

Clinical Research Submission

Last Modified: 4/7/2025, 10:11:52 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

Employee code: 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
Employee code: 251020
Alternate Gmail: shanmukasagar2019@gmail.com
Contact: 8688345501

,
Name: srinivasa rao
Designation: software developer
Qualification: B.Tech
Department: CSE
Investigator Type: Guide
Employee code: 251020
Alternate Gmail: shanmukasagar2021@gmail.com
Contact: 9989943631

,
Name: sujatha
Designation: Devops engineer
Qualification: B.Tech
Department: CSE
Investigator Type: hod
Employee code: 251020
Alternate Gmail: nimstech25@gmail.com
Contact: 9999988888

,
Name: Bharath
Designation: VFX
Qualification: Inter
Department: MPC
Investigator Type: Co-investigator
Employee code: 251020
Alternate Gmail: shanmukasagar2023@gmail.com
Contact: 6309596531

Funding Details

Funding Source: Pharmaceutical Industry sponsored
Total Estimated Budget: ₹ 300000
false false

Sponsor Name: 12345
Sponsor PAN: 254njhg

Sponsor GST:

2154

Total Grant:

₹ 700

Budget Items:

Per completed patients

• total sponsor grant:

300000

Per completed patients

manpower sponsor grant

(PI, Co-PI, coordinator,

• others):

3000

Per completed patients

• overhead:

3000

• Startup fee:

2000

• Archival fee:

5000

NIMS Investigations:

- Name:

sagar

Cost:

500
- Name:

hello

Cost:

200

Personnel:

- Designation:

hello

Fees:

600

Is Outsourced: Yes

Outsourced

Investigations:

- Name:

Lab:

NABL:

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
Employee code: 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
Employee code: 251020
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: sfjskfshskhfk fhshf
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
Employee code: 251020

Consent Details

Seeking Waiver of Consent Type: No
Specify:
Employee code: 251020
Version Number: fshfksfh ks fk

Date: 4/7/2025

Subject: No

Certificates: No

Selected Languages: Telugu

Telugu

Version: fshkfhksfsk fkhk

Date: 10/7/2025

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: sfskfkfhk sff jsfjh f

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

Employee code: 251020

Storage and Access Details

Control Details:

Access Details:

Sample Access Type: No

Sample Details:

Document Access Type: No

Drugs Access Type: No

Employee code: 251020

null

Additional Support Information

Support Type: Yes

Additional Details: jlkjflsjflf sljflsf

Employee code: 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

Cover letter enlisting all documents enclosed

 [View File](#)

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

 [View File](#)

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

 [View File](#)

MOU between collaborating partners

File: null

EC clearance of other centers

File: null

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

 [View File](#)

Advertisement / material to recruit participants

File: null

Assent form for minors (12-18 years)

File: null

Insurance policy / participant coverage details

File: null

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

 [View File](#)

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

 [View File](#)