DATA TRANSFER AGREEMENT

This **DATA TRANSFER AGREEMENT ("Agreement")** is entered into as of _____ ("**Effective Date**").

BETWEEN

(1) Indian Society of Critical Care Medicine **{NAME OF First Party who will receive the data},** having its address, Unit 13 and 14, First floor, Hind Service Industries Premises Co-operative Society, Near Chaitya Bhoomi, Off Veer Savarkar Marg, Dadar, Mumbai-400028 **{detail address}** hereafter referred to as "**Recipient**" which expression shall unless it be repugnant to the context or meaning there of shall mean and include its successors and permitted assigns with the Recipient being represented by Dr Sachin Gupta **{PI NAME},** a representative of the Recipient (hereafter referred to as "**The Recipient Scientist**");

AND

(1) {NAME of Second Party who will send the data}, having its address at **{Details address}** hereafter referred to as "**Provider**" which expression shall unless it be repugnant to the context or meaning there of shall mean and include its successors and permitted assigns with the Recipient being represented by **{PI NAME},** an employee of the Provider (hereafter referred to as "**Principal Investigator**");

(2)

(Hereinafter individually a "**Party**" and collectively the "**Parties**")

Whereas, the Recipient, through the Recipient Scientist, has requested for data relating Trachesotomy Practice in ICU for Study Title **"Salt based Or baLanced solUtion. Trends Existing in Indian intensive care units. A multicenter prospective observational cohort study (SOLUTE study)"**

Whereas, Provider has agreed to share its study data to Recipient for further statistical analysis and evaluation.

In consideration of the premises and mutual covenants contained in this Agreement, the Parties agree as follows:

1 DEFINITIONS

"**Data**" means the details of the data transfer will be as mentioned in Schedule II and III.

1.1 "**Data Subject**" means the person (irrespective of state of health) to whom Data refers and who has been informed of the purpose for which the Data is held and has given his/ her informed consent thereto.

1.2 "**Intellectual Property**" means (i) patents, designs, trade marks and trade names (whether registered or unregistered), copyright and related rights, database rights, know-how and confidential information; (ii) all other intellectual property rights and similar or equivalent rights anywhere in the world which currently exist or are recognised in the future; and (iii) applications, extensions and renewals in relation to any such rights.

1.3 "**Project**" means the project as described in Schedule I.

1.4 "**Registered User**" means the Recipient Scientist and the research staff under the Recipient Scientist's direct supervision who will have access to the Data, all of whom shall agree to be bound by the terms and conditions of this Agreement by completing and signing the Registered User's Acceptance Form set out in Schedule II of this Agreement.

2 PURPOSE

2.1 The Recipient agrees to use Data only for the purpose of the Project.

Primary objective of the main study

- To capture data on the practice of fluid administration in critically ill patients
- To identify any possible relationship between incidence of new onset acute kidney injury with the type of intravenous fluid administered
- To compare normal saline with balanced crystalloid on renal outcomes and survival outcome

3 CONFIDENTIALITY

3.1 The Recipient and its Registered Users, agree to preserve, at all times, the confidentiality of Data pertaining to identifiable Data Subjects. In particular, the Recipient undertakes not to use, or attempt to use the Data to deliberately compromise or otherwise infringe the confidentiality of information on Data Subjects and their right to privacy.

4 REPRESENTATIONS, WARRANTIES AND COVENANTS

4.1 The Recipient and its Registered User represent, warrant and covenant that: -

(a) it will not analyse or make any use of the Data in such a way that has the potential to lead to the identification of any Data Subject or compromise the anonymity of any Data Subject in any way;

(b) it will not use or disclose the Data for the purpose other than as permitted by this Agreement;

(c) it will report to Provider immediately upon it being aware of an unauthorised use or disclosure of the Data;

(d) it will obtain all necessary approvals (including but not limited to the relevant institutional review board approval) for the use of the Data in the Project; and

(e) to comply with all the conditions specified in the protocol and its amendment and/or addenda, Good Clinical Practice guidelines and all other applicable laws and regulations and standards, any condition required by Ethics Committee.

5 ACCESS AND GOVERNANCE

5.1 The Recipient agrees that it, and its Registered User, shall take all reasonable security precautions to keep the Data confidential, such precautions to be no less onerous than those applied in respect of the Recipient's own confidential information.

5.2 The Recipient agrees to only give access to Data to a Registered User. The Recipient agrees that before it gives any Registered User access to Data, it shall first show the Registered User a copy of this Agreement and shall inform the Registered User that he or she must comply with the obligations contained in this Agreement.

6 INTELLECTUAL PROPERTY & PUBLICATION

6.1 Recipient recognizes that nothing in this Agreement shall operate to transfer to the Recipient or its Registered Users any Intellectual Property rights in or relating to the Data.

6.2 Provider grants to Recipient the non-exclusive, worldwide, perpetual, sub-licensable, royalty-free, fully paid up license to use all Data for Recipient's non-commercial, research and educational purposes.

6.3 Recipient shall inform Provider in confidence of Research Results related to the Data, by personal communication or by providing Provider with copies of manuscripts describing the Research Results of the Project at the time the manuscripts are submitted for publication. Provider shall at all times keep confidential and not disclose to any person, the Research Results or manuscripts received from the Recipient, unless with the prior consent of the Recipient.

6.4 Any research findings arising from this collaborative activity may be published / presented at national or international journals/conferences. The terms and conditions for such publications/presentations shall be mutually agreed upon. The authorship of the presentations and publications will be jointly decided by the Parties.

7 TERM AND TERMINATION OF AGREEMENT

7.1 This Agreement shall come into force on the Effective Date and will remain in effect for a period of one (01) year from the Effective Date or on the expiration of a thirty (30) days' written notice by either party.

7.2 This Agreement will terminate immediately upon any breach of the provisions of this Agreement by the Recipient or by any of the Registered Users.

7.3 In the event that this Agreement is terminated in accordance with this Clause 7.1 or 7.2, the Recipient shall return or destroy all Data at the direction of the Provider.

8 LEGAL STATEMENT

8.1 The Recipient and its Registered Users, understands that all the Data is protected by copyright and other intellectual property rights, such that duplication or sale of all of or part of the Data on any media is not permitted under any circumstances, except with the prior written consent of Provider.

8.2 The Provider shall ensure that the Data provided pursuant to this Agreement was collected or will be collected in accordance with the standard patient informed consent procedures of the Provider at the time of collection and subject to approval or an exemption determination by the Provider's Institutional Review Board ("IRB") or equivalent. Recipient may review the consent form used in the collection of the Data as well as any subsequent revisions thereof. Provider shall ensure that the Data provided to Recipient will not be accompanied by personally identifiable patient information. However, if de-identified information ("Information") is provided that nevertheless could be used to identify an individual at a later time, Recipient and Recipient Scientist agree to treat Information in compliance with **{applicable law of data sharing and protection}**. In any circumstances, the Recipient and Recipient Scientist agree to use the Information only for the Project and will not contact or make any effort to identify the human subjects from whom the Data was obtained without specific written approval from the Provider.

9 LIABILITY

9.1 THE DATA ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THE WARRANTY OF NON-INFRINGEMENT.

9.2 Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its direct use of the Data. To the fullest extent allowed by applicable law, neither Party shall be liable to the other Party for consequential, exemplary, punitive or indirect damages or loss incurred by the other Party arising out of

or in connection with this Agreement, even if such Party had been advised of the possibility of such damage.

10 GOVERNING LAW

10.1 This Agreement shall be construed, interpreted and governed by the laws of the India and shall be subject to the exclusive jurisdiction of the Mumbai courts

10.2 In the event of any dispute or difference arising out of or in connection with or in relation to this Agreement, including any question regarding the existence, validity, termination, application or interpretation of this Agreement or any of its provisions, or any claim, disagreement or dispute arising out of or relating to this Agreement or the breach of any of its provisions, the Parties shall use their best endeavours to settle the dispute informally by agreement between themselves. The Parties shall always act in good faith and co-operate with each other to resolve any disputes.

10.3 Any dispute which cannot be resolved by amicable settlement amongst the Parties arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration in Mumbai in accordance with the Arbitration and Conciliation Act, 1996 for the time being in force, which rules are deemed to be incorporated by reference to this clause. The language of the arbitration shall be English. Any award made hereunder shall be final and binding upon the Parties hereto and judgment on such award may be entered into any court or tribunal having jurisdiction thereof.

11 MISCELLANEOUS

11.1 Entire Agreement. This Agreement sets forth the entire agreement and understanding between the Parties as to the subject matter hereof.

11.2 No Agency or Partnership. This Agreement does not create any agency or partnership relationship between the Parties.

11.3 Use of Name or Marks. Neither Party may use the name, or any proprietary marks, of the other Party without the other Party's prior written approval.

11.4 Acknowledgement. Recipient will acknowledge the Provider as the source of the Data in any publication reporting on its use, unless requested otherwise by the Provider.

11.5 Amendments. Any amendment to this Agreement must be made in writing and signed by all Parties.

11.6 Severance. The invalidity or unenforceability of any provision of this Agreement determined by any court or administrative body of competent jurisdiction shall not affect the other provisions of this Agreement, which shall remain in full force and effect.

11.7 No Waiver. No waiver by a Party of any breach or default by the other Party shall operate as a waiver of any succeeding breach or other default or breach by such other Party. A waiver must be specific, irrevocable and in writing, to be effective. A Party's failure or delay in exercising any right or remedy provided under this Agreement or by law shall not constitute a waiver of that or any other right or remedy, nor shall it preclude or restrict such Party from any further exercise of that or any other right or remedy.

11.8 Assignment. Neither party may assign this agreement without the prior written consent of the other party.

11.9 Counterparts. This Agreement is executable in counterparts, each of which constitutes an original, and all of which together constitute one and the same agreement PROVIDED THAT this Agreement shall be of no force and effect until all counterparts are exchanged.

11.10 Electronic Execution. This Agreement and any counterparts may be executed electronically and such electronic version shall be treated as an original.

In witness whereof the Parties have set their hands on the date as first above written:

For and on behalf of **Indian Society of Critical Care Medicine** **Signature:** 	**For and on behalf of:** **Signature:**
Name: Dr Sachin Gupta	**Name:**
Title: National Principal Investigator of the Study	**Title:**
	Head of the Institution
	Name: **Title:** **Signature:**

Schedule I

The Project

Title of Project
(in less than 30 words)

Salt based Or baLanced solUtion. Trends Existing in Indian intensive care units. A multicenter prospective observational cohort study (SOLUTE study)

Research Use Statement
(Please provide a CLEAR description of the Project including the research objectives, the study design, the analysis plan and include key references.)

INTRODUCTION

The intravenous fluid administration is probably the most common intervention that one does in intensive care units (ICU) to increase the intravascular volume. The existing literature favors the use of crystalloids over colloids but within crystalloid the choice is still controversial.
Worldwide, 0.9% sodium chloride also known as normal saline (NS) remains the most preferred resuscitation fluid[1].
The use of NS has been associated with hyperchloremic metabolic acidosis[2] and sometimes with acute kidney injury (AKI)[3]. Nowadays, the practice is shifting towards using crystalloids having compositions similar to that of plasma, known as balanced solutions[4]. Many of the observational studies and other trials have suggested that use of balanced solution is associated with reduced incidence of AKI, renal replacement therapy (RRT) and eventually death. However, the recent SMART trial[5] could not find any such difference.
Till date there has been no data about the practice of fluid administration in Indian ICUs. We would like to collect data prospectively from various ICUs across the country regarding the nature of fluid administration both as boluses and as maintenance fluids. We would conduct this study over 8-month period. We want to compare normal saline with balanced crystalloids for incidence of AKI, need for RRT and overall outcome of the patients over a 28-day follow up period.

OBJECTIVES:

- To capture data on the practice of fluid administration in critically ill patient
- To identify any possible relationship between incidence of new onset acute kidney injury with the type of intravenous fluid administered

- To compare normal saline with balanced crystalloid on renal outcomes and survival outcome

METHODS:

Study design:

- Prospective Observational Multi-Centre National Cohort Study

Patient enrollment:

The study would invite all ICUs across the country to participate in the study. The invites will be sent at frequent intervals by the ISCCM office through emails. Hospitals with more than one ICU can enroll each ICU separately. Each ICU can contribute as much data as possible during the study period. Each ICU will designate one PI and one co-PI for the study who will be responsible for ethical committee clearance (if required), data collection and study co-ordination in their ICU. Each ICU will collect data from 1st May to 31st December. The study would end on 28th January 2021 when the final outcome data will be entered.
Each centre can start recording the data in paper CRF till they get an Ethics approval (if required) and later on can fill the data online.

Study timelines:

Email invitation to all ICUs: **1st April 2020**
Start of data collection: **1st May 2020**
Last date of data collection: **31st December 2020**
Last date of data entry: **28th January 2021**
Data cleaning and analysis: **Uptil 15th February 2021**
Presentation in CRITICARE 2021: **February 2021**
Publication**: 2021**

Inclusion Criteria:

- All adult patients (> 18yeras old) admitted to ICU receiving intravenous fluid administration as per their clinical condition

Exclusion Criteria:

- Patients on renal replacement therapy for end stage renal disease

- Patients expected to undergo or who undergo renal replacement therapy within 6 hours of ICU admission

Data Collection:

There will be no direct patient contact or change in intervention. The fluid administration will be given as per the physician guided protocol or any other protocol existing in the respective ICU. There will be no change in the prevailing practice of ICU. The data will be collected prospectively and filled in the Case Record Form (CRF). The fluid administered will be recorded as bolus (if more than 5ml/kg/hr has been administered within one hour), maintenance (the fluid which is given continuously to meet the daily fluid requirement) and as replacement (fluid which is given for replacement of losses like drain losses, gastric tube losses or given as dilution for antibiotics and other medications)
The following data will be collected:

- ***Baseline characteristics*** – age, gender, weight, co-morbidities, source of ICU admission, diagnosis at the time of admission, APACHE II & SOFA score on ICU admission, baseline serum creatinine
- ***Intervention details*** – Fluid administered in last 24 hours before ICU admission, first three days' details of fluid administration, urine output, fluid balance, laboratory values, arterial blood gases, daily SOFA scores and evidence of Sepsis as per SEPSIS-3 definition
- ***Outcome details*** – Need for renal replacement therapy, indications for RRT, renal outcomes as per RIFLE & KDIGO criteria, need for blood transfusion, ICU & Hospital length of stay, survival status of the patient at or before day 28.

Primary Outcome:

- Comparison of normal saline with balanced crystalloid fluid in incidence of new onset AKI

Secondary outcome:

- Need for renal replacement therapy
- Renal outcome as per RIFLE & KDIGO

- ICU survival status at day 28
- Hospital survival status at day 28

Sample Size:

The plan is to enroll as many ICUs in the country as possible. Each centre will collect data from all consecutive patients being admitted to ICU after ruling out exclusion criteria. An acceptable sample size would be atleast a total of 2000 patients.

STUDY REGISTRATION:

The Principal Investigator (PI) will register the study on CTRI and the registration number would be provided to them once available.

INSTITUTIONAL ETHICS COMMITTEE APPROVAL

All the local PI and Co-PI should ensure that they obtain the necessary Ethics Committee approval for the study, if deemed necessary by the institute. As this is an observational data collection with no intervention, the study can also be approved by the Head of the institute or Medical Superintendent if there is no Ethics Committee in the institute. As per the latest ICMR guidelines, this study falls in minor risk category where it is eligible for ethics exemption or an expedited review by ethics committee.

CONSENT FOR DATA COLLECTION:

This being an observational data collection with no change in the local practice of the institute, the consent is not required from the patient or their legally accepted representative. But if still the institute demands consent, then sample consent forms in Hindi and English will be provided.

STUDY FUNDING:

This is an ISCCM funded study. The ISCCM will fund the PI of the study for the expenses incurred related to software development, secretarial assistance, data analysis and other miscellaneous expenses against actual bills. No funding will be given to other investigators from other centres for contributing the data.

DATA OWNERSHIP:

As this is an ISCCM initiated project, the entire ownership of the data will be with the ISCCM.

PUBLICATION AND AUTHORSHIP POLICY:

The main results of the study will be published in a peer-reviewed medical journal.

The Authorship policy will follow the recommendations laid down by International Committee of Medical Journal Editors (ICMJE). The authorship would be decided on the basis of the contribution in study design, protocol writing, data interpretation and cleaning, data analysis and writing the final manuscript.

Steering Committee: Members would include 2 members from the PIs centre, ISCCM President, ISCCM Past President, President Elect, Research Committee Chairman, and PIs from top 5 centres contributing maximum data. The name of the Steering Committee members will be in the main author list.

The PI and Co PI of all the contributing centres will be included in the list of study collaborators and will be indexed in PubMed.

REFERENCES:

1. Finfer S, Liu B, Taylor C, Bellomo R, Billot L, Cook D, et al. SAFE TRIPS Investigators. Resuscitation fluid use in critically ill adults: an international cross-sectional study in 391 intensive care units. *Crit Care*. 2010;14(5):R185.
2. Yunos NM1, Kim IB, Bellomo R, Bailey M, Ho L, Story D et al. The biochemical effects of restricting chloride-rich fluids in intensive care. Crit Care Med 2011;39:2419-24.
3. Yunos NM, Bellomo R, Hegarty C, Story D, Ho L, Bailey M. Association between a chloride-liberal vs chloride-restrictive intravenous fluid administration strategy and kidney injury in critically ill adults. JAMA 2012;308:1566-72
4. Hammond NE, Taylor C, Finfer S, Machado FR, An Y, Billot L, et al. Patterns of intravenous fluid resuscitation use in adult intensive care patients between 2007 and 2014: an international cross-sectional study. PLoS One 2017; 12(5):e0176292.
5. Semler MW, Self WH, Wanderer JP, Ehrenfeld JM, Wang L, Byrne DW, et al. Balanced Crystalloids versus Saline in Critically Ill Adults. N Engl J Med 2018;378:829-39.