

# AICRO REGULATION

## Article 1

The Articles of Association of AICRO Associazione Italiana Contract Research Organisation, established on 14 May 2004, with registered office in Milan, provide, in the last paragraph of Article 3, that the Association shall have a "Regulation".

## Article 2

### Purpose of the Rules

The purpose of the Rules and Regulations is to define, for the ordinary administration, the Association's operating rules, enabling it to carry out its institutional activities without having to convene the General Meeting of Members each time.

The By-Laws are also intended to establish the requirements, principles and quality control procedures to be observed by the members.

## Article 3

### Amendments to the Rules

The Rules and Regulations are drawn up and may only be amended by the Executive Board.

## Article 4

### Executive Board

The Executive Board consists of five members: President, Vice President and three Board Members. The Executive Board, having heard any recommendations of the Assembly and considering any nominations for specific roles, entrusts 2 of the elected Board Members with the roles of Scientific Director and Treasurer.

The Executive Board may delegate the role of Head of International Relations to 1 of the elected Board members or to one of the AICRO members' representatives who is available and who, in the opinion of the Executive Board, has the appropriate characteristics to carry out the envisaged role.

The characteristic activities of the aforementioned roles are as follows:

- **President:** has the legal representation of the Association, has the powers for ordinary and extraordinary administration; convenes and presides over meetings; for banking transactions has joint signature powers to open current accounts and issue cheques and transfers up to €2,000.00; cannot open credit lines without the appropriate resolution of the Executive Board; has joint signature powers with the Vice President for transactions exceeding €2,000.00;
- **Deputy President:** is responsible for replacing the President when absent and assumes the powers delegated to him by the President;
- **Scientific Director:** is responsible for training and refresher courses for professional figures professionals working in the field of clinical research, in relation to the activities organised by AICRO.
- **Treasurer:** is responsible for keeping the Association's accounts, preparing both the annual budget and the final balance sheet, monitoring the economic trend of management, authorising current expenses up to an amount of €5,000.00, and collecting membership and annual dues.

Expenditure in excess of €5,000.00 shall be decided by the Executive Board.

It has relations with credit institutions. By delegation from the President, the Treasurer may perform all banking transactions required by the role, including payment transactions, with the same limitations as for the President.

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

The Head of International Relations is in charge of representing AICRO at international meetings, including participation in the activities envisaged by AICRO's membership of EUCROF (Association of European CRO Associations), and is in charge of coordinating relations with bodies and associations outside Italy.

In accordance with the Articles of Association, should one of the members of the Executive Board resign, the remaining Board members shall carry out the acts of ordinary administration, including the reassignment of the above-mentioned offices to the remaining Board members, pending replacement.

In the event that, due to changes of company membership after the election, two or more directors are members of the same company/affiliate/subsidiary/etc, one or more directors must be replaced through a new election.

The Executive Board may delegate its members to specific functions, on the basis of its own resolutions defining specific tasks, identifying their time and also their duration.

The Executive Board

- is convened by the President, in written form, at least one week before the date of the meeting;
- is convened whenever the President deems it necessary or when at least two board members request it;
- it may deliberate in written form as provided for in Article 10 of the Statute under point "c"; in this case, the meetings function according to the same rules as assemblies.

The Executive Board also decides on the possible forfeiture of membership status due to the absence of the minimum requirements provided for in Article 4 of the Statute and expressed in the application for admission as per Article 5 of the Rules.

## **Article 5**

Application for Admission to the AICRO

Aspiring members may apply for admission to the Association by sending a written application to the same, which must explicitly state (pursuant to Article 4 of the Articles of Association):

- a) their identification references (name, head office, telephone numbers, legal representative, etc.);
- b) its willingness to comply with national and international standards for the activity of Contract Research Organisation;
- c) the willingness to comply with the objectives and rules contained in the Articles of Association and Rules;
- d) the commitment to submit, within 30 days of the request, all the documentation provided for in Article 6 below;
- e) a commitment to pay the Association's membership fees and subsequent annual dues.

A facsimile of the application is attached to these Rules and Regulations.

The application for admission must be accompanied by the documents listed below:

- Articles of Association (copy)
- Most recent Articles of Association (copy)
- Updated C.C.I.A.A. certificate (with a date no more than 3 months prior to the application for membership ex art. 4 of the Rules)
- For national companies: ISO Quality Certificate; in the absence of ISO quality certification and for multinational companies: self-certification attesting the existence of an equivalent Quality System.

Within 30 days, the Executive Board decides on the admission of the new member. The decision of the Executive Board is final.

## **Article 6**

Membership Fee

The payment of the membership fee is one of the essential conditions for membership and the membership in the AICRO as per Article 4 (letter "e") of the Statutes.

This fee, which is non-refundable, corresponds to:

- Euro 2,000.00 (two thousand/00) per year, to be paid by 31 January of each year following the year of enrolment, as annual membership fee.

Members who have not paid the annual membership fee by the due date shall not have a representative on the Executive Board. If delinquency continues beyond 30 April, the delinquent member shall not be able to benefit from any service offered by the Association, whether free or against payment.

If the arrears continue beyond 31 August, the Member shall be excluded from the Association. The Board shall decide on the exclusion during the Board meeting convened for this purpose, by a majority vote of those present, and in the event of a tie, the President's vote shall prevail. The resolution of exclusion shall be communicated to the excluded member by registered letter with return receipt or by Pec. Any request for readmission shall be submitted according to the procedure set forth in the Articles of Association and the Rules and Regulations in force, and may only be submitted from the following year.

## **Article 7**

Resolutions in written form

In accordance with Article 10 of the statutes, letter "f", the members' meeting may also deliberate 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 are met that permit the management of the meeting in written form, i.e. at the request of the President or of one third of the shareholders, the President 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

- a) the mode of operation of the meeting shall be in writing;
- 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 telephone lines;
- c) it shall be the duty of the President, at the opening of the General Meeting, to inform all participants of the names of the attending members and their mail addresses (e-mail or fax number);
- d) it shall be the duty of the President to appoint the Secretary taking the minutes;
- e) it shall be the duty of the Secretary to record, on file and hard copy, the various speeches and to write the relevant minutes in the meeting book;
- f) it shall be the duty of the President to indicate to all participants, following the established agenda, what is to be discussed or resolved upon;
- g) the shareholders are invited by the Chairman to speak on the items on the agenda; the shareholders must therefore send to all participants, previously indicated by the Chairman, the text of the speech and/or vote and also express any desire to abstain on the resolution under discussion
- h) from the moment the Chairman asks for a vote on one of the items on the agenda, members have half an hour to express their vote; once this time has elapsed to no avail, the absence of a response 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 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 AICRO Statutes).

It is up to the Scientific Director of the AICRO to organise training and refresher courses for professionals involved in clinical research.

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

- title and topics to be addressed;
- list of speakers;
- target audience;
- location and duration;
- budget.

After consultation with the other members of the Executive Board, the President shall endeavour to give his opinion in writing within two weeks of the presentation of the plan.

## **Article 9**

### **Entry into Force**

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