UNIVERSITY *of* LIMERICK
OLLSCOIL LUIMNIGH

For Office Use Only: EHSREC No: 2019_01_07_EHS_RA.

PROCEDURES INVOLVING HUMAN SUBJECTS

Title of Procedure	Measurement of the body composition of adult men and women aged 18 to 80 y by bioelectrical impedance analysis (BIA)
Name of Assessors	Prof. P. Jakeman/ Dr. Julie O'Brien
Assessment date	04/10/2018
Does this procedure already have ethical approval?	**YES**
If so, enter ethical number and expiry date **Note, this is an ULREC approval, not transferred to EHSREC**	**Approval No: ULREC 08/07 incorporating SS079**

1 Please provide a brief description of the procedure

Theory: The human body comprises highly conductive lean tissue containing large amounts of water and conducting electrolytes that present a low resistance electrical pathway. Fat and bone, on the other hand, are poor conductors or a high resistance electrical pathway with low amounts of fluid and conducting electrolytes. Whole body electrical impedance is measured by passing a small constant alternating current (I) through the body and measuring the voltage drop (V) produced as a product of R X I, since I is constant V is directly proportional to R. Established algorithms then convert whole body impedance to a measure of body composition.
Procedure: The procedure takes approximately 1 minute and is performed with the subject standing on what resembles a weighing scale upon which are attached surface electrode indicated by 'feet', left and right upon which the subject stands. A pair of hand grip electrodes are grasped by the subjects. The electrodes are connected to the impedance analyser which delivers a current of 800 uA at 50 KHz passed between the outer two electrodes. The voltage drop between the inner two is measured with a high input impedance amplifier.
Discomfort/Hazard: The high frequency, low amplitude currents present no discomfort or hazard to the subject. The procedure is imperceptible to the subject. For reference, the current required to exceed the pain threshold for this procedure would be approximately 40 **MILLI**amps i.e. 50 fold the current used in this procedure.
Safety: The safety of bioelectrical instrumentation is assessed by two parameters. One is the aspect of electrical isolation from ground potentials for the subject. The instrument is optically isolated and certificated for use with human subjects. The second is the definition of what is a hazardous current *vs.* frequency that can be deliberately introduced into the subject. The above paragraph confirms that the current introduced into the subject is harmless and causes no discomfort and has been formally assessed by an NIH Technical Assessment Panel, details of which can be accessed via the following link http://www.nlm.nih.gov/medlineplus/.

2 Location in which the procedure may take place

√	DXA Room PG052c

3 Eligibility of subject(s) to be used

√	Adult (>18 y) students and staff of the UL campus engaged in projects granted EHSREC ethical approval.

√	Adult (>18y) members of the general public engaged in research projects granted ethical approval.

4 Potential risks. To be explained before obtaining consent

√	None or Minimal discomfort only

Subject:
Positioning of the subject requires minimal manual handling by the trained operator. Subjects are instructed to wear suitable clothing for this purpose.

Operator:
The operator will be fully trained and comply with correct procedures for operating the impedance analyser.

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

1. Stop the procedure. Position the subject to prevent self-injury.
2. If the subject feels faint, 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 : DXA Laboratory, PG052c PESS Building. Phone number Extn. **4723**
    Incident: Subject collapse during body composition analysis, plus any further detail.

6 Level of supervision required for procedure

√	Trained BIA Operator

7 Other documentation required for this assessment

√	Subject Information sheet and Consent Form
√	Standard Operating Procedures (SOP)

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FOR COMPLETION BY HEAD OF DEPARTMENT

Risk Assessment Form – Procedures Involving Human Subjects

In the Department of Physical Education and Sports Sciences

Procedure No	
Title of Procedure	Measurement of the body composition of adult men and women aged 18 to 80 y by bioelectrical impedance analysis (BIA)
Name of Assessor(s)	Prof P. Jakeman (UL)
Assessment Date	04/10/2018

8 Approval of procedure

	Granted
	Subject to conditions (see below)

Comments/conditions

Signed: Date: 07/01/2019

(Dr. Giles Warrington)