**STUDY INFORMATION AND CONSENT FORM**

**Title of Study:** Design and Fabrication of a Low-cost 3D-printed Myoelectric Deep Sensing Prosthesis for Transradial Amputees

**Principal Investigator**: Hossein Rouhani, Faculty of Engineering (780 492 8344)

**Study coordinator:** Leonardo Torres, Faculty of Engineering (780 232 7107)

This information sheet is only part of the process of informed consent. It should give you a basic idea of what the research study is about and what your participation will involve. If you would like more detail about something mentioned here or information not included here, please ask. Please take the time to read this carefully and to understand any accompanying information. You **will receive a copy** of this form for your records.

**WHAT IS THE REASON FOR DOING THE STUDY?**

This study aims to validate using two different electromyography (EMG) sensors to classify various electrical activities of muscles during different grasp tasks. The information collected in this study will be used for developing a new algorithm for a myoelectric prosthesis that enables the user to perform various hand movements. This likely helps improve the quality of life of people with upper limb amputation. Therefore, this study aims to develop a classification algorithm that will be implemented in a new prosthesis.

## WHY AM I BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

We invite you to take part in this research study because **you are an able-bodied person who can perform multiple hand grasps.** Before you decide, one of the researchers will go over this form with you. You **can always ask questions** if you need a better explanation or more information.

## WHAT WILL I BE ASKED TO DO?

If you agree to take part in this study, you should contact the study coordinator at (**780) 232 7107.** We will email you a copy of the information sheet and consent form. You should sign and return the consent form before enrolling you in the study. After receiving your consent, we will book you an appointment in the Neuromuscular Control & Biomechanics Laboratory. The Neuromuscular Control & Biomechanics Laboratory is located at the Mechanical Engineering Building, MECE 4-9, University of Alberta. You will be asked to wear four EMG sensors for the study. The sensors will be placed on your forearm.

You will do three tests, one for each grasp type: pinch, power, and tripod. Each test has a two-minute duration, consisting of performing the corresponding grasp for five seconds and resting for five more seconds. This sequence repeats for two minutes. Then, there is a three-minute resting period before starting the next test.

## WHAT ARE THE RISKS?

The risks associated with participation in this study are minimal, and there are no known risks of wearing the surface EMG electrodes. However, it is not possible to know all risks that may happen in a study, but we have taken all reasonable safeguards to minimize any known risks to you.

Wearing surface EMG electrodes may cause slight skin redness. It might cause skin irritation or an allergic reaction to the tape material in some people in a very rare situation. If you notice any unusual redness or skin irritation, please stop wearing the sensors and immediately contact the study coordinator.

**WHAT ARE THE BENEFITS TO ME?**

You **may not get any benefit** from being in this research study. If you agree to take part in this study, there may not be a direct benefit to you. However, this study may help develop a low-cost myoelectric prosthesis with multiple hand grasps for low income people.

## WHAT HAPPENS IF I AM INJURED BECAUSE OF THIS RESEARCH?

If you become ill or injured as a result of being in this study, you will receive the necessary medical treatment at no additional cost to you. By signing this consent form, you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

## DO I HAVE TO TAKE PART?

No, you do not have to take part in this study. Your participation is **voluntary**. You can ask to stop at any time during the study if you feel you cannot continue or do not want to continue. You may choose not to take part or to withdraw your consent at any time **without penalty** or **loss of benefits** to which you are otherwise entitled. It will **in no way jeopardize** your health care.If you are studying or working at the University of Alberta and choose not to take part or withdraw your consent, **no one** on the University of Alberta campus **will be told**. If you decide to withdraw from the study, we may **analyse** the information collected up to that point and used it for the study, unless you make a request to remove or destroy the information.

**WILL MY INFORMATION BE KEPT PRIVATE?**

All of the information collected will remain strictly confidential. Your privacy will be assured. Only the investigators of this study and the University of Alberta Research Ethics Board will have access to this information. No data relating to this study that includes your name will be released or published by the researchers.

All data will be kept in a secure, either locked or password-protected location after completion of the study. If you decide to withdraw from the study, we may analyse the information collected up to that point and used for the study, unless you make a request to remove or destroy the information.

## WHAT IF I HAVE QUESTIONS?

If you have further questions about matters related to this research, please contact Hossein Rouhani (primary investigator) at 780 492 8344 (hrouhani@ualberta.ca). If you have any questions about your rights as a participant in this study, you may contact the **Health Research Ethics Board**, University of Alberta at (**780) 492-2615**. This office has no affiliation with the study investigators.

**CONSENT**

**REB#:** Pro00104155

**Title of Study:** Design and Fabrication of a Low-cost 3D-printed Myoelectric Prosthesis for Transradial Amputees

**Principal Investigator:** Dr Hossein Rouhani **Phone Number:** 780-492-8344

Yes No

Do you understand that you have been asked to be in a research study? 🞎 🞎

Have you read and received a copy of the attached Information Sheet? 🞎 🞎

Do you understand the benefits and risks involved in taking part in this research study? 🞎 🞎

Have you had an opportunity to ask questions and discuss this study? 🞎 🞎

Do you understand that you are free to withdraw from the study at any time, 🞎 🞎

without having to give a reason and without affecting your future medical care?

Has the issue of confidentiality been explained to you? 🞎 🞎

Do you understand who will have access to the information you provide? 🞎 🞎

Do you want the investigator(s) to inform your family doctor that you are participating in this research study? If so, give his/her name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Who explained this study to you?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I agree to take part in this study: YES 🞎 NO 🞎

Signature of Research Subject: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Printed Name):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_

**THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH SUBJECT**