**FEDERAL UNIVERSITY OF RIO GRANDE DO SUL**
**SCHOOL OF MEDICINE**
**GRADUATE PROGRAM IN HEALTH SCIENCES:**
**GYNECOLOGY AND OBSTETRICS**

# COMPARISON OF LOW-LEVEL LASER THERAPY WITH CRYOTHERAPY IN THE IMMEDIATE POSTPARTUM PERIOD OF PARTURIENTS WITH FIRST- AND SECOND-DEGREE LACERATIONS AND/OR EPISIOTOMY IN REDUCING PERINEAL AND VULVAR PAIN:

**A randomized clinical trial**

Nº do project GPPG ou CAAE 58569421.5.0000.5327

**PORTO ALEGRE**
**04/2024**

## APPENDIX B – INFORMED CONSENT FORM

Project Number GPPG or CAAE 58569421.5.0000.5327
Project Title: Comparison of low-level laser therapy with cryotherapy to reduce perineal and vulvar pain and edema in immediate postpartum women with laceration and episiotomy: a randomized clinical trial.

You are being invited to participate in a research study aimed at evaluating the efficacy of two non-pharmacological techniques for pain and edema relief in the immediate postpartum period of up to 12 hours. This research is being conducted by the Postgraduate Program in Health Sciences - Gynecology and Obstetrics at the Hospital de Clínicas de Porto Alegre/RS (HCPA).

If you accept the invitation, your participation in the research will involve being evaluated for pain and edema in the immediate postpartum period of up to 12 hours after the application of one of the techniques, either low-level laser therapy or cryotherapy. You will be re-evaluated within the 24-hour postpartum period.

Low-level laser therapy and cryotherapy have low risks, including discomfort, a low risk of burn if application time and dosage are not respected, and the risk of not benefiting. Participation in the research, if the effectiveness of the techniques is proven, will have direct benefits for you, such as pain and edema relief; if the effectiveness is not proven, there will be no harm in its use.

Your participation in the research is entirely voluntary, meaning it is not obligatory. If you decide not to participate or withdraw your consent, there will be no prejudice regarding institutional ties or curriculum evaluation that you receive or may receive at the institution.

There is no payment for your participation in the research, and you will have no cost regarding the procedures involved.

In the event of any complication or harm resulting from your participation in the research, you will receive all necessary care at no personal cost.

The data collected during the research will always be treated confidentially. The results will be presented collectively, without identifying the participants, meaning your name will not appear in the publication of the results.

If you have any questions, you may contact the responsible researcher, Élen Cristine Boniatti Constant, by phone at (51) 984608425, or the Research Ethics Committee of the Hospital de Clínicas de Porto Alegre (HCPA), by phone at (51) 3359-7640, email cep@hcpa.edu.br, or at the 2nd floor of HCPA, room 2229, from Monday to Friday, from 8 am to 5 pm.

This form is signed in duplicate, one for the participant and one for the researchers.

Participant's Name: _____

Participant's Signature: _____

Researcher's Name: _____

Researcher's Signature: _____

Location and Date: _____