

Clinical Research Submission

1. Administration

Name of Research Principal: shanmuka sagar

Department: fhshkshfk

Study Title: ksfhksfksafhkg

Review Requested: Expedited Review

Submission Date: 20/6/2025

Submitted At: 19/6/2025, 9:34:46 am

Version Number: 4646fsff

Date: 16/6/2025

Protocol Number: 16546431vsv

Email: test4@gmail.com

Summary: jdlgjlsgjl

Selected Elements:

- Research involving clinical documentation materials that are nonidentifiable (data, documents, records);

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- No more than minimal risk to the trial participants

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- Any other reason, specify

Other Reason: sgdjgljksgljkgs

2. Investigators

Researchers

Name: shanmuka sagar

Designation: software engineer

Qualification: B.Tech

Department: cse

Investigator Type: Principal Investigator

Email: test4@gmail.com

Alternate Gmail: shanmukasagar2019@gmail.com

Contact: 8688345501

Approved: No

Approval Token: df42e798-abfd-46f2-a803-6145565c2bbf

,

Name: shanmuka sagar

Designation: software engineer

Qualification: B.Tech

Department: cse

Investigator Type: Guide

Email: test4@gmail.com

Alternate Gmail: shanmukasagar2021@gmail.com

Contact: 8688345501

Approved: No

Approval Token: 156d58a2-1da1-4b94-96be-73e270cffad5

Funding Details

Funding Source: self-funding

Overview of the Research

Summary: The project is medical clinical trail.
Type of Study: case-control
Other Study Type: hjgjk
External Laboratory Involved: Yes
Specify (if External Lab): fhskfhsf hjkfhskhf
Justification: shkfsfkh
Email: test4@gmail.com

Participants

Type of Participants: vulnerable
Specify (if applicable): N/A
Justification: hfksfhksh jkfhskfhkf jfhskfhskf
Additional Safeguards: ffksfhksfhks jfhskfshfk jhhfhsakfhkaf
Reimbursement Details: hfhsfkshf jjjkshfkshf
Advertisement Details: kfhsfhksfhkalfa fhkfhksf
Payment Type: Yes
Advertisement Type: Yes
Email: test4@gmail.com
{ /* Vulnerable Groups */}
Vulnerable Groups:
Economically and socially disadvantaged
, Children (up to 18 years)

Benefits Details

Reimbursement Details: fkhfkhsf
Risk Management Strategy: fhkfhskf fhksfhk
Anticipated Type of Benefits: Yes
Participant Benefits: Direct
Society Benefits: Direct
Improvement Benefits: Direct
Email: test4@gmail.com

Consent Details

Seeking Waiver of Consent Type: Yes
Specify: Feedback
Email: test4@gmail.com
Version Number: jlgdjgl446
Date: 19/6/2025
Subject: Yes
Certificates: Yes
{ /* Language details */}
Selected Languages: Telugu
Telugu
Version: lgdghklhg
Date: 18/6/2025
{ /* 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

Alternatives procedures / therapies available

{/* Summary */}

Summary: fhfh

{/* 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

certain types of public health studies/surveillance programmes/programme evaluation studies

research on data available in the public domain

research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent.

Compensation & Payment Details

Waiver of Consent Type: Yes

Specify: fsjfgjfgsj hhfshfkjs

Compensation for Research-Related Injury: Yes

Specific Compensation Details: sjfhsfklshKLF SFfkshfkshfk hfghfhfhfhfhfh fhfdhdhfhfdh hfhfhfh fhfhfh fhfhfh fhfh h

Email: test4@gmail.com

Storage and Access Details

Control Details: bmbmgjfjj fhfhfh

Access Details: fhfhfhfhfh fhfhfhfh

Sample Access Type: Yes

Sample Details: Unidentified

Document Access Type: Yes

Drugs Access Type: Yes

Email: test4@gmail.com

null

Additional Support Information

Support Type: Yes

Additional Details: hlkhhl

Email: test4@gmail.com

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

Principal Investigator: shanmuka sagar

Date: 20/6/2025

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
CRF / Interview guides / FGDs (English and translated)	 View File
Copy of the detailed protocol (clearly identified numbered and dated) and synopsis	 View File
Brief CV of all Investigators (updated, signed and dated)	 View File
Advertisement / material to recruit participants	 View File
Insurance policy / participant coverage details	 View File
Assent form for minors (12-18 years)	 View File
EC clearance of other centers	 View File
Participant Information Sheet (PIS) and Informed Consent Form (ICF)	 View File
Application for waiver of consent if applicable	 View File
MOU between collaborating partners	 View File