UNIVERSITY OF LIMERICK
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UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

Procedure No	SS033
Title of Procedure	Measurement of maximum oxygen uptake
Name of Assessors	Giles Warrington
Assessment date	November 2019
Does this procedure already have ethical approval?	**YES**
If so, enter ethical number and expiry date	**Previous Approval No: 2020_01_17_EHS (RA)** **Date expires: December 2029**

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

Maximal oxygen uptake ($VO_{2\ max}$) is defined as the maximal rate at which an individual can take up and utilise oxygen whilst breathing air at sea level and is accepted as the criterion measure of cardiorespiratory fitness (ACSM, 2017). The procedures are well established by the World Health Organization (Lange- Anderson, 1971) and the American College of Sports Medicine (ACSM, 2017) and require the subject to perform an incremental exercise test to volitional exhaustion.

Indirect calorimetry using open circuit spirometry is used to measure $VO_{2\ max}$ or $VO_{2\ peak}$ where the subject either wears a sealed mask around the mouth and nose or mouth piece and nose clip and breaths through a low resistance valve, whilst pulmonary ventilation (VE), oxygen (O_2) and carbon dioxide (CO_2) are measured.

Test Protocol

The subject must have completed a pre-test questionnaire prior to the test outlining that they have no cardiovascular / musculoskeletal contraindications at the time of testing. The following procedure applies to this test:

1. The ergometer used for the test should closely match the activity (e.g. cycle, treadmill, rowing) that the subject is accustomed to.
2. There are a number of population specific test protocols available and the protocol selected should allow the subject to attain volitional exhaustion within 8 to 12 minutes of the onset of the test excluding the designated warm up period. Additionally, there are ergometer incremental protocols, which may be more appropriate and can last up to 30 minutes.
3. Heart rate is monitored continuously (using heart rate monitors / ECG) throughout the test and 5 minutes post-exercise.

4. A warm up period of 5 minutes should precede the test that includes some exercise on the chosen ergometer (for familiarization) as well as a period of time for the subject to perform a series of stretches in preparation for the exercise to follow.
5. Expired gases are normally collected continuously throughout the duration of the test at sampling rates usually of 20-30 seconds which are then averaged over the course of 1 minute.

6. Upon volitional exhaustion the test is terminated and the face mask/mouth piece and nose clip are removed.
7. The participant can rest stationary for up to 5 minutes before being encouraged to re-start low intensity exercise (equivalent to or below warm up intensity) and to maintain this for a minimum of 5 minutes.
8. A capillary blood sample can be taken from the earlobe or finger tip between 2-5 minutes post exercise for determination of peak blood lactate levels. (See SS024 Risk Assessment for Capillary Blood Sampling)
9. Two testers will be present at all times during the testing protocol.

Criteria for Attainment of $VO_{2\ max}$

1. A levelling off in VO_2 even with a higher workload
   < 150 ml/min
   < 2.1 ml/kg/min

   Typically plateau only observed in ~50% of tests therefore 'peak' rather than 'max' is stated.

2. Peak blood lactate exceeding 8 mmol/l

3. RER> 1.10 or 1.00 for older individuals

4. Heart rate >95% predicted HR_{max} (220-age)

(Adapted from ACSM, 2017)

Example of a protocol for an incremental test: Zoladz, J.A., Rademaker, A.C. and Sargeant, A.J., 1995. Non-linear relationship between O2 uptake and power output at high intensities of exercise in humans. The Journal of physiology, 488(1), pp.211-217. https://physoc.onlinelibrary.wiley.com/doi/abs/10.1113/jphysiol.1995.sp020959

2	**Location in which the procedure may take place**
x	PESS Teaching Laboratory (PG050)
x	PESS Research Laboratory (PG047, PG051)

Others, please specify

3	**Eligibility of subject(s) to be used**
x	PESS student (U.G. or P.G.)
x	University staff or campus personnel
x	Members of the general public engaged in research projects granted ethical approval, e.g. high performance athletes

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

This is a test of ***maximal*** exercise tolerance. In normal, healthy subjects, the risks are equivalent to exhaustive strenuous exercise typical of competitive sport. The risks associated with maximal exercise are fatigue, muscle soreness, and shortness of breath. The participant will experience physical discomfort during the test but particularly as they approach volitional exhaustion.

Subjects will experience the discomfort of exhaustive strenuous exercise for at least 5 minutes post-exercise. Some embarrassment may be experienced by the subject by the distress caused by fatiguing exercise. Upon completion, the subject may experience some temporary muscle aches and pain and in the 24-48 hours after the test, some delayed onset muscle soreness.

The subject should **not participate** in the test if there is (1) a recent history of illness (2) current or recurrent injury (3) cardiovascular / musculoskeletal contraindications at the time of testing. These are identified in the pre-test questionnaire.

Exercising maximally on an ergometer carries the risk of the subject falling whilst on the ergometer, e.g. treadmill, cycle ergometer, rowing ergometer. This risk will be minimised by (a) familiarisation session for subjects, (b) researchers being prepared to stop the treadmill or test quickly, and (c) researchers being prepared to react and intervene if the subjects should show signs of falling. Serious accidents on treadmills/ergometers are rare.

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

Testers will explain how and when the test will be terminated. This text involves the subject exercising to maximal tolerance. If the subject shows signs of distress that are not indicative of signs relating to reaching maximal tolerance, the procedure will be terminated.

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 additional PESS First Aider if necessary – 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/ TA staff (Occupational First Aid trained / AED Trained)
x	PESS postgraduate researcher ((Occupational First Aid trained / AED Trained)

Others, please specify

x	If above listed do not have an occupational first aid / AED certification, there must be a PESS staff member who is trained with such qualifications present in the laboratory at the time of testing. **There must be two testers present at all times when assessing maximum oxygen uptake (regardless of protocol / exercise mode).**

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

x	Pre-test subject questionnaire
x	Detailed protocol

Others, please specify

x	Information Sheet
x	Consent Form

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8	**Committee approval for experiment**

√	Granted
x	Subject to conditions (see below)
Others, please specify	
x	PAR-Q / Health Screen

Comments/conditions

Detailed protocol / standard operating procedure for the assessment specific to the ergometer being used.

Individuals supervising the test must have Occupational First Aid Qualification or AED qualification. If persons do not have this qualification, there must be a PESS staff member present who does have such qualification.

There must be two testers at all times when assessing maximum oxygen uptake regardless of protocol or exercise mode.

Participant Health Screen (PAR-Q)

Participants with asthma must have their inhalers in the laboratory.

Signed:  Date: 20/11/2019

Dr Giles Warrington
Head of Department, PESS