

# Research Participants Wanted

**Adults with  
Transhumeral  
(above-the-elbow),  
Elbow Disarticulate, or  
Transradial  
(below-the-elbow)  
Amputations Needed  
for the study:**

**“Effective and Reliable Peripheral  
Nerve Recordings”**

**Adaptive Neural Systems  
Laboratory  
Florida International University**



**Supported by:  
Defense Advanced Research  
Projects Agency (DARPA)  
01/29/2014**

## **Effective and Reliable Peripheral Nerve Recordings**

### **Goal of this Study:**

The purpose of this study is to gather new knowledge about the functioning of the nerves in the residual upper arm (stump) of amputees and to determine if it is possible to record useful information from those nerves over an extended timeframe (6 months).

The study is supported by the Defense Advanced Research Projects Agency (DARPA) and is being conducted by a research team that includes biomedical engineers, scientists, and an occupational therapist from Florida International University (FIU), a surgical team from the Hand Institute (HI) and Miami Hand Center, LLC (MHC), prosthetists from Ortho Pro Associates, Inc., and a consulting biomedical engineer and prosthetist.

If successful, this study will form the foundation for future work directed at developing systems that use these neural signals to provide amputees with the ability to easily and effectively control advanced prosthetic limbs.

### **What is involved?**

To monitor nerve activity, each subject will have fine wires implanted in one or two nerves of their residual upper arm. The nerves will be accessed through a skin incision. The fine wires have a diameter that is smaller than a human hair and the wires are very flexible.

The wires will be bundled so that there will be a few bundles of wires that cross the skin. Outside the skin, the bundles will be permanently connected to a small connector. A patch will be worn on a daily basis to protect the connector and the bundle entry sites.

Each subject will be asked to participate in 50 sessions in the laboratory, each of which will last approximately 2 hours. During the experimental sessions in the laboratory, the connector will be used to connect the implanted wires to an electronic recording system. The subject will be asked to think about making movements with their amputated arm/hand and the system will monitor the activity in nerves of the residual upper arm. In some tasks, the nerve activity will be used to control movement of a virtual object on a computer screen.

### **Who?**

- Individuals 18 years of age or older with an arm amputation (above the elbow, at the elbow, or below the elbow) that was done at least 9 months ago.
- Absence of other major medical concerns (cardiovascular and respiratory disease, diabetes, pressure ulcers, etc.).
- Reliable transportation to and from Florida International University and The Hand Institute/Miami Hand Center, LLC, both located in Miami, FL.

## Is there compensation for participating?

- For each study session at FIU subjects will be compensated \$50 in cash. Upon completion, of the entire research study, the total amount of compensation will be approximately \$2500.
- All research activities including study related medical examinations, study related materials (electrodes and new socket), will be provided free of charge. Subjects will not need to pay for tests and procedures that are done just for this research study.
- All other tests and procedures that are part of the subject's regular health care will have to be covered by the subject or their health plan.

## What are my incentives?

- We do not anticipate that you will gain any personal health benefits from participating in this study.
- We anticipate that you will contribute to general knowledge and understanding of function of the severed nerves of amputees and that this knowledge and understanding will aid in the development of prosthetic technology that could provide amputees with a higher level of functionality.

## How long will I be involved in the study?

You will be in the research study for about 6 months after the electrodes are implanted. You will need about 3 days for completing the preparation for the surgical implant. After the implant, for 12 weeks, you will be required to attend 3 experimental sessions per week; for the next 14 weeks, you will be asked to attend 2 sessions on every other week.

## Where will the study take place?

The implant surgery will occur at Miami Hand Center, LLC and all medical screenings and follow-ups will take place at the Hand Institute, Miami, FL. Some subjects may require modification to the socket of their artificial arm to accommodate the connector. If this is needed, the fitting for the new socket will take place at Ortho Pro Associates in Miami, FL. The experimental data collection of nerve activity will be performed at the Adaptive Neural Systems Laboratory at Florida International University in Miami, FL.



*For further questions about the study please contact:*

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**FIU**