CONSENT FOR PARTICIPATION IN TRIAL

FOCUS: A Study Evaluating the Effectiveness of Carpal Tunnel Syndrome Surgery Kuopio University Hospital

I, _____, have been invited to participate in the above-mentioned medical study, which aims to evaluate the effectiveness of two surgical procedures for carpal tunnel syndrome: carpal tunnel release surgery and placebo surgery. In the lighter intervention, placebo surgery, only the skin is opened and then closed. In the other procedure, carpal tunnel release surgery, the intervention extends to deeper tissues, fully opening the carpal tunnel.

I have read and understood the information sheet provided to me. The information sheet has given me sufficient details about the study, including the collection, processing, and disclosure of data. The content of the information sheet has also been explained to me verbally. I have had the opportunity to ask questions and have received satisfactory answers to all queries related to the study.

The explanations were provided by (name of person) _____ on __ / __ / 20 __.

I have had sufficient time to consider my participation in the study. I have received adequate information about my rights, the purpose of the study, its implementation, and its potential benefits and risks. I have not been pressured or incentivised to participate in the study.

I understand that my data will be handled confidentially and may be disclosed outside the research team. Data may be transferred within and outside the European Union (EU) and the European Economic Area (EEA). If the data is transferred outside the research team, it will always be encoded. I understand that in non-EU/EEA countries, data protection may not be at the same level as within the EU. In such cases, the principal investigator of the study ensures that personal data is transferred using appropriate safeguards, which in this study include the aforementioned encoding, secure email, and password-protected files. If research data is shared outside the research team, the recipient must sign a confidentiality and data processing agreement.

My data may also be processed by national and international regulatory authorities, representatives of the study sponsor, and monitors who have the right to conduct inspections. Additionally, my data may be disclosed to supervisory authorities. The study may involve procurement of laboratory or equivalent support services, in which case the service providers may process my data. Publications where the study results are reported may require access to study data for review. Furthermore, external research groups may request study data after the study's conclusion for additional analyses.

I understand that my participation is voluntary. I have the right to withdraw from the study at any time without providing a reason. Withdrawing from the study will not result in any negative consequences for me, nor will it affect my position as a healthcare service recipient. I am aware that data collected up to the point of withdrawal will still be used as part of the research material.

By signing this document, I confirm my participation in the study described herein and voluntarily consent to be a research participant. I am aware that my personal data may also be processed during inspections by foreign authorities and quality assurance activities conducted by the sponsor's representatives.

Participant Details

_____

Name Personal identification number Address

I consent to participate in the randomised section of the study

_____ _____

Date Signature

I consent to participate in the follow-up group of the study

_____ _____

Date Signature

Consent Received

_____ _____ _____

Recruiter's Name Date Signature

The original signed consent form and a copy of the information sheet will remain in the principal investigator's archives. A copy of the information sheet and the signed consent form will be provided to the participant.