Invitation for Expression of Interest for providing Clinical Trials Liability Insurance for a Randomized Controlled Trial

Government Medical College and Hospital, Chandigarh is conducting a trial, titled **"Standard therapy versus PLasmalyte In children with Dengue Shock Syndrome (SPLID TRIAL): an open labelled randomised control trial."**

The PI is Dr Vidushi Mahajan, Department of Pediatrics, GMCH 32, Chandigarh.

This is a phase III, mono-centre, investigator-initiated, three-arm, parallel-group, stratified and block-randomized controlled trial. The primary objective is to determine the change in serum chloride between standard treatment vs. Plasmalyte within 48 hours of fluid resuscitation in dengue shock syndrome.

This study plans to recruit 144 children of 2 months to 18 years of age who develop dengue shock syndrome (48 patients in Plasmalyte, 48 patients in Ringer Lactate and 48 patients in Normal Saline) and the duration of the trial is 3 years.

Request for proposals are invited from eligible parties who are interested in providing clinical trials liability policy or liability insurance, indicating the conditions and extent of coverage, date of commencement and expiry of coverage, and conditions thereof, including the premium and other costs, as per rules, for the aforementioned study.

The terms of the policy are:

1. Professional Indemnification for: Investigators, physicians, nurses, research staff and the trial site.
2. Compensation for 'trial related injuries' for study participants as per Central Drugs Standard Control Organisation.
   Note- Please download the 'technical specifications' for the details of the coverage and rules for insurance from the GMCH-32 website along with EOI.
3. You also need to sign the CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT for this trial. Please download the document attached to this EOI.

SCHEDULE OF EoI PROCESS

The Schedule of activities during the EoI Process shall be as follows-

Sl. No.	Description	Date
1	Issue of EoI document	**09.11.2024**
2.	Last date of submission of EoI response	**20.11.2024; 17:00 Hrs**

Please submit your expression of interest to Email: drvidushiicmr@gmail.com with complete documentation.

Please email on the above-mentioned email address if you need any further clarification.

Please submit the hard copy to the following address:

Vidushi Mahajan

Dr Vidushi Mahajan
Associate Professor
Department of Pediatrics
GMCH, Sector 32
Chandigarh 160031
Tel +91-172- 2665252-60 Extn. 2503 (Office)

Technical Specifications: Liability Insurance Service (Clinical Trial Liability Insurance)

Project: "Standard therapy versus PLasmalyte in children with Dengue Shock Syndrome (SPLID TRIAL): an open labelled randomized control trial, IIRP-2023-327F1."

S. No.	Item	Specification
1.	Phase of trial and sponsor	Clinical trial (Phase III) sponsored by Indian Council of Medical Research (ICMR), New Delhi
2.	Sites of the trial	Clinical trial will be conducted at Government Medical College & Hospital (GMCH 32), Chandigarh
3.	Sample size and maximum upper limit of subjects to be covered by clinical trial insurance	Total sample size:135
4.	Per patient sublimit (Sub-limit includes liability arising due to no fault compensation for death or SAE as well as legal defense costs)	• INR 9.18 Lacs for per trial related death, • INR 8.26 lacs per child for trial related 100% disability, • INR 4.13 lacs per child for trial related 50% disability, • INR 11490.0 per child for trial related wage loss during hospitalization period.
5.	**Aggregate Any One Year (AOY) Limit**	
	a) Year 1 of the project (To cover 20% of the subjects at risk)	• INR-3097980.00
	b) Year 2 of the project (To cover 40% of the subjects at risk.	• INR-7457940.00
	c)Year 3 of the project (To cover 40% of the subjects at risk)	• INR-7457940.00
6.	**Any One Accident (AOA)**	
	a) Year1 of the project (To cover 16.6% of the subjects at risk)	• INR-3097800.00
	b)Year 2 of the project (To cover 50% of the subjects at risk)	• INR-7457940.00
	c)Year 3 of the project (To cover 33.33% of the subjects at risk)	• INR-7457940.00
7.	The upper limit to the number of claims of compensation for death or SAE or legal defense costs that will be awarded per annum will be limited only by:	a) the total number of patients recruited in that 12-month period
		b) the aggregate compensation that can be accommodated with the AOY amount.
8.	Restrictions to number of claims that can be awarded per annum	Barring points 7(a) and 7(b), there will be no other restriction to the number of claims of compensation for death or SAE or legal defense costs that can be awarded per annum.
9.	Formula used to calculate compensation	Compensation provided to patients participating in the research study for death and serious adverse events (SAE) other than death will be as per the formula devised and revised from time to time by the Central Drugs Standard Control Organization (CDSCO), New Delhi.
10.	Legal defense costs	(a) Legal defense costs included within the per patient sub- limit
		(b) Limit of Liability Proposed Policy Period- 48 months from the date of inception
11.	Reporting period for submitting claims	(a) Reporting period for submitting claim for compensation for death or SAE other than death will ordinarily be in the 12-month annual policy period, within which the SAE or death occurred, irrespective of the date of enrolment of the subject.
		(b) Reporting period for submitting claim for legal costs will ordinarily be in the 12-month annual policy period, within which the legal cost was incurred, irrespective of the date of enrolment of the subject.
12.	Extended reporting period:	To account for death, SAE or legal costs incurred towards the end of a 12-month annual policy period, an extended reporting period of 4 months must be provided after the end of each annual policy period during which time a claim of death, SAE or legal costs can be notified.
13.	Deductibles:	(a) Deductible per claim will not exceed INR 20,000

Vidushi Mahajan

		(b) Aggregate upper limit of the deductibles of all claims will be capped at INR 1 lakh per annum or less.
		(c) The aggregate upper limit on the deductibles will be irrespective of the number of patients for whom claims are submitted and irrespective of the amount claimed within the limits of the AOY, AOA and per-patient sub-limit.
14.	Authority that will decide whether death or SAE is related to participation in the clinical trial	(a)Whether an enrolled patient's SAE or death is related to the clinical trial will solely be determined by the Data Safety Monitoring Committee
		(b)The vendor will have no authority to decide on matters of relationship of the SAE or death to the trial.
15.	Exemption or denial of compensation	Failure of the intervention or the standard treatment in the clinical trial to provide the intended effect will not be considered to be an exemption to deny compensation for death or SAE of any patient enrolled in the trial.
16.	Submission of quotations	The vendor will submit quotes for each year of the Three-year trial upfront for all three participating centers.
17.	Renewal of insurance cover	(a) Insurance cover will be renewed on an annual basis for 3 years.
		(b) The Insurance company/Vendor will not refuse renewal on account of claims if any in the preceding year.
18.	Legal liability coverage	(a) Vendor will provide legal liability cover for the research investigators, the sponsor (ICMR, New Delhi), institutional ethics committee members, all research staff employed under the project, subject to the below mentioned points:
		(b) The policy will cover the costs resulting due to legal cases arising from the conduct of the study.
		(c) The coverage will be extended to include negligent act, error or omission of the insured in rendering or failure to render medical professional services to the enrolled patient during the period that the patient was in the clinical trial, which result in or may result in the adverse event or death of the patient.
		(d) Legal defense costs will be included within the per patient sub-limit of liability, ie. the sub-limit will include both the compensation to patients for death or SAE as well as legal defense costs.
		(e) Time limit for submitting claim for legal defense costs: any time within the 12-month policy period that the legal defense cost was incurred, *irrespective of the time period when the concerned patient actually suffered a SAE or death* plus the extended reporting period.
19.	Arbitration	In case of any dispute regarding insurance claims the standard government norms for arbitration will be followed

Vidushi Mahajan

CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT

THIS CONFIDENTIALITY AND NON-DISCLOSURE AGREEMENT made this ___August, 2024 (here in after referred to as the effective date) between **Department of Pediatrics, Government Medical College & Hospital** whose address is Sector 32, Chandigarh-160030, a Public Medical College in Chandigarh, India through **Dr Vidushi Mahajan, Department of Pediatrics, GMCH 32,** Chandigarh , the authorised representative (here in after referred to as **GMCH 32**) which expression unless repugnant to the context and meaning thereof include its successors and assigns) of the FIRST PART .

AND

..... whose address is ..... through ..... the authorised person of the SECOND PART.

WHEREAS both **GMCH 32** and ..... individually known as a Party, however they are collectively known as Parties.

WHEREAS, the parties wish to disclose Confidential Material related to **"Standard therapy versus PLasmalyte In children with Dengue Shock Syndrome (SPLID TRIAL): an open labelled randomised control trial".** (the purpose); and

WHEREAS, the parties require that the Confidential Material be held in confidence and used for the limited purpose set forth herein.

NOW, THEREFORE, in consideration of the mutual promises herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Definition. **"Confidential Material"** shall mean any and all information that the Disclosing Party discloses to Recipient. "Information" shall include but not be limited to the following types of information: patents and patent applications, clinical and research strategies, trade secrets, proprietary information, business plans, financial information and forecasts, assays, techniques, works of authorship, models, inventions, processes, research, experimental work, development, design details and specifications, processes or plans, manufacturing information, pre – clinical and clinical information and information of any kind whatsoever, whether written or oral, disclosed or provided by one party hereto to the other, or the other's employees and advisors, or discovered by a party, or its employees or advisors, as a result of the work contemplated herein. Confidential Material shall not include:

a. Material that is now in the public domain or subsequently enters the public domain through no fault of the receiving party.

b. Material that is presently known to the receiving party and is at its free disposal (having been generated independently by the receiving party or a third party in circumstances where it has not been derived directly or indirectly from this disclosing party's Confidential Material) prior to its receipt from the disclosing party provided that evidence of such knowledge is furnished by the receiving party to the disclosing party within 30 days of receipt of that Confidential Material from the disclosing party.

c. Material that the receiving party receives from any third party not under any obligation to the disclosing party to keep such information confidential.

d. Restriction on Disclosure. Any receiving party agrees to maintain in confidence all Confidential Material received by it unless required to disclose same by applicable law, by a court of competent jurisdiction, by any governmental agency having supervisory authority over the business of the disclosing party, or by any administrative body or legislative body (including a committee thereof) with jurisdiction to order the receiving party to divulge, disclose or make accessible such information; provided, however, that the receiving party shall provide the disclosing party with notices of any judicial, administrative or other governmental order or decree referencing such disclosure promptly after the receiving party is notified thereof and prior to its disclosure thereof so as to enable the disclosing party to challenge the order or decree compelling such disclosure. The Receiving Party shall only disclose said Confidential Material to their respective employees or legal, financial or other advisory, collectively referred as 'Representatives' strictly on a "need to know" basis only, and these representatives are bound by obligations of confidentiality substantially similar to those in this Agreement.

e. TERM:
The term during which disclosures may be made and received under this Agreement will be five years from the Effective Date. The Receiving Party's obligations under this Agreement will terminate five (5) years from the expiration or termination for any reason of this Agreement.

2. Use of Confidential Material. All Confidential Material shall be used for the sole and limited purpose set forth in this agreement and for no other purpose without the prior written consent of the disclosing party. The Receiving Party may use, copy and make extracts of the Disclosing Party's Confidential Information only in connection with the Purpose.

3. Ownership of Confidential Material. All Confidential Material shall remain the exclusive property of the disclosing party and, unless otherwise agreed by the parties, all written Confidential Material including that portion of the Confidential Material that may be found in analyses, compilations, studies or other documents prepared by or for the receiving party, shall be promptly destroyed upon request of said party without the retention of any copies thereof if and at such time as either party informs the other that it will not go forward with the Affiliation; provided, however, that any receiving party shall be entitled to maintain one copy of the disclosing party's Confidential Material, for the sole purpose of ascertaining its on-going rights and responsibilities in respect of such information. The receiving party shall not be required to destroy any computer files stored securely by the Receiving Party or its Affiliates that are created during automatic system back up; or retained for legal purposes by the legal division of the Receiving Party and its Affiliates. In the event a party requests the other to destroy Confidential Material, the other party shall certify in writing to the requesting party the destruction of such Material.

Remedy. The parties agree that any deliberate and specific material breach of this Agreement by either party hereto may result in irreparable harm to the other that may not be adequate compensable in money damages. The parties therefore agree that each party hereto shall be entitled to seek such injunctive and other equitable relief as may be necessary to protect its Confidential Material. The parties agree and acknowledge that any disclosure of any Confidential Information prohibited herein or any breach of the provisions herein may result in an irreparable injury and damage to the disclosing

party which will not be adequately compensable in terms of monetary damages. The disclosing party will have no adequate remedy at law thereof, and that the disclosing party may, in addition to all other remedies available to it at law or in equity, obtain such preliminary ,temporary or permanent mandatory orders restraining injunctions, orders or decrees as may be necessary to protect itself against, or on account of, any breach by the recipient of the provisions contained herein, and the recipient agrees to reimburse the reasonable legal fees and other costs incurred by the disclosing party in enforcing the provisions of this Agreement.

4. No licenses. No right or licenses express or implied, are hereby granted to the receiving party in or to any patents, copyrights, trade secrets or Confidential Material of the disclosing party as a result of this Agreement or any disclosure made hereunder.

5. Miscellaneous.

a. This Agreement may not be modified, amended or discharged, in whole or in part, except by a writing signed by both the parties.

b. This Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and assigns.

c. This Agreement supersedes all prior agreements, written or oral, between the parties relating to the subject matter of this Agreement.

d. This Agreement shall be governed by and construed with solely in accordance with the laws of India in every particular, including formation and interpretation. Any proceedings arising out of or in connection with this Agreement shall be brought only before the Court of competent jurisdiction in the State Of Haryana. Union territory of Chandigarh.

e. This Agreement may be executed in two counterparts (including by facsimile or electronic copies), both of which shall be deemed an original, and both of which together shall constitute one and the same instrument.

6. Disclaimer

No warranties of any kind are given with respect to the Confidential Information disclosed under this Agreement or any use thereof, except as may be otherwise agreed to in writing. Neither party shall be liable to the other hereunder for amounts representing loss of profits, loss of business or indirect, consequential or punitive damages of the other party in connection with the provision or use of Information hereunder.

7. Waiver

No term or provision hereof will be considered waived and no breach excused by each of the parties, unless such waiver or consent is in writing signed by or on behalf of either of the parties. No consent or waiver of a breach by either party will constitute consent to the waiver of or excuse of any different or subsequent breach by the other party.

8. Severability

If any provision of this Agreement is found invalid or unenforceable, that part will be amended to achieve as nearly as possible the same effect as the original provision and the remainder of this Agreement will remain in full force.

9. Notices

Any notice provided for or permitted under this Agreement will be treated as having been given when
(a) Delivered personally,
(b) Sent by confirmed telecopy,
(c) Sent by commercial overnight courier with written verification of receipt, or
(d) Mailed postage prepaid by certified or registered mail, return receipt requested, to the party to be notified, at the address set forth below or at such other place of which the other party has been notified in accordance with the provisions of this clause.

10. Counterparts

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. The exchange of copies of this Agreement and of signature pages by facsimile transmission shall constitute effective execution and delivery of this Agreement as to the parties and may be used in lieu of the original Agreement for all purposes. Signatures of the parties transmitted by facsimile shall be deemed to be their original signatures for all purposes.

Such notice will be treated as having been received upon actual receipt or five days after posting.

IN WITNESS WHEREOF, THE PARTIES HAVE CAUSED THIS Agreement to be executed by their duly authorized representatives as of the date first written above.

For: - ……..

Signature: _____

Name: ……
Designation: ……

Date: ……

For :-Government Medical College & Hospital (GMCH 32), Chandigarh

Signature: _____

Name: Dr Vidushi Mahajan
Designation: Associate Professor,
Department of Pediatrics

Date: ……..