Quality Control Document:

Laboratory Roles and Duties

# Purpose

Defining and documenting laboratory roles and duties allows the laboratory academic lead (LAL) to confirm that all necessary tasks are being completed by appropriately qualified staff. It also allows laboratory team members to be clear about their role in the trial and provides an audit trail of who was involved in the trial at a given point in time and what their roles were. The purpose of this document is to provide a Laboratory Roles and Duties Log template. The use of this template is optional.

A laboratory roles and duties log is mandatory for clinical trials of investigational medicinal products (CTIMPs) as detailed in the Laboratory Set-up and Management SOP (UoB-CRL-SOP-001). For CTIMPs it must contain, as a minimum, the same content provided in the template below.

A laboratory roles and duties log can also be used, as best practice, for non-CTIMP trials and studies using human tissue. There is a list of laboratory duties provided within the template, some of these duties appear in bold text. The emboldened text indicates duties that are expected to be carried out in non-CTIMPs, and studies working with human biomaterial that is categorised as ‘relevant material’ under the Human Tissue Act 2004.

# Instructions

1. Remove this first instruction page.
2. Update the header to include the trial ID.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. Record the name of the laboratory academic lead on your Laboratory Roles and Duties Log.
5. The log template lists the laboratory duties that are required for compliance with relevant University of Birmingham (UoB) standard operating procedures. Ensure that your list of laboratory duties is updated to include any trial/study-specific duties.

* For CTIMP trials, it is expected that all of the listed duties will be required. However, if there is a duty that is truly not applicable to your trial then it may be removed. For example, if you are not creating clinical sample kits, *Clinical sample kit management* may be removed.
* For non-CTIMP trials and studies, only the duties listed in emboldened text are required. If using this
* template for non-CTIMPs or studies, the duties that are not listed in emboldened text may be removed if they are not needed.

1. All members of the laboratory team who have a role in the trial (for example, analysts, analytical managers, clinical research laboratory managers etc.) will complete a row on the Laboratory Roles and Duties Log, including identifying their trial-specific duties. The LAL will authorise each entry by initialling and dating it.
2. File your Laboratory Roles and Duties Log under the ‘Laboratory Roles and Duties’ section in your laboratory master file. See the Setting Up a Laboratory Master File SOP (UoB-CRL-QCD-001).

# Related documents

* UoB-CRL-QCD-001 Setting Up a Laboratory Master File
* 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

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](mailto:researchgovernance@contacts.bham.ac.uk)).

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Laboratory Role | Name (use block capitals) | Signature | Initials | Duties (supply codes from list below) | Date Involved in Trial | | Laboratory Academic Lead (LAL) | |
| From(dd-mmm-yyyy) | To(dd-mmm-yyyy) | LAL Initials\* | Date of LAL Agreement(dd-mmm-yyyy) |
| Laboratory Academic Lead |  |  |  |  |  |  |  |  |
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\* By initialising an entry, I confirm that the person completing the entry is authorised to perform the trial procedures documented in the tasks section and that the person is competent to undertake these tasks. I also confirm that the person is appropriately informed about the trial protocol and relevant trial procedures.

**Laboratory duties:**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Defining competencies 2. Development and review of contracts and agreements 3. Clinical trial protocol management 4. **Laboratory Master File maintenance** 5. **Temperature monitoring of refrigerators and freezers** 6. Equipment fitness for use and user acceptance testing | 1. **Housekeeping** 2. **Equipment maintenance and calibration** 3. System user access levels 4. Clinical sample kit management 5. **Consent (confirmation and withdrawal)** 6. **Sample receipt** | 1. **Sample labelling, traceability and storage** 2. **Processing of damaged/mislabeled samples** 3. Assay validation 4. Validation report approval 5. Computerised system validation 6. Repeat analysis procedure 7. Analytical plan development | 1. Analytical plan approval 2. Data quality check before reporting 3. Data reporting 4. Identification of reportable issues 5. Management of reportable issues 6. Other:……………………………… 7. Other:……………………………… |