Quality Control Document:

Managing Withdrawal of Consent in the Laboratory

# Purpose

The laboratory team must show due diligence in confirming that samples that arrive at the laboratory as part of a trial or study are from participants who have given their full and informed consent for their analysis. Participants of clinical trials and studies have the right to withdraw from a trial/study at any time. In some instances, the participant may be offered the choice of removing their samples, data or both from the trial/study. Where participants have withdrawn from the trial/study and wish for their samples/data to be removed, the laboratory team must ensure this happens in a timely manner, once notified by the relevant trial/study site or co-ordinating centre, and that the process is documented.

This document is designed to be used for clinical trials and for clinical studies using human tissue. It is possible to create a project specific document to manage withdrawal of consent, in which case it should contain the specifications outlined in the Sample Management SOP (UoB-CRL-SOP-003).

# Instructions

1. Remove this first instruction page.
2. Update the header to include the trial/study ID.
3. Update the footer; include a version date and retain the document reference information relating to this quality control document (QCD).
4. Detail the laboratory procedure to be followed when a participant withdraws their consent.
5. Record the contacting site/co-ordinating centre information (and delete as appropriate). If the withdrawal procedure as outlined in the protocol requires participants to contact the laboratory directly update the form accordingly.
6. If participants haven’t been given the option of removing “samples, data or samples and data”, update to reflect the withdrawal options offered to participants.
7. File a blank version of this form in the ‘Consent’ section of the Laboratory Master File (LMF). See quality control document (QCD) Setting Up a Laboratory Master File (UoB-CRL-QCD-001).
8. Complete this form whenever the laboratory is informed of a participant withdrawing from the trial/study.
9. Send a copy of the completed form to the originating site or co-ordinating centre, if agreed and detailed in the communication plan mentioned under point 4.
10. File completed versions of this form (and any related correspondence) in the ‘Consent’ section of the LMF. See QCD Setting Up a Laboratory Master File (UoB-CRL-QCD-001).

# Related documents

* UoB-CRL-QCD-001 Setting Up a Laboratory Master File
* UoB-CRL-QCD-005 Key Contacts
* UoB-CRL-SOP-001 Laboratory Set-up and Management
* UoB-CRL-SOP-002 Laboratory Facilities
* UoB-CRL-SOP-003 Sample Management
* UoB-CRL-SOP-004 Laboratory Analysis
* UoB-CRL-SOP-005 Reportable Issues

UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (mailto:crct@contacts.bham.ac.uk) and/or from the RGT (researchgovernance@contacts.bham.ac.uk).

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| Laboratory Procedure to be followed when a participant withdraws their consent |
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| Contacting Site/Co-ordinating Centre Information |
| Site name: |  |
| Name of contact from site team/co-ordinating centre: |  |
| Date the laboratory was contacted (dd-mmm-yyyy): |  |
| Name of Laboratory Team member receiving the call/email:  |  |
| Participant Withdrawal Information |
| Participant Number: |  |
| Participant withdraws consent for use of (please tick appropriate):  |
| * Samples (only)
 | * Laboratory generated data (only)
 | * Samples and Laboratory generated data
 |
| Laboratory confirmation of requested sample destruction / data withdrawal |
|  I confirm that the following (please tick all appropriate) have been destroyed/deleted:  |
| * Samples (only)
 | * Laboratory generated data (only)
 | * Samples and Laboratory generated data
 |
| Name: |  |
| Date (dd-mmm-yyyy): |  |
| Signature: |  |