Clinical Research Submission

Last Modified: 12/7/2025, 11:59:19 am

1. Administration

Name:	shanmuka sagar
Department:	Clinical Research
Submission Date:	12/7/2025
Review Type:	Expedited Review
Study Title:	Artificial Intellengence study
Short Title:	MR
Protocol:	1254ABC
Version:	2546NHG
Date:	2025-07-11

2. Investigators

Type:	principal
Name:	Shanmuka Sagar
Designation:	software engineer
Qualification:	MD, PhD
Department:	computer science
Email:	shanmukasagar2019@gmail.com
Contact:	8688345501

Type:	hod
Name:	Bharathwaj
Designation:	Co-Investigator
Qualification:	MD, PhD

Department:	Clinical Research
Email:	shanmukasagar2023@gmail.com
Contact:	9876543210

3. Investigators Count

PI Count:	21
Co-PI Count:	12
Duration:	25

4. Funding Details

Estimated Budget: 50000
Funding Source: Institutional funding
false
Funding Agency: shanmuka sagar
Grant Per Patient: ₹600
Manpower Grant: ₹21
Total Grant: ₹210
NIMS Investigations:

- **Name:** yes
  Cost: 210

Is Outsourced: Yes
Outsourced Investigations:

- **Name:**
  Cost:
  Lab:
  NABL:

5. Overview Research

Summary:	sfsf ff
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:	Indirect
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:	No
Details:	

13. Declaration

- I/We certify that the information provided in this application is complete and correct.
- I/We confirm that all investigators have approved the submitted version of proposal / related documents.
- I/We confirm that this study will be conducted in accordance with the latest NDCT RULES, ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulatory guidelines.

- I/We will comply with all policies and guidelines of the institute and affiliated / collaborating institutions wherever applicable.
- I/We confirm that we will maintain accurate and complete records of all aspects of the study.

Principal Investigator

Name: shanmuka sagar
Signature: shanmuka sagar
Date: N/A

Guide

Name:
Signature:
Date: N/A

Head of Department

Name:
Signature:
Date: N/A

Co-Investigator 1

Name:
Signature:
Date: N/A

Co-Investigator 2

Name:
Signature:
Date: N/A

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	File: null
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	File: null
Others specify	File: null
Participant Information Sheet (PIS) and Informed Consent Form (ICF) - Telugu	View File

Translation Certificate - Telugu View File