**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. **Regulatory approvals – IEC, MTA, etc**
5. **Consent forms and Information brochures**
6. **CV of the Principal Investigator**
7. **Any other supporting document**

**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:

1. 2.2. Qualifications
2. 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:

**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

If yes, Please fill the following tables:

|  |  |
| --- | --- |
| **S.No.**  | **List of other sites**  |
|  |  |

**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 *(delete inapplicable)* |
| **Brief Summary (limit to 250 words)** |
|  |

**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.

**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:

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:

1. 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.

1. 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 |  |  |