SRI RAMACHANDRA UNIVERSITY

INSTITUTIONAL ETHICS COMMITTEE

IEC II - (Other than clinical Evaluation of Drugs/Devices/Diagnostics/Vaccines/Herbal Remedies)

1. Letter from PI to IEC forwarded through HOD
2. Consent from HODs/Dean / Principal of those departments / College, where data collection is planned if it is different from PI department.
3. Protocol/ Study/ Study outcome
4. Informed consent
5. Regional translation of Informed Consent (IC)
6. Biographic Sketch of PI
7. Proforma
8. Inclusion / Exclusion criteria
9. Lab investigations
10. Interventions (Procedure) if any
11. Conflict of interest
12. Statistical analysis of sample size prediction
13. Funding (internal/external)

The proposal should be submitted online and 2 copies with all above documents in spiral / neat binding with page nos.

Initial Review Submission Form for Research Proposal

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualification and designation
4. Name of the Institute / Hospital / Field area where research will be conducted.
5. Forwarding letter from the Head of the Department / Institution / Guide
6. Protocol of the proposed research
7. Ethical issues in the study and plans to address these issues.
8. Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow-up cards etc.
9. Informed consent process, including patient information sheet and informed consent form in English and local language(s)
10. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country / other countries, if available.
11. Usefulness of the project / trial
12. Expected 'benefits' to volunteers / community
13. 'Benefits' to other categories if any
14. Explain all anticipated 'risks' (adverse events, injury, discomfort) of the project.
15. Efforts taken to minimize the 'risks'
16. Research proposal approval by scientific advisory committee, Drug Controller General of India, Health Ministry screening committee etc.
17. Any regulatory clearance required.
18. Source of funding and financial requirements for the project.
19. Other financial issues including those related to insurance.
20. Agreement to report all Serious Adverse Events (SAE) to SRU-IEC.
21. Statement of conflicts of interest, if any.
22. Agreement to comply with the relevant national and applicable international guidelines.
23. Statement describing any compensation given to study participation (including expenses and access to medical care).

24. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.
25. All significant previous decisions (e.g., those .leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
26. Specific ethical issues, as identified by the investigating team.
27. Curriculum vitae of all the investigators with relevant publications in last five years.
28. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
29. Any other information relevant to the study.
30. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.