Clinical Research Submission

1. Administration

Name:	sagar
Department:	computer science
Submission Date:	28/6/2025
Review Type:	Expedited Review
Study Title:	medical research
Short Title:	MR
Protocol:	987897
Version:	8798879
Date:	2025-06-08T18:30:00.000Z

2. Investigators

Type:	principal
Name:	shanmuka sagar
Designation:	software developer
Qualification:	MD, PhD
Department:	Clinical Research
Email:	shanmukasagar2019@gmail.com
Contact:	9876543210

Type:	hod
Name:	shanmuka sagar
Designation:	Co-Investigator
Qualification:	MD, PhD
Department:	Clinical Research
Email:	shanmukasagar2021@gmail.com

Contact:	9876543210

3. Investigators Count

PI Count:	12
Co-PI Count:	25
Duration:	32

4. Funding Details

Estimated Budget:	50000
Funding Source:	Self-funding

false <>
Proposed Budget: ₹ hfkshksf
Cost Per Patient: ₹ fsfsfhskf
Total Project Cost: ₹ 650
NIMS Investigations:

- Name:
- CHT
- Cost:
- 250
  ,
- Name:
- BGT
- Cost:
- 400

Is Outsourced: Yes
Outsourced Investigations:

- Name:
- shanmuka sagar
- Cost:
- 600
- Lab:
- ameerpet

- NABL:
- yes

false false

5. Overview Research

Summary: kjadhkahd kh
Study Type: Academic clinical trials
Other Type:

6. Methodology

Sample Size: 250
Participants per Site: 12
Lab Outsourcing: No
Lab Details:

7. Participants

Type: Patient
Vulnerable Groups:
Other Participant:
Reimbursement: No
Details:
Additional Safeguards:
Justification:

8. Benefits

Any Risk: No
Risk Details:

Risk Strategy:	
Participant Benefits:	Indirect
Social Benefits:	Direct
Scientific Benefits:	Indirect

9. Consent

Waiver Consent:	No
Translated Languages:	
Other Reason:	

10. Payment

Injury Treatment:	No
SAE Compensation:	NA

11. Storage

Docs Control:	No
Drugs Control:	No

12. Additional Info

Any Additional:	No
Details:	

13. Declaration

PI Name:	shanmuka sagar
Guide Name:	
HOD Name:	

14. Checklist

Cover letter	View File
Brief CV of all Investigators- Updated, signed and dated	View File
Good Clinical Practice (GCP) training of investigators in last 3 years	View File
EC clearance of other centers	File: null
Agreement between collaborating partners	File: null
MTA between collaborating partners	File: null
Insurance policy / certificate	View File
Copy of CTA signed with the sponsor	View File
Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs / Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	File: null
Copy of the detailed protocol (clearly identified numbered and dated) and synopsis (summary as far as possible in non-technical language, flowchart, diagrammatic representation of the protocol)	View File
Investigators Brochure (If applicable for drug / biologicals / device trials)	View File
Participant Information Sheet (PIS) and Informed Consent Form (ICF) (English and translated) with version number and dated	View File
Assent form for minors (12-18 years) (English and Translated)	File: null

Proforma / Questionnaire / Case Report Forms (CRF) / Interview guides / Guides for Focused Group Discussions (FGDs) (English and translated)	View File
Advertisement / material to recruit participants (fliers, posters, etc.)	File: null
DCGI Approval letter	View File
Others specify	File: null