A.I.C.R.O. QUALITY REGULATIONS

Article 1

The Articles of Association of A.I.C.R.O., the Italian Contract Research Organization Association, set up on May 14, 2004, with Registered Offices in Milan, specify in the last subsection of Article 3 that the Association is provided with the "A.I.C.R.O. Quality Regulations".

Article 2

Purpose of the Regulations

The purpose of the Regulations is to define the rules for the functioning of the Association, for day-to-day business, thus enabling it to carry out its institutional activities without having to convene a General Meeting each time.

Another purpose of the Regulations is to establish the requirements, principles and procedures for quality control which Members are expected to comply with.

Article 3

Amendments to the Regulations

The Regulations were written and may only be amended by the Board of Directors, in accordance with indications from the General Meeting, as described in section "d", point 3 of Article 9 of the Articles of Association.

Article 4

The Board of Directors

The Board of Directors is composed of 4 Members: the Chairman, the Deputy Chairman and 2 Directors.

The Board of Directors takes into account any recommendations from the General Meeting and bearing in mind any candidatures for specific posts, shall appoint 2 of the elected Directors to the posts of Scientific Director, Treasurer and Director of International Relations.

The characteristic activities of the abovementioned posts are as follows:

The Chairman: is the Association's legal representative, has the authority to carry out ordinary and extraordinary administration; convenes and chairs the Meetings; has sole signature authority for banking procedures and can open current accounts and issue cheques and bank transfers of up to EUR 2,000.00; may not obtain credit without an appropriate resolution by the Board of Directors; has joint signatory authority, together with the Deputy Chairman, for operations involving amounts over EUR 2,000.00.

The Deputy Chairman: is authorized to stand in for the Chairman when he/she is absent.

The Scientific Director: is responsible for the training and updating of professionals operating in the field of clinical research.

The Treasurer: has the task of keeping the Association's accounts and preparing the annual balance sheet based on income and expenditure, and of collecting the Joining Fees and Annual Fees.

He/she is in contact with financial institutions. With the Chairman's proxy, the Treasurer may carry out all the banking operations required by the role, including payment operations, with the same limitations as those placed on the Chairman.

The Director of International Relations: has the task of representing AICRO at International meetings of any type, including participation in the activities required due to AICRO belonging to the EUCROF (European CRO Federation).

Out of respect for the Articles of Association, should one of the Members of the Board of Directors resign, the remaining Directors shall carry out ordinary business procedures during the replacement process, including the reassignment of the abovementioned posts amongst the remaining Directors. Should two or more Directors become Members of the same Company/franchisee/subsidiary, etc., due to their changing Companies after the election, one or more Directors shall be replaced by way of a new election.

The Board of Directors:

- Is convened by the Chairman in writing, at least one week before the date of the Meeting,
- Is convened each time the Chairman deems it necessary or when at least two Directors request it.
- May come to decisions in writing as provided at point "c" in Article 9 of the Articles of Association; in this case the Meetings shall be run according to the same rules as required for the General Meetings, as described from point "a" to point "j" of Article 11 hereunder.

As an integration of point 8 of Article 9 of the Articles of Association, the Board of Directors may also decide on any lapse from the status of Member due to the absence of the minimum requirements as stated in Article 4 of the Articles of Association and expressed in the application for admission as per Article 5 of the Regulations.

Article 5

Application for admission to the AICRO.

Aspiring members may apply for admission to the Association by sending it a written application in which, besides specifying whether the admission is requested as a "Full Member" or as an "Associate Member", the following should be expressly indicated (ex art. 4 Articles of Association):

a) The aspiring member's identification details (Name, Head Office, Telephone numbers, Legal Representative, etc….);
b) The commitment to comply with the National and International Regulations for Contract Research Organization activities;

c) The Commitment to comply with the objectives and the rules specified in the Articles of Association, the Quality Regulations and the Deontological Code of the Association;

d) The commitment to present all the documentation specified in Article 6 hereunder, within 30 of the application;

e) The commitment to pay the Joining Fee for the Association and the subsequent annual fees.

The application template is attached to these Regulations.

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

- Act of Incorporation (copy)
- Most recent Articles of Association (copy)
- Updated Certificate of Chamber of. Commerce or equivalent document(dated no more than 3 months prior to the application for admission ex art. 4 of the Regulations)
- For National Companies: ISO Quality Certification; for Multinational Companies: self-certification attesting to the existence of an equivalent Quality System.
- Orgchart listing 70% minimum of staffed employees complying with regulation requirements

Article 6

Membership Fees

Payment of the Membership Fee constitutes one of the essential conditions for admission to and remaining a Member of the A.I.C.R.O. pursuant to Articles 4 and 6 (letter "e") of the Articles of Association.

These fees, which are not reimbursable, correspond to:

- EUR 2,000.00 (twothousands/00) per year, to be paid by January 31 of each year after the registration year, as annual fee for remaining in the Association.

Article 7

Quality requirements

The list below contains the minimum quality requirements for admission to and remaining in the A.I.C.R.O.

General Requirements (applicable to all member companies)

1. Presence on the market for at least 3 years and its presence in Italy with a registered office.
2. Act of Incorporation and Articles of Association from which the pre-eminent activity of C.R.O. and the active Legal Entity in Italy are inferred
3. Presence of a responsible contact person (Chairman, General Manager, Medical Director, Research and Development Director, Scientific Director)

4. Organization Chart with at least 70% of staff directly employed and with the appropriate technical-scientific characteristics for the services performed
5. Presence of a QA Supervisor
6. Presence of Standard Operating Procedures (SOP's) for the activities carried out
7. Documentation regarding regular internal training of staff and technical-scientific consultants
8. Certification and/or documentation attesting to quality (ISO or other European quality certifications or other quality-related documents which, however, shall be evaluated and approved by the Board of Directors).
9. Compliance with the regulations set forth in Legislative Decree 626/94 (safety at work) and in Legislative Decree 196/03 (privacy)
10. Insurance Policy covering professional liability and public liability.

Specific Requirements

11. For organizations which also or only carry out activities regarding data management and statistics, the presence of adequate computer systems and facilities are required in order to guarantee the physical and logical safety of the data, as well as their integrity. Management of the data shall be conducted by qualified staff with computer and/or statistical skills specifically applied to clinical research. The software applications used for data processing shall conform to regulatory requirements.
12. For organizations which also or only carry out Centralized Laboratory activities, the presence of certified, suitable equipment is required in order to guarantee the precision of the results and the processing of same with the appropriate software. Staff shall be qualified in the medical-laboratory field.
13. For organizations which also or only carry out Centralized Laboratory activities, the presence of certified, suitable equipment is required in order to guarantee the precision of the results and the processing of same with the appropriate software. Staff shall be qualified in the medical laboratory.

Article 8

Resolutions in written format

The General Meeting may also make its decisions in written format (fax or e-mail), as specified in letter "f", Article 10 of the Articles of Association. The Regulations shall set forth the rules for the correct management of the interventions made and of the votes expressed using the above format.

Where the conditions allowing management of the General Meeting in written format apply, such as by request of the Chairman or of one third of the Members, the Chairman is required to convene the Meeting via recorded delivery letter with advice of receipt or via email with read receipt notification at least one month before the date of the Meeting, specifying that:

a) The General Meeting shall take place in the written format;
b) The permitted written formats may either be only via e-mail or only via fax; hybrid formats are only permitted in the event of sudden faults on the telephone lines;
c) On declaring the Meeting open, it is the Chairman's duty to inform all the participants of the names of all Members taking part and their addresses (electronic or fax numbers);
d) The Chairman is required to appoint a Minutes Secretary;
e) The Secretary's task is to record the various interventions on file and with a hard copy, and write up the relevant Minutes in the Meetings Book;
f) It is the Chairman's task to follow the established Agenda and inform all participants which item is being discussed or decided upon;
g) The Members are invited by the Chairman to intervene with regard to the items on the Agenda; the Members shall therefore send all participants, previously indicated by the Chairman, the text of their intervention and/or vote and shall also express their wish to abstain, where applicable, from voicing their opinion on the item being discussed;
h) From the time the Chairman asks them to vote on one of the items on the Agenda, the Members shall have half an hour to express their vote; once this time is up, the absence of any reply shall be interpreted as abstention;
i) The Meeting shall be suspended in the event of faults or problems on the telephone lines;
j) It is the Chairman's task to verify whether the conditions exist to enable him/her to re-start the Meeting or to re-convene it for another date using the same method and with the same Agenda.

Article 9

Training activities

One of A.I.C.R.O.'s objectives is to promote the training of staff involved in clinical research (Article 3 of the AICRO Articles of Association).

A.I.C.R.O.'s Scientific Director is required to organize training and refresher courses for professionals working in the field of clinical research.

The Scientific Director shall submit a detailed plan of each individual training event to the Chairman for approval, including the following:

- Title and subject to be tackled
- List of Speakers
- Target audience
- Location and duration
- Budget

Having heard the opinions of the other Members of the Board of Directors, the Chairman shall undertake to provide his/her opinion within two weeks of receipt of the plan.