



UNIVERSITY of LIMERICK
OLLSCOIL LUIMNIGH

For Office Use Only: EHSREC No: ___/___

UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

	Procedure No	<input type="text"/>				
Title of Procedure	<input type="text" value="Deuterium oxide (D<sub>2</sub>O) incorporation"/>					
Name of Assessor(s)	<input type="text" value="Dr. Joseph Bass/ Prof P Jakeman"/>	Assessment Date <input type="text" value="03/11/2016"/>				
Does this procedure already have ethical approval? (Delete as appropriate)	<input type="text" value="NO"/>					
If YES , enter ethical number and expiry date	<table border="1"> <tr> <td>Approval No:</td> <td></td> </tr> <tr> <td>Expiry Date:</td> <td>/ /</td> </tr> </table>		Approval No:		Expiry Date:	/ /
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Expiry Date:	/ /					

1 Please provide a brief description of the procedure

- Deuterium oxide (D₂O) is a naturally occurring, stable isotope of water.
- The subjects' body mass is used to titrate the required amount of deuterium oxide (D₂O) in water 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.
- 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

<input checked="" type="checkbox"/>	<input type="text" value="Project Laboratory (Room No: PG051)"/>
<input checked="" type="checkbox"/>	<input type="text" value="Research Laboratory (Room No: PG052b)"/>
<input type="checkbox"/>	<input type="text"/>
<input type="checkbox"/>	<input type="text"/>

3 Eligibility of subject(s) to be used

<input checked="" type="checkbox"/>	<input type="text" value="PESS student (U.G. or P.G.)"/>
<input checked="" type="checkbox"/>	<input type="text" value="University staff or campus personnel"/>
<input checked="" type="checkbox"/>	<input type="text" value="Members of the general public engaged in research projects granted ethical approval."/>

4 Potential risks. To be explained before obtaining consent

None, or minimal dizziness

Risk to subject:

Occasionally, volunteers ingesting D₂O report dizziness or nausea, this is due to inner ear effects when the concentration of D₂O rises above 2.5%, therefore our dosing regimen has been designed to be less than 2% labeling.

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

Dizziness: Volunteers will be instructed to stop taking the D₂O 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

7 Other documentation required for this assessment ?

Pre-test measurement of body mass

Detailed protocol

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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8 Approval of procedure

<input type="checkbox"/>	<input type="text" value="Granted"/>
<input type="checkbox"/>	<input type="text" value="Subject to conditions (see below)"/>

Others, please specify

<input type="checkbox"/>	<input type="text"/>
<input type="checkbox"/>	<input type="text"/>

Comments/conditions

Informed consent must be completed.

Signed: Ann Macphail
(Head of Department)

Date: 30/11/16

Standard operating procedure

D₂O incorporation

November 2016

Background

D₂O is water containing one “heavy” deuterium atom in the place of hydrogen. D₂O is incorporated as a tracer into amino acids such as alanine. The fractional synthetic rate of D₂O 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 D₂O.

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

D₂O specific measuring cylinder

70% D₂O

Cup

Procedure to be followed –

1. Using the subjects’ body mass, calculate the required volume of 70% D₂O.
2. Measure the correct volume of D₂O.
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 D₂O 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 D₂O if they experience these symptoms, we will then reduce their dose or offer them to withdraw from the study.
7. One hour after D₂O 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.