Quality Control Document:

Clinical Sample Kits

# Purpose

Clinical sample kits contain the necessary components required to collect clinical samples. It may be required that a laboratory prepares and dispatches clinical sample kits to recruiting sites for the collection of clinical samples.

This document provides templates for a Sample Kit Preparation Record, which can be used to document the procedure to follow when preparing sample kits and record the details of each time sample kits are prepared, a Sample Kit Dispatch Record, to record dispatch of kits and confirm receipt of kits at site, and a Sample Kit Request Form, which sites could use if they need to request a (re)supply of clinical sample kits.

This document is designed to be used for Clinical Trials of Investigational Medicinal Products (CTIMPs) but could also be used for non-CTIMP trials and studies to support best practice. It is possible to create project specific sample kit management documents, which should contain the specifications outlined in the Sample Management SOP (UoB-CRL-SOP-003).

# Instructions

## **Set up the Sample Kit Preparation Record**

1. Remove this first instruction page.
2. Update the trial/study ID in the header.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. Pre-populate the Sample Kit Preparation Record with the information required to prepare sample kits, including:
* The name of the sample kit.
* A description of the sample kit and its purpose.
* Instruction on how the sample kit should be prepared.
* The location of sample kit preparation site. Consider how the areas used to store clinical sample kits will be monitored. Refer to the quality control document (QCD) Housekeeping Schedule (UoB-CRL-QCD-006).
* The sample kit storage and temperature requirements. For example, store the sample kits at 4°C, protected from light.
* The sample kit storage location. Consider how the temperature of areas used to store clinical sample kits will be monitored. See the QCD Temperature Monitoring (UoB-CRL-QCD-007).
1. Pre-populate the Sample Kit Preparation Record with the details of each of the kit components, including the component name, supplier, catalogue number and amount of each component to add per kit. Add or remove rows as necessary.
* Consider and record the number of each component which will trigger re-order for the supplier if met, i.e. the minimum number of each sample kit component that needs to be in stock.
1. Upon preparing sample kits, record:
* The expiry date of each sample kit component
* Whether components need to be reordered, i.e. if the trigger number has been reached
* The total number of sample kits prepared
* The name of who prepared the sample kits and the date on which they were prepared
* The name of who quality checked the clinical sample kits.
1. If preparing batch of sample kits in batches record the sample kit batch number, for example 01-Jan-19.
2. Store Sample Kit Preparation Records safely and securely in the Laboratory Master File throughout the trial and archive with the other trial documents when the trial closes. Refer to the Archiving SOP (UoB-ARC-SOP-001).

## **Set up the Sample Kit Dispatch Record**

1. Set up a separate Sample Kit Dispatch Record for each site that sample kits are dispatched to, each time sample kits are dispatched.
2. Update the trial/study ID in the header.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. Upon dispatch of the sample kits, record the details listed below.
* Contact details of the site that is receiving sample kits
* The temperature requirements of the sample kit while in transit. Consider how the temperature of the sample kits will be monitored during transport. Refer to the QCD Temperature Monitoring (UoB-CRL-QCD-007).
* The number of sample kits dispatched to the site
* The batch number of the sample kits that have been dispatched (if applicable)
* The date on which sample kits were dispatched
* The name and signature of the person who dispatched the sample kits.
1. Ensure the Sample Kit Dispatch Record is sent to each receiving site along with the sample kits.
2. Ensuring that the receiving site confirm receipt of the sample kits is important, particularly where the kits are critical to the sample pathway, or where the time in transit may affect the integrity of kit components. Instruct the receiving site to complete the following information upon receiving sample kits and return the completed Sample Kit Dispatch Record to the dispatching site, for example by email or fax:
* The date the sample kits were received
* Whether the sample kits are received in good order. Instruct the site to liaise with the contact as detailed in the Sample Kit Dispatch Record if the kits are not in good order
* Whether appropriate temperature was maintained during transit (if appropriate). Instruct the site to liaise with the contact as detailed in Sample Kit Dispatch Record if appropriate temperature was not maintained
* The name and signature of who has confirmed receipt of the sample kits
1. Consider a process for managing resupply of sample kits if they are not received in good order or if the temperature in transit is breached, and how to prevent such issues arising again in the future.
2. Store the completed Sample Kit Dispatch Records safely and securely in the Laboratory Master File at both the dispatch and receiving sites throughout the trial and archive with the other trial documents when the trial closes. See the Archiving SOP (UoB-ARC-SOP-001).

## **Set up the Sample Kit Request Form**

1. Update the trial/study ID in the header.
2. Update the footer, retaining the document reference information relating to this quality control document (QCD).
3. Provide details of how and where the Sample Kit Request Form should be sent to by the requesting site to request sample kits.
4. Consider how long it will take for sample kits to reach the site following the request and document on the form.
5. Instruct the requesting site to record:
* The site name and address to which the samples kits need to be sent
* The name of the required sample kits
* The number of sample kits required
* The date that the sample kits are required to arrive at the site by
* The name and signature of who is requesting the (re)supply of sample kits
* The date on which they were requested.

# Related documents

* UoB-ARC-SOP-001 Archiving
* UoB-CRL-QCD-006 Housekeeping Schedule
* UoB-CRL-QCD-007 Temperature Monitoring
* 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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| --- | --- |
| **Name of Sample Kit:** |  |
| **Description of sample kit and purpose:**  |  |
| **Preparation instructions:** |  |
| **Preparation location:** |  |
| **Storage temperature requirements** |  |
|  **Storage location:** |  |

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| --- | --- |
| Details of items to add to each kit | Complete upon kit preparation  |
| **Component Name** | **Supplier** | **Catalogue Number** | **Amount Per Kit** | **Reorder Trigger Number**  | **Expiry date** | **Reorder required?****(Y/N)** |
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**Complete the form below when preparing sample kits**

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| --- | --- |
| **Number of sample kits prepared:** |  |
| **Prepared by:** |  | **Preparation date:** |  |
| **Quality checked by:**  |  | **Quality check date:** |  |
| **Sample kit batch number:****(if required)** |  |

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| --- | --- |
| **Contact details of receiving site:**  |  |
| **Temperature requirements in transit:** |  |
| **Number of Kits Dispatched:** |  |
| **Sample kit batch number:** |  |
| **Date kits are dispatched:** |  |
| **Dispatched by:** | Name: | Signature: |
| To be completed by the receiving site: |
| **Date kits received:** |  |
| **Kits received in good order:** (tick as appropriate) | [ ]  Yes[ ]  No (please document issues noted and liaise directly with (list contact details):  |
| **Confirmation that temperature was maintained during transit:****(tick as appropriate)** | [ ]  Yes[ ]  No (please document issues noted and liaise directly with (list contact details):  |
| **Receipt confirmed by:** | Name: | Signature: |

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| --- |
| Please send supply form via (enter details) to (enter details):  |
| Please allow (enter details) days for the sample kits to arrive at site. |
| **Site name:** |  |
| **Site address:** |  |
| **Sample kit name:** |  |
| **Number of kits required:** |  |
| **Date kits are required by:** |  |
| **Requested by:** | Name: | Signature: | Date: |