Clinical Research Submission

1/7/2025, 3:18:27 pm

1. Administration

Name:	sagar
Department:	computer science
Submission Date:	25/6/2025
Review Type:	Expedited Review
Study Title:	medical research
Short Title:	MR
Protocol:	987897
Version:	8798879
Date:	2025-06-05T18:30:00.000Z

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

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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