Clinical Research Submission

1. Administration

Name of Research Principal: shanmuka sagar
Department: fhsfhkshfk
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);
,
• No more than minimal risk to the trial participants
,
• 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

Total Estimated Budget: ₹254525

Overview of the Research

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

Participants

Type of Participants: vulnerable
Specify (if applicable): N/A
Justification: hfksfhksh jkfhskfhkf jfhskfhsfk
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: fhkfhsfk 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 hfghfhhfhfhfhfh fhfdhdhfhfdh hfhfhfh hfhfh fhfhf fhfhf fhfh h
Email: test4@gmail.com

Storage and Access Details

Control Details: bmbmgjfjj hfhfh
Access Details: fhfhfhfhf 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: hlkhlhl
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

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
Cover letter enlisting all documents enclosed	View File
CRF / Interview guides / FGDs (English and translated)	View File
Good Clinical Practice (GCP) training of investigators in last 3 years	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