

# Clinical Research Submission

## 1. Administration

<b>Name:</b>	sagar
<b>Department:</b>	computer science
<b>Submission Date:</b>	22/6/2025
<b>Review Type:</b>	Full Committee Review
<b>Study Title:</b>	medical research
<b>Short Title:</b>	MR
<b>Protocol:</b>	1254ABC
<b>Version:</b>	2546NHG
<b>Date:</b>	2025-06-22T18:30:00.000Z

## 2. Investigators

<b>Type:</b>	principal
<b>Name:</b>	shanmuka sagar
<b>Designation:</b>	software developer
<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 engineer
<b>Qualification:</b>	B.Tech
<b>Department:</b>	computer science
<b>Email:</b>	shanmukasagar2021@gmail.com

**Contact:** 9876543210

**Type:** hod  
**Name:** Varshitha Reddy  
**Designation:** software developer  
**Qualification:** B.Tech  
**Department:** Clinical Research  
**Email:** shanmukasagar2023@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

<b>Summary:</b>	hkshfkhflaf hkfkhfhkj
<b>Study Type:</b>	BA/BE studies
<b>Other Type:</b>	

## 6. Methodology

<b>Sample Size:</b>	250
<b>Participants per Site:</b>	12
<b>Lab Outsourcing:</b>	No
<b>Lab Details:</b>	

## 7. Participants

<b>Type:</b>	Patient
<b>Vulnerable Groups:</b>	
<b>Safeguards:</b>	
<b>Other Participant:</b>	
<b>Reimbursement:</b>	No
<b>Details:</b>	
<b>Additional Safeguards:</b>	
<b>Justification:</b>	

## 8. Benefits

<b>Any Risk:</b>	No
<b>Risk Details:</b>	
<b>Risk Strategy:</b>	
<b>Participant Benefits:</b>	Direct
<b>Social Benefits:</b>	Direct
<b>Scientific Benefits:</b>	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**

 [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