Participant Information and Consent Form

Dear Madam / Sir,

We invite you to participate in the clinical research study titled:
"Comparison of Arthroscopic Treatment Methods in Relation to Bone Deficiency in Anterior Shoulder Joint Instability",
conducted by **Dr. Andrejs Finogejevs**.

This document provides detailed information about the purpose, procedures, potential benefits, and possible risks of the study.
Please read this document carefully before signing.
You have the right to ask any questions about the study and to receive clear answers before giving consent.

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1. Purpose of the Study

The purpose of this study is to evaluate whether **anterior labrum augmentation using the long head of the biceps brachii tendon** improves shoulder functionality in patients with anterior shoulder instability associated with bone deficiency.

This technique is hypothesized to:

- Improve functional outcomes without significantly increasing operative time or rehabilitation duration.
- Avoid the need for additional implants.
- Achieve functional recovery comparable to standard anterior labrum refixation at the glenoid.

This method may represent a **viable alternative** to other surgical stabilization techniques for the shoulder joint.

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2. Study Procedures

The study will be conducted over a period of **at least two years**.
The first stage involves **patient recruitment, eligibility screening, and necessary diagnostic assessments**.

All examinations and procedures will take place at a medical institution specializing in the treatment of anterior shoulder joint instability. Participants will undergo:

- Clinical assessments
- Magnetic Resonance Imaging (MRI)
- Computed Tomography (CT)
- Other diagnostic tests as needed

Following screening, eligible participants will be randomly assigned to one of two groups:

- **Study Group** – receiving the experimental surgical technique
- **Control Group** – receiving standard arthroscopic treatment

All participants will undergo **arthroscopic shoulder surgery**. Randomization will occur prior to surgery to ensure objectivity and comparability between the groups, under the supervision of medical personnel.

Participants will be asked to complete questionnaires regarding pain, shoulder function, and medication use to assess recovery and treatment efficacy.

If biological samples (e.g., blood) are collected, volumes will be minimal and limited to what is necessary for laboratory analyses. During surgery, **small fragments (3–5 mm) of bone and tendon tissue** may be collected as part of standard procedures, without increasing surgical risk or duration.

All participants and their treating physicians will have access to **individual study-related results** to ensure optimal treatment and follow-up.

Participation will last **at least three years**, though long-term follow-up may continue to evaluate durability and long-term effects of the treatment.

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3. Potential Benefits

Participation in this study may lead to:

- Improved shoulder function and reduced pain due to a more effective surgical approach
- Access to innovative surgical and rehabilitation techniques
- Comprehensive medical monitoring and regular clinical evaluations
- Individualized care and psychological support to manage stress or anxiety
- Increased understanding of your own health condition and treatment strategies
- Access to experienced medical professionals and potentially reduced treatment costs

Additionally, participation will contribute to **medical research and the advancement of future treatment methods**.

Overall, participants may experience **health, psychological, and practical benefits**, leading to improved quality of life and well-being.

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4. Possible Risks and Discomforts

Potential risks associated with participation include:

- Postoperative pain (mild to severe), lasting several days or weeks depending on individual recovery and surgical complexity
- Risk of infection related to surgical incisions or implant use
- Potential complications such as implant rejection, nerve injury, joint stiffness, or recurrent shoulder instability
- Possible allergic reactions to anesthesia or other medications used during surgery

To minimize risks:

- Only suitable candidates will be enrolled, following strict inclusion and exclusion criteria
- Comprehensive preoperative assessment and patient education will be provided
- Multimodal pain management and appropriate medication will be implemented
- Sterile technique will be strictly maintained during and after surgery
- Regular postoperative follow-up and monitoring will be conducted to detect and manage any complications promptly

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5. Confidentiality and Data Protection

All personal data will be processed in accordance with the **Personal Data Processing Law**. Your data will be stored securely within the clinic's IT system, protected by passwords and user authentication.

Collected data may include:

- Gender
- Age
- Patient medical record number

The responsible person for data protection is the principal investigator, **Dr. Andrejs Finogejevs**.

If you have any questions or complaints regarding data processing or storage, please contact:
Dr. Andrejs Finogejevs
Phone: **+371 29951841**
Email: **andrejs.finogejevs@orto.lv**

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6. Voluntary Participation and Right to Withdraw

Your participation in this study is **entirely voluntary**.
You have the right to refuse participation or withdraw from the study at any time, without providing a reason.

Your decision to withdraw will **not affect the quality of your medical care or treatment** in any way.

You will be informed of any new information that may influence your willingness to continue participation.

This document is prepared in **two copies** — one retained by the investigator and one by the participant.

For any questions regarding the study, please contact:
Dr. Andrejs Finogejevs
Phone: **+371 29951841**
Email: **andrejs.finogejevs@orto.lv**

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7. Ethical Approval

This study has been reviewed and approved by the **[Name of Ethics Committee]**.
Ethics Committee contact details: _____

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8. Participant Consent Statement

I hereby confirm that (please mark each box as appropriate):

Statement	Agree	Disagree
1. I have been provided with all information relevant to the study.	☐	☐
2. I have had the opportunity to ask questions about the study and my role in it.	☐	☐
3. I voluntarily agree to participate in the study.	☐	☐
4. I consent to the collection and storage of my data for research purposes (audio or video recording, if applicable).	☐	☐

Signatures

Participant (Interviewee)
Name and Surname: _____
Signature: _____
Date: _____

Researcher (Interviewer)
Name and Surname: _____
Signature: _____
Date: _____

Contact Person:
Dr. Andrejs Finogejevs

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