INFORMATION SHEET

FOR PARTICIPANTS IN THE RESEARCH STUDY OF A HAND

EXOSKELETON FOR ASSESSING HAND SPASTICITY

You will be given a copy of this information sheet.

Study Title: **Development of a Hand Exoskeleton for Precise Stretch and Resistance Measurement in Hand Spasticity Assessment**
Researchers: **Hao Yu (PhD Candidate)**
Principal Investigator: **Mustafa Suphi Erden (Associate Professor)**
Clinical advisor: **Alyson Nelson (Neurorehabilitation Consultant)**
Research Institution: Heriot-Watt University, Earl Mountbatten Building G.08, EH14 4AS, Edinburgh
Experimental Site: Astley Ainslie Hospital, Charles Bell Pavilion, EH9 2HL, Edinburgh
Contact Details: Tel: 01314513265; e-mail: hy2020@hw.ac.uk, m.s.erden@hw.ac.uk

This study has been approved by the UK National Health Service Research Ethics Committee (REC No:)

We would like to invite you to participate in this research project.

Details of the study:

1. PURPOSE OF THIS RESEARCH STUDY

- You are being asked to participate in a research study designed

1) to test if a hand exoskeleton device can provide an objective, quantifiable measure of hand spasticity in post-stroke patients, thereby offering a more reliable and sensitive assessment method compared to current clinical assessments.
2) to evaluate the effectiveness and precision of a hand exoskeleton in measuring the resistance force of spastic hand muscles, with the aim of improving diagnostic accuracy and informing more personalized treatment plans.

2. POSSIBLE BENEFITS OF THE RESEARCH

- **Advancement in Diagnostic Accuracy:** The most significant benefit of this research is the potential improvement in the accuracy of diagnosing hand spasticity in post-stroke patients. This could lead to better personalized treatment plans and potentially improved recovery outcomes.
- **Contribution to Medical Knowledge:** Participants are contributing to valuable research that could benefit future stroke survivors. This sense of contributing to the greater good can be personally rewarding for participants.
- **Enhanced Understanding of Individual Condition:** Participants may gain a deeper understanding of their own condition through the assessments, which can be empowering and informative.

3. What Will Happen in the Study

- First, a trained physiotherapist will evaluate the range of motion and the stiffness in your hand using a common method called the Modified Ashworth Scale (MAS). This will help us know the starting point of your hand's condition.
- Next, we will take some careful measurements of your hand, specifically looking at the length of each part of your fingers and how much your hand joints can move comfortably. This is important so that our exoskeleton device can work with your hand safely and effectively.
- Our exoskeleton device is designed to gently move your hand for you. It can bend and straighten your hand joints at different speeds, starting very slowly and increasing a little at a time, but never going beyond what's comfortable for you. We'll do this movement series five times at each speed to gather consistent data. During these movements, the device will record how your hand's joints move and the force they exert against the device, which will help us understand your hand's condition better.
- After the experiment, we would love to hear about your experience with it. You will be asked to fill out a simple questionnaire called the System Usability Scale. It's a way for you to tell us how easy

and comfortable the device was to use. Your feedback is invaluable and will help us make improvements.
- This study is a step toward better understanding and treating hand spasticity, and your participation is greatly appreciated. Remember, everything we do in this study is designed with your comfort and safety in mind.

4. SOURCE OF FUNDING OF THE RESEARCH

- This research is funded by the EPSRC with project code F16PRJ01. It is part of the EPSRC Centre for Doctoral Training in Robotics and Autonomous Systems under the Grant Reference EP/S023208/1.

5. PARTICIPANTS INCLUSION CRITERIA

- Adults who have been medically diagnosed with hand spasticity.
- Participants' dominant hand is assessed as 1 to 3 MAS.
- Participants should have the cognitive ability to understand the study and provide informed consent form, as well as the ability to communicate any discomfort or issues during the study.
- The capacity to comprehend and adhere to the study's requirements, especially important for interacting with the exoskeleton and providing feedback.

6. PLACE AND TIMING OF THE EXPERIMENTS

- The experiment will take place in Astley Ainslie Hospital, Charles Bell Pavilion, EH9 2HL, Edinburgh.
- The experiment will be performed during the working hours, on a day that you are available.
- Each experiment will last around 60 minutes.

7. POSSIBLE RISKS OR DISCOMFORT

- The mechatronic system of the hand exoskeleton was designed according to the requirements of clinical assessment of hand spasticity and clinicians' advice. It will not cause any physical damage, but your fingers will feel a slight squeeze, and your hand may feel tired over the experiment.
- The exoskeleton will start at a very slow velocity to help your hand get used to the experiment and adjust to a comfortable gesture.
- The robot is equipped with various safety measures based on the angle and force sensors, avoiding high-speed movements or large compression.
- In case of any unforeseen failure (breaking of signal communication, breakdown of the force sensor, uncontrolled motion of the arm), the robot can be stopped at any time with an emergency stop button.

8. COMPENSATION

- You will be paid 10 £ per/hour through the Heriot-Watt Finance department for compensation of your time and for thanking you for your voluntariness.

9. TERMINATION OF RESEARCH STUDY

- You are free to choose whether or not to participate in this study. There will be no disadvantage or penalty if you choose not to participate.
- You are free to choose whether or not to continue to participate in this study at any time of the experiments. There will be no disadvantage, penalty or restriction if you choose not to continue with the experiment at any phase.

10. QUESTIONNAIRES

- You will be asked to answer general questions regarding to your experience with the experimental setup such as overall performance of the human-robot interaction and whether you feel any discomfort over the experiment.

11. CONFIDENTIALITY

- Your identity in this study will be treated as confidential. The results of the study may be published for scientific purposes but we will not give your name or include any identifiable references to you. The collected data are series of numbers that measure the robot's displacement and the forces of your hand. These data are recorded as a text file and will be stored in the laboratory's computers with a coded file name. This code will not reveal your identity.

12. MEDICAL TREATMENT AND INSURANCE COVERAGE

- If you are injured as a direct result of taking part in this research study, emergency medical care will be provided by Heriot-Watt University security and first-aid services.

13. CONTACT INFORMATION

- You can any time contact to the researchers of these experiments, Hao Yu and/or the Principal Investigator Dr. Mustafa Suphi Erden, before or after the experiments.
- Tel: 01314513265; e-mail: hy2020@hw.ac.uk, m.s.erden@hw.ac.uk

Please discuss the information above with others or ask us if there is anything that is not clear or if you would like to receive more information.

It is up to you to decide whether you will take part or not; choosing not to take part will not disadvantage you in any way. As a participant you have the right to withdraw from the study at anytime without giving a reason or facing negative consequences.

All data will be collected and stored safely and reported in an anonymous form. Only the principal investigator and/or the members of the Research Ethics Committee have access to the original dataunder strict confidentiality.