

# Clinical Research Submission

Last Modified: 4/7/2025, 12:38:51 pm

## 1. Administration

<b>Name:</b>	shanmuka sagar
<b>Department:</b>	computer science
<b>Submission Date:</b>	3/7/2025
<b>Review Type:</b>	Expedited Review
<b>Study Title:</b>	medical research
<b>Short Title:</b>	MR
<b>Protocol:</b>	987897
<b>Version:</b>	8798879
<b>Date:</b>	2025-07-07T18:30:00.000Z

## 2. Investigators

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

<b>Type:</b>	guide
<b>Name:</b>	shanmuka sagar
<b>Designation:</b>	software developer
<b>Qualification:</b>	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:** fkhsfkf 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

<% selectedDeclarations.forEach(label => { %>  
• <%= label %>  
<% }) %>

### Principal Investigator

**Name:** <%= declaration.pi\_name %>  
**Signature:** <%= declaration.pi\_signature %>  
**Date:** <%= declaration.pi\_date || "N/A" %>

### Guide

**Name:** <%= declaration.guide\_name %>  
**Signature:** <%= declaration.guide\_signature %>  
**Date:** <%= declaration.guide\_date || "N/A" %>

### Head of Department

**Name:** <%= declaration.hod\_name %>  
**Signature:** <%= declaration.hod\_signature %>  
**Date:** <%= declaration.hod\_date || "N/A" %>

### Co-Investigator 1

**Name:** <%= declaration.co1\_name %>

**Signature:** <%= declaration.co1\_signature %>

**Date:** <%= declaration.co1\_date || "N/A" %>

## Co-Investigator 2

**Name:** <%= declaration.co2\_name %>

**Signature:** <%= declaration.co2\_signature %>

**Date:** <%= declaration.co2\_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