

UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

Risk Assessment Form – Procedures Involving Human Subjects

Procedure No

Title of Procedure

Name of Assessor(s) **Assessment Date**

Does this procedure already have ethical approval ?

If so, enter ethical number and expiry date

Approval No: SS016
End Date: December 2028

1 Please provide a brief description of the procedure

Accelerometers will be attached to several body sites on the individual (for example the knee joint), and the subsequent data recorded by a PC based system or an ambulatory data logger. The accelerometers will be supplied by Analog Devices (Part # - ADXL05 or ADXL202), Shimmer, Delsys Trigno, or similar type devices both wired or wireless.

Where direct application of accelerometers to the skin surface is required all research will be undertaken using isolated circuitry. The data acquisition module/procedure used during these sections will either be optically isolated to <5000V in combination with an ELC (earth leakage circuit breaker) and a surge protector (if a mains powered PC is used) or carried out using battery operated equipment (battery powered laptop PC). These procedures offer the best protection from electric shock currently available. The accelerometers will be encapsulated to further enhance the safety of the system.

This procedure will usually be done in conjunction with 3D analysis of motion (Procedure Nos. SS 010/SS 011)

Note: SOP for Delsys EMG System (wireless) is available on [PESS Sharepoint](#).

2 Location in which the procedure may take place

3 Eligibility of subject(s) to be used

- PESS student (U.G. or P.G.)
- University of Limerick staff or campus personnel
- Members of the general public engaged in research projects granted ethical approval.

4 Potential risks. To be explained before obtaining consent

- None, or minimal discomfort only

In some trials, subjects may be required to wear exercise clothing or swimming costumes so that anatomical landmarks can be easily identified and marked with retroreflective markers or tape.

A third party, preferably of the same sex as the subject, will be present during periods of physical contact between experimenter and subject.

Raw video data can identify a participant. As part of GDPR compliance, participants will be fully informed and made aware that they are being videoed as part of the procedure. Participants must consent to being videoed as part of the procedure. Where raw video capture is being used for research, participants will be fully informed as to how long the data will be stored for, for what purposes it is being stored and who has access to the data.

Raw video capture will be stored on password protected computers until data analysis is complete. Raw video data will be deleted at the end of the project and the anonymised non-identifiable data will be retained.

Note: Online motion capture does not store raw video data, it tracks marker trajectories and stores non-identifiable data.

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 **061-202534**
 - 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
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- | | |
|-------------------------------------|--|
| <input checked="" type="checkbox"/> | PESS lecturing, research staff and teaching assistants |
| <input checked="" type="checkbox"/> | PESS postgraduate researcher |
| <input checked="" type="checkbox"/> | Trained undergraduate or postgraduate student |

7	Other documentation required for this assessment ?
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- | | |
|-------------------------------------|--------------------------------------|
| <input checked="" type="checkbox"/> | PESS standard pre-test questionnaire |
| <input checked="" type="checkbox"/> | Participant Information Sheet |
| <input checked="" type="checkbox"/> | Participant Consent Form |
- Others, please specify

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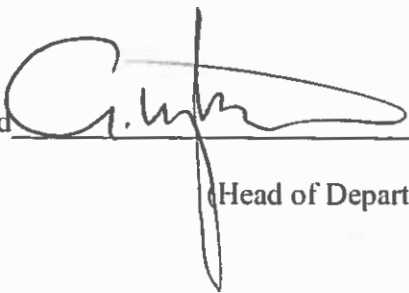
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Others, please specify

Comments/conditions

Signed  Date 11/11/18
(Head of Department)