**INFORMED CONSENT**
**KETASER01 STUDY, version 03 of 04.03.2015**

The UNDERSIGNED …… born on ….....…… in ..... residing in …..... address .....…….. telephone number ……...……..
As the mother/father/legal representative of the minor ……. born on ……..……..... in ……..... and residing in ……..…….. address .....…….. telephone number …….....

**DECLARES the following:**

The nature, purposes, expected benefits, and possible risks and drawbacks of this study entitled "**Efficacy of ketamine in refractory convulsive status epilepticus in children: a multicentre, randomized, controlled, open-label, non-profit, with sequential design study"** have been clearly explained to me by Dr. ……..

1. I have received a copy of the information sheet with comprehensive details on the planned study.
2. I have been given sufficient time to reflect on the information received and to discuss it with others and ask any questions.
3. I have been informed that the study protocol has received a favourable opinion from the Ethics Committee as well as approval from the responsible health/regulatory authority (Italian Medicines Agency).
4. It has been clearly explained to me that I can decide that my child or minor not take part in the study and that I can withdraw consent to participate at any time.
5. I have been assured that should I desire not to adhere to the research or to abandon it while it is underway, this will not modify the relationships with the doctors and the facility at which my child or minor is being treated in any way.

6. □ I grant / □ I do not grant

   authorization to make contact with my child or minor's paediatrician/family doctor.

7. I am aware that the study can be interrupted at any time if the person responsible for the research decides to do so, without prejudice to the health of my child or minor.
8. I have been informed that I will be made aware of any new information that may compromise the study's safety and that I can speak to the doctors who are treating my child or minor for any problems or questions.
9. I have been informed regarding the contraindication to participation in the study in the case in which my daughter or minor is pregnant or is presumed to be.
10. I have been informed that the results of the study will be made known to the scientific community, that my identity and that of my child or minor will not be mentioned in any report of the study, and that all of the information obtained during the trial will be treated as strictly confidential (Art. 13 of Leg. Dec. 30 June 2003, no. 196).

I therefore freely consent that my child or minor participate in the study.

FIRST AND LAST NAME OF THE PARENT _____ SIGNATURE

_____

FIRST AND LAST NAME OF THE PARENT _____ SIGNATURE

_____

FIRST AND LAST NAME OF THE LEGAL GUARDIAN _____

SIGNATURE _____

DATE:.....

The undersigned Dr. …….....…….. confirms to have duly informed, offering the opportunity to ask clarifying questions, Mr./Ms. ..... with regard to the nature, purposes, expected benefits, and possible risks and drawbacks of the study in question, as well as with regard to his/her rights and those of the child or minor that he/she represents.

SIGNATURE OF THE INVESTIGATOR _____

Date _____