Informed Consent form for participation in I TOUCH study.

Intrahospital **T**ransport **o**f **U**nstable **C**ritical Care **H**ospitalized patient
A Practice Pattern Observational Multicenter Study (I TOUCH study)

Steering committee members

Dr. Kapil.G. Zirpe, Dr. Anand.M. Tiwari, Dr. Atul Kulkarni, Dr. Rajesh Pande, Dr. Rajesh Chandra Mishra, Dr. Deepak Govil, Dr. Subhal Dixit, Dr. Srinivas Samavedam, Dr. Manish. Munjal, Dr. Sheila Nainan Myatra, Dr. Sharmila Sinha, Dr. Sudhir khunteta, Dr. Rakesh Garg, Dr.Y P Sing.

ISCCM research project

Introduction

As a Substitute Decision Maker / legally authorized relative (LAR), you are being asked to provide informed consent on behalf of a person who is unable to provide consent for him/herself. If the participant gains the capacity to consent for him/herself, your consent for them will end. Throughout this form, "you" means the person you are representing.

You are being invited to participate in a (I TOUCH) study. You are invited to participate in this study because of need of intrahospital transport for diagnostic or therapeutic purpose. You are above 18 years and unstable sick patient requiring oxygen support/mechanical ventilator/medication for blood pressure support. Unstable condition leads to risks of adverse events during the process.

This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study. Please take your time in making your decision. You may find it helpful to discuss it with your friends and family. Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect current or future health care.

There are no conflicts of interest to declare related to this study.

Purpose of the study-

Despite the existence of various guidelines and a few recommendations there has been no agreement on the best practice guidelines for intrahospital transport in critically ill patients. In a 90-day study period, we would like to collect data prospectively from various ICUs around the country on the practice of intra-hospital transport in unstable adult critical care patients and various issues associated with it. We would like to analyze intrahospital transport practices and difficulties in order to create the optimum Indian Society of Critical Care Medicine (ISCCM) consensus statement addressing intrahospital transport of critically sick hospitalized patients.

Patients taking part in the study-

It is expected that around one thousand (1000) of unstable adult sick ICU patients will participate in this study, with multiple research sites which includes Intensive care unit located across India as applicable to the ISCCM research project.

This investigation should take six months (June -November 2022) and the results should be received in around three months (December -February 2023)

Data base Collection-

The researchers will collect information about you from of your ICU medical chart and enter this information into an electronic database/manually in case research form (CRF). The data will be securely stored, and will be maintained by principal investigator (PI) and Co-PI from centers participating in study. The database can only be accessed by people who are involved in research. Please talk to the research team if there is information that you do not feel comfortable sharing.

Data Sharing and processing maintaining patient's confidentiality -

Information about you kept in this database may be shared with national ISCCM research partners and may be entered in ISCCM research data base. The sharing of this information is meant to assess intra hospital transport practices and associated complications. The information collected from multiple centers will not include information that can directly identify you, such as your name, address or phone number.

Risks or harm of participating in the study-

This being the observational study there are no additional medical risks apart from universal risks identified as per underlying condition while transporting the sick patient.

The risk involved are depicted in the table.

Body system	Adverse effects
Respiratory	Accidental extubation, Selective intubation, bronchospasm, hypoxia, pneumothorax, patient ventilator dysynchrony
Cardio -circulatory	Hypotension, hypertension, cardiac arrythmia, cardiorespiratory collapse
Neurological	Agitation, seizures
others	Equipment failure, human error

Research team member will explain to you regarding risk related to you before intrahospital transport. *

Benefits of participating in study-

Your medical information will be documented and evaluated for risks during intrahospital transport. You will be evaluated before, during and after intra-hospital transport. Continuity of care and required intervention will be done to avert complications. No additional cost will be incurred for participation in the study neither You will be paid for taking part in this study.

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the research team, or the person who is in charge of the study at this institution. That person is:

Name- PI/

CO-PI Phone no.-

SIGNATURES •

All of my questions have been answered,

• I understand the information within this informed consent form,

• I allow access to my medical records as explained in this consent form,

• I do not give up any of my legal rights by signing this consent form,

• I agree, or agree to allow the person I am responsible for, to take part in this study.

_____ _____ _____

Signature of Participant/ Name

Date Substitute Decision-Maker/LAR _____
_____

_____ Signature of doctor Conducting Discussion

Name

Date the Consent

Complete the following section only if the participant is unable to read or requires an oral translation:

The informed consent form was accurately explained to, and apparently understood by, the participant/substitute decision maker, and Informed consent was freely given by the participant/substitute decision maker _____
_____ _____

Signature of Impartial

Witness/Translator (If participant were unable to read/required an oral translation)

Date