JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL EDUCATION & RESEARCH, PUDUCHERRY - 605 006

(Institution of National Importance under Ministry of Health and Family Welfare, Government of India)

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING CLINICAL RESEARCH IN STEM CELLS FOR CLEARANCE BY

INSTITUTIONAL COMMITTEE FOR STEM CELL RESEARCH AND THERAPY OF JIPMER

Submit the Research Project on the prescribed format for Clinical research along with Covering letter with the following information to the Member Secretary, Institutional Committee for Stem Cell Research & Therapy (IC-SCRT)

All research projects involving the use of stem cells needs clearance/approval from this committee. All submissions should be made in the prescribed Format with signatures of all the Investigators.

Guidelines for presentation:

1. The Principal Investigator should first go through "Guidelines on Stem Cell Research and Therapy" published by the Department of Biotechnology and Indian Council of Medical Research (2007).
2. The Principal Investigator (PI) will review current State of the Art Knowledge and submit 4-5 recent scientific publications along with the proposal, at least one week prior to the meeting. Soft copies of the proposal and scientific publications will be mailed to convenor IC-SCRT.
3. The Principal Investigator will make a brief presentation of the proposal to the Committee highlighting the following points:
    - State of the Art Knowledge in the field of study.
    - The study design and procedure to be followed. If it deviates from the best practices, justification for the alternate strategy should be given.
    - The number of centers where such a study has been performed or is underway (if known). Safety and efficacy data must be shown.
    - All standard operating procedures related to the proposals should be in place
4. After a certain minimum number of procedures involving clinical use, the results should be presented to the Data Safety and Monitoring Board (DSMB).

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 Tamil Language.

Clinical Trial Protocol for Stem Cell Therapy and Research

1. Study title:
2. Phase of the study:
3. Institution conducting the trial:
4. Sponsor:
5. Names of Principal Investigator and Co-investigators:
6. Brief CV of all the investigators:
7. Synopsis of the protocol (Summary)
8. Introduction
9. Study Objectives
10. 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

        iii. 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

11. Safety assessment

        Adverse Events document

        i. Definitions

        ii. Documentation of adverse events

        iii. Reporting of serious adverse events

12. Concomitant Medications

    i. Documentation of medications – name, dose, duration

    ii. Intercurrent illness

    iii. Prohibited medications

13. Product information, dose scheme and administration instructions

    i. Product information

    ii. Dose Scheme

    iii. Route of administration

    iv. Cell preparation and administration instructions

14. 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

15. 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)

16. Requirements for study initiation and completion

17. Confidentiality and publication

18. 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