INFORMED CONSENT FORM

Study title	**“Comparative Efficacy of Earplug Usage Instruction : A Randomized Trial of Video-Based and Paper-Based Instruction”**
Acronym of the Study	Comparative Efficacy of Earplug Usage Instruction (CEEUIn)
Name of the Principal Investigator	Sirinthorn Chanaveroj
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PATIENT/PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM FOR CLINICAL RESEARCH

Study Title: Comparative Effectiveness of Earplug Insertion Training: A Randomized Trial of Video-Based versus Paper-Based Instruction

Principal Investigator: Sirinthorn Chanaveroj, M.D.

Affiliation: Department of Otolaryngology–Head and Neck Surgery, Faculty of Medicine, Chiang Mai University

Funding Source/Sponsor: Faculty of Medicine, Chiang Mai University

Summary of Key Points of the Research Project

You are being invited to take part in a research study entitled "Comparative Effectiveness of Earplug Insertion Training: A Randomized Trial of Video-Based versus Paper-Based Instruction."

This study will assess participants' performance of using Foam Earplug before training , immediately after training and again after 1 week, in order to examine the retention of the skill in real-world use. The results of this study will help identify which training method is most appropriate and effective for hospital personnel.

About This Study

Please take time to read this document, which will help you understand what your participation in this study will involve. Your decision to take part in this study is entirely voluntary. If you choose not to participate, this will not affect the medical care or rights to which you are entitled.

Participation in this study is voluntary

- You are free to decide whether or not to take part in this study.
- You may discuss this with your family or treating physician before making a decision, and you may ask any questions about the study; the investigator will provide further explanation and answer your questions until you understand.
- If you agree to take part in this study, you may still withdraw from the study at any time.

Rationale and Significance of the Study

Noise-induced hearing loss is a preventable occupational health problem, which can be avoided by avoiding exposure to loud noise. When exposure cannot be avoided, appropriate hearing protection devices should be selected and used correctly.

This study will recruit personnel working in high-risk, high-noise-level areas at Maharaj Nakorn Chiang Mai Hospital, **aged 20–60 years, during 2026, for a total of 64 participants.**

Study Procedures

- You will be randomly assigned to one of two training groups for the use of foam earplugs: Group 1 will receive the instruction for earplug use via video, and Group 2 will receive the instruction via printed-document.
- Earplug insertion skill will be assessed using the Standardized Foam Earplug Insertion Checklist, both before and after training. Group allocation will be performed using a random number generator program, and the group assignment will be concealed from the assessor to avoid bias in skill scoring.

- The primary outcome of this study is the score for correct earplug insertion according to the Standardized Foam Earplug Insertion Checklist designed by otolaryngology specialists.

Risks and Benefits of Participation

Risks and Discomforts of Participation

- This study has no serious risk to participants.
- You may experience mild discomfort while inserting the earplug, but a research staff member will provide guidance throughout.

Anticipated Benefits of Participation

You will gain knowledge that can be practically applied to prevent occupational hearing loss in noisy work environments.

The following outlines the approach to be taken for situations that may arise during the study:

Situation	Course of Action
• If you withdraw during the study	You may decline or withdraw from the study at any time without any effect on your employment rights or medical care.
• If new information relevant to the study or to your safety becomes available	The investigator will inform you promptly, and you may decide whether to continue participating in the study.

Your information related to this study will be kept confidential in accordance with international human research ethics standards and the Personal Data Protection Act B.E. 2562 (2019). When study results are disseminated at academic conferences or in academic journals, no information that identifies or can be linked to you will be included. If some data must be entered into a database required by an academic journal for sharing with other researchers, this data will be in a form that cannot identify or be linked to you. However, certain parties may request access to your personal data, including the Institutional Review Board, research coordinators, research supervisors, and officials from government institutions or organizations with oversight responsibility, for the purpose of verifying the accuracy of the data and the study procedures.

You will receive compensation for travel expenses/time for participating in this study. You will receive compensation of 100 Baht per visit, after the first training session and after the second training session at the 1-week follow-up.

This travel/time compensation will not influence your decision to participate in or withdraw from the study, and does not constitute compensation for risk in the event that you experience side effects or adverse events from participating in this study.

If you have any questions about the study or about safety during your participation, you may ask the investigator directly, or contact the Department of Otolaryngology–Head and Neck Surgery, Faculty of Medicine, Chiang Mai University.

Person to Contact for Further Information or to Report Side Effects/Adverse Events

Sirinthorn Chanaveroj , M.D. Tel. +6684-609-3537

If you have any questions regarding your rights, you may contact the Department of Otolaryngology–Head and Neck Surgery, Faculty of Medicine, Chiang Mai University, at +6653-935562, to ensure that your rights, safety, and well-being are protected in accordance with international human research ethics standards.

PARTICIPANT CONSENT FORM

I, _____, have decided to take part in the research study entitled "Comparative Effectiveness of Earplug Insertion Training: A Randomized Trial of Video-Based versus Paper-Based Instruction."

I have received information and an explanation about this study, and I have had the opportunity to ask questions and have received satisfactory answers.

I have had sufficient time to read and thoroughly understand the information in the participant information sheet, and I have had sufficient time to decide whether to take part in this study.

I understand that I am free to decline to take part in this study, and that during my participation I may withdraw from the study at any time, without affecting my medical care or the rights to which I am entitled.

By signing this form, I do not waive any of my legal rights, and after signing I will receive one copy of this information sheet and consent form.

Participant's Signature: _____ Date: _____

(_____)

WITNESS STATEMENT (Independent, with No Conflict of Interest in the Study)

I was present during the informed consent process and confirm that the person seeking consent read/explained the information sheet to _____, who had the opportunity to ask questions and voluntarily agreed to take part in the study after understanding the information as presented in this document.

Witness's Signature: _____ Date: _____

(_____)