**STUDY INFORMATION AND CONSENT FORM**

**Title of Study:** Design and Fabrication of a Multi-Functional Low-cost 3D-printed Myoelectric 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 design a low-cost and multi functional prosthetic hand. The first goal is to use two brands of electromyograph (EMG) sensors for multiple grasp classification and develop an algorithm for a myoelectric prosthesis. EMG classification for prosthesis control enables the user to perform different hand movements thus improving her life quality. In addition, participates will attend in an experiment for sensory substitution function development. Individual with transradial amputation cannot sense the environment with the current developed prosthetic hands. Hence, adding a deep sensing mechanism will enable them to sense the environment by transferring the sensed force at fingertips to their skin. This study tries to develop the most effective transitional function to transfer force information as vibrations on the skin.

EMG sensors are electrical electrodes which records small electrical voltage changes on skin caused by muscle activities.

Sensory substitution is a research terminology which refers to the technologies or methods that helps us to replace a lost sensory with another.

The vibrators are some tiny motorized devices which applies small vibrations on the participants skins.

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

Models and algorithms are developed based on a rich dataset which are collected from the able-bodied subjects. We are inviting you to take part in this research study because **you are an able-bodied individuals that can perform multiple hand grasps.** And, we will collect your data (muscle activation by EMG sensors and hand positions by motion captures) 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?

Individuals who are willing to join this study should contact the study coordinator at (**780) 232 7107.** We will send participants a link to a secure website (REDCap) where participants can use it to give their consent to take part in the study. After receiving the consent, we will ask the participant a few questions such as name and contact details. It will take less than 5 minutes to answer all the questions over the phone. During the experiment participants will be asked to wear several surface EMG sensors and vibrators for the study. The experimental equipment will be placed on participants’ arm skin mainly on the muscle positions.

Participants will do two sessions of tests; EMG classification tests and sensory substitution tests. For EMG classification, the EMG sensors and motion capture markers are mounted on the participants skin and the muscle activity and hand positions are recorded for several grasp configurations; e.g., pinch, power, and tripod. For sensory substitution tests, participants wear a glove that contains force sensors on the fingertip. Also, vibrators, EMG sensors, and motion capture markers are placed on the participants’ skin where for different object grasp vibrations are applied on the skin and EMG sensor and motion capture data are collected. The whole duration of experiment is one hour containing experimental preparations (e.g., wearing EMG sensors, glove, and vibrators) and performing the main experiment (e.g., EMG classification and sensory substitution tests). Each test session takes about 25 min where between sessions we have considered 10 min for rest.

## WHAT ARE THE RISKS?

This experimental study is a low risk and its risk is not more than normal life and daily activities. The risks associated with participation in this study are minimal, and there are no known risks of wearing the sensor device. 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 sensors 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 direct benefit** to participate in this research study. However, this study will benefit the human society by helping individuals with transradial amputation to regain part of their abilities to do some of their daily activities. In addition, it provides them a chance to afford a low-cost myoelectric prosthesis with multiple hand grasps and different functionalities.

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

This is a low risk experimental study and research team have studied the risks of this experiment in different conditions and designed the experiment to minimize such risks. However, 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, participants do not have to take part in this study. The participation is **voluntary**. The participants can ask to stop experiment at any time during the study if they feel that they cannot continue or do not want to continue. They may choose not to take part or to withdraw their consent at any time **without penalty** or **loss of benefits** to which they are otherwise entitled. It will **in no way jeopardize** their health care.If they 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 they decide to withdraw from the study, the research team may **analyse** the information collected up to that point and used it for the study, unless the participant makes a request to remove or destroy the information.

**WILL MY INFORMATION BE KEPT PRIVATE?**

All of the information collected will remain strictly confidential. The participants 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 the participant decides to withdraw from the study, research team may analyse the information collected up to that point and used for the study, unless the participant makes a request to remove or destroy the information.

## WHAT IF I HAVE QUESTIONS?

If the participants have further questions about matters related to this research, they can contact Hossein Rouhani (primary investigator) at 780 492 8344 (hrouhani@ualberta.ca). If they have any questions about your rights as a participant in this study, they 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**