

## PATIENT CONSENT FORM

Project Information	
<b>Project Title:</b> Anatomical Evaluation of Supraspinatus Tendinitis through Ultrasonography and Biomechanical Measurements following different combinations of Physical therapies	
<b>Principal Investigator:</b> Dr. SI & Dr. IG	
<b>IRC Ref No:</b> 34/IRC/BMR/DATED:30/12/2025	<b>Organization:</b> UVAS
<b>Address:</b> UVAS Lahore, Anatomy Department	<b>Phone:</b>
<b>Other Investigators:</b> IG	<b>Organization:</b> Sehat Medical Complex
<b>Address:</b> Orange Line Metro Train Station Hanjerwal	<b>Phone:</b>

I am Dr. Imran Ghafoor from Department of Anatomy and Histology University of Veterinary and Animal Sciences, Lahore and doing research on “*Anatomical Evaluation of Supraspinatus Tendinitis through Ultrasonography and Biomechanical Measurements following different combinations of Physical therapies.*”

Shoulder pain is the 3<sup>rd</sup> most common musculoskeletal pain disorder in Pakistan and worldwide. It occurs during the overhead repetitive movements in daily life. The supraspinatus tendinitis of rotator cuff muscles is involving the most commonly and patient loss their movements in initial range and sometime loss of total shoulder function. The commonly used physiotherapy is less effective and not make enough difference in pain management. A new technique blood flow restriction therapy and shock wave therapy is supposed to be effective in treatment of rotator cuff disease especially supraspinatus tendinitis but there is not enough evidence that as it is as good as other techniques in shoulder pain management.

It should then state the following:

### 1. PURPOSE OF THIS RESEARCH STUDY

- You are being asked to participate in a research study designed to evaluate the effects of physiotherapy techniques on shoulder structure and function using clinical, anatomical and ultrasound-based assessments. The study is conducted to check the beneficial effects of the single or combinations of therapies on shoulder joint to reduce pain and improve function.

### 2. PROCEDURES

- Describe procedures: You will be asked to do some muscle training of the shoulder in different directions with specific weight. Some training may require to wear blood pressure cuff while performance. Some training requires to expose the shoulder and shock wave therapy will be given. An electric heating pad and TENS machine will be applied before any other treatment written in sealed envelope.
- Before the start of the 1<sup>st</sup> session and in between of 4, 8 and 12<sup>th</sup> week session, ultrasound measurements will be taken of the shoulder joint.
- The total time will be taken for one session around 30-45 minutes.

- You will be allowed to take 3 sessions per week, total 36 sessions.

### **3. POSSIBLE RISKS OR DISCOMFORT**

- Patient may feel mild to moderate pain in shoulder area after the session some time.
- A deep aching feeling in the treated tendon.
- A short-term increase in your usual shoulder pain for 1–2 days.
- Mild bruising.
- Temporary soreness, redness, or slight swelling on the skin.
- Increased pain if there are calcium deposits in the tendon.
- Tightness, pressure, or heaviness in the arm during cuff exercises.
- A burning or tired feeling in the muscles during exercise.
- Mild temporary numbness or tingling if the cuff is too tight.
- Bruising under the cuff.
- A rise in blood pressure during exercise.
- Very rare risk of a blood clot or nerve irritation.
- Mild pressure from the ultrasonic probe on sensitive areas.
- Coolness or minor skin irritation from the ultrasonic gel.

Most side effects are mild, temporary, and settle on their own within a short time. You should inform the therapist immediately if you feel unusual pain, numbness, or discomfort during any part of the procedure. There is a “mild, transient, and self-limiting adverse effects,” with serious complications being rare as investigator follow screening guidelines.

### **4. POSSIBLE BENEFITS**

- Reduction in shoulder pain during daily activities.
- Improved movement and flexibility of the shoulder joint.
- Better strength and function of the arm and shoulder muscles.
- Faster recovery of tendon or soft-tissue problems.
- Better understanding of your shoulder condition through ultrasound imaging.

### **5. FINANCIAL CONSIDERATIONS**

- “There is no financial compensation for your participation in this research.”

### **6. AVAILABLE TREATMENT ALTERNATIVES**

- There are experimental treatment options along with conventional treatment options and will have very low risk.

### **7. AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES**

- “This study involves (minimal risk) (greater than minimal risk).”
- If you are injured as a direct result of taking part in this research study, emergency medical care will be provided by Sehat Medical Complex medical emergency staff and all the expenses will be beard by the investigator.

### **8. CONFIDENTIALITY**

- “Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you.”
- “However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor or by ERC members”.

In addition, list steps to protect confidentiality such as codes for identifying data.

### **9. TERMINATION OF RESEARCH STUDY**

You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to

participate. You will be provided with any significant new findings developed during the course of this study that may relate to or influence your willingness to continue participation. In the event you decide to discontinue your participation in the study at any time. In addition, your participation in the study may be terminated by the investigator without your consent.

**10. AVAILABLE SOURCES OF INFORMATION**

- Any further questions you have about this study will be answered by the Investigator: IG  
Phone Number:  
Any questions you may have about your rights as a research subject will be answered by:  
Name  
Phone Number:  
In case of a research-related emergency, call: Day Emergency Number: official number of SMC
- Night Emergency Number: official number of SMC

**11. AUTHORIZATION**

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study.

Name of participant/Parents/Guardian (Printed or Typed): \_\_\_\_\_

Signature/Thumb Impression of participant/Parents/Guardian: \_\_\_\_\_

Date: \_\_\_\_\_

Name of person obtaining consent: \_\_\_\_\_

Signature of person obtaining consent: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of Principal Investigator: \_\_\_\_\_

Date: \_\_\_\_\_