Clinical Research Submission

1. Administration

Name:	shanmuka sagar
Department:	computer science
Submission Date:	30/6/2025
Review Type:	Expedited Review
Study Title:	medical research
Short Title:	MR
Protocol:	987897
Version:	8798879
Date:	2025-06-11

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
Other Details:	

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	File: null

for proposed study (whether in same location or elsewhere) and modification(s) to protocol	
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