

Form IB

Proforma to be submitted to the Pondicherry University Institute Committee- Stem Cell Research (IC-SCR).

Note: Kindly submit 10 copies of proforma and consent forms (in English and local language) through the proper channel to the Member Secretary, Institute Ethics Committee (Human studies), Pondicherry University, Puducherry along with the Doctoral Committee recommendation (for student projects).

1. Title of the project:
2. Name of the investigators/co-investigators with designation & department:
3. Number of projects already with the investigators/co-investigators:
4. Sources of funding:
5. Objectives of the study:
6. Justification for the conduct of the study:
7. Methodology: It should provide details of type of stem cells including source, isolation procedures, culturing methods, treatment (if any), investigations to be done etc.
8. Permission from Drug Controller General of India (DCGI) if applicable
9. Costs involved (Appx. in Rs.)
 - a) Investigations
 - b) Disposables
 - c) Samples

Who will bear the costs of the requirements? 1. Subject 2. Project 3. Exempted

 4. Others.
10. Ethical issues involved in the study:
Less than minimal risk / minimal risk / more than minimal risk to the study subjects (for guidance please consult ICMR guidelines)
11. Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications?
12. Whether Consent forms part 1 and 2 in English and in local language are enclosed?
13. Brief CV of investigators (including no. of projects with him/her)
14. Conflict of interest for any other investigator(s) (if yes, please explain in brief)

Certificate

We, the undersigned, have read and understood this protocol and hereby agree to conduct the stem cell research in accordance with this protocol and to comply with all requirements of the ICMR-DBT Stem Cell guidelines (2013)

Signature of the Investigators & Date :

Signature of the Head of the Department & Date :