

UNIVERSITY OF LIMERICK EHS RESEARCH ETHICS COMMITTEE

PROCEDURES INVOLVING HUMAN SUBJECTS

Procedure No

Title of Procedure

Name of Assessor Assessment date

Does this procedure already have ethical approval ?

If so, enter ethical number and expiry date

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In this procedure the ability of healthy adult volunteer subjects to balance on one leg will be assessed using a force plate. The procedure is similar in many respects to the Romberg test. The test will be performed for a period of 30 – 60 seconds under two conditions: eyes open and eyes closed. The tester will observe the participant throughout the period of the test and should the participant appear to lose balance and begin to fall, the subject will be instructed to stop, open their eyes and regain their balance. The force plate will be used to obtain a variety of indices of balance, e.g. centre of pressure (COP) 95% confidence ellipse area, sd of COP loci, etc.

In this procedure simultaneous 3D motion analysis can also take place, where the participant is videoed during the movement. In this case, the participant will be required to wear exercise clothing or swimming costumes so that anatomical landmarks can be easily identified and marked with retroflective markers or tape. 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 only tracks marker trajectories and stores non-identifiable data.

Note: Standard Operating Procedure for the AMTI Force platforms are available on the [PESS Sharepoint](#)

2	Location in which the procedure may take place
<input checked="" type="checkbox"/>	Teaching Laboratory (PG040)
<input checked="" type="checkbox"/>	Research Laboratory (PG043)
Others, please specify	
<input type="checkbox"/>	

3	Eligibility of subject(s) to be used
<input checked="" type="checkbox"/>	PESS student (U.G. or P.G.)
<input checked="" type="checkbox"/>	University of Limerick staff or campus personnel
Others, please specify	
<input checked="" type="checkbox"/>	Fit and healthy adults or athlete volunteers engaged in research projects granted ethical approval

4	Potential risks. To be explained before obtaining consent
<input checked="" type="checkbox"/>	Low risk

In some trials where simultaneous 3D motion analysis also takes place, participants 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.

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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>

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Level of supervision required for procedure

<input checked="" type="checkbox"/>	PESS lecturing or research staff, PESS teaching assistants
<input checked="" type="checkbox"/>	PESS postgraduate researcher
<input checked="" type="checkbox"/>	Trained undergraduate or postgraduate student

Others, please specify

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Other documentation required for this assessment ?

<input checked="" type="checkbox"/>	PESS standard pre-test questionnaire
<input checked="" type="checkbox"/>	Participant Information Sheet
<input checked="" type="checkbox"/>	Participant Consent Form
<input type="checkbox"/>	

Others, please specify

For office use only

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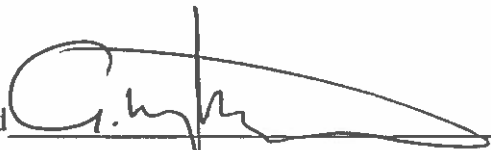
Name of Assessor

Assessment date

End Date: December 2028

Others, please specify

Comments/conditions

Signed 
(Head of Department)

Date 11/1/19