UNIVERSITY *of* LIMERICK

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UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

Procedure No	EHSREC09 _RA01
Title of Procedure	Physiological Assessment of the Energy Cost and Lactate Profile During Incremental, Sub-Maximal Cycling 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: / /

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 cycling on an inclined motorised treadmill whilst attached to a pulley (see Figure 1). The exercise intensity is regulated by addition of weights to the pulley system as per that described by Jakeman *et al*. *British Journal of Sports Medicine* 27, 157-161 (1993).

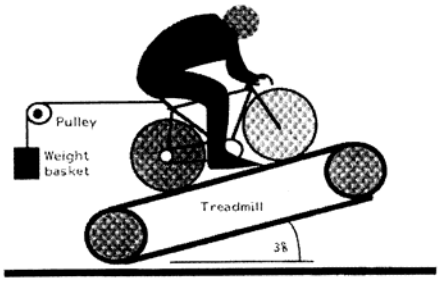

Figure 1. Treadmill cycle ergometry

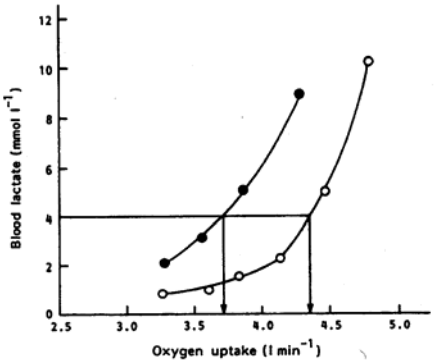

Figure 2. Interpolation of onset of blood lactate accumulation (OBLA) from blood lactate data before (O—O) and after (●—●)

Procedure:

1. Subject to cycle on his/her tailored road bike with crank length, gear ratio and tyre pressure optimised for the individual.
2. The subject is fitted with a Polar™ Heart Rate Monitor.
3. Subject is stabilised by experimenter whilst the treadmill velocity is increased until a stable velocity is reached (normally 12kph) and the cyclist cycles freely at his/her chosen pedal cadence.
4. Subject maintains a set cycling velocity, ranging between 14 and 17.5 kph, depending on ability, on a treadmill inclined to 2%. 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*.

5. Intensity of exercise is incrementally increased by addition of known mass (range 0.5 to 3kg) to the pulley. Exercise intensity is linearly related to pulley mass (Jakeman *et al* , 1993).
6. The energy cost of cycling 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.
7. 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).
8. The test is terminated when the blood lactic acid concentration exceeds 4mmol/l.
9. 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.

* Karvonen Formula : Target HR = RHR + %VO_2max(MHR-RHR)
Where: RHR = Resting Heart Rate, MHR= Max Heart Rate – if known or 220-Age if predicted
and %VO_2max = required intensity expressed as a fraction of the maximal oxygen uptake

2 Location in which the procedure may take place

√	Project Laboratory (Room No: PG052) or Main Physiology Lab (PG050), PESS Building

3 Eligibility of subject(s) to be used

√	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

√	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

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

√	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 ?

√	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

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In the Department of : __Physical Education and Sport Sciences__

Procedure No	
Title of Procedure	Physiological Assessment of the Energy Cost and Lactate Profile During Incremental, Sub-Maximal Cycling 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)