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UNIVERSITY OF LIMERICK
OLLSCOIL LUIMNIGH

UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

Procedure No	2009_10_02_RA
Title of Procedure	Oral Glucose Tolerance Test
Name of Assessor(s)	Professor P. Jakeman
Assessment Date	25 /10 /2009
Does this procedure already have ethical approval? (Delete as appropriate)	~~YES~~/NO
If **YES**, enter ethical number and expiry date	**Approval No:**
	Expiry Date: 25 / 10 / 2019

1 Please provide a brief description of the procedure

General conditions:

- The subjects will have completed a pre-test questionnaire (PAR-Q) and will have provided written, informed consent.
- An approved protocol for capillary blood sampling (SS024) is used in this procedure.
- The code of Practice is informed by the Report of Expert Committee on the Diagnosis and Classification of Diabetes Mellitus (Diabetes Care 20: 1183-1197, 1997).

Code of Practice pertaining to the OGTT procedure.

1. The subject is given guidelines so as to consume a diet containing at least 3-4 g of carbohydrate per kg of body mass for a period of 3d prior to the test.
2. The subject is to report to the laboratory following an overnight fast (at least 8, but not more than 16h). On the morning of the test the subject is instructed to drink only water, consume no food and to abstain from smoking.
3. A urinary sample is provided and tested for the presence of glucose, ketone and protein using a proprietary urine dip stick.

If urine sample is positive for glucose, ketone or protein then stop test and refer to medical practitioner

If urine sample is negative for glucose, ketone and protein, then continue

4. The subject is to rest for 15 min then a mixed capillary blood sample (SS024) is taken and analysed for blood glucose.

If blood glucose is > 7mmol/L then re-test after 30 minutes, if still > 7.0mmol/L then stop test and refer to medical practitioner

5. The subject is then asked to ingest 75g (40g/m^2BSA) of glucose dissolved in 400ml of flavoured cordial (Polycal™ Liquid. Nutricia Clinical Care, Dublin) over a period no longer than 5minutes.
6. The subject remains within the vicinity of the laboratory for the next 3h. The subject must remain at rest but may undertake academic study during this period.
7. Further capillary blood samples are withdrawn every 15 minutes for 120 minutes and

at 180 minutes following the ingestion of glucose.

8. A further urinary sample is provided and tested for the presence of glucose.

If urine sample is positive for glucose then refer to medical practitioner

2	Location in which the procedure may take place

√	Project Laboratory (PG052) & Main Physiology Laboratory (PG050), PESS Building

3	Eligibility of subject(s) to be used

√	UL staff, students or campus personnel recruited for projects granted PESSREG approval
√	Members of the general public recruited for projects granted PESSREG approval

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

√	None, or minimal discomfort only as described in SS024 – Capillary Blood Sampling

If the risks are other than trivial please provide a brief description.

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

Please provide a clear statement of appropriate action including contact names and telephone numbers.

1. Stop the procedure. Position the subject to prevent self-injury.
2. 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 : Project Laboratory (PG052), Sports Building. Phone number Extn. **2856**
    Incident: Subject collapse during Oral Glucose Tolerance Test.

6	Level of supervision required for procedure

√	Faculty staff, post-graduate or undergraduate researcher trained to level of supervision required by principal researcher of PESSREG approved study.

7	Other documentation required for this assessment ?

√	Informed consent relating to PESSREG approved project using this procedure.
√	Pre-test subject questionnaire (PAR-Q)

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FOR COMPLETION BY HEAD OF DEPARTMENT

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In the Department of : Physical Education and Sport Sciences

		Procedure No	
Title of Procedure	Oral Glucose Tolerance Test		
Name of Assessor(s)	Professor P. Jakeman	**Assessment Date**	25/10/2009

8 Approval of procedure

	Granted
	Subject to conditions (see below)

Others, please specify

Comments/conditions

Signed: _____ Date: _____

(Head of Department)