

AICRO REGULATION

Article 1

The Statute of the AICRO Italian Association Contract Research Organization, established on May 14, 2004, with registered office in Milan, provides, in the last paragraph of Article 3, that the Association is provided with a "Regulation".

Article 2

Purpose of the Regulation

The Regulation aims to define, for ordinary administration, the rules of operation of the Association, allowing the Association to carry out its institutional activities without having to convene each time the Shareholders' Meeting.

The Regulation also aims to establish the requirements, principles and quality control procedures that members are required to comply with.

Article 3

Amendments to the Rules of Procedure

The rules are drawn up and can be amended only by the Executive Board.

Article 4

The Executive Board

The Executive Board consists of 4 members: President, Vice President and 2 Directors. The Executive Board, after hearing any recommendations of the Assembly and taking into account any nominations for specific roles, entrusts the roles of Scientific Director and Treasurer to 2 of the elected Directors.

The Executive Board may delegate the role of Head of International Relations to 1 of the elected directors or to one of the representatives of the AICRO members who is available and who, in the opinion of the Executive Board, has the appropriate characteristics to play the intended role. The characteristic activities of these roles are as follows:

- **President:** has the legal representation of the Association, has the powers for ordinary and extraordinary administration; convenes and chairs meetings; in the case of banking operations, it has separate signature powers to open c/c and issue cheques and credit transfers up to 2,000,00 euro; may not open credit facilities without appropriate deliberation by the Governing Council; has joint signature powers with that of the Vice-president for operations in excess of EUR 2000.00.
- **Vice President:** is responsible for replacing the President when absent and assumes the powers conferred on him by the President.
- **Scientific Director:** is responsible for the training and updating activities of professionals working in the field of clinical research, in relation to the activities organized by
- AICRO.
- **Treasurer:** has the task of keeping the accounts of the Association, to prepare the annual budget both estimate and balance sheet, monitor the economic performance of the management,

authorize current expenditure up to an amount of €5,000.00 and require registration fees and annual fees.

Expenditure in the amount of more than €5,000.00 will be decided by the Executive Board.

He has relationships with credit institutions. By delegation of the President, the Treasurer may carry out all banking operations required by the role including payment transactions, with the same limitations as those provided for by the President.

The Treasurer is responsible for the administrative management of human resources.

- **The Head of International Relations** has the task of representing AICRO at international meetings, including participation in the activities provided by the membership of AICRO EUCROF (Association of European CRO associations) and is responsible for coordinating relations with bodies and associations outside the Italian territory.

In accordance with the Statute, if one of the members of the Executive Board is resigned, the Directors who remain in office will perform, pending the replacement, the acts of ordinary administration, including the reassignment of the above-mentioned offices to the remaining Councillors.

If, due to changes in membership after election, two or more directors are members of the same company/subsidiary/subsidiary /etc., one or more directors must be replaced by a new election.

- The Executive Board may delegate its members to specific functions, on the basis of its deliberations that define specific tasks, identifying the time and also the duration. The Executive Board:
 - shall be convened by the President in writing at least one week before the date of the meeting;
 - shall be convened whenever the President deems it necessary or when at least two Councillors so request;
 - may decide in writing as required by art. 10 of the Statute under "c"; In this case, the meetings operate under the same rules as the assemblies.
- The Executive Board also decides on the possible decay from the status of member for absence or loss of the minimum requirements provided for by art. 4 of the Statute and expressed in the application for admission as per art. 5 of the Regulation.

Article 5

Application for admission to the AICRO

Aspiring members can apply for admission to the Association by delivering to the same a written application, in which they must be explicitly indicated (ex art. 4 Statute):

- a) its identification references (name, location, telephone numbers, legal representative, etc...);
- b) the will to respect the national and international norms for the activity of Contract Research Organization;
- c) the willingness to comply with the objectives and rules contained in the Statute and the Rules of Procedure;

d) an undertaking to submit, within 30 days of the request, all the documentation referred to in Article 6 below;

e) the commitment to pay the membership fees to the Association and subsequent annual ones. The facsimile of the application is annexed to this Regulation.

The application for admission must be accompanied by the following documents:

- Articles of association (copy)
- Most recent statutes (copy)
- Certificate C.C.I.A.A. updated (with a date not exceeding 3 months prior to the application for registration pursuant to art. 4 of the Regulations)
- for national companies: ISO quality certificate; for multinational companies: self-certification attesting to the existence of an equivalent Quality System.

Within 30 days, the Executive Board shall decide on the admission of the new member. The judgment of the Executive Board is final.

Article 6

Membership fee

The payment of the membership fee is one of the essential conditions for the registration and permanence of members in the AICRO as per Article 4 of the Statute. This portion, non-refundable, corresponds to:

- Euro 2.000,00 (two thousand/00) per year, to be paid by 31 January of each year following that of registration, as an annual stay fee.

Members who have not paid the annual membership fee within the deadline will not be able to have a representative in the Executive Board. In the event that the delay lasts beyond 30 April, the member will not be able to benefit from any service offered by the Association, whether it is free or paid.

If a member remains in arrears beyond 31 August, he shall be excluded from the Association. The Board shall decide on the exclusion during the Board meeting convened for this purpose, by a majority of those present, and in the event of a tie, the vote of the President shall prevail. The resolution of exclusion must be communicated to the excluded member by letter registered letter or by Pec. Any request for readmission shall be submitted in accordance with the procedure set out in the Articles of Association and the current Rules and Regulations, and may only be submitted for the following year.

Article 7

Resolution in writing

In accordance with Article 9 of the Statutes, letter "f", the General Assembly may also resolve in writing (fax or e-mail). The Rules of Procedure shall lay down the rules for the proper handling of speeches and votes cast in this manner.

If the conditions allowing the management of the meeting in written form are met, i.e. at the request of the Chairman or of one third of the members, the Chairman must convene the meeting by registered letter RR or e-mail with acknowledgement of receipt at least one month before the date of the meeting, specifying that:

- a) the proceedings of the General Assembly shall be in written form;
- b) the admissible written forms may be either exclusively by e-mail or exclusively by fax; hybrid forms are only admissible in the event of sudden failure of the telephone lines;

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c) it shall be the duty of the Chairman, at the opening of the General Assembly, to inform all participants of the names of participating members and their e-mail addresses or fax numbers

d) it shall be the duty of the Chairman to appoint the Secretary to take the minutes;

e) the Secretary's task shall be to record, on file and in hard copy, the various interventions and to write the relevant minutes in the meeting book;

f) it shall be the duty of the Chairman to indicate to all participants, in accordance with the established agenda, what is to be discussed or resolved upon;

g) members are invited by the Chairman to speak on the items on the agenda; members must therefore send to all participants, indicated in advance by the Chairman, the text of their speech and/or vote and also express any wish to abstain on the resolution under discussion

h) from the moment the Chairman asks to vote on one of the items on the agenda, members have half an hour to express their vote; once this time has elapsed, the absence of a reply will be interpreted as abstention;

i) in the event of faults or problems on the telephone line the meeting shall be suspended;

j) The Chairman shall be responsible for verifying the existence of the conditions allowing the meeting to be resumed or reconvened on another date with the same operating procedures and the same agenda.

Article 8

Training activities

One of the objectives of the AICRO is to promote the training of personnel involved in clinical research (Article 3 of the AICRO Statutes).

The Scientific Director of the AICRO is responsible for organizing training and refresher courses for professionals working in the field of clinical research.

For each single training event, the Scientific Director shall submit to the President for approval a detailed plan of said event including

- title and topics to be covered
- list of speakers
- target audience
- location and duration
- budget

Having consulted the other members of the Board, the President will endeavour to give his opinion in writing within two weeks of the presentation of the plan.

Article 9

Entry into force

The Rules enter into force upon their approval. All amendments made shall take effect on the day of approval.

