

# Clinical Research Submission

---

Last Modified: 4/7/2025, 9:44:50 am

## 1. Administration

Name of Research Principal: Shanmuka Sagar

Department: computer science

Study Title: AI

Review Requested: Expedited Review

Submission Date: 3/7/2025

Submitted At: 3/7/2025, 9:55:55 am

Version Number: 2154BHG

Date: 3/7/2025

Protocol Number: 1254HGF

Email: 251020

Summary: Doing project based on artificial intelligence.

Selected Elements:

- No more than minimal risk to the trial participants
- ,
- Research involving clinical documentation materials that are nonidentifiable (data, documents, records);
- ,
- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;

Other Reason:

## 2. Investigators

### Researchers

Name: shanmuka sagar

Designation: software engineer

Qualification: B.Tech  
Department: CSE  
Investigator Type: Principal Investigator  
Email: 251020  
Alternate Gmail: shanmukasagar2019@gmail.com  
Contact: 8688345501  
Approved: No  
Approval Token: dfe3b7c4-36e0-428f-b486-32feb5f96095

,  
Name: srinivasa rao  
Designation: software developer  
Qualification: B.Tech  
Department: CSE  
Investigator Type: Guide  
Email: 251020  
Alternate Gmail: shanmukasagar2021@gmail.com  
Contact: 9989943631  
Approved: No  
Approval Token: 353b462a-c68c-4e55-9c1d-450e2275a51c

,  
Name: sujatha  
Designation: Devops engineer  
Qualification: B.Tech  
Department: CSE  
Investigator Type: hod  
Email: 251020  
Alternate Gmail: nimstech25@gmail.com  
Contact: 9999988888  
Approved: No  
Approval Token: c5bb92f3-996f-438b-b9a3-1221813eb7e7

,  
Name: Bharath  
Designation: VFX  
Qualification: Inter  
Department: MPC  
Investigator Type: Co-investigator  
Email: 251020  
Alternate Gmail: shanmukasagar2023@gmail.com  
Contact: 6309596531  
Approved: No

## Funding Details

Funding Source: Pharmaceutical Industry sponsored

Total Estimated Budget: ₹ 300000

false false < >

Sponsor Name: undefined

Sponsor PAN: undefined

Sponsor GST: undefined

Total Grant: ₹ undefined

Budget Items:

undefined

NIMS Investigations:

undefined

Personnel:

undefined

Is Outsourced: No

Outsourced Investigations:

undefined

## Overview of the Research

Summary: sfhfhsk fsk fskfhk fslfjslfjs f slfjslf

Type of Study: retrospective

Other Study Type: null

External Laboratory Involved: No

Specify (if External Lab):

Justification: sfsfhskf

Sample Size: slkjslkfj

Email: 251020

## Participants

Type of Participants: vulnerable

Specify (if applicable): N/A

Justification: fjkshfks kfs fkshfk

Additional Safeguards: fshfkshfksf skfs kfsf

Reimbursement Details: slfsklf s fkshfkls

Advertisement Details:

Payment Type: Yes

Advertisement Type: No

Email: 251020

{/\* Vulnerable Groups \*/}

Vulnerable Groups:

Economically and socially disadvantaged

,

Unduly influenced due to fear/benefits

,

Children (up to 18 years)

,

Women in special situations

## Benefits Details

Reimbursement Details: sfjskfhs khfk fhsf

Risk Management Strategy: fkshfkjshfks fshfksjfh k fhskfhk ff ksfks fksfhks fk

Anticipated Type of Benefits: Yes

Participant Benefits: Direct

Society Benefits: Direct

Improvement Benefits: Direct

Email: 251020

## Consent Details

Seeking Waiver of Consent Type: No

Specify:

Email: 251020

Version Number: fshfksfh ks fk

Date: 4/7/2025

Subject: No

Certificates: No

{/\* Language details \*/}

Selected Languages: Telugu

**Telugu**

Version: fshkfhksfsk fkhk

Date: 10/7/2025

{/\* PIS selected items \*/}

PIS Selected Items:

Statement that study involves research & explain purpose of research

,

Statement that consent & participation are voluntary

,

Expected Risks and benefits to the study subject

{/\* Summary \*/}

Summary: sfskfkfhk sff jsfjh f

{/\* Waiver Selected Elements \*/}

Waiver Selected Elements:

research cannot practically be carried out without the waiver and the waiver is scientifically justified

,

retrospective studies, where the participants are de-identified or cannot be contacted

,

research on anonymized biological samples/data

**Compensation & Payment Details**

Waiver of Consent Type: Yes

Specify: fsfhskfhskfhsk f

Compensation for Research-Related Injury: Yes

Specific Compensation Details: fhskfhksfj sfkhskf

Email: 251020

**Storage and Access Details**

Control Details:

Access Details:

Sample Access Type: No  
Sample Details:  
Document Access Type: No  
Drugs Access Type: No  
Email: 251020  
null

## Additional Support Information

Support Type: Yes  
Additional Details: jlkjflsjflf sljflsf  
Email: 251020

## Declaration

### Selected Declarations:

- 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 ICMR  
National Ethical Guidelines for Biomedical and Health Research involving  
HumanParticipants and other applicable regulations and guidelines including  
responsible  
,
- I/We will comply with all policies and guidelines of the institute and affiliated /  
collaborating institutions wherever applicable  
,
- I/We confirm that we shall submit any protocol amendments, adverse events  
report,significant deviations from protocols, regular progress reports and a final report  
and also participate in any audit of the study if needed  
,
- I/We confirm that we will maintain accurate and complete records of all aspects of the  
study.  
,

- I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.

Principal Investigator: Shanmuka sagar

Date: 3/7/2025

Signature: shanmuka sagar

## 14. Checklist

**Copy of the detailed protocol (clearly identified numbered and dated) and synopsis**

 [View File](#)

**Cover letter enlisting all documents enclosed**

 [View File](#)

**Participant Information Sheet (PIS) and Informed Consent Form (ICF)**

 [View File](#)

**MOU between collaborating partners**

File: null

**Good Clinical Practice (GCP) training of investigators in last 3 years**

 [View File](#)

**EC clearance of other centers**

File: null

**CRF / Interview guides / Focused Group Discussions (English and translated)**

 [View File](#)

**Assent form for minors (12-18 years)**

File: null

**Advertisement / material to recruit participants**

File: null

**Insurance policy / participant coverage details**

File: null

**Brief CV of all Investigators (updated, signed and dated)**

 [View File](#)