Book of Minutes.

The Association's income and resources shall be used exclusively for the objectives of the Association, as defined in these by-laws.

ARTICLE 25. FINANCIAL RESOURCES.

The financial resources envisaged for the development of the Association's aims and activities shall be as follows:

1. Affiliation, periodic or extraordinary fees.
2. Subsidies, which may be received legally by associates or by third parties.
3. Any other lawful resource.

CHAPTER VII DISSOLUTION

ARTICLE 26. DISSOLUTION.

The Association will be dissolved:

1. By the will of the associates expressed by means of an agreement of the General Assembly, called to this end by a qualified majority of two thirds of the associates.
2. If it is impossible to comply with the aims envisaged in the by-laws, assessed by the General Assembly.
3. By court ruling.

ARTICLE 27. LIQUIDATION COMMITTEE.

In the event of dissolution, a liquidation committee shall be appointed, which, once all debts have been settled, and if there are any excess funds, shall earmark said excess funds for non-profit purposes, in accordance with that agreed upon by the General Assembly.

The liquidators shall have those duties established in Sections 3 and 4 of Article 18 of Organic Law 1/2002 of 22 March.

MADRID, JUNE 23rd, 2014