**IC – SCRT Forms**

* **Checklist**
* **Form – 9 :** Application for Review of Biomedical Research

 Proposal

* **Annexure – I:**  Clinical Trial Protocol for Stem Cell Therapy
* **Annexure – II :**  Initial Review Submission Form by Investigator for

 Search Proposal

* **Annexure – III:** Ongoing Approved Research Review Submission form by Investigator
* **Form – 10:** Acknowledgement

**Note:** The members are requested to submit 4 sets with all the above documents and 7 study synopsis. The covering letter forwarded by the HOD, should attach to all the sets including synopsis. Addressed to the Member Secretary, IC – SCRT, NIMS

Checklist

*Application must be submitted along with all essential documents for review. Also see list of documents –along with Annexure I & II*

Check List of documents to be submitted along with application for the IC-SCRT Review along with duly filled in Annexure I & II

|  |  |  |  |
| --- | --- | --- | --- |
| S.No. | Documents to be submitted |  Yes |  No |
| 1. | Signed and dated application form and Annexure I & II in prescribed format |  |  |
| 2. | The Protocol of the Proposed research (Clearly identified, numbered and dated), together with supporting documents and annexures. |  |  |
| 3. | A summary (as far as possible in non-technical language, synopsis, or diagrammatic representation-flowchart of the protocol) |  |  |
| 4. | A description (usually included in the protocol) of the ethical considerations involved in the research |  |  |
| 5. | Case Report Forms, diary cards and other questionnaires intended for research participants  |  |  |
| 6. | In case the research involves a study product (such as pharmaceutical or device under investigation, an adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study product to date – e.g. recent investigator’s brochure, published data, a summary of the product’s characteristics); (product information) |  |  |
| 7. | Investigator’s curriculum vitae (updated, signed and dated) |  |  |
| 8. | Source of obtaining Stem Cell used in the present study  |  |  |
| 9. | Degree of manipulation and details of the same  |  |  |
| 10. | Written and other forms of information for potential research participants (clearly identified and dated) in English and local languages understood by the participants. |  |  |
| 11. | Informed consent forms (clearly identified, numbered and dated) in English and local languages understood by the research participants. |  |  |
| 12. | A statement describing any compensation for study participants (including expenses and access to medical care) to be given to the research participants and financial compensation for research related injury apart from medical treatment. |  |  |
| 13. | A description of arrangement for indemnity, if applicable |  |  |
| 14. | A description of arrangement for insurance coverage for research participants, if applicable |  |  |
| 15. | Investigator Agreement with Sponsor (Submitted to Project Registration Committee)  |  |  |
| 16. | All previous IC-SCRT’s decisions (eg. those leading to a negative decision or modified protocol) by other Ethics Committees or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions must be provided. |  |  |
| 17. | Investigator’s undertaking from applicable regulatory bodies like NAC/DBT/DST |  |  |
| 18. | Drugs Controller General of India’s (DCGI) No Objection Letter (NOL) if applicable and CTRI registration number if available |  |  |

SOP No.: NIMS-IC-SCRT-008 Form 9

Application for Review of Biomedical Research Proposal

To,

The Member Secretary

Institutional Ethics Committee,

Nizam’s Institute of Medial Sciences,

Hyderabad.

|  |  |  |
| --- | --- | --- |
| Full Name of the Applicant  |  | Date: |
| Designation  |  |
| Complete Postal Address of Applicant |  |
| Title of the Project |  |
| Name and Address of Sponsor  |  |
| CTRI Registration Number if available |  |
| Type of Study  | National (√) | International (√) |
|  |  |
| Single Centre (√) | Multi Centre (√) |
|  |  |
| Principal Investigator’s Telephone No. (off) | Fax No | Email: |
|  |  |  |
| Protocol No.Amendment No. | Version NoVersion No | Version DateVersion Date |
|  |  |  |
| Principal Investigator  | Name | Signature |
|  |  |
| Co-investigator (s) |  |  |
|  |  |
|  |  |
| Name of Applicant | Signature   | Date |

**Annexure – I**

CLINICAL TRIAL PROTOCOL FOR STEM CELL THERAPY

|  |  |  |
| --- | --- | --- |
| **Section** |  | **Description** |
| 1. | Study title: |
|  |  |
|  | Protocol ID: |
|  | Phase of the study: |
|  | Sponsor: |  |  |
|  | Contract Research Organization (CRO) |
|  | Investigator/s and Institution/s |
|  |  |
| 2. | Synopsis of the protocol (Summary) |
|  |  |
| 3. | Introduction (including preclinical and clinical experience) |
|  |  |
| 4. | Study rationale (including potential risks and benefits) |
|  |  |
| 5. | Study objectives (primary and secondary objectives) |
|  |  |
| 6. | Study design |
|  | Number of patients |
|  |  |
|  | Eligibility criteria |
|  | a. | Inclusion |
|  | b. | Exclusion |
|  |  |
|  | Study activities: Phase |
|  | a. | Screening |
|  | b. | Treatment |
|  | c. | Post –treatment |
|  | d. | Follow-up |
|  |  |
|  | Schedule of visits and activities at each visit |
|  |  |
| 7. | Withdrawal of patients prior to study completion |
|  |  |
| 8. | Safety assessment |
|  | a. | Definitions |
|  | b. | Documentation of adverse events |
|  | c. | Reporting of serious adverse events |
| 9. | Efficacy assessment: Outcome |
|  | a. | Primary efficacy |
|  | b. | Secondary efficacy |
|  |  |
| 10. | Concomitant Medications |
|  | a. | Documentation of medications – name, dose, duration |
|  | b. | Intercurrent illness |
|  | c. | Prohibited medications |
|  |  |
| 11. | Investigational New Entity |
|  | a. | Chemistry Manufacturing and Control (CMC) information |
|  | b. | Dosage |
|  | c. | Route of administration |
|  | d. | Cell preparation and administration instructions |
|  | e. | Accountability of Investigational drug/product |
|  |  |
| 12. | Data evaluation/statistics |
|  | a. | Sample size determination |
|  | b. | Study population analyses |
|  | c. | Efficacy analysis/methods |
|  | d. | Safety analysis/methods |
|  | e. | Adverse events |
|  | f. | Clinical laboratory studies |
|  |  |
| 13. | Ethical and Administrative Issues |
|  | a. | Informed consent including audio video consent from Patient /Parent/ |
|  |  | Relative |
|  | b. | Risks and benefits |
|  | c. | Approval of IEC, IC-SCR and CDSCO |
|  |  |
| 14. | Data Safety Monitoring Board (DSMB) |
|  |  |
| 15. | Adherence to the protocol |
|  | a. | Protocol deviation/amendment |
|  |  |
| 16. | Data collection, source documentation and retention of patient records |
|  |  |
| 17. | Monitoring of the study and audit |
|  |  |
| 18. | Intellectual Property Rights (IPR) issues (patent obtained/filed) |
|  |  |
| 19. | Confidentiality |
|  |  |
| 20 | References |
| 21. | Enclosures |
|  | a. | CMC in case of stem cell or cell based product (if not included in Investigator |
|  |  | brochure) |
|  | b. | Investigator brochure including background, rationale, product details, |
|  |  | pre-clinical study results, human trials, references and publication list and |
|  |  | reprints |
|  | c. | Case Record Form |
|  | d. | Manual for efficacy assessments, safety assessments, laboratory |
|  |  | procedures etc. |
|  | e. | Approved patient information sheet and consent form (including audio |
|  |  | video consent) |
|  | f. | MOU/MTA in case of National/International collaboration with transfer of |
|  |  | biological materials |
|  | g. | Funding of the project/sponsor |
|  | h. | Conflict of interest declaration |
|  | i. | Clearances of IEC, IC-SCR and CDSCO |
|  | j. | Charter of DSMB |
|  | k. | Certificate of Registration of IEC and IC-SCR |

**Annexure – II**

**Nizam’s Institute of Medical Sciences**

**Institutional Committee Stem Cell Research**

Initial Review Submission by Investigator Form For Research Proposal

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualification and designation
4. Name of the Institute / Hospital / Field area where research will be conducted
5. Forwarding letter from the Head of Department / Institution / Guide
6. Protocol which should include objective, summary, duration of the study, details of the protocol nature & source of cells, level of manipulations and End point parameters
7. Ethical issues in the study and plans to address these issues.
8. Proposals should be submitted with all relevant enclosures like performed, case report forms, questionnaires, follow – up cards. Etc.
9. Informed consent process, including patient information sheet and informed consent form in English and local language(s)
10. For any drug / device trial, all relevant pre – clinical animal data and clinical trial data from other centres within the country / other countries, if available.
11. Usefulness of the project / trial
12. Expected ‘benefits’ to volunteers / community
13. ‘Benefits’ to other categories if any
14. Explain all anticipated ‘risks’ (adverse events, injury, and discomfort) of the project.
15. Efforts taken to minimize the ‘risks’
16. Research proposal approval by scientific advisory committee, Drug Controller General of India, Health Ministry screening committee etc.
17. Any regulatory clearance required
18. Source of funding and financial requirements for the project
19. Other financial issues including those related to insurance
20. Agreement to report all Serious Adverse Events (SAE) to NIMS IC – SCRT
21. Statement of conflicts of interest, if any
22. Agreement to comply with the relevant national and applicable international guidelines
23. Statement describing any compensation given to study participation (including expenses and access to medical care).
24. Description of the arrangements for indemnity, if applicable in study – related injuries and description of the arrangements for insurance coverage for research participants, if applicable
25. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other IEC or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
26. Specific ethical issues, as identified by the investigation team.
27. Curriculum vitae of all the investigators with relevant publications is last five years
28. Plans for publication of results / positive or negative while maintaining the privacy and confidentiality of the study participants.
29. Any other information relevant to the study
30. Kindly indicate wither the proposed study is under
31. Permitted & Restricted areas of research 7 & 8 page No. 21 to 25 for stem cell \*\*\*

Above a & b Please refer ICMR – DBT guidelines on stem cell research 2017

1. Research using human stem cells must have prior approval of IC-SCRT for permitted research and of the NAC – SCRT for restricted research (ICMR DBT guidelines – 2017)
2. Signature of the principal investigatory with date.

**Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal**

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 protection of rights and welfare of all trial subjects including the conduct of study and ethical performance of the project.

I agree to comply will all rules and regulations of IC-SCRT and Nizam’s Institute of Medical Sciences of the conduct of the trial. I here by declare.

* Qualified personnel according to IC-SCRT will conduct the study.
* No change will be made in the protocol or consent form until approved by the IC-SCRT.
* Legally effective informed consent will be taken from Human subjects if applicable.
* Adverse events will be reported to IC-SCRT as per ICH GCP/DCGI Adverse event reporting policy.

I further certify that the proposed research is not currently being conducted and will not begin until IC-SCRT approval has been obtained.

|  |  |  |  |
| --- | --- | --- | --- |
| Investigators |  Name  | Signature | Date |
| Principal Investigator |  |  |  |
| Co-Investigator 1/ Guide/Co-Guide |  |  |  |
| Co-Investigator 2/ Guide/Co-Guide |  |  |  |
| Co-Investigator 3/ Guide/Co-Guide |  |  |  |

***Annexure III***

**Nizam’s Institute of Medical Sciences**

**Institutional Committee Stem Cell Research**

Ongoing Approved Research Review Submission Form by Investigator

1. Reference number
2. Month / year of approval
3. Number of ongoing review
4. Title of the research proposal
5. Name of the Principal Investigator (PI) with qualification and designation
6. Name of the Co-investigator(s) (Co-PI) with qualification and designation
7. Duration of the Project
8. Source of funding & financial allocation for the project / trial
9. Has subject recruitment begun?
10. If subject recruitment has not begin, give reasons and proceed to No.: 20
11. How many participants have been screened?
12. How many participants have been recruited?
13. How many more to be recruited?
14. Is subject recruitment continuing?
15. Are there any ‘drop outs’?
16. Are participants still receiving active intervention?
17. Have there been any adverse events? If yes, give details
18. Have there been any Serious Adverse Events adverse events? If yes, give details.
19. Have there been any unanticipated study – related problems? If Yes, give details.
20. Is there any new risk or benefit information? If yes, give details
21. Are there any interim changes to the protocol or consent form? If yes, give details including submission of revised protocol and consent form for approval
22. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?
23. List of attachments for review, if any
24. Remarks, if any
25. Signature of Principal Investigator with date

**Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal**

**Annexure – IV**

Review Proforma by I C – SCRT Members

**IC-SCRT Regn No:**

 **Protocol Title:**

**Name of PI:**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Mark and comment on whatever items applicable to the study

|  |  |  |
| --- | --- | --- |
| 1 | Objectives of the Study  clear unclear  | What should be improved? |
| 2 | Methodology: clear unclear | What should be improved? |
| 3 | Background Information and Data  sufficient insufficient | Comment: |
| 4 | Risks and Benefits Assessment  acceptable unacceptable | Comment: |
| 5 | Inclusion Criteria  appropriate inappropriate | Comment: |
| 6 | Exclusion Criteria  appropriate inappropriate | Comment: |
| 7 | Source of Stem Cell Mentioned Yes No | Comment: |
| 8 | Degree of Manipulation mentioned Yes No | Comment: |
| 9 | Discontinuation and Withdrawal Criteria  appropriate inappropriate | Comment: |
| 10 | Involvement of Vulnerable Participants Yes No | Comment: |
| 11 | Sufficient number of participants?  Yes No | Comment: |
| 12 | Control Arms (placebo, if any)  Yes No  | Comment: |
| 13 | Contents of the Informed Consent Document clear unclear  | Comment: |
| 14 | Language of the Informed Consent Document  clear unclear  | Comment: |
| 15 | Privacy & Confidentiality in Informed Consent Document Yes No  | Comment: |
| 16 | Inducement for Participation  Unlikely Likely | Comment: |
| 17 | Provision for Medical Support appropriate inappropriate | Comment: |
| 18 | Provision for Treatment of Study-Related Injuries appropriate inappropriate | Comment: |
| 19 | Provision for Compensation  appropriate inappropriate | Comment: |
| 20 | Study design appropriate inappropriate | Comment: |
| 21 | Statistical analysis appropriate inappropriate | Comment: |

Any specific comments:  |

Name of the reviewer:

Signature: Date:

SOP No.: NIMS-IC-SCRT-008 Form 10

Institutional Committee Stem Cell Research

Nizam’s Institute of Medical Sciences, Hyderabad

Acknowledgement

 Date:

Study Proposal Registration No.: NIMS-IC-SCRT/201 / 0\_\_\_\_\_\_\_\_\_\_\_

Received \_\_\_\_\_\_\_\_\_\_\_\_\_copies of study proposal.

Protocol No.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Version No. Dated:

Amendment No.: Version No: Dated:

Entitled: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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From Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Designation \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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For ethical review:

Name of IC-SCRT staff \* Signature:

receiving application:

\* Date:

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\* For office use only. Not to be filled by the applicant.

(To be filled by the applicant in duplicate)