UNIVERSITY *of* LIMERICK
OLLSCOIL LUIMNIGH

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PROCEDURES INVOLVING HUMAN SUBJECTS

Title of Procedure	Measurement of the body composition of adult men and women aged 18 to 80 y by dual energy X-ray absorptiometry (DXA)
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	**Expiry Nov 2029**

1 Please provide a brief description of the procedure

Measurement of bone density by dual energy X-ray absorptiometry (DXA) is a standard procedure in bone research. The procedure is non-invasive and conducted by trained operators. The subject completes a pre-test questionnaire (attached) written informed consent (attached) prior to the test. The subject arrives for the scan dressed in a tracksuit, or similar, loose fitting clothing. The subject is positioned comfortably (lying) on the bed of the DXA scanner and scans of regions of the spine and upper leg recorded and analysed. The subject is repositioned between each scan.

Individual scans require a scan time and an exposure dose that presents an ionising radiation risk as per Table 1 and cumulative dose for bone densitometric and total body scans as per Table 2.

Table 1. Scan time and an exposure dose for iDXA

Scan Site	Scan Mode	Scan Time (s)	Exposure Dose (µGy)
AP Spine	Thick	30	329
	Standard	30	146
	Thin	30	37
Femur	Thick	30	329
	Standard	30	146
	Thin	30	37
Total Body	Thick	240	6
	Standard	240	3
	Thin	240	3

Table 2. Cumulative exposure dose for iDXA

Scan Mode	Bone Density only (µGy)	Bone Density plus Total Body (µGy)
Thick	658	664
Standard	292	295
Thin	74	77

Directive 97/43/Eurotaom[1] assists those planning research and research ethics committees on radiation exposure to healthy volunteers in biomedical research. Regulations for the purpose of giving effect to Council Directive 97/43/ Euratom on health protection of individuals against the dangers of ionising radiation in relation to medical exposure is provided by S.I. No. 478/2002 - European Communities (Medical Ionising Radiation Protection) Regulations 2002[2]. The Radiation Safety Procedures (Local Rules) and Standard Operating Procedures (SOP) by which the operation of the scanner is in accordance with these directives governing best practice, appended to this Risk Assessment.

1. http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/099_en.pdf
2. http://www.irishstatutebook.ie/eli/2002/si/478/made/en/print

Assessment of Risk:
Relevant to this risk assessment the regulations cited above apply to;

- the exposure of individuals as part of health screening programmes;
- the exposure of healthy individuals or patients voluntarily participating in medical or biomedical, diagnostic or therapeutic, research.

The ULBC research study has been active for 10y. Research-based studies conducted under ULBC fall into 4 main research-based activities (Table 3). The Research Activities have been assessed by the consultant radiologist Dr. Julie O'Brien (UHL) in consultation with the lead PI, Prof Phi Jakeman (PESS, UL) and a designated ionising radiation Exposure Dose Risk Category assigned to each Research Activity.

In keeping with the ICR 62 Radiological Protection in Biomedical Research guidelines, the exposure dose used in the Total Body scan is classified as Category I (<100 µGy) and describe this as:
'*This category involves a risk (total detriment from the radiation exposure) for normal subjects of the order of one in a million or less. The level of risk is considered trivial; the level of benefit needed as the basis of approval for such investigations will be minor and would include those investigations expected "only to increase knowledge"*
and
the cumulative exposure dose used in Bone Density (AP and/or Femur) and Body Density (AP and/or Femur) combined with Total Body is classified as Category IIa (>100 to <1000 µGy) and describe this as:
'*This category involves risks of the order of one in a hundred thousand. In order to justify such risks the benefit of a research project should probably be related to "increases in knowledge leading to health benefit".'*

Under these guidelines, informed consent (attached) will include the relevant statement of Risk to the subject (as per category of risk, see above).

Table 3: Research-based Body Composition Analysis by DXA defined by Research Activity and Category of Risk

Research Activity	Purpose of research	Mode	Frequency (p.a.)	Exposure Dose Risk Category
[1]A	Survey of adult body composition (University of Limerick Body Composition Study, ULBC – www.ul.ie/bodycompositionstudy)	Total Body AP Femur	1	I
B	Fundamental body composition research (e.g. effect of hydration status on lean tissue mass)	Total Body	Up to 4 within 10d	I
C	Longitudinal Research (e.g. development of athletes between and within seasonal competition)	Total body	Normally 4 per annum (2-3 month intervals) up to 8 y	I
D	Interventional Research (e.g. effect of nutrient supplement on site-specific BMD, or effect of nutrient supplement on lean tissue mass)	Total Body AP Femur	Up to 4 within 6 to 12 months	IIa

1. **Note:** Research Activity A (ULBC) is also us as a pre-screening criterion for the majority of intervention studies conducted under Research Activity D (see attached Figure depicting ULBC interlinks to Research Activities)

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 <u>before</u> obtaining consent

√	Minimal discomfort only

Subject:
The subject should **not participate** in the test if there is a risk that the subject is pregnant or if the subject is known to be pregnant. This is identified in the pre-test questionnaire.
Positioning of the subject on the bed of the scan requires minimal manual handling by the trained operator.
Access is required to identify anatomical landmarks and palpation of surface anatomy.
Subjects are instructed to wear suitable clothing for this purpose.
Operator:
The operator is trained to comply with correct procedures for operating the scanner and minimize his/her personal exposure to ionising radiation. The Radiological Protection Advisor to the University (RPA; Dr. John Upton) has assessed potential risk to the operator *in situ* and finds the potential risk not to require the operator to wear a personal dosimeter monitor.

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 DXA scan, plus any further detail.

6	Level of supervision required for procedure

√	Trained DXA Operator

7	Other documentation required for this assessment

√	Subject Information sheet and Consent Form
√	Radiation Safety Procedures (RSP)
√	2018 iDXA Commissioning Report

√	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 adults by dual energy X-ray absorptiometry (DXA)
Name of Assessor(s)	Prof P. Jakeman (UL) and Dr Julie O'Brien (UHL)
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)

Figure 1: Interlink of Research Activities to UL Body Composition Study