FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN STEM CELLS FOR CLEARANCE BY INSTITUTIONAL COMMITTEE FOR STEM CELL RESEARCH AND THERAPY OF AIIMS

Submit eleven (11) copies of the Research Project on the prescribed format for Clinical/ Basic research, available on the web page, along with Covering letter and a ‘soft copy’ on CD with the following information to the Member Secretary, Institutional Committee for Stem Cell Research & Therapy (IC-SCRT) at Stem Cell Facility, 1st Floor, ORBO, AIIMS, (Tel: 26593085 ;Extn. No. 3085)

All research projects involving the use of stem cells needs clearance/approval from this committee.

All submissions should be made in the prescribed Format (copy enclosed) with signatures of all the Investigators.

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 ICSCRT meeting.

**Note:** Submission of clinical research project should have Participant Information Sheet (PIS) and Patient Informed Consent Form (PICF) in English Language and True Translation of the same in Hindi Language.
Clinical Trial Protocol for Stem Cell Therapy and Research

Study title:

Phase of the study:

Institution conducting the trial:

Sponsor:

Names of Principal Investigator and Co-investigators:

Brief CV of all the investigators:

1. Synopsis of the protocol (Summary)

2. Introduction

3. Study Objectives

4. Study plan
   a. Study design
   b. Number of patients
   c. Inclusion criteria
   d. Exclusion criteria
   e. Chart of schedule of visits and activities at each visit
   f. Ethical considerations – risks and benefits
      i. Screening Phase
      ii. Treatment phase
      ii. Post – treatment phase
      iv. Withdrawal of patients prior to study completion
   g. Efficacy assessment
      i. Primary efficacy outcome
ii. Secondary efficacy outcome

iii. Efficacy measurements

5. Safety assessment

Adverse Events document

i. Definitions

ii. Documentation of adverse events

iii. Reporting of serious adverse events

6. Concomitant Medications

i. Documentation of medications – name, dose, duration

ii. Intercurrent illness

iii. Prohibited medications

7. Product information, dose scheme and administration instructions

i. Product information

ii. Dose Scheme

iii. Route of administration

iv. Cell preparation and administration instructions

8. Data evaluation / Statistics

a. Sample size determination

b. Study population analysis

c. Efficacy analysis / methods

d. Safety analysis / methods

e. Adverse events

f. Clinical laboratory studies
9. Ethical and Administrative Issues
   a. Patient’s / Parent / Relative’s Informed consent
   b. Institutional Review Board Approval
   c. Data and safety monitoring board
   d. Adherence to the protocol
   e. Protocol amendment approval
   f. Data collection, source documentation and retention of patient records
   g. Accountability of Investigational drug / product
   h. Monitoring of the study and audit
   i. Retention of patient Records
   j. IPR issues: (patent obtained / filed)

10. Requirements for study initiation and completion

11. Confidentiality and publication

12. Enclosures
   I. Investigator brochure including background, rationale, product details, Pre-clinical studies results, human experience, references and Publication reprints.
   II. Case Record Form
   III. Manual for efficacy assessments, safety assessments, laboratory Procedures etc.
   IV. Administrative approvals
      a. DCGI for IND / NDA
      b. IEC ( of each center)
c. Approved patient information sheet and consent form

d. IC-SCRT / NAC-SCRT approval if required

e. MOU / MTA in case of National / International collaboration
   with transfer of biological materials

f. Funding of the project / sponsor

g. Conflict of interest declaration

h. Incentives to investigators / patients / donors

i. Post – trial benefits

j. Medical Insurance coverage for SAEs

k. Sponsor’s responsibility towards cost of trial /
   complications

l. Investigators bio – data / acceptance