Annexure-I

SRI RAMACHANDRA MEDICAL COLLEGE & RESEARCH INSTITUTE
INSTITUTIONAL COMMITTEE STEM CELL RESEARCH
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 which should include objective, summary, duration of the study, details of the protocol nature & source of cells, level of manipulations and End-point parameters. *(format for clinical trial to be as per NGSCR-2017)*
7. Ethical issues in the study and plans to address these issues.
8. Proposal should be submitted with all relevant enclosures like preformed, 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) *(as per NGSCR-2017)*
10. Patient information sheet should be as per Annexure IV *(ref: page 66 NGSCR 2017)*
11. Audio / Video recording, form as per Allogenic transplantation of NGSCR 2017
12. 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, and 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 SRMC & RI-IC-SCR.
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. Kindly indicate whether the proposed study is under
    a) Permitted areas of research 8.1 page no. 22 for stem cell ***
    b) restricted areas of research 8.2 page no. 22 for stem cell ***

    Please refer NGSCR, ICMR- DBT guidelines on stem cell research 2017
31. Research using human stem cells must have prior approval of IC-SCR for permitted research and of the NAC-SCRT for restricted research as per NGSCR, ICMR DBT guidelines 2017.
32. Proposal format for clinical trial should be as per NGSCR-2017
33. 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.

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UNDERTAKING BY PI FOR STEM CELL RESEARCH

Date:

I have read the NGSCR, ICMR-DBT guidelines 2017 for pursuing Stem Cell Research. My area of research involves _____ and I will abide by the NGSCR, ICMR-DBT guidelines 2017.

I will provide a six months report to IC-SCR to comply with IC-SCR, SRMC & RI and NAC Stem Cell Research.

I will be familiar with ICMR guidelines on Biomedical Research in human beings and also to adhere to the Principles of good clinical practice. I will submit the final report after the completion of study to the IC-SCR.

Principal Investigator		Guide/Co-PI	
Name	:	Name	:
Designation	:	Designation	:
Affiliation	:	Affiliation	:
Signature	:	Signature	:

All proposals are reviewed by two committees - Institutional Committee for Stem Cell Research (IC-SCR) and INSTITUTIONAL ETHICS COMMITTEE (Clinical Evaluation of Drugs / Procedures / Devices / Diagnostics /Vaccines / Herbal remedies) or INSTITUTIONAL ETHICS COMMITTEE (other than Clinical Evaluation of Drugs / Procedures / Devices / Diagnostics /Vaccines / Herbal remedies) and approval obtained.