Quality Control Document:

Biopsy Sampling Permission Form

# Purpose

This document contains the biopsy sampling permission form to record the authorisation of a non-medically qualified person to perform a muscle biopsy. The authorisation will be provided by the medical supervisor, and it will be valid for three years.

# Instructions

1. Remove this first instruction page.
2. Update the document’s footer text, retaining the document reference information to this quality control document (QCD).
3. Complete the biopsy sampling permission form.
4. Submit the form to the medical supervisor for approval.
5. Medical supervisor to state a minimum number of biopsies for the technician to perform each year.
6. File the original signed form with the technician approved for biopsy sampling, and a scanned copy with the medical supervisor.

# Related documents

* UoB-SMB-QCD-001 Biopsy Training Programme and Record
* UoB-SMB-QCD-003 Anaesthetic Stock Control Form
* UoB-SMB-QCD-004 Biopsy Record Form
* UoB-SMB-QCD-005 Biopsy Information Sheet
* UoB-SMB-SOP-001 Skeletal Muscle Biopsies

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

# Muscle biopsy sampling permission form

The University of Birmingham, as sponsor, recognises that there are currently no certifications or licensing programmes for researchers seeking to conduct skeletal muscle biopsies for research and non-therapeutic purposes. However, the university has in force a public liability policy and/or clinical trials policy, which provides cover for claims for "negligent harm". The activities here are included within that coverage.

## Criteria

Any non-physician wishing to perform a biopsy independently (i.e. without direct supervision) must meet the three criteria listed below.

1. Evidence of biopsy training.
2. Evidence of up-to-date emergency first aid at work training (or higher).
3. Evidence of a competency assessment by the medical supervisor in performing the biopsy procedure and administering the local anaesthetic.

An authorised physician (medical doctor) with relevant experience in performing a skeletal muscle biopsy must provide oversight for research projects involving biopsies. There is no requirement for the medical supervisor to be in attendance or in the building while biopsies are being performed. However, it is expected that the medical will be available if required (as minimum, by telephone). The technician will also provide 6-monthly reports to the medical supervisor, detailing the number of biopsies performed and the number of participants who have had a biopsy (if different), and a declaration to confirm the absence/existence of any problems during a biopsy procedure.

|  |  |
| --- | --- |
| Permission awarded to: |  |
| Permission awarded on: |  |

### Permission valid for 3 years from date of issue

|  |  |
| --- | --- |
| Valid until: |  |

**After the expiration date of this permission form, the individual under this authorisation shall ensure no further biopsies are carried out until they have been granted further approval to do so.**

# Declarations

## Person to perform biopsies and administer local anaesthetic

“I hereby confirm as a person performing biopsies and administering local anaesthetic that, to the best of my knowledge and belief, I have been appropriately trained in skeletal muscle biopsies and local anaesthetic administration, and will continue any further training as may be needed from time to time in order to maintain the required level in performing this procedure, which shall in all circumstances be carried out in accordance with the Skeletal Muscle Biopsies SOP (UoB-SMB-SOP-001) (which I confirm I have read and understood). I will not administer anaesthetic in any circumstances where I am aware contraindications to its use have been identified, or I have reason to believe it should not be used.”

|  |  |
| --- | --- |
| Date of last biopsy competency assessment |  |

### Signature

|  |  |
| --- | --- |
| Name: |  |
| Date: |  |
| Signature: |  |

## Medical Supervisor

“As the medical supervisor, I hereby confirm that <insert name of person to perform the biopsies> has met the criteria outlined above. In addition, I confirm that <insert name anaesthetic e.g. lidocaine> administration for pain relief is required during any biopsy performed and I hereby authorise the use of this medicine and accordingly direct the person named herein to administer the local anaesthetic provided that the items listed below are met.

1. The named person remains suitably trained at the time of administering the lidocaine. For this, the named person must perform a minimum of <insert number> biopsies per year.
2. Prior to administration of the local anaesthetic, all normal and customary checks and precautions have been carried out and no contraindications to its use have been identified.
3. The administration of the local anaesthetic is only be carried out in accordance with the Skeletal Muscle Biopsies SOP (UoB-SMB-SOP-001).
4. The named person provides me with a report at the end of every six months in which the local anaesthetic has been administered pursuant to this authorisation, detailing the project, numbers of participants to whom local anaesthetic has been administered and a declaration to confirm the absence/existence of any problems. For the avoidance of doubt, failure to provide these reports may invalidate this authorisation.
5. I retain the right to withdraw this authorisation at my discretion, which if invoked shall require written confirmation from me to the named person and upon receipt <insert name of person to perform the biopsies> shall ensure no further administration of the local anaesthetic is carried out in this clinical research project under this authorisation.”

### Signature

|  |  |  |
| --- | --- | --- |
| Name: |  | GMC registration number: |
| Date: |  |  |
| Signature: |  |