Clinical Research Submission

Last Modified: 8/7/2025, 11:44:28 am

1. Administration

Name of Research Principal: Shanmuka Sagar
Department: compuer science
Study Title: Artificial Intellegence.
Review Requested: Expedited Review
Submission Date: 4/7/2025
Submitted At: 3/7/2025, 9:55:55 am
Version Number: 2154BHG
Date: 30/6/2025
Protocol Number: 1254HGF
Employee code: 251020
Summary: Doing project based on artificial intellegence.
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: Bharath
Designation: VFX
Qualification: Inter
Department: MPC
Investigator Type: Co-investigator
Employee code: 251020
Alternate Gmail: shanmukasagar2023@gmail.com
Contact: 6309596531
,
Name: sujatha
Designation: Devops engineer
Qualification: B.Tech
Department: CSE
Investigator Type: hod
Employee code: 251020
Alternate Gmail: nimstech25@gmail.com
Contact: 9999988888

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: sfjskfhskhfk 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
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

Copy of the detailed protocol (clearly identified numbered and dated) and synopsis	View File
EC clearance of other centers	File: null

CRF / Interview guides / Focused Group Discussions (English and translated)	View File
MOU between collaborating partners	File: null
Cover letter enlisting all documents enclosed	View File
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
Good Clinical Practice (GCP) training of investigators in last 3 years	View File
Advertisement / material to recruit participants	File: null
Brief CV of all Investigators (updated, signed and dated)	View File