**For Office Use Only: EHSREC No: ____/____**

UNIVERSITY OF LIMERICK
OLLSCOIL LUIMNIGH

# UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

## RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

| | |
|---|---|
| **Procedure No** | 2016/ 12/21_RA |
| **Title of Procedure** | Micro-needle muscle biopsy procedure from *m. vastus lateralis* |
| **Name of Assessor(s)** | Dr.Joseph Bass/ Prof P Jakeman/ Dr Emmet Kerin |
| **Assessment Date** | 03/11/2016 |
| Does this procedure already have ethical approval? (Delete as appropriate) | **NO** |
| If **YES**, enter ethical number and expiry date | **Approval No:** |
| | **Expiry Date:** 2/11/2026 |

## 1 Please provide a brief description of the procedure

1. Obtain written, informed consent from the subject.

The following is then undertaken by a qualified person.

2. Prepare the site using antiseptic skin preparation solution.
3. Administer local anaesthetic (2% Xylocaine®, lidnocaine hydrochloride).
4. Insert biopsy needle into the muscle, the centre of the needle is raised before quickly being depressed.
5. The needle is withdrawn and wound closed with steri-strips.
6. Pressure is applied to the wound for 5 minutes.
7. An adhesive dressing and compression bandage are applied.

## 2 Location in which the procedure may take place

| | |
|---|---|
| ✓ | Clinical Research Laboratory (Room No: PG052b) |
| | |
| | |
| | |

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

| | |
|---|---|
| ✓ | PESS student (U.G. or P.G.) |
| ✓ | University staff or campus personnel |
| ✓ | Members of the general public engaged in research projects granted ethical approval. |

## 4 Potential risks. To be explained before obtaining consent

| | |
|---|---|
| ✓ | Minimal discomfort only |

**Risk to subject:**
Muscle biopsy of *vastus lateralis* (quadriceps) under local anaesthetic - In all cases there is a slight risk of infection at biopsy sites; this will be minimized by the use of local sterile techniques in a designated clinical investigation room. Micro-biopsy sites are closed by a few sterile adhesive strips at the end of studies and dressed with sterile waterproof dressings. Subjects are comfortably able to perform exercise after micro-biopsies. All wounds will be monitored for 7 days and subjects asked to notify the investigators of any sign of infection. Scarring is hardly perceptible and fades with time to near invisibility. Some muscle tenderness and stiffness may be felt for 2-3 days afterwards but simple painkillers usually effectively abolish this. There is a slight risk of damaging cutaneous and other soft tissue nerves during biopsy techniques. These nerves usually grow back with restoration of normal sensation, without difficulty.

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

**This procedure is undertaken by a qualified clinician who will attend to any medical emergency.**

**Needle stick injury**

1. Needles should never re-sheathed
2. Wash immediately, do not suck, and encourage to bleed
3. Report incident through accident report form.
4. Refer to clinical care team (normally GP) for further action.

**Muscle biopsy procedure:**
**Subject fainting**

1. Ensure all biopsies are taking with subject lying supine.
2. If subject complains of feeling light headed/sweaty/hot stop procedure, apply fan, tilt bed head down, allow a drink of water and recommence procedure once symptoms pass if subject happy to proceed.
3. If subject faints tilt bed head down and raise legs and wait for them to regain consciousness

**Muscle biopsy bleeding**

1. Apply pressure to wound following steri-strip administration
2. Keep pressure applied for 5 minutes before applying an adhesive dressing
3. Apply compression bandage following biopsy
4. If bleeding continues, reapply adhesive dressing

**Emergency actions:**
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** : Physiology Laboratory, PESS Building. Phone number Extn. **2856**
    **Incident**: Subject collapse following micro-biopsy of thigh muscle.

## 6 Level of supervision required for procedure

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|---|---|
| ✓ | Clinician trained in the procedure |
| ✓ | Delegated person (see detailed protocol) |

| 7 | Other documentation required for this assessment ? |
|---|---|

| | |
|---|---|
| ✓ | Detailed protocol |
| | |

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# FOR COMPLETION BY HEAD OF DEPARTMENT

## RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

## IN THE DEPARTMENT OF : PHYSICAL EDUCATION AND SPORT SCIENCES

| | | | |
|---|---|---|---|
| | | **Procedure No** | |
| **Title of Procedure** | Micro-needle muscle biopsy procedure | | |
| **Name of Assessor(s)** | Dr.Joseph Bass/ Prof P Jakeman/ Dr Emmet Kerin | **Assessment Date** | 03/ 11/2016 |

**8 Approval of procedure**

| | |
|---|---|
| | Granted |
| | Subject to conditions (see below) |

Others, please specify

| | |
|---|---|
| | |
| | |

**Comments/conditions**

Informed consent must be completed.

Signed: _____ Date: _____

(Head of Department)

# Standard operating procedure

# Micro-needle muscle tissue biopsy of *m. vastus lateralis*

# November 2016

**Background**

Correct micro-needle muscle biopsies will induce minimal discomfort for the subject, whilst providing the best possible tissue for future analysis. This document has been constructed to provide general guidance to study personnel on how to safely and correctly take a muscle biopsy from *m. vastus lateralis.*

**Personnel – qualified person**

For the purpose of this document, a qualified person is defined as a medical doctor with full registration provided by the Irish Medical Council.

**Immunisation**

Current and effective immunisation against Hepatitis B is required for all research staff and qualified persons who handle human biopsy samples.

**Equipment:**

Gauze
Razor
Antiseptic skin preparation solution
Adhesive aperture drape
2% Xylocaine®
21” needle
10ml/ 20ml syringe
Sterile gown and gloves
Biopsy needle
Steri-strips
Rectangular dressing 10x10cm
Compression bandage
Sharps bin

# Micro-needle muscle tissue biopsy

# Procedure to be followed by qualified person

**Please ensure sterile technique is followed at all times, especially when retrieving biopsy from micro needles. Wear gloves and appropriate PPE during tissue collection.**

1. Obtain consent (verbal if written is already obtained) and ask subject to recline supine.
2. Ask the subject to contact the knee extensors and palpate *m. vastus lateralis* locating a site for the biopsy in the mid belly approximately one third along the thigh proximal to the knee
3. Prepare the site using antiseptic skin preparation solution. If the skin is hairy, the area is shaved prior to applying the antiseptic.
4. Place an adhesive aperture drape over the biopsy site.
5. Inject local anaesthetic using sterile technique subcutaneously and intramuscular at the biopsy site, approx. 5-10ml, 2% Xylocaine® (lidnocaine hydrochloride) is usually appropriate.
6. Ensure that the subject has no pain sensations by testing with needle tip before commencing to the next step (confirm with the subject).
7. Insert the biopsy needle downward into the muscle (some pressure may be required).
8. The non-dominant hand stabilises the needle by holding the shaft at the skin surface in the 'V' between thumb and forefinger, while the middle, ring and little finger squeeze gently onto the side of the thigh.
9. The dominant hand then pulls the centre of the needle up by about an inch so that the window, now located in the muscle opens (gentle sideways pressure encourages the tissue to lie within the window).
10. The centre of the needle is then depressed and the cut piece of muscle will remain within the barrel of the needle.
11. Three snips may be taken, following which the whole needle is withdrawn. Normally, 30-50mg of muscle tissue is acquired.
12. Immediately after withdrawing the needle, sterile swabs are placed over the biopsy site and pressure is exerted for at least 5 min to reduce potential bleeding within the tissue.
13. If no further bleeding is seen, a steri-strip is placed over the incision and an adhesive dressing placed on top before applying a compression bandage.
14. Instruction is provided to the patient about after care of the leg and wound. Provide dressings and date for removal.
15. The qualified person must dispose of all equipment and contaminated items appropriately.

**Emergency / spillage procedure –** Clean any blood or tissue spillages immediately with detergent wipe and then disinfect with Vircon solution and dispose of wipes into a clinical waste bin for incineration.

**Disposal and decontamination –**All sharps must be discarded in sharps bin only. Clinical waste must be placed into a clinical waste bin for incineration.