Quality Control Document:

Biopsy Training Programme and Record

# Purpose

This document details the minimum requirements for a biopsy training programme and provides a template to document evidence of the necessary training. It also contains the declaration required to be completed in order to continue biopsy training using human volunteers.

# 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. Develop and document training materials required based on the training programme outlined in this document.
4. Complete the declaration before proceeding with muscle biopsies performed under supervision.
5. File the training record and declaration with the trainee technician, and a scanned copy of the declaration with the medical supervisor.

# Related documents

* 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-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 training programme

The training course will consist of two parts. First, the individual will develop a theoretical understanding of the procedures and practical skills on a model muscle, as well as assisting (activity participating, but not taking the muscle biopsy) in a minimum of 15 biopsy procedures with an individual trained to perform the procedure.

The second part will consist of practical training with human participants; including a competency assessment overseen by a medically qualified individual experienced in the muscle biopsy procedure. The individual must perform at least three biopsies observed by and performed to the satisfaction of the medically qualified individual experienced in the muscle biopsy procedure. Once satisfied, the medical practitioner will provide authorisation for the candidate to complete at least a further seven muscle biopsies under the supervision and guidance of an individual experienced in the muscle biopsy procedure.

Note: in order to obtain authorisation to perform biopsies independently (without supervision), you will also need to evidence up-to-date Emergency First Aid at Work training (or higher).

## Part I

* Theoretical understanding
* Practical learning on a model muscle
* Assisting with a minimum of 15 muscle biopsies

### Theoretical understanding

To develop the theoretical understanding of the muscle biopsy procedure, the individual will cover the topics listed below.

* Anatomy of the muscle (including innervations, vasculature, skin and connective tissue (fascia)).
* Knowledge of local anaesthetics and procedures to administer them.
* Knowledge of the techniques for making an incision.
* Minimizing risk for complications and wound care.
* Procedures to maintain sterility.
* Emergency procedures.

Practical learning

For the practical learning, the individual will perform the key practical aspects of the muscle biopsy procedure on a model. This will include:

* administration of the local anaesthetic
* making an incision
* assisting taking a biopsy
* taking a muscle biopsy
* closing an incision.

### Number of assisted biopsies

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| # | Date | Ethics Number | Participant ID | Name of person taking the biopsy | Signature of person taking the biopsy |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |
| 4 |  |  |  |  |  |
| 5 |  |  |  |  |  |
| 6 |  |  |  |  |  |
| 7 |  |  |  |  |  |
| 8 |  |  |  |  |  |
| 9 |  |  |  |  |  |
| 10 |  |  |  |  |  |
| 11 |  |  |  |  |  |
| 12 |  |  |  |  |  |
| 13 |  |  |  |  |  |
| 14 |  |  |  |  |  |
| 15 |  |  |  |  |  |

## Part II

* Performing at least three human muscle biopsies under medical supervision
* Performing at least seven human muscle biopsies under supervision

### Number of muscle biopsies performed under medical supervision

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| # | Date | Ethics Number | Participant ID | Name of medical supervisor | Signature of medical supervisor |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |

## Declarations

In order to proceed to the final stage of the muscle-biopsy training course, which will involve at least a further seven supervisor muscle biopsies, the individual must meet the following criteria:

1. have theoretical understanding of the muscle-biopsy procedure
2. have received practical training in performing a muscle biopsy on a piece of meat
3. have assisted in at least 15 muscle-biopsy procedures
4. have performed at least three muscle biopsies observed by and to the satisfaction of a medically qualified individual experienced in the muscle-biopsy procedure.

### Name of individual training to perform muscle biopsies

“As the individual training to perform muscle biopsies, I confirm I have met the criteria outlined above, and shall in all circumstances carry out the muscle-biopsy procedure, including the administration of the local anaesthetic, in accordance with the Skeletal Muscle Biopsies SOP (UoB-SMB-SOP-001) (which I confirm I have read and understood). I will not administer <insert name anaesthetic e.g. lidocaine> 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.”

### Signature

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

### Medical Supervisor

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

1. The named person informs me prior to every muscle biopsy procedure, detailing the project name and participant number, and remains under the direct supervision of an individual experienced in performing the muscle-biopsy procedure.
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 should only be carried out in accordance with the Skeletal Muscle Biopsies SOP (UoB-SMB-SOP-001).
4. The named person provides me with a declaration to confirm the absence/existence of any problems. For the avoidance of doubt, failure to provide this report 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 candidate and upon receipt <insert name of trainee> shall ensure no further muscle biopsies or administration of the local anaesthetic is carried out for this training course under this authorisation.”

### Signature

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

### Number of muscle biopsies performed under supervision

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| # | Date | Ethics Number | Participant ID | Name of person taking the biopsy | Signature of person taking the biopsy |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |
| 4 |  |  |  |  |  |
| 5 |  |  |  |  |  |
| 6 |  |  |  |  |  |
| 7 |  |  |  |  |  |
| 8 |  |  |  |  |  |
| 9 |  |  |  |  |  |
| 10 |  |  |  |  |  |