**For Office Use Only: ULREC No: ____/____**

UNIVERSITY OF LIMERICK
OLLSCOIL LUIMNIGH

# UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

## RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

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|---|---|
| **Procedure No** | 2009_10_03_RA |
| **Title of Procedure** | Physiological Assessment of the Energy Cost and Lactate Profile During Incremental, Sub-Maximal Running on a Motorised Treadmill |
| **Name of Assessor(s)** | Professor P. Jakeman |
| **Assessment Date** | 22 /10 /2009 |
| Does this procedure already have ethical approval? (Delete as appropriate) | ~~YES~~/NO |
| If **YES**, enter ethical number and expiry date | **Approval No:** |
| | **Expiry Date:** 22 / 10 / 2019 |

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

### General conditions:

- The subjects will have completed a pre-test questionnaire (PAR-Q) and will have provided written, informed consent.
- The procedure involves running on an inclined motorised treadmill. The exercise intensity is regulated by the velocity of the treadmill belt.

### Procedure:

1. The subject is fitted with a Polar™ Heart Rate Monitor.
2. Subject maintains a set running velocity on a level treadmill ranging between 10 and 15 kph, depending on ability. The starting intensity of exercise is set to a heart rate equivalent to between 50 and 55% of maximal oxygen uptake calculated using the Karvonen Formula*.

* Karvonen Formula : Target HR = RHR + %$VO_2$max(MHR-RHR)
Where: RHR = Resting Heart Rate, MHR= Max Heart Rate – if known or 220-Age if predicted
and %$VO_2$max = required intensity expressed as a fraction of the maximal oxygen uptake

3. Intensity of exercise is incrementally increased by increase in treadmill velocity Exercise intensity is linearly related to treadmill velocity.
4. The energy cost of running for each incremental increase in exercise intensity is measured by indirect calorimetry using an off-line Douglas Bag technique or on-line Metabolic Cart (SS009) during the last minute of each stage of the test.
5. A capillary sample of blood is taken (SS024) during the last 15s seconds of each stage of the test to determine the blood lactic acid concentration using a dry (Lactate Pro™) or wet (Analox GM7) lactate analyser (Figure 2).

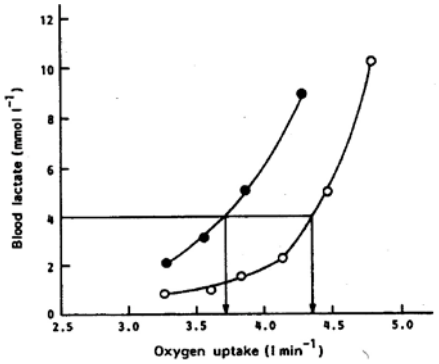



**Figure 2.** Interpolation of onset of blood lactate accumulation (OBLA) from blood lactate data before (O—O) and after (●—●) viral illness (for details see text)

6. The test is terminated when the blood lactic acid concentration exceeds 4mmol/l.
7. The test may be terminated an earlier stage should the subject show undue signs of stress or exceed a heart rate >=90% of maximal oxygen uptake as predicted from the Karvonen Formula.

| 2 | **Location in which the procedure may take place** |
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| √ | Project Laboratory (Room No: PG052) or Main Physiology Lab (PG050), PESS Building |
| | |

| 3 | **Eligibility of subject(s) to be used** |
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| √ | UL staff, students or campus personnel recruited for projects granted PESSREG approval |
| √ | Members of the general public recruited for projects granted PESSREG approval |

| 4 | **Potential risks. To be explained <u>before</u> obtaining consent** |
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| √ | None, or minimal discomfort only |

If the risks are other than trivial please provide a brief description.

| 5 | **Action to be taken in the event of an foreseeable emergency** |
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Please provide a clear statement of appropriate action including contact names and telephone numbers.

1. Stop the procedure. Position the subject to prevent self-injury.
2. Raise the subject's lower limbs to improve blood flow and counteract the vasovagal influence. Should the subject fail to respond **summon help immediately**.
3. Check vital signs airways, breathing and circulation (ABC)
4. If required attempt CPR
5. Contact telephone numbers:
    a. During normal working hours 9am-5pm, use lab phone to contact the Student Health Centre on **2534**
    b. 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.

When contacting the above clearly state:

**Location** : Project Laboratory (PG052), Sports Building. Phone number Extn. **2856**
**Incident**: Subject collapse during treadmill exercise.

| 6 | Level of supervision required for procedure |
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| √ | Faculty staff, post-graduate or undergraduate researcher trained to level of supervision required by principal researcher of PESSREG approved study. |
| | |

| 7 | Other documentation required for this assessment ? |
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| √ | Informed consent relating to PESSREG approved project using this procedure. |
| √ | Pre-test subject questionnaire (PAR-Q) |

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# FOR COMPLETION BY HEAD OF DEPARTMENT

## RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

**In the Department of : Physical Education and Sport Sciences**

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| **Procedure No** | |
| **Title of Procedure** | Physiological Assessment of the Energy Cost and Lactate Profile During Incremental, Sub-Maximal Running on a Motorised Treadmill |
| **Name of Assessor(s)** | Professor P. Jakeman |
| **Assessment Date** | 22/10/2009 |

**8 Approval of procedure**

| | |
|---|---|
| | Granted |
| | Subject to conditions (see below) |

Others, please specify

| | |
|---|---|
| | |
| | |

**Comments/conditions**

Signed: _____ Date: _____

(Head of Department)