Quality Control Document:

Biopsy Information Sheet

# Purpose

This document provides general information regarding the potential risks associated with undergoing skeletal muscle biopsies (not intended for diagnostic purposes) that participants must be made aware of prior to them providing consent to undergo the procedure.

Participants must also be aware of any others risks identified based on the project-specific biopsy procedure.

# Instructions

The risks included in this document, together with any other risks identified as part of the project-specific procedures, are to be included, as appropriate, in the information provided to participants prior to them consenting and undergoing a muscle biopsy.

# Related documents

* UoB-SMB-QCD-001 Biopsy Training Programme and Record
* UoB-SMB-QCD-002 Biopsy Sampling Permission Form
* UoB-SMB-QCD-003 Anaesthetic Stock Control Form
* UoB-SMB-QCD-004 Biopsy Record Form
* UoB-SMB-SOP-001 Skeletal Muscle Biopsies

Access to the full UoB QMS for clinical research is available via the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx).

# Risks to participants undergoing a skeletal muscle biopsy procedure

* There are minimal risks associated with skeletal muscle biopsies (less than 1%).
* You may notice a small scar at the site of the biopsy, but scars should improve within 6-12 months after the biopsy.
* There is an extremely low risk of Infection (1 in 1,700)
* You may experience symptoms of infection that could include malaise, fever, swelling, pain, tenderness, redness or drainage (pus).
* There is low risk of bleeding (1 in 4,500)
* You may notice bleeding at the site of the wound.
* You may also experience bleeding within the muscle that appears as swelling or bruising which may take several days to appear.
* There is a low risk of allergic reaction to local anaesthetic.
* You may experience pain and numbness around the biopsy site including,
* the area around the biopsy feeling numb initially due to the local anaesthetic. Following this the muscle may also feel sore and bruised for about 24 hours before easing off.
* damage to nerves around the biopsy site resulting in,
* altered sensation or numbness of an area of skin adjacent to the biopsy. This is caused by injury to a small sensory nerve branch and after a few months awareness of this disappears.
* atrophy of the affected segment of muscle. This is caused by damage to a motor nerve branch. This will not be initially obvious but will only become apparent after several months. Although this may be cosmetically visible this complication has never been demonstrated as having any effect on muscle function or performance.
* At the time of writing, there has been one complication recorded in more than 1,000 biopsies (from 2013-2023) at the University of Birmingham.
* To minimise this risk, samples will be taken by qualified personnel under sterile conditions.
* Aftercare instructions will be provided to ensure the biopsy site can heal correctly.