CONSENT FORM

Comparison of Ultrasound-Guided Penile Block and Pudendal Block under Neurostimulation for Perioperative Analgesia in Pediatric Post-Circumcision Surgery: A Prospective, Randomized Study at Caen University Hospital
PINEPAPPLE – Coordinating Investigator: Dr. Marine ROLLAND

I, the undersigned [Last name, First name], freely consent to participate in this clinical research study as described in the information sheet, and I confirm the following:

- I have had sufficient time to read the information provided, to consider participation in the study, and I have received appropriate answers to my questions.
- I have been informed of the objectives of the study, the potential risks, and the constraints associated with my participation.
- I certify that I am covered by, or a beneficiary of, a social security scheme, unless an exceptional waiver applies.
- I understand that I have the right to refuse to participate or to withdraw my consent at any time, without any impact on my medical care and without incurring any liability or disadvantage.
- I acknowledge that I may discontinue my participation in this research at any time, without providing justification, and I will inform the investigator responsible for my follow-up in the study. This will not affect the quality of my subsequent medical care.
- I understand that the investigator may discontinue my participation at any time if deemed necessary.
- I acknowledge that I have the right to access, rectify, restrict, and, where applicable, object to or request the deletion of my personal data. These rights may be exercised primarily through the investigator responsible for my participation, who has access to my identity.
- I understand that this study has been authorized by the French National Agency for Medicines and Health Products Safety (ANSM) and has received a favorable opinion from the Ethics Committee for the Protection of Persons (Comité de Protection des Personnes Sud Méditerranée I) on October 28, 2024. The study sponsor has obtained civil liability insurance coverage from **RELYENS, Société d'Assurance Mutuelle**, in case of any harm related to participation.
- I understand that my consent does not release the investigator or the sponsor from their legal responsibilities toward me. I retain all rights guaranteed under applicable law.
- I understand that the overall study results will be communicated to me at the end of the research if I request them from the investigator.
- I understand that I may request additional information at any time after the start of the study from Dr. Marine ROLLAND.
- Two original copies of this consent form have been prepared: one has been given to me, and the other will be kept by the investigator. Both will be retained in the study file for a minimum of 15 years following the completion of the research.
- I have been informed about how my personal data and, where applicable, my biological samples may be collected, used, and shared as described in this document.

Information Sheet for Children Participating in the Research Study

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PINEPAPPLE – Coordinating Investigator: Dr. Marine ROLLAND

Why is this study being done?

We are doing this study to help children feel more comfortable and to prevent pain during and after a surgery called circumcision.
To do this, we will compare two different methods of local anesthesia (medicine given to the area where the operation takes place). This will be done while you are asleep under general anesthesia.
We need your help to find out which method works best and is safest for children.

What will this change for you?

If you take part in this study, the doctor will use one of the two local anesthesia methods to make you more comfortable during and after the operation.
When you are completely asleep, the anesthesiologist will inject medicine in the area of the surgery, either:

- by using an image (ultrasound guidance), or
- by using a gentle electrical stimulation (not painful).

After the operation, your comfort and your pain will be checked using a scale, and you will be given all the medicines you need.

What will you have to do?

- Before going to the operating room, you will receive medicine so you do not feel pain.
- During the operation, you will be fully asleep thanks to general anesthesia.
- After the operation, you will stay for a short time with the nurses and doctors so they can check how you feel. They will ask if you are in pain and make sure everything is fine before letting you go back to the surgery ward and then return home.

Will it hurt?

The local anesthesia will be done while you are asleep, so you will not feel anything at that time.
It is possible that you may feel some pain or discomfort where the surgery was done after the operation, but this does not always happen. If it does, we will do everything we can to relieve your pain quickly.
We are here to care for you and to keep you safe.

Can I say no?

You do not have to take part in this study. If you do not want to participate, that is absolutely fine. The doctor will still take very good care of you, and you will continue to receive the best treatment.

What happens if I say yes?

If you would like to participate, your parents also need to agree. This will not change anything in the way you are cared for on the day of your surgery.

Assent Form for Child Participant

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PINEPAPPLE – Coordinating Investigator: Dr. Marine ROLLAND

My name is: _____ Today's date is: _____
Date of birth: _____

Why am I signing this form?

During the consultation with the anesthesiologist, it was explained to me that I am going to have surgery, during which I will be completely asleep (general anesthesia).
To make me more comfortable during and after the surgery, the anesthesiologists will also give medicine in the area where the surgery is done (local anesthesia).

There are two different ways to do this local anesthesia, and the anesthesiologists are doing a study to compare them.
They would like me to take part in this study.
I was told that if I agree to participate, I will receive one of the two local anesthesia techniques. But I can choose whether or not I want to take part.

What does it mean if I say "yes"?

If I say "yes," it means I agree to help the doctors by taking part in the study.
While I am asleep, they will use one of the two local anesthesia techniques.
After my surgery, they will check my pain, take notes, and do everything they can to keep me comfortable. If I have pain, I will receive medicine to help.

Can I change my mind?

Yes! Even if I say "yes" now, I can change my mind at any time. I just need to tell my parents or the doctors.

I understand that:

- Taking part in this study is **my choice**. I can say "no" if I do not want to.
- If I say "no," nothing bad will happen. I will still be cared for just as well.
- I can ask as many questions as I want, whenever I want.

Do I want to take part? ☐ Yes, I want to help the doctors and take part in the study.

Signature : _____