Study: **Proper identification of ribs underlying the rhomboid major and trapezius muscles using palpation.**

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NCT number: 0084226

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Project summary: This study will determine the accuracy of medical practitioners in locating the posterior ribs underlying the rhomboid major and trapezius muscles in individuals of different Body mass indices.

Consent and Authorization Document

for Minimal Risk Research

BACKGROUND

You are being asked to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

The purpose of the study is to ultimately identify how accurate medical practitioners are when they insert needles into the back. However, this research project does not involve any needles – we are only examining anatomical landmarks with an ultrasound machine. We will have a medical practitioner mark a spot on your back and then verify their position with an ultrasound probe.

STUDY PROCEDURE

It will take you approximately 10 minutes to complete this study. As part of this study, a practitioner (either a physician or a trained physical therapist) will position you to palpate muscles and ribs on your back. They will make a small mark with a skin-marking pen over the location of a rib. A second practitioner will then use an ultrasound machine to determine how close the skin marking was to the actual rib.

RISKS

The risks of this study are minimal. You may feel uncomfortable when the practitioner is applying gentle palpation over the rib but there will be no pain associated with the study. There will be no needle inserted into the skin.

BENEFITS

There are no direct benefits for taking part in this study. However, we hope the information we get from this study may help prevent any punctured lungs (a "pneumothorax") by other practitioners in the future.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact Dan Cushman, MD at 801-581-5328 during regular business hours. If you feel you have been harmed as a result of participation, please call the same number, or seek immediate care at your local hospital.

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Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION
Research studies include only people who choose to take part. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later. This will not affect your relationship with the investigator or any of the medical practitioners.

COSTS AND COMPENSATION TO PARTICIPANTS
There are no costs and/or compensation to study participants.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION
Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Height and weight
- Your age (not your date of birth)
- All tests and procedures that will be done in the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. For our study, we will only collect your name with this consent form. Otherwise, we will only record your age, height, weight, and ultrasound images of your back; we will not collect any personally-identifiable information. We may also need to disclose the information that we collected if required by law.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  - Members of the research team and *University of Utah Health Sciences Center*
  - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;

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- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

CONSENT:

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date

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