

Clinical Research Submission

1. Administration

Name:	shanmuka sagar
Department:	computer science
Submission Date:	18/6/2025
Review Type:	Full Committee Review
Study Title:	medical research
Short Title:	MR
Protocol:	1254ABC
Version:	2546NHG
Date:	2025-06-18T18:30:00.000Z

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:	shanmukasagar2023@gmail.com

Contact: 9876543210

Type: hod
Name: Varshitha Reddy
Designation: software developer
Qualification: B.Tech
Department: Clinical Research
Email: shanmukasagar2021@gmail.com
Contact: 9999999999

Type: co-investigator
Name: Bharadwaj
Designation: software engineer
Qualification: B.Tech
Department: computer science
Email: nimstech25@gmail.com
Contact: 8688345501

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 hkfkhfhkj
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:	
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 ghkgghd

13. Declaration

PI Name: shanmuka sagar
Guide Name:
HOD Name:

14. Checklist

Cover letter

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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