University of Birmingham

Clinical research compliance

The Clinical Research Compliance Team ensures clinical research projects and in particular clinical trials are conducted in line with any applicable regulations, international standards and University standards.

The Research Facilitators / Administrators will function as a first port of call; they will be able to sign post researchers to teams within the University with further detailed knowledge.

General QMS

Open all sections

Research Quality Manual (password protected)

- **Research Quality Manual** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Mar--15-Docs/UoB%20Research%20Quality%20Manual%20v%20%201%200%20for%20web.docx)

QMS Development (password protected)

- **Quality Management Systems SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-GEN-QMS-SOP-001%20QMS%20development%20and%20maintenance%20v2.0%20(EAv1.0)%20for%20web%20Update.docx)
- **SOP templates** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-GEN-QMS-QCD-001%20SOP%20template%20v1.0%20(EAv1.0).docx)
- **QCD template** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-GEN-QMS-QCD-002%20QCD%20template%20v1.0%20(EAv1.0).docx)
- **QCD Review Form template** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-GEN-QMS-QCD-003%20QCD%20review%20form%20v1.0%20(EAv1.0).docx)

Training (password protected)

- **Training SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-GEN-TRN-SOP-001%20Training%20UoB%20Staff%20v%201.0%20(EAv1.0)%20for%20web.docx)
- **CV template** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-GEN-TRN-QCD-001%20CV%20Template%20v.%201.0%20dd.%2014-Aug-14.docx)
- **Employee Training Record template** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-GEN-TRN-QCD-002%20Employee%20Training%20Record%20template%20v%20%201.0%20dd%20%2014-Aug-2014.docx)
- **Training Attendance Log** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-GEN-TRN-QCD-003%20Training%20Attendance%20Log%20v%20%201.0%20(EAv1.0).docx)

Audits (password protected)

- **Audits SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-GEN-AUD-SOP-001%20Audits%20v1.0.docx)
- **Audit Program template** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-GEN-AUD-QCD-001%20Audit%20Programme%20Template%20v1.0.docx)

Clinical Trials QMS

Clinical Trials Quality Manual (password protected)

- **Clinical Trials Quality Manual** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/Clinical%20Trials%20Quality%20Manual%20v.%201.0%20(EAv1.0)%20for%20web.docx)

Glossary of Terms (password protected)

- **Glossary of Terms** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-CTM-QCD-001%20Glossary%20of%20Terms%20v2.0.docx)

Clinical Trial Management (password protected)

- **Clinical Trial Management SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Mar--15-Docs/UoB-CLN-CTM-SOP-001%20Clinical%20Trial%20Management%20v%203.0%20(EAv2.0)%20for%20web.docx)

Randomisation and Blinding (password protected)

- **Randomisation and Blinding SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-CTM-SOP-002%20Randomisation%20and%20Blinding%20%20SOP%20Version%201.0%20(EAv1.0)%20for%20web.docx)

Trial Quality Management (password protected)

- **Trial Quality Management SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-TQM-SOP-001%20Trial%20Quality%20Management%20v1.0%20(EAv1.0)%20for%20web.docx)
- **Risk Assessment Template** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-TQM-QCD-001%20Risk%20Assessment%20Template%20v1.0.docx)

Essential Documents (Trial Master File) development and maintenance (password protected)

- **Essential Documents SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-ESD-SOP-001%20Essential%20Documents%20development%20and%20maintenance%20v.%201.0%20(EAv1.0)%20for%20web.docx)
- **Essential Documents checklist** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-ESD-QCD-001%20Essential%20Document%20Checklist%20CTIMPs%20v.%201.0%20(EAv1.0).docx)
- **Protocol template** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-ESD-QCD-002%20protocol%20template%20v1.0%20dd.%2014-Aug-2014.docx)
- **Site Signature and Delegation Log** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-ESD-QCD-003%20SS&DL%20v1.0%20dd.%2014-Aug-2014.docx)

Data Management (password protected)

- **Data Management SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-DMA-SOP-001%20Data%20Management%20v%201.0%20(EAv1.0)%20for%20web.docx)

Investigational Medicinal Product (IMP) Management (password protected)

- **IMP SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-IMP-SOP-001%20IMP%20Management%20SOP%20v%201.0%20(EAv1.0)%20for%20web.docx)

Trial Systems development and management (password protected)

- **Trial Systems development and management SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-TSM-SOP-001%20Trial%20systems%20development%20and%20management%20v1.0.docx)

Site Management (password protected)

- **Site Management SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Mar--15-Docs/UoB-CLN-SMA-SOP-001%20Site%20Management%20v1.0%20for%20web.docx)

Adverse Event Reporting (password protected)

- **Adverse Event Reporting SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-AES-SOP-001%20Adverse%20Event%20Reporting%20v%20%201.0%20(EAv1.0)%20for%20web%20Update.docx)
- **SAE Form template** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-AES-QCD-002%20SAE%20Form%20template%20v.%201.0%20(EAv1.0).docx)
- **Internal process for SAE handling example** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-AES-QCD-003%20Internal%20process%20for%20SAE%20handling%20example%20v.%201.0%20(EAv1.0).docx)
- **DSUR template** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/UoB-CLN-AES-QCD-004%20DSUR%20template%20v2.0%20(EAv1.0)Update.docx)

Serious Breach Reporting (password protected)

- **Serious Breach Reporting SOP** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Mar--15-Docs/UoB-CLN-SBR-SOP-001%20Serious%20Breach%20v1.0%20dd18-Mar-15%20for%20web.docx)

GCP in the Laboratory documents (password protected)

- **Procedures for GCP compliance in the laboratory** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-SOP-001%20Procedures%20for%20GCP%20compliance%20in%20the%20laboratory%20v1.0%20(EAv1.0).docx) (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/gcp/UoB-LAB-SOP-001ProceduresforGCPcomplianceinthelaboratoryv10.docx)
- **GCP compliance in the laboratory checklist** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-001%20GCP%20compliance%20in%20the%20laboratory%20checklist%20v1.0%20(EAv1.0).docx)
- **Equipment maintenance and calibration checks** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-002%20Equipment%20maintenance%20and%20calibration%20checks%20v1.0%20(EAv1.0).docx)
- **Temperature monitoring** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-003%20Temperature%20monitoring%20v1.0%20(EAv1.0).docx)
- **Laboratory access** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-

004%20Laboratory%20access%20v1.0%20(EAv1.0).docx)

- **Laboratory housekeeping** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-005%20Laboratory%20housekeeping%20v1.0%20(EAv1.0).docx)
- **Management of shared equipment** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-006%20Management%20of%20shared%20equipment%20v1.0%20(EAv1.0).docx)
- **Receipt and traceability of trial participant samples** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-007%20Receipt%20and%20traceability%20of%20trial%20participant%20samples%20v1.0%20(EAv1.0).docx)
- **Analytical assay validation** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-008%20Analytical%20assay%20validation%20v1.0%20(EAv1.0).docx)
- **Analytical assay failure** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-009%20Analytical%20assay%20failure%20v1.0%20(EAv1.0).docx)
- **Impact assessment of equipment failure or equipment calibration failure** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-010%20Impact%20assessment%20of%20equipment%20failure%20or%20equipment%20calibration%20failure%20v1.0%20(EAv1.0).docx)
- **Handling and maintaining raw data** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-011%20Handling%20and%20maintaining%20raw%20data%20v1.0%20(EAv1.0).docx)
- **Receipt, labelling and storing of reagents** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-012%20Receipt%20labelling%20and%20storage%20of%20reagents%20v1.0%20(EAv1.0).docx)
- **Management and storage of analytical standards** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-013%20Management%20and%20storage%20of%20analytical%20standards%20v1.0%20(EAv1.0).docx)
- **Laboratory manual** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-014%20Laboratory%20Manual%20v1.0%20(EAv1.0).docx)
- **Review and release of results** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-015%20Review%20and%20release%20of%20results%20v1.0%20(EAv1.0).docx)
- **Adverse events in the analytical laboratory** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-016%20Adverse%20events%20in%20the%20analytical%20laboratory%20v1.0%20(EAv1.0).docx)
- **Laboratory audits and quality checks** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-017%20Laboratory%20audits%20and%20quality%20checks%20v1.0%20(EAv1.0).docx)
- **Repeat analysis** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-018%20Repeat%20analysis%20v1.0%20(EAv1.0).docx)
- **Procedures following failure of a storage unit** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-019%20Procedures%20following%20failure%20of%20a%20storage%20unit%20v1.0%20(EAv1.0).docx)
- **Laboratory training record** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-020%20Laboratory%20training%20record%20v1.0%20(EAv1.0).docx)
- **Equipment maintenance record** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-021%20Equipment%20maintenance%20record%20v1.0%20(EAv1.0).docx)
- **Single channel pipette calibration check record** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-022%20Single%20channel%20pipette%20calibration%20check%20record%20v1.0%20(EAv1.0).docx)
- **Multi-channel pipette calibration check record** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-023%20Multi%20channel%20pipette%20calibration%20check%20record%20v1.0%20(EAv1.0).docx)
- **Thermometer and temperature probe calibration check record** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-024%20Thermometer%20and%20temperature%20probe%20calibration%20check%20record%20v1.0%20(EAv1.0).docx)
- **Balance calibration check record** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-025%20Balance%20calibration%20check%20record%20v1.0%20(EAv1.0).docx)
- **Housekeeping record** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-026%20Housekeeping%20record%20v1.0%20(EAv1.0).docx)
- **Training record for shared equipment** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-027%20Training%20record%20for%20shared%20equipment%20v1.0%20(EAv1.0).docx)
- **Analytical failure report** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-028%20Analytical%20failure%20report%20v1.0%20(EAv1.0).docx)
- **Impact assessment of equipment failure of equipment calibration failure** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-029%20Impact%20assessment%20of%20equipment%20failure%20or%20equipment%20calibration%20failure%20report%20v1.0%20(EAv1.0).docx)
- **Reagent receipt and storage record** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-030%20Reagent%20receipt%20and%20storage%20record%20v1.0%20(EAv1.0).docx)
- **Temperature monitoring record** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-031%20Temperature%20monitoring%20record%20v1.0%20(EAv1.0).docx)
- **Averse event report** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-032%20Adverse%20event%20report%20v1.0%20(EAv1.0).docx)
- **Analytical assay validation plan** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-033%20Analytical%20assay%20validation%20plan%20v1.0%20(EAv1.0).docx)
- **Analytical assay validation report** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-034%20Analytical%20assay%20validation%20report%20v1.0%20(EAv1.0).docx)
- **Analytical plan** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-035%20Analytical%20plan%20v1.0%20(EAv1.0).docx)
- **Self assessment of GCP compliance in the laboratory** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Feb-15-GCP-Docs/UoB-CLN-LAB-QCD-036%20Self-assessment%20of%20GCP%20compliance%20in%20the%20laboratory%20v2.0%20(EAv1.0).docx)

Guidelines (password protected)

- **Patient identifiable information guideline** (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/Patient%20identifiable%20information%20guideline%20v.%201.0%20dd.%2002-May-2013.docx)

- **NHS information security summary (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/NHS%20information%20security%20summary%20v%20%201.0.docx)**
- **Completion of Personal Data Notification Form (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/Guideline%20Personal%20Data%20Notification%20Form%20completion%20for%20a%20clinical%20research%20database%201.0.docx)**
- **Clinical Trial Costing Template (https://intranet.birmingham.ac.uk/mds/documents/staff/rkto/newrkto/Jan-15-UpdatedDocs/Clinical-Trial-Costing-Template-v-10.xls)**

What we do

The team has a number of key responsibilities relating to clinical trials:

- Developing University wide clinical trials policies and Standard Operating Procedures (SOPs). By adhering to these policies and SOPs any University staff involved in clinical trials and the University as an institution can be assured that the rights and wellbeing of the subjects participating in clinical trials are protected and trial data are accurate, complete and verifiable from source documents and the trial is in compliance with the approved protocol/amendment(s), Good Clinical Practice (GCP) and the applicable regulatory requirements
- Performing quality checks and audits to assess adherence of researchers and/or CTUs to compliance to any international standards, guidelines, regulations, local policies or SOPs relating to clinical trials
- Reviewing any Serious Breaches, audit reports and inspection reports for trials (co-) sponsored by the University of Birmingham to ensure appropriate action has been taken and identify any areas for further improvement on a University wide level
- Supporting University staff involved in clinical trials focussing on problem resolution, training and signposting

The CRCT works closely together with the Research Governance Team to ensure new trials are set up as per University's policies and Standard Operating Procedures and appropriate Sponsor oversight is maintained. It also works closely together with the three UKCRN fully registered Clinical Trials Units (CTUs), i.e. the **Cancer Research UK Clinical Trials Unit (/research/activity/mds/trials/crctu/index.aspx)**, the **Birmingham Clinical Trials Unit (/research/activity/mds/trials/bctu/index.aspx)** and the **Primary Care Clinical Research and Trials Unit (/research/activity/mds/trials/pccrtu/index.aspx)**, to ensure best practices are shared across the University. The CRCT reports to the Clinical Trials Oversight Committee (CTOC), which is the main operational arm of the **Birmingham Centre for Clinical Trials (/research/activity/mds/centres/bcct/index.aspx)**.

The CTRC has two responsibilities; firstly to advise the Research Governance Team whether or not a clinical trial using an Investigational Medicinal Product to be managed outside the CTU should receive University sponsorship and secondly for ensuring Sponsor oversight.

The CRCT also supports researchers involved in projects which use and store human tissue to ensure compliance with the Human Tissue Act (2004).

Find out more

Comprehensive information on all of the topics covered by the MDS Clinical Research Compliance Team is available to all our researchers via the **Research Support Handbook (https://intranet.birmingham.ac.uk/mds/college-services/rkto/research-handbook/index.aspx)** (adf login required).

There you will also find associated forms and guidelines available for download, plus contact details for specific members of staff.

For general enquiries to the MDS Clinical Research Compliance Team, please contact

E: **rktoffice@contacts.bham.ac.uk (mailto:rktoffice@contacts.bham.ac.uk)** T: +44 (0)121 414 9299

Or follow us on Twitter (**@uob_mdsrkto (https://twitter.com/UoB_MDSRKTO)**)

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