Clinical Research Submission

Last Modified: 4/7/2025, 12:16:38 pm

1. Administration

Name:	shanmuka sagar
Department:	computer science
Submission Date:	4/7/2025
Review Type:	Expedited Review
Study Title:	medical research
Short Title:	MR
Protocol:	987897
Version:	8798879
Date:	2025-07-08T18:30:00.000Z

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 false 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
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Per completed patients manpower sponsor grant (PI, Co-PI, coordinator, others): fhskfhksf f

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Per completed patients overhead: fksfhksfhk f

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Startup fee: fkhskfh kfh

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Archival fee: fhshfkf

NIMS Investigations:

Name: fsdff
Cost: 200

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Name: fsf
Cost: 300

Personnel:

Designation: fsff
Fees: fsfsf

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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

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 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