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** | 2016_12_20_EHS |
| **Title of Procedure** | Deuterium oxide ($D_2O$) 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:** / / |

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

1. Deuterium oxide ($D_2O$) is a naturally occurring, stable isotope of water.
2. The subjects' body mass is used to titrate the required amount of deuterium oxide ($D_2O$) 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.
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

| | |
|---|---|
| ✓ | Project Laboratory (Room No: PG051) |
| ✓ | Research Laboratory (Room No: PG052b) |
| | |
| | |

### 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. |

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

| | |
|---|---|
| ✓ | None, or minimal dizziness |

**Risk to subject:**

Occasionally, volunteers ingesting $D_2O$ report dizziness or nausea, this is due to inner ear effects when the concentration of $D_2O$ 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 $D_2O$ 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 |
| | |
| | |

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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 oxide ($D_2O$) incorporation

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

**8 Approval of procedure**

☐ Granted

☐ Subject to conditions (see below)

Others, please specify

☐

☐

**Comments/conditions**

Informed consent must be completed.

Signed: Ann MacPhail (Head of Department) Date: 30/11/16

# Standard operating procedure

# $D_2O$ incorporation

## November 2016

**Background**

$D_2O$ is water containing one "heavy" deuterium atom in the place of hydrogen. $D_2O$ is incorporated as a tracer into amino acids such as alanine. The fractional synthetic rate of $D_2O$ 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 $D_2O$.

**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**

$D_2O$ specific measuring cylinder

70% $D_2O$

Cup

**Procedure to be followed –**

1. Using the subjects' body mass, calculate the required volume of 70% $D_2O$.
2. Measure the correct volume of $D_2O$.
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 $D_2O$ 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 $D_2O$ if they experience these symptoms, we will then reduce their dose or offer them to withdraw from the study.
7. One hour after $D_2O$ 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.