**SRI BALAJI VIDYAPEETH**

(Deemed University)

Accredited by NAAC with ‘A’ Grade

Pillaiyarkuppam, Puducherry – 607 402

**CLINICAL TRIAL APPLICATION FORM**

(Six copies to be submitted to the Member Secretary, Clinical Trial Research Committee)

CTRC NO:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(to be filled by the Office)

1. Title of the Clinical Trial:

2. Name of Principal Investigator:

3. Designation :

4. Department :

5. Sponsor’s Name and Address:

6. Proposed date of start of Clinical Trial:

7. Proposed date of termination of Clinical Trial :

8. Duration of Clinical Trial :

9. IHEC approval received : Yes No

 If Yes, approval number and date :

10. Budget details / Plan :

|  |  |  |
| --- | --- | --- |
| Sl.No | BUDGET HEADS  |  Amount (Rs) |
| 1 | Equipment and Consumables |  |
| 2 | Salary |  |
| 3 | Investigators fee/Honororium |  |
| 4 | Hospital expenses (Investigation, hospital stay charges etc.)  |  |
| 5 | Subject compensation (transport, lodging etc.) |  |
| 6 | Travel (investigator’s meet, conferences, project work etc.) |  |
| 7 | Contingencies (Xerox, stationary, postage, telephone etc.)  |  |
| 8 | Insurance charges (for investigators, patients/volunteers)  |  |
| 9 | TOTAL COST OF CLINICAL TRIAL  |  |
| 10 | Add Institute Over Head Charges (20 %) |  |
| 11 | GRAND TOTAL  |  |

11. Signature of the investigators

Name Department Designation Signature

Principal Investigator

1.

Co-Investigators

1.

2.

3.

CTRC NO:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(to be filled by the Office)

**CHECK LIST FOR ENCLOSURES**

1. Covering letter Enclosed Yes / No
2. Prescribed Clinical Trial Application Form Enclosed Yes / No
3. Application fee as prescribed Enclosed Yes / No
4. Request letter from Sponsor (if applicable) Enclosed Yes / No
5. Clinical trial protocol Enclosed Yes / No
6. Investigator’s brochures (COA, GMP) Enclosed Yes / No
7. DCGI approval Enclosed Yes / No
8. Proof of registration with Clinical Trial Registry Enclosed Yes / No
9. Copy of IHEC Application / Approval Enclosed Yes / No
10. Financial declaration Enclosed Yes / No
11. Insurance cover Enclosed Yes / No
12. Informed consent information and form(s) Enclosed Yes / No
13. Any other documents enclosed (give details):

**Signatures of the investigators**

Name Department Designation Signature

Principal Investigator

1.

Co-Investigators

1.

2.

3.

**SRI BALAJI VIDYAPEETH**

Puducherry – 607 403

**RECOMMENDATION OF THE CTRC**

**For office use**

Date: CTRC NO:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(to be filled by the Office)

Project Title:

Principle Investigator:

Comments / Suggestions:

**Decision: Approved / Not Approved**

CHAIRMAN GM-Finance

 CTRC SBV

Date: