Clinical Research Submission

1. Administration

Name:	sagar
Department:	computer science
Submission Date:	23/6/2025
Review Type:	Full Committee Review
Study Title:	medical research
Short Title:	MR
Protocol:	1254ABC
Version:	2546NHG
Date:	2025-06-23T18:30:00.000Z

2. Investigators

Type:	principal
Name:	shanmuka sagar
Designation:	software developer
Qualification:	B.Tech
Department:	computer science
Email:	shanmukasagar2019@gmail.com
Contact:	8688345501

Type:	guide
Name:	shanmuka sagar
Designation:	software engineer
Qualification:	B.Tech
Department:	computer science
Email:	shanmukasagar2021@gmail.com

Contact:	9876543210

3. Investigators Count

PI Count:	5
Co-PI Count:	10
Duration:	20

4. Funding Details

Estimated Budget:	50000
Funding Source:	Institutional funding
Other Details:	

5. Overview Research

Summary:	hkshfkhflaf hkfhkfhkj
Study Type:	BA/BE studies
Other Type:	

6. Methodology

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

7. Participants

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

8. Benefits

Any Risk:	No
Risk Details:	
Risk Strategy:	
Participant Benefits:	Direct
Social Benefits:	Direct
Scientific Benefits:	Direct

9. Consent

Waiver Consent:	No
Translated Languages:	Telugu
Other Reason:	

10. Payment

Injury Treatment:	No
SAE Compensation:	No

11. Storage

Docs Control:	No
Drugs Control:	No

12. Additional Info

Any Additional:	Yes
Details:	kdghkdghk jghdgkhlhlg ghkghd

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