Standard Operating Procedures

INDIAN ACADEY OF PEDIATRICS

National Independent Ethics Committee

Indian Academy of Pediatrics
Kamdhenu Business Bay,
5th Floor, Plot No.
51, Sector 1, Juinagar East,
(Near Juinagar Railway Station),
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1. Objective

The objective of these Standard Operating Procedures is to facilitate the effective functioning of Independent Ethics Committee of the Indian Academy of Pediatrics (IAP IEC). This document provides standard operating procedures for a quality and consistent ethical review mechanism for health and biomedical research as prescribed by the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, Indian Council of Medical Research 2017 and National Ethical Guidelines for Biomedical Research Involving Children 2017 (henceforth jointly referred to as ICMR Ethical Guidelines, 2017), Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules 1945 (including the amendments), and New Drugs and Clinical Trials Act and Rules 2019 and the amendments from time to time. IAP IEC will be registered with Department of Health Research, Ministry of Health and Family Welfare, New Delhi.

The objectives of the IAP IEC are-

1. to conduct scientific and ethical review of the biomedical and health research projects related to children's health and diseases, and
2. to promote ethical conduct of research by IAP members.

2. Roles and Responsibilities of IAP IEC

IAP IEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants. Human samples/material likely to affect human health will also come under the purview of the IAP IEC. Internal audit and prescription audit will however, require only an intimation to the IAP IEC. However, this does not preclude any administrative permission whenever needed. The goals of research, however important, shall never be permitted to override the health and wellbeing of the research subjects.

The IAP IEC will take care that all the cardinal bioethical principles of research ethics viz. Autonomy, Beneficence, Non - maleficence and Justice in planning, conduct and reporting of the proposed research shall be followed. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit; and provisions for appropriate compensations wherever required. It will review the proposals before starting the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports and site visits for assessment of quality of conduct of research, documentation, reporting of Serious Adverse Events, and data safety and storage, etc. The committee shall also examine compliance with all regulatory requirements, applicable guidelines and laws.

The mandate of the IAP IEC will be to review all research projects involving human subjects (including any biological samples and behavioural issues) to

be conducted anywhere in India, irrespective of the funding agency or when no external funding agency is supporting the research.

Policy to monitor or prevent the conflict-of-interest

2.1.1 The IAP IEC members are responsible for declaration of Conflict of Interest to the Chairman / Member Secretary at each meeting and it will be ensured that the same is recorded in the minutes.

2.1.2 All IAP NIEC members will fill and sign the conflict of interest form before the proceedings of the meeting begins.

2.1.3 The members will declare if any conflict exists with regard to the research protocol being discussed.

2.1.4 The conflict of interest exists when a member is one of the PIs, has commercial interest in the product / equipment is proposed to be used in the research, has commercial interest in the sponsoring agency/company, or his/her family member(s) are owner or employee of the company sponsoring the project.

2.1.5 The member having a conflict of interest shall not participate in the decision-making process with regard to such project(s).

2.1.6 The Chairperson will take a final decision on the existence or no-existence of the conflict of interest.

3. Terms of reference (TOR) for ECs

1. The TOR for the NIEC and its members will be specified in the NIEC SOPs.
2. The SOPs will be updated periodically to reflect changing requirements.
3. A copy of the latest version of SOPs should be made available to each member and they would be trained on the SOPs.
4. The SOPs must be available in the secretariat of the NIEC shall be as follows-

    i SCOPE, STATUS, GUIDING PRINCIPLES, TENURE AND RENEWAL POLICY – The scope, status and guiding principles of the committee are as follows-

        1 The IAP NIEC shall act as a national independent ethics committee.

        2 The IAP NIEC will consider the research proposals submitted by IAP Members.

        3 It will consider only non-regulatory research proposals.

        4 It will consider investigator-initiated proposals, academic research, and the sponsored research proposals (for non-regulatory research) also.

        5 It will charge a fee of Rs 5,000 for all types of sponsored research proposals for initial consideration and Rs 2,000 for consideration of amendments in the protocol, etc. However, IAPNIEC can waive off the fee on a case-to-case basis.

6 It will consider the proposals of multi-specialty research (from outside IAP) involving children only when at least one IAP Member is a Principal Investigator, and the proposal is submitted by this IAP member. This IAP member will stand guarantor (to IAP NIEC) for the research under consideration.

7 At least one IAP member should be PI at every site (or city in case of community research) where multi center research is proposed to be conducted.

ii TENURE

1 The tenure of the committee shall be 3 (three) years.

iii RENEWAL POLICY

1 The half of the committee members will be changed after 3 years.

2 The new committee will be nominated by the Office Bearers of IAP.

5. The members of the EC should not have any known record of misconduct.
6. The EC should be registered with the relevant regulatory authorities i.e. Department of Health Research (Indian Council of Medical Research).
7. The IAP administration will provide infrastructure and funds for smooth functioning of IEC.

4. Composition of IEC

The President, IAP shall constitute the IAP IEC, of which the Chairman shall be from outside the IAP (i.e. should not be a member of IAP). The ICMR Ethical Guidelines, 2017 and the New Drugs and Clinical Trial Act & Rules, 2019 shall be followed while constituting the IAP IEC.

As the present IAP IEC has 15 members, a minimum of FIVE persons will be required to constitute a quorum. The quorum shall include both medical, non-medical members. At least one non-affiliated member shall be part of quorum. Preferably lay person should be a part of quorum. Preferably Chairman and Member Secretary should be present in all meetings. The Member Secretary shall belong to the IAP and should conduct the business of the Committee. The affiliations, qualifications, member specific roles and responsibilities of IEC will be according to the ICMR Ethical Guidelines, 2017 and the same is given in Annexure-1.

If required, subject experts will be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee.

However, such member(s) will not take part in decision making on the project.

5. Authority under which IAP IEC is constituted:

The President of Indian Academy of Pediatrics shall constitute the IAP IEC.

6. Membership requirements and Procedure for resignation, replacement or removal of the members

a) The committee would be multi-disciplinary and multi-sectoral.
b) There should be adequate representation of age and gender.
c) Preferably 50% of the members should be non-affiliated or from outside the institution.
d) The number of members in an EC would be 15 and a minimum of five members should be present to meet the quorum requirements.
e) The EC would have a balance between medical and non-medical members/technical and non-technical members.
f) The Composition, affiliations, qualifications, member specific roles and responsibilities of the committee would follow the ICMR Guidelines. 2017 (Annexure-1).
g) The duration of appointment initially shall be for a period of 3 years.
h) At the end of 3 years, the Committee should be reconstituted, and one-third of the members will be replaced by a defined procedure (those who have had the longest standing in the IEC shall be phased out and new members taken in against the vacant posts).
i) A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

j) A member can tender resignation from the Committee with 1 month notice and with proper reasons (optional) to do so. The Chairperson will forward the resignation with his/her comments to The IAP President for further action. The IAP President can accept the resignation of a member. The IAP President can nominate another person as member in case a member resigns.
k) The IAP President can remove a member if he/she does not attend the regular meetings (absent in 3 or more subsequent meetings without information).
l) All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
m) Conflict of interest should be declared by members of the IAP IEC if any is there at any time for any project or decision.

7. Quorum requirements:

A minimum of 05 members are required to compose a quorum. All decisions will be taken in meetings and not by circulation of project proposals only.

8. Conduct of meeting

The Chairman will conduct all meetings of the IAP IEC. If for reasons beyond control, the Chairman is not available; the members present in the meeting will elect one of the members as Chairman who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman

before communicating to the researchers. The records shall be archived for a period of 5 years from the end of the project. Possibility of archiving shall be explored in view of the space and cost constraints. Where indicated, archiving may be done for a longer time. The meetings can be held on virtual platform also as per the requirements.

9. Independent consultants

IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views but do not take part in the decision making process which will be made by the members of the IAP IEC. Member Secretary can take comments of experts (preferably prior to the meeting) if it is likely to assist the IAP IEC in the review of the project.

10. Application Procedures:

10A. Eligibility to apply

a. A Life member of IAP can apply and submit the research proposal for consideration by IAP IEC for ethical approval.
b. Such a member should ***not*** be linked / attached in any capacity to a hospital or institution or centre or clinic or any other organization that have a duly constituted and functional ethics

committee for human research. They shall be required to give an undertaking to the effect.

c. The site of research should be within India.
d. The study is ***not*** planned to be used for seeking the regulatory approvals from government authorities.

10B. Process of application

a. All proposals should be submitted in the prescribed application form by email, the details of which are given under Documentation; and (2) one printed copy of all the relevant documents with signatures in ink as needed at all the required places to be sent by post to the office of the IAP IEC in Navi Mumbai.
b. All relevant documents should be enclosed with application form.
c. One copy of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be forwarded to the IAP IEC.
d. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications. A power point presentation in the prescribed format should be kept handy. It should be presented in the meeting/online by PI or Co-PI or Coinvestigator. PPT shall be prepared by the PI/Co-PI and not the sponsor, if any.

e. The decision will be communicated in writing or by email. In case of Research Proposal where the PI happens to be the Member-Secretary of IEC, the approval letters and routine correspondence shall be signed/countersigned by the Chairman of IAP IEC.
f. If revision is to be made, the revised document (1 printed copy) and also the soft copy (pdf copy) should be submitted within a stipulated period of time as specified in the communication or 2 weeks before the next meeting.
g. IAP IEC will charge a fee Rs 5,000 for initial review and Rs 2,000 for subsequent reviews. The fees should be deposited in the account of the IAP. IAP EC may allow waiver of this fee in the circumstances as deemed fit by IAP IEC on a case-to-case basis.

11. Documentation:

For a thorough and complete review, all research proposals should be submitted with the following documents:

a. **Covering letter* to the Member Secretary mentioning the type of review requested [Exempt from review/ Expedited review /Full committee review]**
b. **Application Form for initial review*.**
c. **Research protocol***
d. **The correct version of the informed consent and Assent document (ICD) in English and the local language(s)*; translation and back translation certificates (if applicable).**
e. **Case record form/questionnaire***
f. **Presentation slides including the details of research protocol, patient information sheet, informed consent form and case record form, and any other information likely to support the decision making by IAP IEC.**
g. Recruitment procedures: advertisement, notices (if applicable).
h. Patient instruction card, diary, etc. (if applicable)
i. Investigator's brochure (as applicable for drug/biologicals/device trials)
j. Details of funding agency/sponsor and fund allocation (if applicable) including those related to insurance.
k. **Brief curriculum vitae (1-2 pages maximum) of all the study researchers* including research experience**
l. **A statement on Conflict of Interest***

m. Good Clinical Practices training certificate (preferably within 5 years) of investigators, if available.

n. **List and the status of the on-going research studies earlier approved by IAP**

IEC including all studies where the investigator of the current proposal is Principal Investigator or Co- Principal Investigator or Co-investigator*. If the current proposal is the first proposal of the investigator, then the same may be mentioned in this document.

One researcher is allowed to conduct not more than 5 research projects at a time.

o. Any other information or training evidence or document which is likely to supplement the review of the current proposal.

p. Undertaking with signatures of investigators [including undertaking to report any serious adverse events (SAE) to IEC within 24 hours; undertaking to comply with the relevant national and applicable international guidelines*.

q. Regulatory permissions (as applicable)

r. Approval by any other committee and other relevant administrative approvals (such as HMSC approval for International trials)

s. Site specific Insurance policy (it is preferable to have the policy and not only the insurance certificate) for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable) as per the New

Drug and Clinical Trial Act and Rules, 2019 or any other act or rules applicable.

t. Site specific Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)
u. Any additional document(s), as required by EC (such as other EC clearances for multi-centric studies)
v. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centres within the country / countries, if available. If it is a

new drug or device (or unlicensed drug or device) then the permission of DCGI/CDSCO for conduct of the research study.

w. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
x. Any other information relevant to the study.

***The research protocol should include the followings-**

1. The title page carrying the title of the proposal with signatures of the investigators;
2. Brief summary/ lay summary of the protocol;
3. Background including brief review of literature with rationale of why a human study is needed to answer the research question;
4. Justification of inclusion/exclusion of vulnerable populations;
5. Clear research question, hypothesis, objectives and end points (outcome variables); sample size basis and calculation,

6. Type of study, duration of study, and location of the study;
7. Eligibility criteria and participant recruitment procedures;
8. Detailed description of the methodology of the proposed research, including outcome variable(s), sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention (if any), dosages of drugs, route of administration, duration of treatment and details of invasive procedures, and a flow chart;
9. Justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld, justification for the same;
10. Procedure for seeking and obtaining informed consent (and/or assent) with a sample of the patient/participant information sheet and informed consent forms in English and local languages. AV recording if applicable; informed consent for stored samples;
11. Plan for statistical analysis of the study;
12. Plan to maintain the privacy and confidentiality of the study participants;
13. For research involving more than minimal risk, an account of management of risk or injury;
14. Case record form,
15. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period;
16. Provision of ancillary care for unrelated illness during the duration of research;
17. An account of storage and maintenance of all data collected during the trial;

18. Plans for publication of results –positive or negative – while maintaining confidentiality of personal information/ identity; and
19. Ethical considerations and safeguards for protection of participants.

12. Review procedures:

a. The meeting of the IAP IEC will be held whenever sufficient number of projects / proposals are there for review and about 9-10 meetings will be held annually. Additional meetings may be called upon by the Member-Secretary after approval of the Chairman.

b. Research involving vulnerable population will be reviewed in the full meeting of the committee.

c. The proposals (as soft copy) will be sent to members at several days in advance by e-mail. For every proposal, minimum one primary and one secondary reviewer will be identified from amongst the IAP IEC members. These reviewers will first study the submitted documents and enclosures as defined above and will lead the discussion during IEC meeting.

d. Decisions will be taken by consensus after discussions in the meeting, and whenever needed voting will be done.

e. Researchers will be invited to make presentation and to offer clarifications, if needed.

f. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed. Opinion of independent expert may be taken by mail/email, if needed.

g. IAP IEC will carry out various types of reviews including (1) Exemption from review,

(2) Expedited review, and (3) Full committee review.

g. The decisions will be recorded in the minutes and Chairman's approval will be taken in writing through email/post.

13. Elements of review

IAP IEC will consider the following ethical issues related to reviewing a protocol-

a. Social values;
b. Scientific design and conduct of the study;
c. Benefit-risk assessment;
d. Selection of study population and recruitment of research participants

i. Policy for consideration of research involving vulnerable population

- The IAP NIEC shall ensure that researchers have justified the inclusion of vulnerable population in the research and the same justification shall be recorded.
- The research involving children (fetal life, neonate, children and adolescence i.e. 0 to 18 years) as research participants will be considered a research involving vulnerable population.
- The IAP NIEC will consider the research proposals involving the vulnerable population only in the full committee meetings for initial and continuing review, and also to accord approvals.
- The IAP NIEC members will ensure that when an individual from vulnerable population lacks the ability to consent, a Legally Accepted Representative (LAR) including parents and guardians is involved in decision making including consent and withdrawal of consent, etc.

- The IAP NIEC shall assess additional safety measures and examine the risk minimization strategies.
- The IAP NIEC will ensure that the research includes adequate measures to safeguard the dignity, rights, safety and well- being of these individuals.

    1. The IAP NIEC shall ensure that there is no coercion, force, undue influence, threat or misrepresentation or incentives for participation during the entire research period.

e. Payment for participation;
f. Protection of research participants' privacy and confidentiality;
g. Community considerations;
h. Qualification of researchers, number and status of the on-going research projects, and adequacy assessment of study sites;
i. Disclosure or declaration of potential conflict-of-interest(s);
j. Plan for medical management and compensation for study related injury;
k. Review of the informed consent process;
l. Justification for placebo in control arm, if any;
m. Availability of products after the study, if applicable;
n. Adherence to all regulatory requirements and applicable guidelines;
o. Competence of investigators, research and supporting staff;
p. Facilities and infrastructure of study sites; and
q. Criteria for withdrawal of patients, suspending or terminating the study.

14. Expedited review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the permission of the Chairman to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review will be specified at the time of the consideration of the original proposal. An expedited review, when designated for a particular proposal during its original discussion, will require the Chairman /Member-Secretary, 1-2 Internal member(s) and preferably one External member. Approvals granted through expedited review must be ratified in next full review committee meeting. Verification of furnished documents and regulatory clearances can be done at the level of the Member-Secretary.

15. Decision-making

a. Members will discuss the various issues before arriving at a consensus decision.
b. A member will be required to withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the Chairman prior to the review of the application and recorded in the minutes.
c. Decisions will be made only in meetings where quorum is complete.
d. Only members can make the decision. The expert consultants will only offer their opinions.

e. Decisions by IEC may be (1) approved – with or without suggestions or comments, (2) revision with minor modification / amendments, (3) revision- with major modifications for re-submission or (4) not approved.
f. Specific suggestions for modifications, and reasons for 'non approval' should be given. No conditional approval would be granted.
g. Modified proposals may be re-assessed through an expedited review through identified members or by the Member Secretary.
h. Procedures for appeal by the researchers include representation within four weeks of the decision communicated to the researcher. The appeal should be directed to the President of IAP with a copy to the Member-Secretary.
i. The IAP Governing Body for Independent Ethics Committee chaired by the IAP President will be the appellate authority.

16. Communicating the decision

a. Decision will be communicated by the Member Secretary in writing /or by e mail registered in the application. In case of the research, where the Principal Investigator (PI) happens to be the Member-Secretary of IEC, the decisions of IEC and other routine correspondence shall be signed/countersigned by the Chairman IAP IEC or a member designated for this purpose.
b. Suggestions for modifications, if any, will also be communicated by the Member Secretary.
c. Reasons for rejection should be informed to the researchers.
d. The schedule / plan of ongoing review by the IAP IEC should be communicated to the PI.

17. Follow up procedures

The following should be adhered to by PI-

a. Reports of the on-going projects/studies should be submitted at yearly (or quarterly depending upon number of proposals) intervals for review. Status report of the on-going projects [non-thesis projects] should be submitted twice a year by 31 July and 31 January each year.

b. Final report should be submitted at the end of study.

c. All adverse events and the interventions undertaken should be intimated to IAP

IEC.

d. Causality assessment of all SAEs should also be submitted as early as possible in the prescribed format and within 24 hours of occurrence by PI to IEC, Head of the Institute, and Sponsor.

e. In next 14 days the sponsor (in case of academic studies the head of the Institution/PI will be considered the sponsor) has to submit an analytic report of causality assessment to the IAP IEC, DCGI and Head of Institution, if applicable.

f. IEC has to review it over next 30 days and decide on causality of injury, quantum of injury and compensation to research subject (as per the seventh schedule of New Drugs and Clinical Trials Rules 2019) in cases the cause of SAEs is found to be related to the administration of the interventional product to each of the following criteria mentioned under Rule 41 of New Drugs and Clinical Trials Rules, 2019.

g. Protocol deviation, if any, should be informed with adequate justifications.

h. Any amendment to the protocol should be resubmitted for renewed approval.

i. Any new information related to the study should be communicated.

j. Premature termination of study should be notified with reasons along with summary of the data obtained so far.

k. Change of investigators / sites should be informed.

18. Record keeping and archiving

The following documents should be stored.

a. Curriculum Vitae (CV) of all members of IAP IEC.

b. Copy of all study protocols with enclosed documents, progress reports, AE and SAEs.

c. Minutes of all meetings duly signed by the Chairman/Member Secretary.

d. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.

e. Copy of all correspondence with members, researchers and other regulatory bodies. Email prints to be archived (certified by the Member-Secretary). f. Final report of the approved projects.

g. All documents should be archived for five-year period, unless there is a specific requirement for a longer time.

19. Updating IAP IEC members

a. All relevant new guidelines should be brought to the attention of the members.

b. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

20. Auditing and inspection of the committee

a. The IEC will be audited / inspected by a competent agency / expert every 3 years.

b. The IEC will make efforts for accreditation by a competent agency (e.g. NABH).

c. The member secretary will manage auditing, inspection and accreditation with support from IAP administration.

21. Validity of the IAP IEC SOPs

The SOPs enlisted above shall remain in force for a period of three years. However, these may be amended/updated from time to time by the IEC and same shall be archived appropriately.

(Dr. Harish K Pemde) **(Dr. Anant Bhan)**

Member-Secretary, IAP IEC ***Chairman, IAP IEC***

Annexure-1

The affiliations, qualifications, member specific roles and responsibilities of IEC

S. No.	**Members of EC**	**Definition/description**
1.	**Chairperson/Vice Chairperson**(optional) Non-affiliated to IAP Qualifications - A well-respected person from any background with prior experience of having served/ serving in an EC	• Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations • Ratify minutes of the previous meetings. • In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

2.	**Member Secretary/ Alternate Member Secretary** (optional) Affiliated to IAP Qualifications - • Should be a Life Member of IAP • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication Skills • Should be able to devote adequate time to this activity which should be protected by the institution	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication, and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption

		from review or full review. Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. Ensure quorum during the meeting and record discussions and decisions.
3.	**Basic Medical Scientist(s)** Non-affiliated to IAP Qualifications - • Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

4.	**Clinician(s)** Affiliated to IAP and should be a life member of IAP Qualifications - • Should be individual/s with recognized medical qualification, expertise and training	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5.	**Legal expert/s** Non-affiliated Qualifications - • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any
6.	**Social scientist/ philosopher/ ethicist/theologian** Non-affiliated Qualifications - • Should be an individual with social/ behavioural science/ philosophy/ religious	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any. • Serve as a patient/participant/ societal/community representative and bring in ethical and societal concerns.
	qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	

7.	**Lay person(s)** Non-affiliated Qualifications - • Literate person from the public or community • Has not pursued a medical science/ health related career in the last 5 years • May be a representative of the community from which the participants are to be drawn. • Is aware of the local language, cultural and moral values of the community. • Desirable: involved in social and community welfare activities	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any.

[Source: ICMR Ethical Guidelines, 2017]