

# Clinical Research Submission

## 1. Administration

<b>Name:</b>	sagar
<b>Department:</b>	computer science
<b>Submission Date:</b>	27/6/2025
<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>	2025-06-07T18:30:00.000Z

## 2. Investigators

<b>Type:</b>	principal
<b>Name:</b>	shanmuka sagar
<b>Designation:</b>	software developer
<b>Qualification:</b>	MD, PhD
<b>Department:</b>	Clinical Research
<b>Email:</b>	shanmukasagar2019@gmail.com
<b>Contact:</b>	9876543210

<b>Type:</b>	hod
<b>Name:</b>	shanmuka sagar
<b>Designation:</b>	Co-Investigator
<b>Qualification:</b>	MD, PhD
<b>Department:</b>	Clinical Research
<b>Email:</b>	shanmukasagar2021@gmail.com

**Contact:** 9876543210

### 3. Investigators Count

**PI Count:** 12  
**Co-PI Count:** 25  
**Duration:** 32

### 4. Funding Details

**Estimated Budget:** 50000  
**Funding Source:** Self-funding

false <>

Proposed Budget: ₹ hfkshksf

Cost Per Patient: ₹ fsfsfhskf

Total Project Cost: ₹ 650

NIMS Investigations:

**Name:** CHT

**Cost:** 250

,

**Name:** BGT

**Cost:** 400

Is Outsourced: Yes

Outsourced Investigations:

**Name:** shanmuka sagar

**Cost:** 600

**Lab:** ameerpet

**NABL:** yes

false false

### 5. Overview Research

<b>Summary:</b>	kjadhkahd kh
<b>Study Type:</b>	Academic clinical trials
<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>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>	Indirect
<b>Social Benefits:</b>	Direct
<b>Scientific Benefits:</b>	Indirect

## 9. Consent

**Waiver Consent:** No  
**Translated Languages:**  
**Other Reason:**

## 10. Payment

**Injury Treatment:** No  
**SAE Compensation:** NA

## 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

<b>Cover letter</b>	 <a href="#">View File</a>
<b>Brief CV of all Investigators- Updated, signed and dated</b>	 <a href="#">View File</a>
<b>Good Clinical Practice (GCP) training of investigators in last 3 years</b>	 <a href="#">View File</a>
<b>EC clearance of other centers</b>	File: null
<b>Agreement between collaborating partners</b>	File: null
<b>MTA between collaborating partners</b>	File: null
<b>Insurance policy / certificate</b>	 <a href="#">View File</a>
<b>Copy of CTA signed with the sponsor</b>	 <a href="#">View File</a>
<b>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</b>	File: null
<b>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)</b>	 <a href="#">View File</a>
<b>Investigators Brochure (If applicable for drug / biologicals / device trials)</b>	 <a href="#">View File</a>
<b>Participant Information Sheet (PIS) and Informed Consent Form (ICF) (English and translated) with version number and dated</b>	 <a href="#">View File</a>
<b>Assent form for minors (12-18 years) (English and Translated)</b>	File: null
<b>Proforma / Questionnaire / Case Report Forms (CRF) / Interview guides / Guides for Focused Group Discussions (FGDs) (English and translated)</b>	 <a href="#">View File</a>

**Advertisement / material to recruit participants  
(fliers, posters, etc.)**

File: null

**DCGI Approval letter**

 [View File](#)

**Others specify**

File: null