SRI RAMACHANDRA UNIVERSITY
INSTITUTIONAL ETHICS COMMITTEE

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.

IEC I- Check List to submit the proposal. (Clinical trial)

1. Letter from PI/HOD to IEC
2. Letter from HOD to other Participating departments
3. Consent from HODs of participating departments
4. Protocol/ Study/ Study outcome
5. Informed consent
6. Regional translation of IC
7. Biographic Sketch of PG
8. CV of guide
9. CV of co guide
10. Proforma
11. Inclusion / Exclusion criteria
12. Lab investigations
13. Interventions (Drug/Procedure)
14. Conflict of interest
15. Statistical analysis of sample size prediction
16. Funding (internal/external)
17. The proposal submitted in 8 copies with all above documents in spiral / neat binding.
18. Regulatory documents of CTRI, CTA / MOU & Insurance

INFORMED CONSENT

Adequate information about the research should be given in simple, easily understandable, unambiguous language in the Participant/ Patient Information Sheet.

Title of the project

Name of the Principle Investigator:

Description of the Study:

- Nature and purpose of study stating it as research
- Voluntary participation
- Duration of participation with number of participants
- Procedures to be followed
- Investigations, if any, to be performed
- any alternative procedures or courses of treatment that might be as advantageous to the participant as the procedure or treatment to which she is being subjected
- Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results

Possible Risks to the participant: Availability of medical treatment for such injuries or risk management. Policy on compensation.

Possible Benefits to the participant, community or medical profession as may be applicable.

Cost and Payments to the participant: (There is no cost for participation in this study. Participation is completely voluntary and no payment will be provided)

Confidentiality: Information obtained in this study is strictly confidential. Your name will not be used in reporting of information in publications or conference presentations.

Participants' right to withdraw from the study: You have the right to refuse to participate in this study, the right to withdraw from the study and the right to have your data destroyed at any point during or after the study, without penalty.

Voluntary consent by the participant: PARTICIPATION IN THIS STUDY IS COMPLETELY VOLUNTARY, AND YOUR CONSENT IS REQUIRED BEFORE YOU CAN PARTICIPATE IN THIS STUDY.

I have read this consent form (or it has been read to me) and I fully understand the contents of this document and voluntarily consent to participate in the study. All of my questions concerning this study have been answered. If I have any questions in the future about this study they will be answered by the investigators listed below. I understand that this consent ends at the conclusion of this study.

Contact Address with phone number:

PI – from SRMC	Collaborator (if any) outside SRMC

A copy of the participant/patient information sheet should be given to the participant for her/ his record.

[In case of illiterate participant, the information is explained and thumb impression is obtained, in the presence of an unrelated witness. Left hand thumb impression for male and right hand thumb impression of female]

By signing this form, I agree to participate in this study. A copy of this form has been given to me.

Date:

Name:
Participant's signature
Thumb impression
Witness name
Witness signature

Certification of INFORMED CONSENT

I certify that I have explained the nature and purpose of this study to the above-named individual, and I have discussed the potential benefits of this study participation. The questions the individual had about this study have been answered, and we will always be available to address future questions.

Date:

Signature of person obtaining consent

Name:

Signature of PI

BIOGRAPHICAL SKETCH

Name	Title	**BIRTH DATE** *(Month, Day, Year)*

EDUCATION

INSTITUTION AND LOCATION	**DEGREE (UG/PG)**	**YEAR CONFERRED**	**FIELD OF STUDY**

TEACHING & RESEARCH EXPERIENCE

Institute	From	To	Designation

RESPONSIBILITIES

PUBLICATIONS AND CONFERENCE PRESENTATIONS (last five years and the relevant ones for the presenting study)

AWARDS

PROFESSIONAL MEMBERSHIP

PI undertaking:

Format of Letter from PI /Co-PI

I/We state that the study "……." will be conducted as per Guidelines of Indian Council of Medical Research & Principles of Good Clinical Practice and on completion of the study, one copy of the report will be submitted to Ethics Committee.

Name: PI / Co-PI Signature with Date:

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