UNIVERSITY OF LIMERICK
OLLSCOIL LUIMNIGH

UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

		Procedure No	**SS 002**
Title of Procedure	EMG / ECG recording		
Name of Assessor	Alan Donnelly	Assessment date	Nov 2018
Does this procedure already have ethical approval ?			**YES**
If so, enter ethical number and expiry date			**Approval No:2019_11_SS 002_RA** **End Date: December 2028**

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

These procedures involve electrical recording from active muscle or myocardium. Both procedures involve placement of recording electrodes on the skin surface, either over the muscle for EMG, or at standard lead positions for ECG. The apparatus used is electrically isolated, and conforms to EU guidelines for electrical isolation (and carries CE Marking). The signal recorded is converted to a digital signal, and stored on a computer system. The recordings are made for UG laboratory classes and research purposes.

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 (adolescents age 13+, adults) engaged in research projects granted ethical approval.

4 Potential risks. To be explained before obtaining consent

X	None, or minimal discomfort only

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.

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

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 standard pre-test questionnaire
x	Detailed protocol

Others, please specify

x	Participant Information Sheet & Consent Form
x	Consent from parents/guardians for minors (under 18)

For office use only

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Name of Assessor Alan Donnelly Assessment date Nov 2018

W Committee approval for experiment

ILi Granted

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Others, plyse s]ecify .

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Comments/conditions

Signed --=-------=-4.. V:t rL Date 118_1')

(Head of Department)