

Clinical Research Submission

Last Modified: 8/7/2025, 4:47:17 pm

1. Administration

Name of Research Principal: Dr.PPoonam Baral

Department: Clinical Pharmacology and Therapeutics

Study Title: Knowledge ,Attitude and Practices of caregivers in diarrheal diseases of under 5 children with special reference to the use of medications

Review Requested: Full Committee Review

Submission Date: 8/7/2025

Submitted At: 8/7/2025, 6:02:22 am

Version Number: 01

Date: 29/6/2025

Protocol Number: AB12

Employee code: 51046

Summary:

Selected Elements:

Other Reason:

2. Investigators

Researchers

Name: Dr.Poonam Baral

Designation: Senior resident

Qualification: MBBS MD

Department: Clinical Pharmacology and Therapeutics

Investigator Type: Principal Investigator

Employee code: 51046

Alternate Gmail: shanmukasagar2019@gmail.com

Contact: 9937840937

Name: Dr.Abinash Panda
Designation: Associate professor
Qualification: MBBS MD
Department: Pharmacology
Investigator Type: Guide
Employee code: 51046
Alternate Gmail: shanmukasagar2021@gmail.com
Contact: 9874563452

Name: Dr.JAYANTI Prava Behera
Designation: PROFESSOR
Qualification: MBBS MD
Department: PHARMACOLOGY
Investigator Type: hod
Employee code: 51046
Alternate Gmail: shanmukasagar2023@gmail.com
Contact: 9987879986

Funding Details

Funding Source: self-funding

Total Estimated Budget: ₹ 50000

Proposed Budget: ₹ 50000

Cost Per Patient: ₹ 50

Total Project Cost: ₹ 50000

NIMS Investigations:

- **Name:** CYP 3A4 Study
Cost: 500

Is Outsourced: Yes

Outsourced

Investigations:

- **Name:**
Cost:
Lab:
NABL:

false false

Overview of the Research

Summary: To study the genetic profile of patients on warfarin

Type of Study: cross-sectional

Other Study Type: null

External Laboratory Involved: No

Specify (if External Lab):

Justification: To simplify drug dosing

Sample Size: 50

Employee code: 51046

Participants

Type of Participants: patient

Specify (if applicable): N/A

Justification:

Additional Safeguards:

Reimbursement Details:

Advertisement Details:

Payment Type: No

Advertisement Type: No

Employee code: 51046

Vulnerable Groups:

Benefits Details

Reimbursement Details:

Risk Management Strategy:

Anticipated Type of Benefits: No

Participant Benefits: Indirect

Society Benefits: Indirect

Improvement Benefits: Direct

Employee code: 51046

Consent Details

Seeking Waiver of Consent Type: No

Specify:

Employee code: 51046

Version Number: 01

Date: 8/7/2025

Subject: No

Certificates: No

Selected Languages: Telugu

Telugu

Version: cpt/tel

Date: 8/7/2025

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
- Alternatives procedures / therapies available
- Contact information of PI and Member Secretary of EC
- Financial compensation and medical management in SAE
- Right to withdraw from study at any time
- Expected duration of participation
- Maintenance of Confidentiality
- Responsibility of subject

Summary:

Waiver Selected Elements:

Compensation & Payment Details

Waiver of Consent Type: No

Specify: hksfhkshf

Compensation for Research-Related Injury: Yes

Specific Compensation Details: fhskhfksfh

Employee code: 51046

Storage and Access Details

Control Details: documents will be kept under lock and key

Access Details:

Sample Access Type: Yes

Sample Details: Unidentified
Document Access Type: Yes
Drugs Access Type: NA
Employee code: 51046
null

Additional Support Information

Support Type: No
Additional Details:
Employee code: 51046

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: Dr. Poonam Baral

Date: 8/7/2025

Signature: poonam

<>

Co-PI / Guide: Dr. Padmaja

Date: 8/7/2025

Signature: Padmaja

<>

HOD: Dr. P Usharani

Date: 8/7/2025

Signature: Usharani

14. Checklist

Cover letter enlisting all documents enclosed

 [View File](#)

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

 [View File](#)

EC clearance of other centers

File: null

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

 [View File](#)

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

 [View File](#)

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

 [View File](#)

MOU between collaborating partners

File: null

Advertisement / material to recruit participants

File: null

Assent form for minors (12-18 years)

File: null

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

 [View File](#)

Insurance policy / participant coverage details

File: null