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UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

Procedure No	2017_12_36_RA
Title of Procedure	Doubly labelled water technique for measurement of free-living energy expenditure
Name of Assessor(s)	Dr.Joseph Bass/ Prof P Jakeman
Assessment Date	13/12/2017
Does this procedure already have ethical approval? (Delete as appropriate)	**NO**
If **YES**, enter ethical number and expiry date	**Approval No:**
	Expiry Date: 12 / 12 / 2027

1 Please provide a brief description of the procedure

1. Doubly labelled water (DLW) is a mixture of two stable isotopes, i.e. deuterium the stable isotope of hydrogen and oxygen-18, the stable isotope of oxygen. This water is completely safe to drink, as both isotopes are stable and are present in all the water on earth.

2. The subjects' body mass is used to titrate the required amount of DLW to achieve incorporation into the body water pool. DLW has no difference in taste or texture to normal water and offers no harm.

3. Subjects are required to drink the DLW (normally less than 250ml in volume) at selected time points according to the study design.

2 Location in which the procedure may take place

✓	Project Laboratory (Room No: PG051)
✓	Research Laboratory (Room No: PG052b)
✓	Free-living environment

3 Eligibility of subject(s) to be used

✓	PESS student (U.G. or P.G.)
✓	University staff or campus personnel

✓	Members of the general public engaged in research projects granted ethical approval.

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4	Potential risks. To be explained before obtaining consent

✓	None as this is a stable, non-toxic, isotope of water

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

AS consumption of water is of no risk there is no foreseeable emergency related to this procedure. However, should the subject PERCEIVE there to be a harmful effect s/he can withdraw as per normal ethical guidelines.

6	Level of supervision required for procedure

✓	Dr Joe Bass, Prof P Jakeman
✓	Delegated person (see detailed protocol)

Others, please specify

7	Other documentation required for this assessment ?

✓	Pre-test measurement of body mass
✓	Detailed protocol

FOR COMPLETION BY HEAD OF DEPARTMENT

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IN THE DEPARTMENT OF : PHYSICAL EDUCATION AND SPORT SCIENCES

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8 Approval of procedure

	Granted
	Subject to conditions (see below)

Others, please specify

Comments/conditions

Informed consent must be completed.

Signed: _____ Date: _____

(Head of Department)

Standard operating procedure

Doubly labelled water (DLW) technique for measurement of free-living energy expenditure

December 2017

Background

Doubly labelled water (DLW) is a mixture of two stable isotopes, i.e. deuterium the stable isotope of hydrogen and oxygen-18, the stable isotope of oxygen. This water is completely safe to drink, as both isotopes are stable and are present in all the water on earth.

The subjects' body mass and total body water is used to titrate the required amount of DLW to achieve incorporation into the body water pool. DLW has no difference in taste or texture to normal water and offers no harm. When the subject metabolises energy to carbon dioxide and water the amount of isotope released provides a direct measure of the rate of energy expenditure.

This document provides general guidance to study personnel on how to administer safely DLW.

Personnel

An "appropriate delegated person" is one who has received training and is experienced in the performance of the specified procedure.

Immunisation

Current and effective immunisation against Hepatitis B is required for all research staff who handle human samples, in this case urine samples.

Equipment

DLW specific measuring cylinder and capped drinking bottle

DLW

Procedure

To be undertake in the evening prior to bedtime

1. Using the subjects' total body water volume, calculate the required volume of DLW
2. Measure the correct volume of DLW into a drinking bottle, capped and given to the subject.
3. The subjects is to provide a urine sample prior to consumption of the DLW.
4. The subject to drink the DLW straight from the bottle INSTRUCTED NOT TO DECANT INTO A CUP OR OTHER VESSEL
5. Having consumed the contents of the bottle the subject is required to refill the bottle with normal drinking water, cap, mix and then consume the rinse solution straight from the bottle.

Emergency / spillage procedure – If sample is spilled, the subject is instructed to inform the experimenter (mobile 'phone contact) who will advise on what to do (dependent on the amount lost).

Disposal and decontamination – There is no special precaution for disposal of spillage as the DLW is harmless to the person and the environment.