For Ortice Use Only: EHSREC No: ___ /___

UNIVERSITY OF LIMERICK
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UNIVERSITY OF LIMERICKRESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM-PROCEDURES INVOLVING HUMAN SUBJECTS

Procedure No 2016_12_20_RA

Title of Procedure Deuterium oxide (1)_20) incorporation

Name of Assessor(s) Dr.Joseph Bass/ Prof P Jakeman **Assessment Date** 03/11/2016

Does this procedure already have ethical approval'? (Delete as appropriate) NO

If **YES,** enter ethical number and expiry date

Approval No:

Expiry Date: 2/11/2026

I **Please provide a brief descripdon of the procedure**

1. Deuterium oxide (D_20) is a naturally occurring, stable isotope of water.
2. The subjects' body mass is used to titrate the required amount of deuterium oxide (DiO) in waler to achieve incorporation into the body water pool. The deuterated water has no difference in taste or texture to normal water and offers no harm.
3. Subjects are required to drink the deuterated water (normally less than 200ml in volume) at selected time points according to the study design.

2 **Location** in **which the procedure may take place**

D { Project Laboratory (Room No: PG051)

D Research Laboratory (Room No: PG052b)

D

D

13 **Eligibility or subject(s) to be used**

D PESS student (U.G. or P.G.)

D University staff or campus personnel

☐ Members of the general public engaged in research pr rniects granted ethical approval.

(4 **Potential risks. To be explained before obtaining consent**

D None, or minimal dizziness

Risk to subject:

Occasionally, volunteers ingesting 0_20 report dizziness or nausea, this is due to inner ear effects when the concentration of D_20 rises above 2.5%, therefore our dosing regimen has been designed to be less than 2% labeling.

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

Dizziness: Volunteers will be instructed to stop taking the 0_20 if they experience these symptoms, we will then reduce their dose or offer them to withdraw from the study.

(6 **Level of supervision required for procedure**

☐ (Dr Joe Bass, Prof P Jakeman

☐ (Delegated person (see detailed protocol)

Others, please specify

D

D

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

CJ (Pre•test measurement of body mass

CJ (Detailed protocol

D

D

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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

Procedure No

Title of Procedure [Deuterium mdde (D20) incorporation

Name of Assessor(s) [Dr.Joseph Bass/ Prof P Jakeman **Assessment Date** 03. 11.2016

S **Approval of procedure**

D [Granted

D [Subject to conditions (see below)

Others, please specify

D

D

Comments/conditions

lnfonned consent must be completed.

Signed: Aviv1 Madh4i (Head of Department) Date: JO / l,

Standard operating procedure

D2O incorporation

November 2016

Background

D_20 is water containing one "heavy" deuterium atom in the place of hydrogen. D_20 is incorporated as a tracer into amino acids such as alanine. The fractional synthetic rate of D_20 bound to for example, alanine, in the muscle vs. the total alanine body pool can then be measured giving rates of muscle protein synthesis. This document has been constructed to provide general guidance to study personnel on how to safely administer D_20.

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 and medics who handle human samples.

Equipment

D_20 specific measuring cylinder

70% D2O

Cup

Procedure to be followed -

I. Using the subjects' body mass, calculate the required volume of70% D_20.
2. Measure the correct volume of 0_20.
3. Pour the volume into a plastic cup ready for consumption. It may be necessary to split the volume between two cups.
4. Ensure a pre.bolus saliva sample has been taken.
5. Allow the subject to drink the D_20 at a reasonable pace, ensuring all liquid is consumed.
6. Advise subjects some dizziness may be felt due to possible inner ear effects. Subjects will be instructed to stop taking the D_20 if they experience these symptoms, we will then reduce their dose or offer them to withdraw from the study.
7. One hour after D_20 consumption retrieve another saliva sample.

Emergency / spillage procedure - If sample is spilled, mop up with absorbent towel, gloves and lab coat to be worn.

Disposal and decontamination -Dispose of tissue in clinical bin for incineration.