INFORMED CONSENT FOR PEDIATRIC GENERAL/LOCO-REGIONAL ANAESTHESIA

A. IDENTIFICATION:

NAME OF THE PHYSICIAN: ..... Date: .....

B. INFORMATION:

The purpose of anaesthesia is to eliminate any pain during the operation and to provide overall control of the patient. It is administered and supervised by an anaesthesiologist (a member of the Anaesthesiology and Resuscitation Department and accustomed to paediatric anaesthesia), who will be responsible for monitoring the process at all times. The aim is to avoid any pain and anxiety, to reduce the psychological impact on the child, and to enable the surgery, examination or complementary test to be performed in the optimal conditions required and with the greatest efficiency and safety.

There are several types of anaesthesia:

- **General anaesthesia:** This child will be sound asleep. To administer it, a device must be placed in the mouth or nose to maintain respiratory function.
- **Loco-regional anaesthesia:** is rarely the only technique in children. It should be combined with sedation or general anaesthesia. It is performed by injection into the path of the nerves supplying the area, sometimes guided by an ultrasound reader.
- **Combined anaesthesia:** this consists of combining several anaesthetic techniques (general or sedation + loco-regional) for better control of the anaesthesia during the operation and for better analgesia in the hours or days following the end of the operation.

Before entering the operating theatre, if possible, the child's anxiety is reduced in order to overcome this moment with the least possible trauma. To achieve this, oral or nasal medication will be administered.

Occasionally, it may be necessary to insert catheters into larger blood vessels to measure vital constants and/or infuse sera, blood or blood derivatives.

Anaesthesiologists can administer medications in the perioperative period, such as Dexmedetomidine, intravenous Ibuprofen or others for the analgesic and anti-inflammatory treatment, sedation... of your child which, despite their proven safety and efficacy, have yet to be included in the Product Summary of the European community, but not in America.

C. RISKS AND COMPLICATIONS:

- Mortality resulting from anaesthesia is exceptional, (1 in 10,000 patients) increasing in children under 12 years of age (5 in 10,000 patients) and is higher in younger children and urgent surgery (8 in 10,000 patients).
- Patients with asthma, respiratory, cardiac, hepatic or renal disease, diabetes or significant obesity are at increased risk, which must be assessed on an individual basis.
- Potentially serious respiratory problems can occur, especially in ENT surgery, such as bronchospasm, laryngospasm, barotrauma-lung injury, respiratory infections; they are often triggered by recent or ongoing catarrhal processes.
- There exist risks of unforeseen reactions and secondary injuries to anaesthetic techniques (allergies, haemodynamic alterations, arrhythmias, lung and liver lesions, glottis oedema, malignant hyperthermia, etc.) and secondary to the technology or medication used (fluids, blood, blood products, latex, radiological contrast, electric scalpel, heating systems, postural injuries, etc.). Allergic reactions are rare and do not warrant prior testing.
- Due to the difficulty of the technique, in the paediatric population there may be several attempts to cannulate a line.

Complications of central vein cannulation are rare, and usually mild (haematoma at the site). Some cases may be moderately severe (air in the pleura, nerve root injury, cannulated vein thrombosis). Exceptionally, mortality may occur with this technique.

Complications specific to general anaesthesia:

- Nausea-vomiting, dizziness, throat discomfort and hoarseness, symptoms which usually disappear within a few hours.
- Insertion of a device into the mouth can sometimes prove difficult and can damage teeth and, rarely, cause injury to the trachea or oesophagus, and/or bronchoaspiration (passage of stomach contents into the lungs), especially if fasting rules are not observed.

Complications specific to regional anaesthesia:

- Discomfort such as cramps and tingling may sometimes occur due to irritation of local nerves, which are usually short term. Exceptionally, long-term nerve injury may occur.
- Several puncture attempts may be necessary due to technical difficulties.
- Exceptionally, due to the difficulty in placing the local anaesthetic in a particular site, it may pass into the blood or nervous system, producing an effect similar to that of general anaesthesia, and may be accompanied by serious complications such as haemodynamic disturbances and seizures.
- In the case of spinal-epidural anaesthesia, complications may range from mild back discomfort, transient headache (occurring in 5% of patients), nerve irritation, infection of the catheter with abscess in the back, to very rare cases of epidural haematoma with severe outcomes such as paralysis of the lower limbs.

THE HOSPITAL WILL MAKE AVAILABLE THE NECESSARY MEANS TO TREAT ANY POSSIBLE COMPLICATIONS.

D. NOTIFY US:

It is necessary to notify us of possible drug allergies, coagulation disorders, cardiopulmonary diseases, the existence of prostheses, pacemakers, current medications or any other circumstance, as these may increase the frequency or severity of risks or complications.

E.-PERSONALISED RISKS:

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F. ALTERNATIVES:

These will be assessed by the anaesthesiologist based on the estimated risks.

Basic information on personal data protection: The interested party is informed that their personal data will be processed by Osakidetza - Basque Health Service. The purpose of processing the MEDICAL HISTORY is to make the patient's medical history data available for patient follow-up and management of the healthcare activity, in order to comply with the undertaking carried out in the public interest or in the exercise of public powers conferred on the data controller. Data may be disclosed to the Department of Health of the Basque Government, the INSS, judicial authorities and insurance companies. The data come from the person concerned, from the Basque Government Department of Health and from Osakidetza health staff. The data subject has the right to access, rectify, delete, restrict or object to the processing of his/her data. Further information on data protection can be found at the following website: http://www.osakidetza.euskadi.eus/protecciondatos.

I SIGN THIS DOCUMENT AFTER HAVING READ IT AND HAVING HAD THE OPPORTUNITY TO ASK QUESTIONS AND CLARIFY ANY DOUBTS. THEREFORE, AFTER HAVING UNDERSTOOD WHAT IS TO BE DONE TO ME, THE EXPECTED RESULTS AND THE RISKS THAT MAY ARISE FROM IT.

THERE IS A PRESUMPTION IN LAW THAT PARENTAL AUTHORITY IS EXERCISED FOR THE BENEFIT OF THE CHILD AND, THEREFORE, THAT A PARENT WHO ACTS WITHOUT THE OTHER PARENT IN RESPECT OF HIS OR HER CHILD DOES SO FOR THE BENEFIT OF THE CHILD, SUCH THAT, WITH RESPECT TO BONA FIDE THIRD PARTIES, EACH PARENT SHALL BE PRESUMED TO BE ACTING IN THE ORDINARY EXERCISE OF PARENTAL AUTHORITY WITH THE CONSENT OF THE OTHER PARENT.

The Patient
Patient's name, surname and ID card number .....
Signature(s) and date .....

The Doctor
Name, surname and Medical Assoc. number .....
Signature and date.....

Representative: in the event of incapacity of the patient or minor.
Name, two surnames, ID card number and relationship of the legal representative ..... Signature and date.....

WITHDRAWAL of patient or legal representative
I understand the scope and risks of not UNDERGOING the indicated procedure. I hereby exercise my right of withdrawal. .....
Signature and date.....