PARTICIPANT INFORMATION SHEET

# Study: “Non-invasive characterization of the human neuromuscular function”

JRCO number: 18IC4685

You are invited to take part in a research study titled “Non-invasive characterization of the human neuromuscular function”. Before you decide on whether or not you would like to participate, it is important that you understand why the research is being conducted and what it will involve. Please take time to read the following information carefully, ask any questions and discuss it with whom else you see fit. This document describes the purpose of the study and provides the details of the study protocol.

Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep identifiable information about you until 2028.

The College and those conducting this research study subscribe to the ethical conduct of research and to the protection, at all times, of the interests, comfort, and safety of participants. This research is being conducted under permission of the Imperial College Research Ethics Committee (ICREC).

For non-health related research, we will conduct scientific research in compliance with the law and the recommendations and guidance published by the UK Information Commissioners Office.

By signing this form you acknowledge that you have received a document which describes the procedures, possible risks and benefits of this research study, that you have received an adequate opportunity to consider the information in the documents describing the study, and that you agree to participate in the study at your own will.

Thank you very much for taking your time to read and familiarize yourself with this document.

## Purpose of the study

This study aims to investigate the neural code of motor commands delivered to the upper and lower limbs in participants during different voluntary contractions. These experiments will provide a large spectrum of applications for future prosthetic and exoskeleton devices while, at the same time, unravelling unknown physiological aspects of motor control such as muscle co-ordination. We plan to publish the results of this study in scientific journals and/or present them at scientific conferences.

## Your participation

Your participation in the study is entirely voluntary. This means that you will only be included in the study if you provide your written consent. You must be of adult age to give your consent and participate in the study. You will be free to, at any point, decide not to participate in or to withdraw from the study without any explanation or negative consequences.

## Procedure of the study

In this study, we will record muscle activity. This is done by using so-called ”surface EMG electrodes”. These will be placed on the surface of the skin covering relevant skeletal muscles. The skin will be shaved if needed and cleansed using either alcohol swaps or surgical spirit. Medical tape might be applied in order to reinforce the attachment of the sensors and/or relevant sensing equipment. Proprietary software will be used to record the signals, direct feedback and cue the participant for the duration of the experiment. All, some or none of the listed perturbations will be delivered in the following manner:

* *Electro-tactile*: Electrical stimuli will be applied on the surface of the skin. The stimulation will not be painful.
* *Mechanical*: Vibration stimuli will be delivered on the surface of the. To create a feeling of vibration, slight mechanical stimuli will be applied up to 1500 times per second. (We use a frequency of 175Hz to 1.5GHz.) This vibration will not be painful.
* *Visual and auditory* : Computer screens, placed at a comfortable distance and viewing angle will be used to show visual cues. Additionally, auditory cues will be used. These cues will give you feedback (e.g. on your muscular activation or joint position) and/or may indicate what we ask you to do.

You will be asked to perform a series of muscle contractions (as muscle contractions without moving or within task from daily living) not exceeding the comfortable level in accordance to the provided prompts, supported by the experimenter’s guidance. You might be asked to control an actual commercialised/custom made prosthetic device, exoskeleton or a virtual cursor. For some of the tasks, we might restrict your movements with a splint. For measurements on the lower limb, this might include walking on a treadmill or other terrains. We might also record your movements and applied forces during the experiment. This will be done using an external motion capture system and force sensors as well as so-called Inertial Measurement Units (IMUs) that can detect acceleration and orientation within space and sensors that detect if they are bent. For some specific tasks, we might also use a CE-certified ultrasound device as often used in medical diagnostics, or Mechanomyography sensors, which are placed on the surface of the skin to record muscle activity. None of these measurements will cause any pain or lead to any injury. They might be applied of the upper and/or the lower extremity. The experiment will take up to three hours following which the participant will be relieved of the all applied sensors and actuators and offered additional alcohol pads to remove any traces of electrode adhesive.

You may be asked to take part in a separate session during which an MRI 3D volumetric scan of your upper/lower limb will be recorded. At the start of the session, you will be interviewed by an MR radiographer to ensure that you hold no contra-indication to an MR examination. You may be asked to change some of your clothes to MR-safe garments. You will be asked to lay on the bed of the MRI with one your upper/lower limbs positioned in a special support. You will be given a button that, when pressed, ends the experiment and moves the bed out of the MR bore. The time inside the scanner will never exceed 90 minutes (typically shorter than 60 minutes).

## Contingency plan for injuries

There are no injuries related to this experiment likely to occur. Any injury unrelated and/or indirectly related to the execution of the experiment will be managed with the maximum possible care and attention. First aid kits are available in the laboratory where the experiment takes place as well as in other locations on the floor. A telephone indicating the (internal and external) numbers to call in case of emergency is available in the laboratory.

## Confidentiality

Imperial College London will collect information from you for this research study in accordance with our instructions. All information which is collected about you during the course of the experiment will be kept strictly confidential. Any information about you which leaves Imperial College London will have your name and address removed so that you cannot be recognised from it. You will not be required to write your name or any other identifying information on research materials. Materials will be maintained in a secure location. All procedures for handling, processing, storage and destruction of their data are compliant with the Data Protection Act 1998. Imperial College London will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded to oversee the quality of the study. Individuals from Imperial College London and regulatory organizations may look at your research records to check the accuracy of the research study. The only people in Imperial College London who will have access to information that identifies you will be people who need to contact you to confirm or audit the data collection process. The people who analyze the information will not be able to identify you and will not be able to find out your name or contact details.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organization and in other organizations. These organizations may be universities, or companies involved in health and care research in this country or abroad. Your information will only be used by organizations and researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/).

Your information could be used for research in any aspect of health or care and could be combined with information about you from other sources held by researchers, or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified, your data will only be used in research that has been independently reviewed by an ethics committee.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. Should you wish to obtain detailed information regarding your rights as a participant in research, or about the responsibilities of researchers conducting the study you can contact ICREC directly (http://www3.imperial.ac.uk/researchethicscommittee).

For any questions related to the study procedure, concerns and complaints please contact:

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Should you have any remaining concerns or complaints that you feel that have not been addressed after contacting Prof. Dario Farina, please feel free to reach out to the Joint Research Compliant Office (JRCO) at [jrco@imperial.ac.uk](mailto:jrco@imperial.ac.uk) or visit their website at <http://www3.imperial.ac.uk/clinicalresearchgovernanceoffice>.

## Finding out about result

If interested, you can find out the result of the study by contacting Prof. Dario Farina. You will be able to consult the published results.

## Funding

Some parts of the experiments are financed by the ERC PoC project Interspine, the H2020 project INPUT, Natural BionicS, EXTEND, EUROBENCH and SOMA. Moreover, financial support for some of the measurements has been obtained through CDT scholarships.

## Contact Details

If you have any questions regarding the study, please contact:

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