Consent for prospective observational study Deferred participant consent for Participation in the study

Study Title: NATIONAL (i**N**dian **A**nalgoseda**TION A**nd de**L**irium): Multi-center prospective study of analgo-sedation practices and delirium in Indian ICUs **[INSTINCT** (**IN**haled **S**eda**T**ion **IN C**ri**T**ically ill patients) study Group]

I understand that a study "NATIONAL (i**N**dian **A**nalgoseda**TION A**nd de**L**irium): Multi-center prospective study of analgo-sedation practices and delirium in Indian ICUs **[INSTINCT** (**IN**haled **S**eda**T**ion **IN C**ri**T**ically ill patients) study Group]" conducted by "(**add Name, Department & address of PI here)**" involves the analysis of my medical data that has been collected as part of my 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 my medical records have been assessed for the demographic details (age, sex, and weight etc.), admission data, clinical data (diagnosis, risk factors /other accompanying diseases, length of hospital stay) and addiction history if available from charts. Detailed information regarding the treatment used for sedation and analgesia have been collected. Follow up data will be collected until 30 day from the ICU admission.

I understand that there were no additional medical procedures done over and above those which I encountered during standard treatment.

I understand that this study has been approved by the Institutional Ethics Committee, _____ and does not pose any additional risk to me beyond that which I encounter while undergoing routine physical or psychological examinations or tests and/or which I would encounter in routine daily life activities. I further understand that confidentiality with regard to my medical data will be ensured, and that the results published will not in any way be linked to me. I understand that my 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. My 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, my 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 participation in this study or withdraw my consent at any stage of the study my medical treatment will not be affected and Principal Investigator will not use my 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 I experience any adverse effect as a result of participating in this study, then I can contact,

Name & Designation of PI: _____

Department: _____

Name of Hospital & Address:_____

Tel of PI: _____ **Email of PI:** _____

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

Name of member Secretary: _____

Name of Institutional Ethics Committee

Address of IEC: _____

Tel no: _____

I am willing to allow the use of my 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:	