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Guidelines for inferential Dual energy X-ray absorptiometry (iDXA)-based Research Ethics Approvals

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Introduction

Inferential Dual energy X-ray absorptiometry (iDXA) is a non-invasive medical imaging technique which can accurately assess bone mineral density (BMD), hip bone geometry, vertebral fracture and body composition. The DXA machine is a high resolution, fan beam, research-grade GE Lunar iDXA and is located in the Carnegie Research Institute, Headingley Campus.
http://www3.gehealthcare.com/~/media/Downloads/us/Product/Product- Categories/Bone-Health/DXA/Lunar%20iDXA%20for%20Bone%20Health/Lunar%20iDXA%20Brochure.pdf

DXA is the gold standard for the diagnosis of osteoporosis (in postmenopausal women and men over the age of 50 years) and low BMD (in men, young adults (>50 years) and children) according to the World Health Organisation http://www.who.int/chp/topics/Osteoporosis.pdf and the International Society for Clinical Densitometry (ISCD) http://www.iscd.org . Guidelines for the interpretation of DXA in adults and in children are described in the ISCD Official Position Stands which can be accessed from the website http://www.iscd.org . DXA is also used for the assessment of body composition, particularly lean mass, and in the fields of sports science and medicine.

DXA involves the utilisation of ionising radiation through low energy X-rays. Given the involvement of ionising radiation, guidelines must be followed during all stages of the research process, from research study concept to completion. This document describes the guidelines and special considerations for the use of DXA in University research. Whether the primary outcome of a research study is bone-related or body composition, Faculty level (and in some cases IRAS level) ethical approval must be obtained.

The project will be overseen by a lead researcher who must communicate the scan protocols, frequency and their interpretation to the DXA operator once the project has been approved via a relevant ethics committee.

Ionising Radiation for Medical Exposure Regulations (IRMER)

IRMER was introduced in 2000 and updated in 2017, and intends to protect patients/research participants by ensuring that proper procedures are in place to control exposure to radiation. They specify a legal requirement that staff who fulfil the operator role, should have a basic knowledge of the hazards of radiation, the statutory requirements governing its use, and the principles of radiation protection.

a. Approved Operators Criteria

For all applications to SREC, an approved DXA operator should be named. In order to be an 'approved operator', the member of staff or postgraduate research student should meet the following criteria:

- Have a qualification in physiology, science, health or medical imaging
- Completed theoretical training in IRMER and obtained a certificate
- Practical training in DXA through shadowing DXA scans and performing supervised DXA scans
- Be competent in performing the in vitro DXA calibration block test
- Have read, understood and signed the *Local Rules* governing the safe use of DXA in the Carnegie DXA Unit.

Once an 'approved operator' is competent to perform DXA scans, they should inform the RPS of any proposed scans. Only 'approved operators' are permitted to conduct DXA scans in University research projects. The 'approved operator' must be named in the application to FREC.

b. Current Approved Operators

Matthew Barlow, Marina Alexander (RPS).

c. Roles of the RPA/MPE, RPS and CRE

The RPA and MPE for the Carnegie Faculty is Ishmail Badr. He is based in The Radiological Protection Centre, (Medical Physics Department) of St. George's University Hospitals NHS Foundation Trust. He advises our Faculty on radiation protection and is our designated expert to assess and authorise radiation doses to research participants depending on the type and number of scans they are expected to receive. The iDXA research lead is Matt Barlow who is based in the Carnegie School of Sport. He liaises with the RPA to ensure that the requirements of IRMER are met in terms of research, and is the first point of contact for any staff or students who are considering using DXA in their research. It is essential that He is contacted prior to any ethics submission in order to ensure that the relevant guidelines have been followed Matthew.Barlow@LeedsBeckett.ac.uk. The RPS is Marina Alexander, She is responsible for securing compliance with the Ionising Radiations Regulations 2017, in respect of work carried out in an area which is subject to Local Rules. The Clinical Radiation Experts (CRE) are Marina Alexander and Olga Satahr who assess and authorise research according to the ALARP principle.

d. As Low As Reasonably Practicable (ALARP) Principle

The ALARP principle describes the restriction of radiation exposure. Investigations will only be approved if they produce a positive net benefit. With DXA, scans should only be approved if there is a strong and valid rationale for inclusion, and that no other method could obtain the same outcome at a lower risk. For example, a study that proposes to assess change in BMD in participants on 3 occasions over 3 months would not be approved because detection of a significant change in bone over such a short period is not possible given established biological principles. The rationale in this case is not justified. Similarly, applications should have a health rationale to ensure benefits outweigh the health risks of radiation exposure.

It is accepted that studies might recruit healthy participants where there is no direct health benefit to the participant but provides benefit to society. It is recommended that staff and students contact Dr Matt Barlow to discuss the rationale for proposed research studies and ensure that any scans that may be included are justified according to the ALARP principle.

e. Pregnancy

All research participants of childbearing age **must** be asked if they are or if they think that they may be pregnant. This question should be included in the Participant Consent Form. The Participant Information Sheet should inform potential research participants that with ionising radiation exposure, there is a risk to the unborn child. Immediately prior to a DXA scan, each woman of childbearing age **must** also be asked this question again and their response recorded in the iDXA Scan Record.

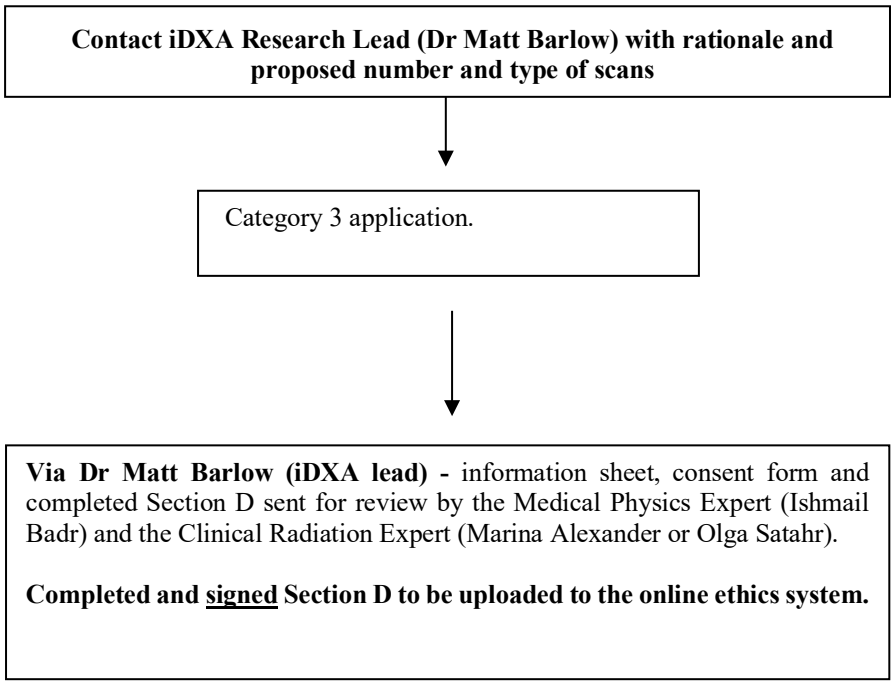
f. Provision of Reports and Protocol for Health Concerns

Central (lumbar spine, hip, and vertebral fracture assessment) DXA results are clinical and can indicate conditions such as osteoporosis, scoliosis, kyphosis and fracture. The current procedure for DXA results suggestive of a medical condition, is that they should be explained fully to the research participant so that they can, on their own accord, make an appointment with their GP for qualified attention. Under the current operating procedures without CQC registration the bone density data should not be provided to the participant as this would then become part of care pathway and breach CQC rules. A generic letter of concern will be provided for the participant to take to their GP.

Copies <u>should not</u> be given to coaches/other persons unless specific, signed consent has been provided.

Protocol for obtaining Research Ethical approval

The following flow chart illustrates the protocol that should be followed for obtaining ethical approval for the use of DXA in research.



Section D forms are available by contacting matthew.barlow@leedsbeckett.ac.uk.