

UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

Procedure No

Title of Procedure

Name of Assessor(s) Assessment Date

Does this procedure already have ethical approval? (Delete as appropriate)

Does this procedure already have ethical approval?

If so, enter ethical number and expiry date

Body Mass Index is an indicator of weight for height. It is calculated by dividing total body weight in kilograms by one's height squared (kg/m^2).

Body mass is recorded using an electronic scales. The scales should be calibrated using a known weight and reset to zero. The participant removes shoes and any heavy clothing, steps on the scales and maintains an upright body position, facing forwards. The full surface area of each foot should be on the scales. Measures will be read to the nearest 0.1-kilogram.

Height is measured using a standard collapsible portable stadiometer. The participant should be instructed to remove shoes. If hairstyle affects participant's height, ask them to adjust it for the test. The participant stands with heels and toes together on the base and arms loosely by their side. Back straight against the vertical measuring rods. Look straight ahead. Take a deep breath and stand as straight as possible without their heels lifting off the ground. Take this recording twice.

Bioelectric Impedance Analysis (BIA) is a non-invasive measure of body composition. Bioelectrical impedance measures the resistance of body tissues to the flow of a small, harmless electrical signal. The proportion of body fat can be calculated as the current flows more easily through the parts of the body that are composed mostly of water (such as blood, urine & muscle) than it does through bone, fat or air. The same procedure for measuring body mass is used (step on BIA). An estimate of body fat % correct to one decimal place is provided. (See ESHREC 2019_01_07_EHS_RA : Measurement of the body composition of adult men and women aged 18 to 80 y by bioelectrical impedance analysis (BIA))

Skinfold Thickness: Skinfold thickness will be measured using a Harpenden skinfold calliper. The sum of the skinfolds, measured at standard sites (biceps, triceps, subscapular and supriliac) will be used. Measurements will be made to the nearest 0.2-mm. The skinfold will be firmly grasped by the thumb and index finger of the left hand and pulled away from the body. The amount of tissue pinched up must be enough to form a fold with approximately parallel sides. Skinfold measurements will be taken on the right hand side of the body. The caliper arms are positioned one at a time. The dial is read approximately 2 seconds after the pressure from the hand has been released on the lever arm of the caliper jaw. Three measurements will be taken at each site with a minimum of 15 seconds between measurements to allow the skinfold site to return to normal. Measurements will not be taken when the skin is moist as there is a tendency to grasp extra skin. The mean of the three measurements will be used as the representative value for each site.

Biceps: a vertical fold will be picked up on the anterior midline of the upper arm (over the biceps muscle). The elbow will be flexed lightly and in a relaxed state. Participant remains seated for this measurement.

Triceps: a vertical fold will be picked up on the posterior midline of the upper arm (over the triceps muscle), halfway between the acromion and olecranon processes. The elbow will be in extended and in a relaxed state. Participant remains standing for this measurement.

Subscapular: a fold will be taken on a diagonal line coming from the vertebral border to 1-2cm from the inferior angle of the scapula. Participant remains standing for this measurement.

Suprailiac: a diagonal fold will be taken above the crest of the ilium at the spot where an imaginary line would come down from the anterior axillary line. Participant remains standing for this measurement.

Body Dimensions: Body dimensions such as bone width and length are measured using either an anthropometer or tape measure. This procedure involves locating various bony processes e.g. acromion process and measuring the distance between each process. The subject is wearing a T-shirt and shorts for all measurements.

2	Location in which the procedure may take place
----------	-------------------------------------------------------

<input checked="" type="checkbox"/>	PESS Teaching Facilities
-------------------------------------	--------------------------

<input checked="" type="checkbox"/>	PESS Research Facilities
-------------------------------------	--------------------------

Others, please specify

<input checked="" type="checkbox"/>	PESS Sports Hall, PESS Gymnasium, UL Arena
-------------------------------------	--------------------------------------------

<input checked="" type="checkbox"/>	Off site locations, e.g. schools, clubs etc
-------------------------------------	---------------------------------------------

3	Eligibility of subject(s) to be used
----------	---------------------------------------------

<input checked="" type="checkbox"/>	PESS student (U.G. or P.G.)
-------------------------------------	-----------------------------

<input checked="" type="checkbox"/>	University of Limerick staff or campus personnel
-------------------------------------	--------------------------------------------------

<input checked="" type="checkbox"/>	Members of the general public engaged in research projects granted ethical approval (adults, adolescents, children)
-------------------------------------	---------------------------------------------------------------------------------------------------------------------

4	Potential risks. To be explained <u>before</u> obtaining consent
----------	-------------------------------------------------------------------------



None, or minimal discomfort only

When the weight of each participant is being measured other participants will not be permitted to be in viewing distance of the weight scales.

For the measurement of the subscapular skinfold the investigator will have to raise the participants clothing slightly so that the scapula is exposed. For the measurement of the suprailiac skinfold, participants will have to raise their clothing slightly so that area above the hip is exposed. The participants will not be required to remove their upper garments. In order to avoid any potential embarrassment, this procedure will be carried out behind a screen or in a private room if one is available.

A third party, preferably of the same sex as the subject, will be present during periods of physical contact between experimenter and subject.

5

Action to be taken in the event of a foreseeable emergency

The procedure will be terminated if the volunteer shows any sign of distress.

Standard first aid procedures may be required depending on the severity of the situation. The following standard procedure should be followed in the event of an incident occurring in the PESS building / UL Facility:

1. Stop the procedure. Position the subject to prevent self-injury.
2. If appropriate, raise the subject's lower limbs to improve blood flow. Should the subject fail to respond summon help immediately.
3. Check vital signs airways, breathing and circulation (ABC)
4. If required attempt CPR as soon as possible.
5. Requesting Help: Emergency Contact telephone numbers are listed on laboratory door:
 - During normal working hours 9am-5pm, use lab phone to contact the Student Health Centre on **061-202534**
 - 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. If in PESS, contact one of the PESS First Aiders – names are listed on the PESS laboratory door.
6. When contacting the above clearly state: Location, Building, Room Number, Nature of Incident/Accident and provide a contact number.
7. Complete the UL 'Accident & Emergency' form (completed by the investigator, not the volunteer). Forms available on UL HR website: <https://www.ul.ie/hr/hr-policies-procedures-and-forms-z>

If an emergency or incident occurs offsite, follow the local procedures for dealing with such an event. **Ensure you are aware of the offsite local safety procedures in the event of a foreseeable emergency.** In the event of a foreseeable emergency the School Principal/ Vice Principal or another member of staff shall be immediately contacted by a member of the testing team. The school's emergency procedure will then be put into effect.

6 Level of supervision required for procedure

PESS Lecturers, Researchers, Teaching Assistants

PESS Postgraduate Researchers

Others, please specify

7 Other documentation required for this assessment ?

Pre-test subject questionnaire

Detailed protocol

Others, please specify

Participant information sheet and consent form

Parental consent form and child consent form if participant is less than 18

UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

Procedure No

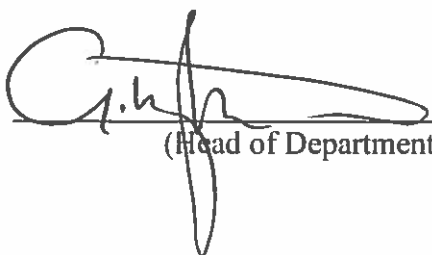
Title of Procedure

Name of Assessor(s) Assessment Date

8 Approval of procedure

Others, please specify

Comments/conditions

Signed: 
(Head of Department)

Date: 1/11/18