

RULES AND REGULATIONS
OF
INDIAN SOCIETY FOR CLINICAL RESEARCH

1. INTERPRETATION/DEFINITION :

In these Rules and Regulations unless the context otherwise requires :

- a) The Society shall mean and include the 'Indian Society for Clinical Research'
- b) Office Bearers shall mean and include President, General Secretary, Treasurer and Executive Committee Members for the time being of the Society.
- c) The Act shall mean the Societies Registration Act, 1860 and Bombay Public Trusts Act, 1950 or any modification thereof for the time being in force.
- d) Funds of the Society : Funds of the Society shall mean and include all investments of funds, moveable or immovable property belonging to the society whether held in General fund or any special fund created by any donors.

2. OPERATION AREA :

Area of operation will be anywhere in India.

3. ACCOUNTING YEAR :

Accounting year shall be ending 31st March, every year.

4. MEMBERSHIP & REGISTRATION:

Membership of the Society will be open to individuals and to accredited organizations defined in Section 5 of this document. The registration of the said members will be done on fulfillment of criteria and payment of membership fees stipulated for the different types of membership.

5. TYPES OF MEMBERSHIP:

The Society will have the following types of members :

I. Individual Members

Individuals will be eligible for membership on fulfillment of the following three criteria and the payment of membership fees of Rs.1500/- or U.S. \$ 250/- per annum or as determined from time to time:

1. A graduate or higher degree in a discipline related to clinical research or biometrics such as in Medicine, Pharmacy, Biological Sciences, Nursing, Statistics or Information Technology. This criterion may be waived for non-scientific members of Ethics Committees and non-scientific staff in clinical research operations.
2. Current involvement or at least 2 years past experience in a clinical research related job or function(s).
3. Proficiency in understanding and application of ICH Good Clinical Practice guidelines and Indian clinical trial regulations, as attested to by an aggregate score of 80% or above in an on-line assessment test devised by ISCR for the purpose.

II. Honorary Members

Members of the Executive Council/Committee may propose honorary memberships to be granted to eminent retired persons previously associated with clinical research, members of regulatory authorities, eminent office bearers of sister organizations within or outside the country, and key functionaries of institutions associated with clinical research. Such membership will require ratification by a majority vote of the Executive Council/Committee. Honorary members will be involved in activities of the Society by invitation but will not be liable to pay membership fees and will not be voting members of the Society.

III. Accredited Member Organizations

Organizations will be accredited for membership of the Society subject to fulfillment of the following criteria, approval by the Executive Council/Committee, and payment of one-time joining fee of Rs 2,00,000/- and membership fees of Rs. 50,000/- per annum from the beginning of the second year of membership or as determined from time to time.

1. Current engagement in clinical research activities with commitment to ICH GCP as evidenced by written operating procedures specifying compliance to ICH GCP as a mandatory requirement and/or policies consistent with ICH GCP.
2. Adequate staffing to assure ability to conduct ICH GCP compliant studies.
3. All key technical managers and at least 50% of clinical research staff should qualify for individual membership of ISCR.
4. Existence of auditable systems for study monitoring, clinical supplies handling, quality assurance, documentation of training, and adverse event reporting and documentation, with at least 2 years' operation in clinical research or related activities.

5. Accredited Member Organizations (AMOs) that do not have any outstanding dues to the Society will be entitled to 2 free individual memberships to enable AMO representation within the Society.
6. AMO representatives are expected to form an AMO Council within the auspices of the Society to discuss and debate matters pertaining to AMOs.
7. The AMO council will elect/nominate 2 representatives to the Executive Committee of the Society.

6. CANCELLATION OF MEMBERSHIP:

Membership of an existing member is liable to be cancelled under the following circumstances :

1. Demise of the member
2. Non-payment of dues within a reasonable period after notification
3. Activities counter to the objectives of the Society and/or detrimental to the reputation of the Society as determined by a majority vote of the Executive Council
4. Voluntary withdrawal of membership by a member

The Society will not be liable for refund of membership fees or other contributions received from the member under any of these circumstances.

7. GENERAL BODY MEETING AND ITS FUNCTIONS:

- I. The first General Meeting of the Society will be convened as per the Societies Registration (Maharashtra) Rules 1971, within a period of six months of the launch of the Society (defined as the date of commencement of initial membership drive) to transact the following business:
 - a) To admit new members.
 - b) To admit a Statement of Accounts and submit a report of transactions done 14 days prior to the date of General Meeting.
 - c) To approve the Interim Executive Council till the elections are held as per the rules of the Society. The Interim Executive Council will have the same authority and responsibility as an elected committee.
 - d) Any other matter as per the rules of the Society.
 - e) To initiate the process to elect the Executive Committee

The General Body will have all powers/authorities to transact Society's business as per the rules and provisions under Societies Act.

- II.** Society will convene a General Body Meeting of its members, as per the applicable rules, at least once every year after the launch of the Society to transact the following business :
- a) To confirm the minutes of the last meeting.
 - b) To adopt the annual report, balance sheet, profit and loss statement, auditors report, etc., and send these to the Registrar of Societies.
 - c) Any other subject as per the rules of the Society.

8. NOTICE OF A GENERAL BODY MEETING & QUORUM:

Members of the Society will be given 14 days notice prior to the date of a General Body Meeting, informing of the date, place and time of the meeting along with the report of Executive Committee, Balance Sheet and Agenda for the meeting. A notice of the meeting will be displayed on the Notice Board of the society.

The meeting will be held as scheduled provided there is a Quorum. A Quorum will be defined as one-thirds of the current members.

9. SPECIAL/EXTRAORDINARY MEETINGS :

Special/Extraordinary Meetings of the Executive Committee, sub-committees and councils, and general body, can be convened after giving 10 days notice to the members for transacting the business mentioned in the notice. To facilitate more frequent interaction among its members, the Society will explore options for the use of telecommunications as a means of group interactions, meetings and collective decision-making.

10. FOUNDER EXECUTIVE COUNCIL:

The Society will be set up by a council of 7 to 11 Founder Members. The Founder Executive Council will facilitate registration of the Society under the Societies Registration Act, 1860, finalize an inaugural constitution, and initiate the development of the website, through a process of collective decision-making and voluntary effort. The Executive Council will arrange for the first election of Office Bearers to the elected Executive Committee, and will manage the affairs of the Society in the interim with the same authorities, and responsibilities as described for the elected Executive Committee in Section 17 of this document.

11. ELECTION OF OFFICE BEARERS AND DURATION:

The Society will elect office bearers once every two years either by consensus or secret ballot. The first elections will be held within a reasonable amount of time within 18 months of launch of the Society. Franchise will be open to all individual members. The following officials will be elected :

President
General Secretary
Executive Committee Members (5)

In addition the following positions will be nominated to the Executive Committee:
Treasurer – from elected Executive Committee members
Members (2) representing the Council of Accredited Member Organizations

12. OFFICE BEARERS AND THEIR FUNCTIONS:

The Executive Committee will be chaired by the President, and its affairs will be managed by the General Secretary, and both these office bearers will be voting members of the Committee. The President and General Secretary may be re-elected for two consecutive terms, but thereafter, can only be proposed for election after a gap of 4 years. However, they may continue to be members of the Executive Committee subject to being elected as such by members of the Society.

I. PRESIDENT :

- a) Members of the Society will elect a President from among themselves.
- b) The President will be responsible for conducting all Executive Committee meetings and will lead all discussions and deliberations pertaining to the functioning of the Society.
- c) The President will preside over all elections and administrative matters pertinent to the Society.
- d) In case of anticipated absence, the President will nominate an Executive Committee Member as acting Chairperson. The acting Chairperson will have all the powers of the President for that meeting.

II. GENERAL SECRETARY:

- a) Members of the Society will elect a General Secretary from among themselves.
- b) In consultation with the President, the General Secretary will be responsible for the following functions :
 - 1) Receiving all proposals pertaining to the objectives of the Society.
 - 2) Preparation and dissemination of agenda for all Council meetings.

- 3) Inviting special attendees from the field of Clinical Research or other relevant fields to the scheduled meetings.
- 4) Preparation and circulation of minutes (within 14 days of the meeting).
- 5) Retention and safekeeping of all records and documentation as described.
- 6) Performance of other duties assigned by the President.

III. TREASURER:

- a) Members of the Executive Committee will elect a Treasurer from among themselves.
- b) In consultation with the President and General Secretary, the Treasurer will be responsible for the following functions :
 - 1) Receiving/collecting the membership fees from members and issuing receipts.
 - 2) Maintaining the Society's bank account/s and documents.
 - 3) Maintaining the books of accounts of the Society.
 - 4) Performance of other duties assigned by the President and General Secretary.

13. MEETINGS OF THE EXECUTIVE COMMITTEE:

The Executive Committee will hold meetings as and when appropriate and feasible but at least twice in a year. The Director or Chief Executive of the Society Secretariat will be invited to convene and attend these meetings as a non-voting member.

14. NOTICE OF AN EXECUTIVE COMMITTEE MEETING AND QUORUM :

All regular members will be given notice of meeting 10 days in advance. A shorter notice period will be permissible if 8 or more of the 11 members have no objection. A Quorum will be defined as one-half of the current members.

15. PROCEDURE & RULES OF ELECTION OF EXECUTIVE COMMITTEE:

Office bearers of the Executive Committee (EC) will be elected as per item 11 of this document either by consensus or by secret ballot. The incumbent General Secretary will call for nominations through notice on the ISCR website and/or mailers to each of the individual members. A member may nominate himself/herself to any of the positions of office open for election, if eligible. A candidate may not be nominated to more than one post in any particular year. If more than 5 nominations are received, a preliminary ballot will be held to identify the top 3 nominees. The nominee polling the highest number of votes to each post will be declared elected to that post.

Two places on the EC will be reserved for members from academia. If the President and/or the General Secretary are not full-time academicians, the top polling academicians from among member nominees for election will be elected to the EC.

One place each on the EC will be preferentially allotted to nominees from the North, South, East, and West. However, if there are no nominees from any one of these regions of the country, nominees from other regions may be elected to those places. For this purpose Rajasthan, Haryana, Delhi, UP, and states further north will constitute the North region, Bihar, Chattisgarh, Orissa and states further east will constitute the East region, Gujarat, MP, Maharashtra, Goa, and adjoining territories will constitute the West region and the four southern states and island territories in the Bay of Bengal and Arabian Sea will constitute the South region.

The General Secretary will notify all members and nominees of the outcome of the elections. The new incumbents will take office for a period coinciding with the commencement of the financial year as stated in item 18 of this document.

16. FILLING UP OF POSTS:

- a) Vacant posts in the Executive Committee/Office Bearers created under the following circumstances will be filled in by election or nomination as applicable :
 - 1) When a regular Executive Committee member/Office Bearer completes his tenure and does not continue his Membership of the Committee.
 - 2) If a regular Executive Committee member/Office Bearer resigns.
 - 3) If a regular Executive Committee member/Office Bearer is unable to continue working on the Committee.
 - 4) If a regular Executive Committee member/Office Bearer fails to perform his responsibilities as described in this document, and as judged by the President on specific grounds.
 - 5) When the mandate of a nominated member is withdrawn by the corresponding stakeholder.

17. AUTHORITIES & RESPONSIBILITIES OF THE EXECUTIVE COMMITTEE:

- 1) The Executive Committee shall manage the property, affairs and the activities of the Society.
- 2) The Executive Committee is responsible for carrying out Society's activities and its governance by establishing direction, laying down policies, organizing its administration and operations.
- 3) The Executive Committee will be responsible for authorizing expenditure of funds towards fulfillment of its objectives.
- 4) The Executive Committee will function on debate-consensus-vote style of functioning.

- 5) The Executive Committee will be authorized to set up ad-hoc sub-Committees for the various endeavors and functions of the Society as it deems fit.
- 6) The Executive Committee will be authorized to appoint salaried executives to the Secretariat of the Society.

18. FINANCES – FUNDS, INCOME & EXPENDITURE:

While initially supported by donor organizations with an interest in clinical research in India, the Society is expected to be self-financing within 24 months of registration. Funds to support its activities will be obtained from joining and annual membership fees, from advertisements and linking fees on the website, and from fund generating activities relevant to the objectives of the Society. A bank account for the Society will be operated jointly by the President, General Secretary, and Treasurer of the Society. All expenses in excess of Rs. 25,000 will require authorization by the Executive Council/Committee. The Society being a voluntary organization, the office bearers (other than staff appointed to the Secretariat) will not receive any remuneration for their services. Society finances will be audited by certified auditors annually. The financial year will begin on April 1 and end on March 31 of each year. The Society will post an Annual Report of its activities and finances on its website.

19. LOAN AND DEPOSIT, ETC.

The Society can raise loans or accept deposits for fulfillment of the objectives of the Society subject to prior permission of the Charity Commissioner, M.S. Mumbai as required under section 36(A) (3) of the Bombay Public Trust Act, 1950.

20. SALE, ETC.

The Society can sell or exchange or gift any of its properties with the permission of the Charity Commissioner M.S. Mumbai under section 36 of the aforesaid Act.

21. BANK ACCOUNT:

The Account or Accounts shall be opened in such Scheduled Bank/s or approved Co-Operative Bank/s as may be decided by the Executive Council in the name of the Society and shall be operated with joint signature of the any two of the following while the third member is kept informed through written or e-mail communication, of the nature and amount of transaction:

1. President
2. General Secretary
3. Treasurer

22. REGISTER OF MEMBERS:

The Society shall maintain a list of members as per provision of Rule 15 of the Societies Registration (Maharashtra) Rules 1971 in the form of the Schedule to the said rules in respect of such members within the meaning of Section 15 of Societies Registration Act, 1860 giving the names, addresses, occupations, type of membership, their qualifications and affiliations, i.e., hospitals, clinics, institutions, organizations, etc.

23. AMENDMENTS :

The Memorandum of Association of the Society and these Rules and Regulations and any Rules and Regulations hereafter made by the Society may from time to time be amended, or revoked by a majority of not less than three-fifths of members of the Society present at a General Meeting called for the purpose of such variation, addition or revocation provided that in the case of any alteration, abridgment or addition to the purposes of the Society the provisions of Section 12 of the act shall apply.

24. CHANGE IN THE NAME AND OBJECTIVES:

In case there is any change in the name and/or objectives of the Society, the procedure as laid down under relevant sections of the S.R.Act, 1860 and rules framed thereunder shall be applied.

25. DISSOLUTION:

By a majority of not less than three-fifth of the members, the Society may determine that it shall be dissolved and thereupon the Society shall be dissolved forthwith or at such time then agreed upon.

If upon dissolution there remains, after the satisfaction of all debts and liabilities, any property whatsoever, the same shall not be paid or distributed among the members but shall be transferred to some other society or organization to be determined by three-fifth of the members present personally. The procedure as laid down under section 13 & 14 of the S.R. Act, 1860 shall be applied.