**Appendix i.d Participant Information Sheet - Experiment Two**

**Study Title**: Repetitive Control and electrode array pattern selection for FES-based Drop-Foot Assistance– feasibility study

**Researcher**: Aaron Page

**ERGO number: ERGO// 47517**

**Date – 09/04/2019 Version 4**

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

To be able to partake in the study there are several criteria:

**Inclusion/Exclusion criteria:**

For your safety:

* Have no pacemakers or attached electronic equipment to avoid the risk of interference of these electronic devices

To ensure additional factors do not affect the study:

* Be healthy, have no know lower limb impairment, because adults with motor dysfunction or diagnosed systemic conditions such as MS, stroke, diabetes or rheumatoid arthritis may add confounding factors to the study.

You will be asked to confirm these in the consent form.

Some definitions are given first to help the participant understand exactly what this research is about.

**Some definitions:**

* **Functional Electrical Stimulation** (FES) is when a small current from a FES device is applied to a muscle to make it contract. It often gives a tingling feeling.
* **Repetitive control** (RC) - is a control law that has been written and included in the FES device that will learn and predict any voluntary motion and provide additional assistance to reach/follow a desired reference.
* **Point-to-Point repetitive control -** Essentially is an extension to the traditional control law that redefines the points within the tracking reference that are used to work out the output stimulation. Essentially the number of points tracked are reduced to 4 or 5 rather than 80+ points. This has many favourable characteristics for a controller such as being more robust and converging faster

**What is the research about?**

This research is being undertaken as part of the doctoral of philosophy (PhD) qualification of the researcher.

Approximately 20% to 30% of people who have a stroke will be left with damage to the path ways between their brain and the muscles that control ankle movement. This damage means that people are either unable to or are less able to control the movement which can lead to an increased likelihood of falling and leads directly to decreasing the individuals quality of life. Different medical solutions are available, the most prominent is functional electrical stimulation (small electrical signals that can cause a muscle to contract) however current systems can be difficult to set up – requiring careful positioning of two electrode pads.

This research aims to map out the relationship between stimulation and muscle response in the lower limb (specifically to stimulate the peroneal nerve). This information will be used to better understand how to select the optimal pad and whether there is a statistical similarity between various people.

The second part of this reach is to look into how we can make it easier for people to set up their FES devices using array technology and how we can develop better algorithms to search for the best place to apply stimulation.

**Why have I been asked to participate?**

We are specifically asking you, as you are a healthy individual (no know lower limb impairments) as we wish to investigate the relationship of pad placement and muscle response to stimulation.

**What will happen to me if I take part?**

You will be asked to sit in a slightly elevated chair. We will place an electrode array onto your left leg. There are some buttoned elastic straps to keep this attached additionally a sports sock will go over this. Around the ankle joint a device called an ankle goniometer (a specially designed device to measure the angle around the ankle – supplied by biometrics ltd.), this will be attached to the elastic loops of the specially designed sock. This is linked to a computer so we can collect data about your ankle movement.

If you agree to be included in this study you will be asked to perform the following actions.

* Sign a written consent form just before we start the data collection.
* Allow a fabric printed electrode array to be attached to your leg.
* Allow the FES stimulation device to be attached to the jelly electrodes so we can stimulate the muscle.

At all times a hardware stop button is available to you and the researcher.

We will then apply stimulation to each pad building up a set of data corresponding to the pad mapping to your leg response. This data will help us to develop better algorithms and hardware systems with the main aim of making initial set up faster and more effective. You will be then asked to take off the device and put it back on again (allowing us to build uncertainty into the data mapping with the aim of understanding how much any pattern may alter with pad array placement. We will look to gather 5 sets of data.

This experiment will take approximately an hour.

**Are there any benefits in my taking part?**

There will be no direct benefit to you from this study nor will there be any monetary compensation. However, the study will provide the evidence needed to build future FES devices to provide assistance to people with Drop-Foot. It is also expected that the technology in this study will also go on to underpin developments in rehabilitation FES used in relation to cycling and rowing.

This will ultimately benefit MS and stroke patients, helping to improve their quality of life. You will be eligible to receive details of the study’s results. The results of this study will be published in an academic journal but your identity will be kept completely anonymous.

**Are there any risks involved?**

There are no disadvantages or risks to taking part in this research. The only discomfort you may experience is the tingling sensation from the FES device but if you find this too uncomfortable/painful we will stop the session.

Any stimulation from the FES device is temporary and only lasts while the FES device is attached (the electrode is pushed against the skins surface). So there are no long term side effects of taking part.

Additionally, the techniques used here have significant clinical research and background and is currently used and supplied to people on the NHS.

**What data will be collected?**

The only data that could be classed as personal that will be linked to the rest of the data is your age. For the first week your name will be linked to the data via the consent forms. After this time the data will be anonymised and you will no longer be able to remove your experiment data results from the study.

All other data we would like to collect will not be able to identify you. This includes ankle angle (dorsiflexion, and role/inversion) during stimulation, initial twitch response (minimum stimulation need to cause contraction), the control effort (stimulation used to generate the ankle movement). The above will be processed to find the convergence speed of the controller, accuracy of tracking and how the control effort changes with time (how the system handles fatigue).

**Will my participation be confidential?**

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

The data collected only includes the values regarding the ankle dorsiflexion/roll during the experiment. It is completely impossible to identify you with these values. No other personal data is required or tied too the above. This means all the reads are entirely anonymous.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

**What happens if I change my mind?**

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. If you would like to remove your participation (data) from the study you will have one week after the initial experiment. Then the data will be placed with the rest of the data and it will be impossible to know what data belongs to you, please email the researcher – app2g13@soton.ac.uk.

**What will happen to the results of the research?**

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

The aim of this research is to produce a journal paper that cover how we can develop better electrode arrays in the future.

**Where can I get more information?**

Please contact me, Aaron Page, the researcher, at app2g13@soton.ac.uk or my supervisors, Christopher Freeman, at cf@ecs.soton.ac.uk, or Bing Chu, b.chu@ecs.soton.ac.uk, at the University of Southampton.

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. You can email them at – app2g13@soton.ac.uk

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer (data.protection@soton.ac.uk).

**Thank you for taking the time to review this document and considering to take part in the research mentioned.**