CLINICAL HOSPITAL DUBRAVA, ZAGREB
ETHICS COMMITTEE

Appendix T1: Participant Information

Dear Sir/Madam,

We invite you to participate in a scientific study as a subject. The main aim of this research is to investigate the impact of regional anesthesia on patients scheduled for breast reconstruction surgery. The project leader is Dr. Domagoj Eljuga. This project is being conducted at CHD without funding from any external sources.

Your participation in the study should be based on a clear understanding of the research goals, methods, and procedures, as well as the potential benefits and risks for you as a participant. Therefore, before making a decision, we kindly ask you to carefully read and review this information. If you encounter any unclear terms or phrases, please feel free to ask the researchers and doctors involved in the study, who are obligated and willing to answer any questions.

DESCRIPTION OF THE KEY ISSUE AND RESEARCH HYPOTHESIS

The primary objective of this proposed research is to investigate the impact of regional anesthesia on patients undergoing breast reconstruction surgery. The fundamental scientific hypothesis is that regional anesthesia in breast reconstructive surgery is associated with lower pain levels, reduced consumption of analgesics and opioids, fewer postoperative complications, and shorter hospital stays.

OBJECTIVE AND PURPOSE OF THE RESEARCH

- Patients will complete a questionnaire assessing pain levels before surgery and at 6 and 24 hours postoperatively. Pain levels will be compared between the two patient groups.
- We will monitor the consumption of analgesic therapy and record complications in both patient groups (e.g., dizziness, nausea, vomiting).
- The length of hospital stays will also be compared between the two patient groups.

YOUR ROLE AS A STUDY PARTICIPANT

Patients who consent to participate in the study will be divided into two groups. One group will undergo standard anesthesia during breast surgery, while the other group will receive regional anesthesia, which numbs the nerves that supply the breast, chest muscle, and armpit, avoiding the need for conventional general anesthesia.

POSSIBLE BENEFITS FOR YOU

The expected benefit is a lower level of postoperative pain in the group of patients undergoing regional anesthesia, along with a faster postoperative recovery.

POSSIBLE RISKS FOR YOU

There are no additional risks compared to the standard procedure.

ARE THERE OTHER TREATMENTS, DIAGNOSTIC METHODS, OR SURGICAL APPROACHES AVAILABLE?

Participants are free to decline participation in the study and will receive anesthesia according to the standard protocol.

DO YOU HAVE TO PARTICIPATE IN THE STUDY?

Participants have been informed that their decision to participate is entirely voluntary. You are free to decide whether or not to participate in this study. Participation is voluntary, and you may withdraw at any time, without giving a reason and without any consequences. If you withdraw, you will continue to receive standard treatment for your condition. Should you decide to withdraw, please inform the project leader and their associates in a timely manner.

CONFIDENTIALITY AND ACCESS TO DOCUMENTATION

All your personal data will be stored and processed electronically. The project leader and associates are obligated to fully adhere to prescribed procedures for personal data protection. Your data will be recorded using your initials and a special code. Your medical documentation will only be reviewed by the project leader and associates, and your name will never be disclosed to third parties. Representatives of the Ethics Committee at your treatment facility (local Ethics Committee) and the Ethics Committee of the Medical Faculty (which oversees the approval and monitoring of this study) may also access your records.

WHAT WILL THE DATA FROM THIS STUDY BE USED FOR?

The data obtained from this study may be beneficial in clinical practice and for further development and advancement of science. It is anticipated that this data will be published in relevant scientific journals and publications. Your identity will remain entirely anonymous and protected.

WHO IS ORGANIZING AND FUNDING THIS STUDY?

This study is not funded by any external source.

WHO APPROVED THIS STUDY?

This study has been approved by the Ethics Committee of Clinical Hospital Dubrava after a thorough review of the research proposal and accompanying documentation. It is being conducted in accordance with all applicable guidelines designed to ensure proper research conduct and the safety of participants, including the "Principles of Good Clinical Practice" and the "Helsinki Declaration."

WHO CAN YOU CONTACT FOR ADDITIONAL INFORMATION AND QUESTIONS?

If you need any additional information or have further questions, please feel free to contact the project leader or their associates:

- **Project Leader's Name**: Domagoj Eljuga
- **Project Leader's Address**: CHD, Clinic for Plastic Surgery
- **Project Leader's Phone Number**: +385 1 290 2572

YOUR WRITTEN CONSENT TO PARTICIPATE

You and the project leader will each receive a copy of the consent form to sign if you agree to participate in the study. The original document will be retained and securely stored by the project leader.

Thank you for reading this document and considering your participation in this scientific study.

This information has been prepared in accordance with the provisions of the Healthcare Act of the Republic of Croatia (NN 121/03) and the Patients' Rights Act of the Republic of Croatia (NN 169/04).

Note: When submitting documentation to the Ethics Committee of Clinical Hospital Dubrava, this Participant Information and the Consent Signature Page **MUST** be signed by the research leader.