Quality Control Document:

Key Contacts

# Purpose

It is imperative that laboratory members have quick and easy access to key trial contact information. Ideally, a list of key contacts will be filed at the front of the laboratory master file (LMF). Accessible key contacts may be needed for a number of reasons such as: the contemporaneous reporting of safety issues (see *Reportable Issues SOP* (*UoB-CRL-SOP-005*)); to confirm they hold the most up-to-date version of the protocol and to report to sites when samples received by the laboratory are damaged, unexpected or mislabelled (see quality control document *Processing of Damaged, Unexpected or Mislabelled Samples (UoB-CRL-QCD-016*)).

The purpose of this document is to provide a Key Contacts form template; the use of this template is optional.

Clinical trials of investigational medicinal products (CTIMPs) are expected to maintain an up-to-date key contacts list. To support best practice, a key contacts list can also be used by non-CTIMP trials and studies.

# Instructions

1. Remove this first instruction page.
2. Update the header to include the study/trial ID.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. Include a version date in the footer, to clarify when the information was collated and found to be correct.
5. Complete the form by entering the contact details of relevant members of the trial team.

* Enter the chief investigator’s contact details
* Enter details for a trial team member who can be contacted to verify whether the protocol version that the laboratory holds, is up to date. See the Laboratory Set-up and Management SOP (UoB-CRL-SOP-001).
* Enter the contact details for a key contact for each trial site/co-ordinating centre.

1. Use this form to capture any other trial-specific key contacts.
2. File the form in the ‘Key Contacts’ section of the laboratory master file (LMF).
3. When made aware of changes in contact details, update the form following instructions 4 to 7.

# Related documents

* UoB-CRL-QCD-001 Setting Up a Laboratory Master File
* UoB-CRL-QCD-016 Processing of Damaged, Unexpected or Mislabelled Samples
* 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 ([crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk)) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

# Key Contacts List

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| --- | --- |
| Chief Investigator | |
| Name: |  |
| Phone number: |  |
| Email address: |  |
| Sponsor (or their representative) | |
| Name: |  |
| Phone number: |  |
| Email address: |  |
| Protocol updates | |
| Name: |  |
| Phone number: |  |
| Email address: |  |
| Site(s)/Co-ordinating Centre | |
| Site name: |  |
| Contact name: |  |
| Phone number: |  |
| Email address: |  |
| Site name: |  |
| Contact name: |  |
| Phone number: |  |
| Email address: |  |
| Site name: |  |
| Contact name: |  |
| Phone number: |  |
| Email address: |  |