



ICSCR-UOH Number:

APPLICATION PROCEDURE

All Principal Investigators are requested to submit (not more than 3) new project proposals for the review of Institutional Committee on Stem Cell Research (IC-SCR) on or before schedule date as indicated by the Member/Secretary of the ICSCR in the prescribed **proforma (E-Copy)** and in a **single print hard copy** set for consideration.

Office of the Member Secretary, ICSCR – University of Hyderabad
(Dr. M. Surya Durga Prasad / Mr Jayanth)
School of Medical Sciences
Science Complex, Old Life Science Block,
University of Hyderabad, Telengana – 500046
Email: ic-scrt@uohyd.ac.in

Application should be sent along with duly filled Proforma I and II. Principal Investigators are requested to provide the information in this Proforma - I for review along with protocol proposal. Principal Investigator must fill the relevant information in proforma II and enclose for ICSCR committee meeting.

Principal investigator / Co-Investigator is requested to come (students will not be allowed to present the proposal) prepared with a 5 minutes power point presentation (maximum 10 slides) of the proposal to interact with the committee during ICSCR meeting.

Application Checklist:

- 1. Covering letter for each of the application**
- 2. Duly filled and signed Proforma parts I & II with information**
- 3. Structured Project Proposal in brief not exceeding 3 A4 pages**
- 4. Detailed Proposal copy**
- 5. Regulatory approvals – IEC, MTA, etc**
- 6. Consent forms and Information brochures**
- 7. CV of the Principal Investigator**
- 8. Any other supporting document**



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PROFORMA – I

INSTITUTIONAL COMMITTEE ON STEM CELL RESEARCH (ICSCR) UNIVERSITY OF HYDERABAD HYDERABAD – 500 046

PROTOCOL SUBMISSION FORM

Date:

1. Title of the Project,

2. Principal Investigator:

2.1 Name of the Investigator:

2.2. Qualifications

2.3 Designation:

2.4 Department :

3. Co-Investigators:

3.1.1. Name of the Co- Investigator 1;

3.1.2 Qualifications

3.1.3 Department :

3.1.4 Name of the Institution:

3.2.1. Name of the Co- Investigator 2;

3.2.2 Qualifications:

3.2.3 Department:

3.2.4 Name of the Institution:

3.3.1. Name of the Co- Investigator 3;

3.3.2 Qualifications

3.3.3 Department:

3.3.4 Name of the Institution:



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3.4.1. Name of the Co- Investigator 4;

3.4.2. Qualifications:

3.4.3 Department:

3.4.4 Name of the Institution:

Note: If more co-investigators are involved, please photocopy this form and use

4. Level of review required:

Full

Expedited

Amendment

5. Funding source:

5.1 Internal Funding (Only for Academic Projects).

5.2 External Funding

5.2.1 National/ International

5.2.2 National Agency/CRO/ Industry

Other Specify: _____

Name of the Funding Agency:

Address and Contact Details of Funding Source:

6.0 Performance Sites:

Has application been reviewed by any other hospital/ Institute / DCGI/ appropriate regulatory authority:

Yes

No

6.1 Additional Performance Sites / Collaborating Centers

Any other sites are involved in the present study?



Yes

No

N/A

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If yes, Please fill the following tables:

S.No	List of other sites



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PROFORMA II

7. Details of Basic Science Research Projects

Basic Science Research Project	
Title	
Funding Agency	
Duration of the project	
Objectives	
Nature and source of cells	
Level of manipulation	Minimal / Substantial / Major (<i>delete inapplicable</i>)
Brief Summary (limit to 250 words)	



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8. Description of Study

8.1 Describe the procedures or tasks/tests the subjects will be asked to Complete or undergo using non-technical language.



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8.2 Does the research involve the use of any drugs?

Yes No

If yes, please submit the Drug information Brochure / Investigator's Brochure

8.3 Does the research involve the use of any device?

Yes No

If yes, Please submit the device information Brochure

8.4 If the research does not involve 8.2 or 8.3 e then write in 150 words what the research proposes to do and submit the Information Brochure?

9.0 Administrative approvals

- 9.1 DCGI for IND / NDA :
- 9.2 IEC (of each center) including host institution:
- 9.3 Approved participant information sheet and consent form:
- 9.4 IC-SCR / NAC-SCR approval if required:
- 9.5. MOU /MTA in case of National/International collaboration for bio-material:
- 9.6 Funding of the project / sponsor:
- 9.7 Conflict of interest declaration:
- 9.8 Incentives to investigators/participants/patients/donors:
- 9.9 Mention Post – study benefits if any:
- 9.10 Medical Insurance coverage/Any indemnity clauses:



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- 9.11 Sponsor’s responsibility towards cost of research if any:
- 9.12 Investigators bio – data/CV/acceptance

10. Details of contact persons of research team for any queries during research period.

11.. Investigator’s Assurance

I certify that the information provided by me is complete and correct.
 I understand that as principal Investigator, I will take full responsibility for the conduct of study and ethical performance of the project.
 I agree to comply will all rules and regulations of IEC/ICSCR and University of Hyderabad for the conduct of the study.

I hereby declare that:

- Qualified personnel according to ICSCR will conduct the study.
- No change will be made in the protocol or consent form until approved by the ICSCR.
- Legally effective informed consent will be taken from Human subjects if applicable.
- I further certify that the proposed research is not currently being conducted and will not begin until ICSCR approval has been obtained.

Investigators	Signature	Date
Principal Investigator:		
Co-Investigator 1		
Co-Investigator 2		
Co-Investigator 3		
Co-Investigator 4		
Co-Investigator 5		
Co-Investigator 6		



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