Quality Control Document:

Clinical Trials Task Delegation Log

# Purpose

This quality control document (QCD) contains a Clinical Trials Task Delegation Log template that lists the duties to be undertaken in a clinical trial. The log allows for the sponsor, CI and CTU to clarify who will take the lead for specific duties, including those that have been delegated to them by the trial’s sponsor.

A University of Birmingham’s (UoB) CTU may choose to develop their own clinical trials task delegation log; it must contain the same content that is provided within this document’s template, but its design/format is optional.

CTUs that are external to the UoB must clearly define and document the delegation of duties between the CI and CTU for each of the project’s activities listed in the Clinical Trials Task Delegation Log template within this QCD. This could be documented within, for example, the contractual agreement between the UoB and the external UKCRC-registered CTU. See the Clinical Research Quality Manual (UoB-CQM-POL-001), section ‘External UKCRC-registered CTU’.

# Instructions

1. Remove the instruction pages.
2. Update the footer, retaining the document reference information relating to this quality control document (QCD).
3. Complete the Clinical Trial Details section.
4. The CI and CTU will agree who will lead each activity/duty listed in the log and will indicate this with a tick in the appropriate column ‘CI’, or ‘CTU’.
5. If the CI and CTU agree to share the lead for an activity, use the field ‘Other, please specify’ to document how tasks will be allocated.
6. If the activity is being led by a vendor, for example an investigational medicinal product (IMP) supplier, include their name in the ‘Other, please specify’ field.
* Where vendors or organisations other than the University are delegated tasks in relation to the trial, list their details in the ‘Vendor/organisation’ table.
1. The sponsor’s relevant standard operating procedure (SOP) is listed in the end column ‘Relevant sponsor SOP’. Related QCDs are listed when of direct relevance. In all other cases relevant QCDs will be referred to in the listed SOP.
* Relevant CTU SOPs/QCDs may also be added in this column for reference.
1. Sign and date the agreement fields at the end of the log or provide dated, electronic approval.
2. File in the trial master file (TMF).
3. Complete the log and forward it to the RGT when requesting the sponsor’s review of the IRAS form.

# Related documents

* UoB-CRG-SOP-001 Sponsor Oversight
* UoB-CQM-POL-001 Clinical Research Quality Manual

Note the 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) and/or from the RGT (researchgovernance@contacts.bham.ac.uk).

# References

* CI declaration (Internal CI agreement, UoB sponsor) for CTIMPs. Available upon request from the RGT (researchgovernance@contacts.bham.ac.uk)
* CI declaration ((internal CI agreement, UoB sponsor) for non-CTIMPs and studies. Available upon request from the RGT (researchgovernance@contacts.bham.ac.uk)
* Data Protection Resources: [https://intranet.birmingham.ac.uk/executive-support/legal-services/what-we-do/data-protection/data-protection-resources.aspx](https://intranet.birmingham.ac.uk/executive-support/legal-services/what-we-do/data-protection/data-protection-resources.aspx#id_token=eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6Ild3dXdRSWFCSWZvRURkbHd4VXpSRUVJbmtvMCIsImtpZCI6Ild3dXdRSWFCSWZvRURkbHd4VXpSRUVJbmtvMCJ9.eyJpc3MiOiJodHRwczovL2Ntcy11b2IuY2xvdWQuY29udGVuc2lzLmNvbS9hdXRoZW50aWNhdGUiLCJhdWQiOiJXZWJzaXRlQWRmc0NsaWVudCIsImV4cCI6MTY0ODYzODA4NiwibmJmIjoxNjQ4NjM3Nzg2LCJub25jZSI6ImU3MmU0OTIzYmZlZDQ1MzY5ZTNhMTVhMmE3ZDU2YTc1IiwiaWF0IjoxNjQ4NjM3Nzg2LCJzaWQiOiJiOGJhNmM3NTQ0NGIzYjQzYWZiNmRiM2Q1M2YzY2RmOSIsInN1YiI6ImY5OTg1ODI4LTZkNjUtNDVkNi05MzdmLTM1Y2Q4ZjZkYjJmZSIsImF1dGhfdGltZSI6MTY0ODYzNzc4NSwiaWRwIjoiaWRzcnYiLCJhbXIiOlsicGFzc3dvcmQiXX0.fEsaiqzNOaX6P3oSO7foXEdNtoM_n7blbubMo0I3QcB2KbIgpUHnOY5yAJkFgOd7-vbEKrZERuGbeS5c8Jo3lpTadM_q7YS5ruzp_xaX_S7a6RI20vbc7A18LLGwkVhzRmx3olY20fC6TMXc2iEmrAqJzHDVJ2Bn6NQAno3qhXiB_yz6Ca_jVMwFthR3DfUt6XMF0dC97ldikNCkmpvkOt42RL-A-xb6czaks8MdfoXflmeUimzHUrDAmBVNFZtatJUkAYgT62juxagr7lF0tLI6eVE5xuSivbAii4PcdtfXDxkfOgn22S00s5ilexki0q0r77D-Pt08jWX79Vw_6Q&scope=openid&state=75b8da5d11fa44d7b5865b5ff8df6882&session_state=eyoAXYpFCntXQLcij3xKeL89t43rmxFX9YpAAItl7ww.c15fac1b88fc224a4c35d8b5207bd838) (UoB login required)
* Research Finance: <https://intranet.birmingham.ac.uk/finance/rss/research-support-group/research-finance/index.aspx>
* HRA. (2017). UK policy framework for health and social care research. Available at: <https://www.hra.nhs.uk/documents/1068/uk-policy-framework-health-social-care-research.pdf>

# Clinical Trial Details

|  |  |
| --- | --- |
| Sponsor reference: | RG\_ |
| IRAS number: |  |
| Public registry number: | <for example the ISRCTN registry number or EudraCT number > |
| Chief investigator: |  |
| Clinical trials unit: |  |
| Trial coordinator: |  |
| Other key staff members:  |  |

This log lists the duties to be undertaken in a clinical trial. The trial’s sponsor delegates the duties to the chief investigator (CI) through the CI declaration. This document allows for the CI to further delegate (those that have been delegated to them by the trial’s sponsor) to a clinical trials unit (CTU) and clarifies who will take on the lead for specific duties.

Complete the log below and forward to the Research Governance Team (RGT) when requesting sponsor review of the IRAS form.

| Activity/Duty | Led by: | Evidence/Outcome | Relevant sponsor SOP |
| --- | --- | --- | --- |
| CI | CTU | Other, please specify: |
| Trial design before funding |  |  |
| 1. Trial methodology
 |  |  |  | Protocol | UoB-ESD-SOP-001 |
| 1. Trial feasibility
 |  |  |  | Protocol | UoB-ESD-SOP-001 |
| 1. NIHR CRN Clinical Study Group approval, where applicable
 |  |  |  | Protocol | UoB-ESD-SOP-001 |
| 1. Trial budget, including excess treatment costs
 |  |  |  | Budget approval by CTU/CI | UoB-SMA-SOP-001 |
| 1. Sponsorship: ensure sponsorship is feasible for the trial prior to the grant application
 |  |  |  | Where needed, evidence of referral to, and agreement from, RGT  | UoB-SET-SOP-001 |
| 1. Insurance feasibility: ensure insurance cover can be obtained for the trial prior to making an application for funding
 |  |  |  | Where needed, evidence of referral to, and agreement from, RGT | UoB-SET-SOP-001 |
| 1. Grant application submission
 |  |  |  | Fully approved grant application | Outside QMS scope, see [Research Support Services (RSS)](https://intranet.birmingham.ac.uk/finance/rss/index.aspx) for further information. |
| 1. Peer review (if required)
 |  |  |  | Peer review report (and responses to points raised, if applicable) | UoB-SET-SOP-001UoB-PRV-SOP-001 |
| Trial design and set up after funding |  |  |
| 1. Trial master file set-up and maintenance
 |  |  |  | Trial Master File | UoB-ESD-SOP-001UoB-CLN-ESD-QCD-001  |
| 1. Risk assessment and process implementation for risk mitigation
 |  |  |  | Risk assessment report  | UoB-POS-SOP-001UoB-CLN-TQM-QCD-001 |
| 1. Vendor assessments
 |  |  |  | Vendor assessment report | UoB-CPR-SOP-001 |
| 1. Draw up contracts/agreements with funders, vendors, sites
 |  |  |  | Fully signed contracts and agreements in Trial Master File | UoB-SET-SOP-001UoB-CPR-SOP-001UoB-SMA-SOP-001 |
| 1. Insurance obtained
 |  |  |  | Insurance certificate | UoB-SET-SOP-001 |
| 1. Participant entry, randomisation, blinding and emergency unblinding: decide on processes as applicable
 |  |  |  | Protocol | UoB-RND-SOP-001UoB-SMA-SOP-001 |
| 1. IMP/medical devices sourcing and management
 |  |  |  | Protocol  | UoB-MED-SOP-001 |
| 1. Adverse event reporting: decide on processes relating to i) classification; ii) communication pathways for reporting and trend analysis.
 |  |  |  | Protocol | UoB-AES-SOP-001 |
| 1. Identify trial-specific reference safety information and establish a process for monitoring updates to it for the duration of the trial.
 |  |  |  | Investigator Brochure/SmPC/Reference Safety Information | UoB-AES-SOP-001UoB-ESD-SOP-001 |
| 1. Research laboratory (if involved in any CTIMP endpoint analysis): set up laboratory in line with GCP in the Lab standards
 |  |  |  | Laboratory manual | UoB-CRL-SOP-001UoB-CRL-SOP-002UoB-CRL-SOP-003UoB-CRL-SOP-004UoB-CRL-SOP-005UoB-CRL-SOP-006 |
| 1. Personal data (where collected): set up processes for data collection, handling, storage and destruction in line with the Data Protection Act.
 |  |  |  | Protocol, Information Sheet/ Consent Form | See [UoB Data Protection resources (birmingham.ac.uk)](https://intranet.birmingham.ac.uk/executive-support/legal-services/what-we-do/data-protection/data-protection-resources.aspx#id_token=eyJ0eXAiOiJKV1QiLCJhbGciOiJSUzI1NiIsIng1dCI6Ild3dXdRSWFCSWZvRURkbHd4VXpSRUVJbmtvMCIsImtpZCI6Ild3dXdRSWFCSWZvRURkbHd4VXpSRUVJbmtvMCJ9.eyJpc3MiOiJodHRwczovL2Ntcy11b2IuY2xvdWQuY29udGVuc2lzLmNvbS9hdXRoZW50aWNhdGUiLCJhdWQiOiJXZWJzaXRlQWRmc0NsaWVudCIsImV4cCI6MTY0OTc2NDI1OCwibmJmIjoxNjQ5NzYzOTU4LCJub25jZSI6ImU2ZGNhYmRjNmMyMDRjZmI5OGQwNGM4YTg5MTZkZmM5IiwiaWF0IjoxNjQ5NzYzOTU4LCJzaWQiOiI2MTc4NmI3MTNkYzdhMWNiYmM5N2VlZmU5ZGI3ZTkxYyIsInN1YiI6ImY5OTg1ODI4LTZkNjUtNDVkNi05MzdmLTM1Y2Q4ZjZkYjJmZSIsImF1dGhfdGltZSI6MTY0OTc2Mzk1NywiaWRwIjoiaWRzcnYiLCJhbXIiOlsicGFzc3dvcmQiXX0.W2HWZgYZWADdxI6GdlVNgqVjyv7MpeNlAnLXzsQP1vijS6EXXQy-mxovHYPhAcTvbUcbo6AuLX6JdSJewgXimS8ty5mqBdeU4kcAQdaL8GOpLlZbcQiKJNBqmgSD8AANBi8iFkCpA7OCo-UG-8yo4Ene2p1idW9IadW8R6QyQs45gvOfMS6kF3ap_jziSMan-61AHrC6t_fIPHP-cEXMwyxahDVbChelkaqxxYy0-JKUzp9HG_OBO6gkIwPXhSPGYbUkrNjBGb4MvzgJLrlDf3mKyFmMvXB5NXT2hcdzN-j7LDWkp3frXvCn5rufT0BqrWy4jqoUuhmNgsjou3uKqA&scope=openid&state=8e9a1f0666bb451c8c136557a072226f&session_state=O8I8M8qjWrAqsY45ZpFHmw_xUd7nXRbPVFXgaNAG8N0.13e5f4a6b2e0d0a240d80c3549b620e5)(UoB login required). |
| 1. Tissue sample collection (where applicable): set up processes for tissue-sample collection, handling, storage and destruction in line with the Human Tissue Act.
 |  |  |  | Protocol | UoB-ESD-SOP-001UoB-CRL-SOP-001UoB-CRL-SOP-002UoB-CRL-SOP-003 |
| 1. Independent trial oversight: set up a trial steering committee and/or data monitoring committee as applicable
 |  |  |  | Protocol | UoB-POS-SOP-001 |
| 1. Develop an Information Sheet/Consent Form and other required trial documentation
 |  |  |  | Information Sheet/Consent Form, other required documents  | UoB-ESD-SOP-001UoB-PEI-SOP-001 |
| 1. Register trial in a public clinical-trial-registration database
 |  |  |  | Protocol | UoB-SET-SOP-001 |
| 1. Protocol finalisation
 |  |  |  | Protocol | UoB-ESD-SOP-001 |
| 1. Sponsorship approval
 |  |  |  | Sponsorship approval letter | UoB-SET-SOP-001 |
| 1. NIHR portfolio adoption application (if applicable)
 |  |  |  | Confirmation letter | UoB-SET-SOP-001*UoB-SMA-SOP-001* |
| 1. HRA approval
 |  |  |  | HRA approval letter | UoB-SET-SOP-001 |
| 1. REC favourable ethical opinion
 |  |  |  | Fully signed IRAS form, REC favourable-ethical-opinion letter listing the approved document set | UoB-SET-SOP-001UoB-ESD-SOP-001 |
| 1. Competent authority’s authorisation (as applicable)
 |  |  |  | Fully signed IRAS form, Clinical Trial Authorisation letter | UoB-SET-SOP-001UoB-ESD-SOP-001 |
| 1. NHS Trust permissions (capacity & capability approval)
 |  |  |  | Fully signed IRAS form, R&D permission letter | UoB-SET-SOP-001UoB-ESD-SOP-001UoB-SMA-SOP-001 |
| 1. Any other required approvals, opinions or permissions relevant to the application (e.g. GP practice approval, ARSAC, IRMER).
 |  |  |  | Approval letters | UoB-SET-SOP-001UoB-ESD-SOP-001 |
| 1. CRF development
 |  |  |  | CRF | UoB-CRT-CRF-SOP-001UoB-ESD-SOP-001  |
| 1. Statistical-analysis-plan development
 |  |  |  | Statistical analysis plan | UoB-CRT-STA-SOP- 001 |
| 1. Database building for the collation of trial data
 |  |  |  | Database | UoB-CRT-DMA-SOP-001  |
| 1. Trial quality management: set-up processes
 |  |  |  | Protocol, monitor plan, audit program | UoB-POS-SOP-001UoB-CPR-SOP-001  |
| 1. Site identification, set-up and initiation
 |  |  |  | Site initiation reports | UoB-SMA-SOP-001  |
| 1. Training of trial team and site staff
 |  |  |  | Training logs | UoB-TRN-SOP-001UoB-SMA-SOP-001 |
| Trial management throughout the duration of the trial  |  |  |
| 1. Site management
 |  |  |  | Reports from/to sites, correspondence with sites, evidence of trial management group meetings, completed site signature and delegation log | UoB-SMA-SOP-001 UoB-ESD-SOP-001 |
| 1. Data management
 |  |  |  | Data tracking sheets, data queries, data management plan | UoB-CRT-DMA-SOP-001 |
| 1. Interim analyses as per the statistical analysis plan
 |  |  |  | Interim analysis reports | UoB-STA-SOP-001 |
| 1. Independent oversight of the trial: arrange regular meetings for oversight committees e.g. Trial Steering Committee, Data Monitoring Committee
 |  |  |  | Evidence of meetings e.g. agenda, report to the Committee, meeting minutes, follow up letter | UoB-POS-SOP-001 |
| 1. IMP/medical devices: ongoing supply, return and destruction
 |  |  |  | Supply management system, supply order, shipment, return and/or destruction forms  | UoB-MED-SOP-001 |
| 1. Serious breach investigations, where required
 |  |  |  | Serious breach report, evidence of submission of report to REC and CA (if required)  | UoB-DSB-SOP-001 |
| 1. Safety signal detection
 |  |  |  | Annual Safety Report/Development Safety Update Report, Data Monitoring Committee report | UoB-AES-SOP-001 |
| 1. Clinical evaluation of SAEs
 |  |  |  | Documented evidence e.g. through clinical evaluation form or on actual SAE form. | UoB-AES-SOP-001 |
| 1. Unexpected and Related SAEs/SUSARs processing.
 |  |  |  | Unexpected and Related SAE/SUSAR report, evidence of submission of report to REC and CA (if applicable). | UoB-AES-SOP-001 |
| 1. Urgent safety measure processing if required
 |  |  |  | Evidence of reporting to the REC and CA (if applicable) and to participating sites. | UoB-AES-SOP-001 |
| 1. Substantial and non-substantial amendments management
 |  |  |  | Evidence of substantiality decision, evidence of approval from the REC, CA (if applicable) and other bodies as required, evidence of distribution to sites. | UoB-SET-SOP-001 |
| 1. Annual progress reporting to the REC
 |  |  |  | Annual progress reports, evidence of reports being submitted to the REC. | UoB-SET-SOP-001 |
| 1. Annual safety reporting to the REC and competent authority (as applicable)
 |  |  |  | Annual Safety Report/Development Safety Update Report, evidence of submission of report to the REC and CA (if applicable).  | UoB-AES-SOP-001UoB-CLN-AES-QCD-004 |
| 1. Annual reporting to anyone else e.g. funders, sponsor
 |  |  |  | Reports to others. Evidence of reports being submitted. | UoB-SET-SOP-001UoB-AES-SOP-001 |
| 1. Subject recruitment monitoring and taking action as required to ensure recruitment targets are met
 |  |  |  | Reports from/to sites, reports from/to trial oversight committees. | UoB-PEI-SOP-001 |
| 1. Vendor management
 |  |  |  | Evidence of communication with the vendor(s); evidence of reviewing each vendor’s contract compliance. | UoB-CPR-SOP-001 |
| 1. Trial-quality management: perform in-house and/or on-site monitoring and/or audit activities
 |  |  |  | Evidence of: in-house monitoring activities performed; on-site monitoring visit reports; audit reports. | UoB-POS-SOP-001UoB-CPR-SOP-001 |
| 1. Trial-finance management
 |  |  |  | Evidence of a review of the trial’s finance. | See [UoB research finance resources (birmingham.ac.uk)](https://intranet.birmingham.ac.uk/finance/rss/research-support-group/research-finance/index.aspx/)UoB login required.  |
| Trial management at the end of the trial |  |  |
| 1. Site close-out assessments
 |  |  |  | Site close-out report. | UoB-SMA-SOP-001 |
| 1. End -of -study notifications and reports to the REC and sponsor, and (if applicable) CA and any third parties
 |  |  |  | End-of-study report, evidence of report being sent to relevant parties. | UoB-CLO-SOP-001 |
| 1. Final analysis as per statistical analysis plan
 |  |  |  | Evidence of analysis. | UoB-STA-SOP-001 |
| 1. Clinical study report: generation and dissemination to sites
 |  |  |  | Clinical study report, evidence of dissemination to sites. | UoB-CLO-SOP-001 |
| 1. Present/publish trial results
 |  |  |  | Evidence of trial results made available on public domain. | UoB-CLO-SOP-001 |
| 1. Archive of Trial Master File
 |  |  |  | Archive records. | UoB-ARC-SOP-001 |

|  |
| --- |
| I agree with the division of activities between myself and the CTU as described in the above table and agree to follow the CTU’s QMS as required.  |
| Name CI: |
| Signature:  |
| Date:  |
|  |
| I agree with the division of activities between the chief investigator and the CTU as described in the above table: |
| Name CTU Representative (Team leader): |
| Signature:  |
| Date:  |

Where other vendors/organisations than the University are delegated tasks in relation to the trial please list their details below:

|  |
| --- |
| Vendor/organisation for: <specify activity here> |
| Vendor/organisation |  |
| Address |  |
| Telephone number |  |
| Fax number |  |
| Web site address |  |
| Contact name |  |
| Contact job title |  |
| Contact address (if different from above) |  |
| Contact direct telephone number |  |

|  |
| --- |
| Vendor/organisation for: <specify activity here> |
| Vendor/organisation |  |
| Address |  |
| Telephone number |  |
| Fax number |  |
| Web site address |  |
| Contact name |  |
| Contact job title |  |
| Contact address (if different from above) |  |
| Contact direct telephone number |  |