Quality Control Document:

Biopsy Record Form

# Purpose

This document contains a template that can be used to document details of each biopsy, including the cleaning and decontamination, details of anaesthetic and biopsy needle used.

# 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. Insert the project details and participant ID.
4. Document cleaning and decontamination, anaesthetic details and biopsy needle details.
5. For the vial information, the label can be peeled off and added to the biopsy record form.
6. The form should be reviewed and approved by the person performing the biopsy.
7. File completed versions of this record and all related correspondence in the relevant study/trial master file and site/lab file as applicable.

# 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-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).

# Project details

|  |  |  |  |
| --- | --- | --- | --- |
| **Project title:** |  | | |
| **Principal investigator:** |  | **Ethic number:** |  |
| **Participant ID:** |  | **Date & time:** |  |

# Cleaning and decontamination

|  |  |  |  |
| --- | --- | --- | --- |
| **Before:** | Yes | **After:** | Yes |

# Anaesthetic details

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Body mass (kg)** | **Volume injected (mL)** | **Dosage (mg/Kg)** | **Site of administration** | **Vial information** | |
|  |  |  |  | *Drug name* | *Batch number & expiry date* |

# Biopsy needle details

|  |  |  |
| --- | --- | --- |
| **Sterilisation ID** | **Sterile expiry date** | **Needle ID** |
|  |  |  |
| *Sample comments (e.g., approx. weight, presence of blood, connective tissue):* | | |
| *Participant comments (e.g., discomfort, bleeding):* | | |

# Signature

|  |  |  |  |
| --- | --- | --- | --- |
| Completed by | | Reviewed and approved by | |
| Name: |  | Name: |  |
| Function: |  | Function: |  |
| Date: |  | Date: |  |
| Signature: |  | Signature: |  |