

Guidelines for constitution of an Institutional Committee for Stem Cell Research (IC-SCR)

The following guidelines must be followed while constituting an IC-SCR:

1. The IC-SCR shall have a minimum of 11 members. Other experts as per study requirements should be included.
2. Presence of the following members is mandatory for quorum and for decision making: Chairperson/Vice-Chairperson, Member Secretary, experts from law, ethics and social sciences, community/lay-person and two stem cell/cell and molecular biology expert with appropriate expertise and no COI. In the absence of Chairperson, the Vice-Chairperson can conduct the meeting. The members of quorum except the Member Secretary should never have been affiliated to the institution.
3. Persons affiliated to the institution, except the Member-Secretary, cannot be members of IC-SCR. Ex-employees of the institute can become a member only after 2 years of leaving the institution.
4. The Chairperson/Vice-Chairperson should have biomedical qualification with a postgraduate (medical)/doctorate degree (non-medical) with minimum of ten (10) years' experience after obtaining the postgraduate/doctorate degree.
5. Members from law, ethics, social sciences and community/lay-person must be from outside the institute and with no COI.
 - i) All members should have a minimum of 5 years' experience after post-graduation in their respective areas of proficiency except for community/lay-person.
 - ii) The legal expert should be a law graduate with five years of experience. S/he should be well versed with the existing acts, rules, regulations and guidelines.
 - iii) The social scientist should have a postgraduate/doctorate degree in social sciences/social work.
 - iv) The ethics expert should have a minimum six months training or demonstrable experience in bioethics.
6. IC-SCR should have at least two stem cell/cell and molecular biology experts who should be from outside the institution. They should have a postgraduate (medical)/doctorate degree (non-medical) with a minimum of five (5) years' experience in the field of stem cell research after obtaining postgraduate/doctorate degree.
7. The Member Secretary should be affiliated to the institute but should not be a part of the scientific/clinical management team and must not have any COI related to stem cell research activities.
8. Persons affiliated to the institute/company such as President/Vice-President/Chairperson/Director/CEO/Dean/CSO/MD/Financial and Legal Advisers/Administrative Heads/etc. cannot be members of the IC-SCR. They cannot attend meetings of IC-SCR in any capacity.
9. Any member having COI with a particular proposal must abstain from the discussion and decision making process of that proposal.
10. IC-SCR members must be familiar with the current bioethical guidelines and those for stem cell research.
11. Subject experts with no COI and not affiliated to the same institute may be invited for specific projects. The invitee will not have voting rights.
12. NAC-SCRT may nominate an observer on the IC-SCR to educate and to create awareness regarding existing guidelines and regulations.
13. The IC-SCR shall not act as an IEC. Separate approvals must be obtained from both committees for human stem cell related projects.

Guidelines for framing SOP for functioning of IC-SCR

The applicants must submit standard operating procedure (SOP) for functioning of IC-SCR including, but not limited to, the following details:

1. Constitution and functioning of IC-SCR
- 2. Terms of reference of members**
3. Detailed review and approval process
4. Frequency of meetings
5. Monitoring and follow-up of approved projects
6. Maintenance of records
7. Record of Conflict of Interest (COI)
8. Record of confidentiality agreement

Please read the following instructions

- a. Enclose latest CVs of all the IC-SCR members and SOP with the duly filled form.
- b. Brief summary of all projects (ongoing/completed) must be submitted in the format provided.
- c. **Provide details of all investigators working in the field of stem cell research at the institution.**
- d. Provide valid e-mail ids for communication, failing which communications may be delayed.
- e. Member Secretary must be responsible for all communications with the NAC-SCRT.
- f. If there are any changes to be made after the submission, please contact the NAC-SCRT Secretariat.
- g. Ensure that all details are complete and accurate to avoid delays in registration.
- h. For any query kindly email on nacsrt.pg@icmr.gov.in

The institute must ensure that its IC-SCR is always independent and appropriately competent to review the proposals being submitted to them.

It is the responsibility of the IC-SCR to ensure that the research conducted under its ambit is scientific and ethical.