Important Information regarding submission of documents

Application procedures:

1. All research proposals conducted in ASRAMS shall seek mandatory prior ethics committee approval from Institutional ethics committee. **No proposal/ project/ Paper/ Publication will be considered for review retrospectively**.
2. All Research proposals (Includes- Application for initial review, Curriculum vitae, Protocol, Informed consent document, Case record form/ Proforma/ Questionnaire) (3 hard copies and a soft copy sent to asrbhrec@asram.in) shall be submitted before 20th of January, April, July and October, in an academic year.
3. All relevant documents should be enclosed with application form. (Documents will be available with Member - Secretary, IEC and Institutional Website https://asram.in/ in the Downloadable section).
4. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators shall be guided to the Chairperson IEC, through member secretary. In his absence via any person nominated by chairperson. Receipt of the application will be acknowledged by the IEC office.
5. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the Principal Investigator to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.
6. The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

Review procedures:

1. The meeting of the IEC will be held on periodic intervals, every three months (January, April, July, October) unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.

2. The proposals should be sent to the IEC at least 4 weeks in advance of scheduled meeting.
3. The IEC's member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review and full review (**explanation is given below).**
4. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final.
5. Researchers will be invited to offer clarifications if need be. The principal investigator will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co PI will present the proposal.
6. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
7. The decisions will be minuted and Chairperson's approval taken in writing.

Types of review

1. Exemption from review

Proposals with less than minimal risk where there are no linked identifiers, for example;

• Research conducted on data available in the public domain for systematic reviews or meta-analysis;

• Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;

• Quality control and quality assurance audits in the institution;

• Comparison of instructional techniques, curricula, or classroom management methods;

• Consumer acceptance studies related to taste and food quality; and

• Public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

2. Expedited review

Proposals that pose no more than minimal risk may undergo expedited review, for example;

• Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;

• Research involving clinical documentation materials that are non-identifiable (data, documents, records);

• Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);

• Revised proposals previously approved through expedited review, full review or continuing review of approved proposals;

• Minor deviations from originally approved research causing no risk or minimal risk;

• Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and

• For multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.

• Research during emergencies and disasters

3. Full committee review

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are;

• Research involving vulnerable populations, even if the risk is minimal;

• Research with minor increase over minimal risk

• Studies involving deception of participants

• Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;

• Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;

• Major deviations and violations in the protocol;

• Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;

• Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

Essential elements in review of research proposal.

1. Scientific design and conduct of the study.
2. Approval by appropriate scientific review committees / Research committee.
3. Examination of predictable risks/harms
4. Examination of potential benefits.
5. Procedure for selection of subjects including inclusion / exclusion, withdrawal criteria and other issues like advertisement details.
6. Management of research related injuries, adverse events.
7. Compensation provisions.
8. Justification for placebo in control arm, if any
9. Availability of products, benefits to subjects after the study is completed if applicable.
10. Patient information sheet, informed consent form in English and in local languages.
11. Protection of privacy and confidentiality.
12. Involvement of the community, wherever necessary
13. Plans for data analysis and reporting.
14. Adherence to all regulatory requirements and applicable guidelines.
15. Competence of investigators, research and supporting staff.
16. Facilities and infrastructure of study sites.
17. Criteria for withdrawal of patients, suspending or premature termination of the study in ASRAMS.