

Short consent for prospective observational study
LAR Consent for Participation in the study

Study Title: NATIONAL (iNdian AnalgosedatiON And deLirium): Multi-center prospective study of analgo-sedation practices and delirium in Indian ICUs [INSTINCT (INhaled SedaTion IN CriTically ill patients) study Group]

I understand that a study “NATIONAL (iNdian AnalgosedatiON And deLirium): Multi-center prospective study of analgo-sedation practices and delirium in Indian ICUs [INSTINCT (INhaled SedaTion IN CriTically ill patients) study Group]” conducted by “_____” involves recording of my relative’s data collected as part of his/her routine medical care.

Delirium is an acute state of confusion, characterized by restlessness and illusions which develops over a short period of time and fluctuates in severity. This is common in patients who are very sick and admitted in Intensive care unit (ICU). High-risk populations include elderly and mechanically ventilated ICU patients. The overall occurrence of delirium is 16-89% in hospitalized patients. It is highest in mechanically ventilated patients (81%). Incidence of post-operative delirium varies from 10% to 70%. This state of confusion (delirium) may persist even after patients get discharge from the ICU. Delirium has been associated with increased ICU and hospital stay. Hence it is important to identify and treat delirium in ICU.

I have been explained about the purpose of the study. It is to find out the current sedation practices (practice of giving medicines to help patient relax and fall asleep) and the rate of occurrence of delirium in critically ill cancer patients.

I understand that if I agree to allow my relative to participate in this study his/her medical records will be assessed for the demographic details (age, sex, and weight etc.), admission data, clinical data (diagnosis, risk factors /other accompanying diseases, length of hospital stay), addiction history if available from charts. Detailed information regarding the treatment used for sedation and analgesia will be collected. Follow up data will be collected until 30 day from the ICU admission.

I understand that there will not be any additional medical procedures over and above those which he/she would encounter during standard treatment.

I understand that this study has been approved by the Institutional Ethics Committee, Tata Memorial Centre and does not pose any additional risk to him/her beyond that which he/she encounter while undergoing routine physical or psychological examinations or tests and/or which he/she would encounter in routine daily life activities. I further understand that confidentiality with regard to his/her medical data will be ensured, and that the results published will not in any way be linked to him/her. I understand that his/her name and identity, however, will not be disclosed to anyone but the doctor and his team as well as the hospital authorities may know about the same. His/Her medical records, to the extent of the applicable laws and regulations, will not be made publicly available. In the event of any publication regarding this study, his/her identity will remain confidential.

I understand that the Principal Investigator _____ would be willing to provide me with any additional information that I would want to know regarding the study. I understand

that if I decline to give consent for my relative's participation in this study or withdraw my consent at any stage of the study his/her medical treatment will not be affected and Principal Investigator will not use his/her data for any analysis or report.

I understand that if I have any queries at any time about the study or the procedures, or if my relative experiences any adverse effect as a result of participating in this study, then I can contact,

Name of PI: _____,

Department: _____

Hospital name with address: Parel, Mumbai 400012

Tel no of PI: _____, **Email of PI :** _____

If I have any questions about my relative's rights as a participant, then I can contact,

Name of member Secretary: _____,

Name of Institutional Ethics Committee: _____,

Hospital Name with address: _____

Contact no. : _____, **Email address:** _____

I am willing to allow the use of my relative's data for the study.

Participant's name:	
Participant's signature/ Thumb impression & date:	
Legal Acceptable Representative name:	
Legal Acceptable Representative signature/ Thumb impression & date (if applicable):	
Impartial Witness's name:	
Impartial Witness's signature & date (if applicable):	
Name of PI or Co-PI/Co-I:	
PI or Co-PI/Co-I sign & date:	