

7. The decision was arrived at through consensus/unanimous or majority opinion amongst the voting members of IEC. Member(s) of the committee who is/are listed as investigator(s) on a research proposal opted out from all deliberations on the proposal and did not participate in decision making. Neither PI nor any of proposed study team members participated during the decision making of the IEC.
8. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to colleague after obtaining clearance from HOD and/or convener of the PI's DMG and IEC. Status report, including accounts details should be submitted to HOD and extramural sponsors.
9. The IEC functions in accordance with its SOP and is compliant with the Schedule Y (Drugs & Cosmetic Act 1940), ICMR guidelines and Indian/ICH GCP
10. In the events of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms as follows:
 - a) The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
 - b) Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
 - c) If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Institutional Ethics Committee for approval.
 - d) If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
 - e) If there are any amendments in the study design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IEC, only then can they be implemented.
 - f) Approval for amendment changes must be obtained prior to implementation of changes. Without including all the above points, the amendment is unlikely to be approved by the IEC.
11. Any Serious Adverse Events (SAEs) occurring on the study should be reported to IEC
12. Any deviation/violation/waiver in the protocol must be informed to the IEC.
13. Principal Investigator should conduct the study in accordance to the IEC approved protocol
14. Principal Investigator should comply with regulations and guidelines as applicable

Thanking you,
Yours sincerely,



Dr. Prafulla Parikh
Member Secretary
IEC III