Clinical Research Submission

Last Modified: 7/9/2025, 9:50:19 AM

1. Administration

Name:	shanmuka sagar
Department:	computer science
Submission Date:	6/30/2025
Review Type:	Expedited Review
Study Title:	medical research
Short Title:	MR
Protocol:	987897
Version:	8798879
Date:	2025-07-04T18:30:00.000Z

2. Investigators

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

Type:	guide
Name:	shanmuka sagar
Designation:	software developer
Qualification:	MD, PhD

Department:	Clinical Research
Email:	shanmukasagar2021@gmail.com
Contact:	9989943631

Type:	hod
Name:	Bharath
Designation:	software engineer
Qualification:	B.Tech
Department:	computer science
Email:	shanmukasagar2023@gmail.com
Contact:	9876543210

3. Investigators Count

PI Count:	12
Co-PI Count:	215
Duration:	213

4. Funding Details

Estimated Budget:	50000
Funding Source:	Pharmaceutical Industry sponsored

false
Sponsor Name: fhskfhk sfhsf
Sponsor PAN: sfhksf sfksf
Sponsor GST: fskfhskf fh f
Total Grant: ₹ 500
Budget Items:

- **Per completed patients total sponsor grant:** fskfksfhk
- **Per completed patients manpower sponsor grant (PI, Co-PI, coordinator, others):** fhskfhksf f
- **Per completed patients overhead:** fksfhksfhk f
- **Startup fee:** fkhskfh kfh
- **Archival fee:** fhshfkf

NIMS Investigations:

- **Name:** fsdff
  Cost: 200
- **Name:** fsf
  Cost: 300

Personnel:

- **Designation:** fsff
  Fees: fsfsf
- **Designation:** fsfsf
  Fees: fsff

Is Outsourced: Yes
Outsourced Investigations:

- **Name:**
  Lab:
  NABL:

5. Overview Research

Summary:	fsfsf
Study Type:	Academic clinical trials
Other Type:	

6. Methodology

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

7. Participants

Type: Vulnerable person

Vulnerable Groups:

- Economically and socially disadvantaged
- Unduly influenced due to fear/benefits
- Children (up to 18 years)

Other Participant:

Reimbursement: No

Details:

Additional Safeguards: jgj

Justification: sfsfhskf

8. Benefits

Any Risk: No

Risk Details:

Risk Strategy:

Participant Benefits: Indirect

Social Benefits: Indirect

Scientific Benefits: Indirect

9. Consent

Waiver Consent: Yes

Translated Languages:

Other Reason: gdgdgdggd

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 will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.

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	📎 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