UNIVERSITY OF LIMERICK EHS RESEARCH ETHICS COMMITTEE

PROCEDURES INVOLVING HUMAN SUBJECTS

		Procedure No	**SS 004**
Title of Procedure	Electrical stimulation of muscle		
Name of Assessor	Alan Donnelly	Assessment date	November 2018
Does this procedure already have ethical approval ?			**Yes**
If so, enter ethical number and expiry date	**Approval No: SS004** **End Date: December 2028**		

1 **Please provide a brief description of the procedure**

This procedure involves percutaneous electrical stimulation of human muscle. In this procedure, large surface electrodes are placed at either end of the muscle, and a small current is delivered through the muscle to induce muscle contraction. All electrical human stimulators in PESS, comply with the EU medical directive for safety in human use and must be CE marked. In these stimulators, the stimulator circuit is optically isolated from mains current. The electrical stimulation protocol is used on a number of muscles in laboratory use, but the principal use would be on leg quadriceps and on gastrocnemius muscles. Volunteers will wear shorts and will self place the electrodes under the direction of the researcher. When this procedure is being carried out for research purposes, best practice would be that a third person would be present, of the same sex as the volunteer.

Stimulation would be delivered at varying frequencies, depending upon the protocol (one use is in demonstrating force-frequency relationship in human muscles, which involves ramping up through a frequency range of 1 – 100 Hz). In all experiments with the stimulators, the volunteer is familiarised with the feeling of electrical stimulation before the main experiment begins. In this familiarisation session, the volunteers are asked to increase the current being delivered from zero, so that they set their own threshold of tolerance. The stimulation duration during experiments is rarely more than a few seconds. Participants will wear a waist belt or a seat belt on the testing apparatus to ensure their safety during the test.

Electrical stimulation is unpleasant, and tolerance of the procedure varies greatly between individuals. As in all experiments, the volunteers are informed of their right to withdraw from the experiment at any time. Volunteers will be informed that if they find the level of electrical current or the frequency to be unpleasant, the experiment will cease or the current will be reduced in consultation with the volunteer.

2	**Location in which the procedure may take place**

x	PESS Teaching Facilities
x	PESS Research Facilities

Others, please specify

3	**Eligibility of subject(s) to be used**

x	PESS student (U.G. or P.G.)
x	University of Limerick staff or campus personnel

Others, please specify

x	Members of the general public engaged in research projects granted ethical approval.

4	**Potential risks. To be explained <u>before</u> obtaining consent**

x	Low Risk

Electrical stimulation of muscle is relatively safe, but can be unpleasant for the volunteers. There is a very small risk that if the current were delivered across the chest of a volunteer, that arrhythmia could be induced. However, we would never place electrodes in this configuration, and the total power delivered by the stimulator is far less than that used in defibrillation. Volunteers are asked to adopt a cross armed position and must not on any condition touch the electrodes with their hands.

Volunteers who find the procedure very unpleasant would be encouraged to withdraw from the experiment. **All volunteers would be counseled about the unpleasant nature of the procedure prior to participation.**

High force isometric contractions induced during contractions also carry a small risk of injury to the knee joint. Subjects who respond on the questionnaire that they have had any recent lower limb musculoskeletal injury will not be allowed to proceed with the test. If anyone complains of excessive joint pain during the test, the procedure will be stopped.

5	**Action to be taken in the event of a foreseeable emergency**

The procedure will be terminated if the volunteer shows any sign of distress.

Standard first aid procedures may be required depending on the severity of the situation. The following standard procedure should be followed in the event of an incident occurring in the PESS building / UL Facility:

1. Stop the procedure. Position the subject to prevent self-injury.
2. If appropriate, raise the subject's lower limbs to improve blood flow. Should the subject fail to respond summon help immediately.

3. Check vital signs airways, breathing and circulation (ABC)
4. If required attempt CPR as soon as possible.
5. Requesting Help: Emergency Contact telephone numbers are listed on laboratory door:
   - During normal working hours 9am-5pm, use lab phone to contact the Student Health Centre on **061-20**2534
   - Outside of normal working hours, or if the Student Health Centre number is engaged/busy, use the laboratory phone to dial 3333 for UL security personnel who will then contact the ambulance service. Contact one of the PESS First Aiders – names are listed on the PESS laboratory door.
6. When contacting the above clearly state: Location, Building, Room Number, Nature of Incident/Accident and provide a contact number.
7. Complete the UL 'Accident & Emergency' form (completed by the investigator, not the volunteer). Forms available on UL HR website: https://www.ul.ie/hr/hr-policies-procedures-and-forms-z

If an emergency or incident occurs offsite, follow the local procedures for dealing with such an event.

6	**Level of supervision required for procedure**

x	PESS lecturing, research staff and teaching assistants
x	PESS postgraduate researcher

Others, please specify

7	**Other documentation required for this assessment ?**

x	PESS Pre-test subject questionnaire
x	Participant Information Sheet

Others, please specify

x	Participant Consent Form

For office use only

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8	**Committee approval for experiment**

X	Granted
Others, please specify	

Comments/conditions

Signed _____ Date 11/1/19

(Head of Department)

SS 004

Standard Operating Procedure for Electrical Stimulation of Muscle

Electrical stimulation causes a muscle to contract directly, i.e. the subject does not initiate the contraction.

1. Two large electrodes are placed on the skin at either end of a particular muscle, e.g. thigh.
2. The electrodes are attached to an electrical stimulator, which can generate different levels of contraction.
3. The participant will be given an opportunity to familiarise themselves with the feeling of electrical stimulation, from the lowest level to a level they feel tolerable.
4. The participant will be asked to slowly increase the current whilst the stimulator is active, to reach a point where the muscle is developing sufficient force. Once this has been done, the current that the participant has set will be used for further stimulation.

Note:

- There is no chance of electrocution as the electrodes are isolated from the main current.
- The procedure is relatively safe, however the stimulation may at times be unpleasant for the participant. If the participant finds the procedure very unpleasant they can withdraw from the experiment.
- With high force contractions of the thigh, there may be a small risk of injury to the knee joint.
- If the participant has recently injured their knee, they will not be allowed to proceed with the test.
- If the participant experiences excessive joint pain during the test, the test will be stopped immediately.