Standard Operating Procedure:

Training

# Purpose

This standard operating procedure (SOP) describes how staff training should be performed and documented.

# Scope

The SOP is applicable to all staff involved in clinical research sponsored by the University of Birmingham (UoB). Where staff are involved in clinical research sponsored by another institution, this procedure should be followed as far as possible, and in line with the contractual agreement between the UoB and the other institution. This SOP also applies to staff involved in clinical research approved by a UoB Research Ethics Committee (REC) that are required to follow the UoB Principles of Good Clinical Practice (GCP) for Clinical Research (UoB-GCP-POL-001). This SOP may be used as a guidance document in all other cases.

# Implementation plan

This SOP will be implemented in line with this document’s effective date.

# Stakeholders

* Manager (or delegate) – this term is used to define the role that has the responsibility for ensuring staff are trained. This may be the chief investigator (CI) or UoB lead for the clinical research project. For clinical research approved by a UoB research ethics committee (REC), the role of CI may be referred to as the principal investigator (PI), or the supervisor for postgraduate research students.
* UoB staff members working in accordance with the UoB clinical research quality management system (QMS), other relevant external standards and regulations or any other QMS referring to this SOP.

# Background and rationale

The key to a successful QMS relies on staff being trained on standards and regulations which underpin it, as well as the policies and procedures it contains. The [UoB Code of Practice for Research (PDF – 357 KB)](http://www.birmingham.ac.uk/Documents/university/legal/research.pdf) states that the PI [CI for clinical research] is accountable for ensuring that all researchers are appropriately qualified by training and experience to carry out their role in the research.

Training typically starts during an employee’s induction period and is expected to continue thereafter to ensure staff remain up to date with the latest practices and regulatory requirements. This SOP covers the general process. It is expected that for each topic the required training will be described in the topic-specific instructions, SOPs and/or quality manual.

# Process map



# Procedure

## Recruitment of qualified staff

1. Following the UoB recruitment procedures, the manager (or delegate) will recruit staff members who are appropriately qualified by education and/or experience to perform tasks, or who would be able to perform their tasks following further training.
2. The staff member will keep on file a (paper or electronic) copy of their signed and dated research CV containing proof of relevant education and/or experience. See the Employee CV (UoB-TRN-QCD-001) for a template has been developed in line with [HRA CV guidance](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/). Where appropriate, the staff member’s job application form may be used.

Note: personal details (such as home address and personal telephone numbers) are not required for a research CV and should not be included/kept to a minimum.

1. For CTIMPs, the staff member will keep on file a copy of their job description, or an overview of tasks to be undertaken by the individual that are related to the clinical research (here on referred to as the job description). The job description will be signed and dated by the staff member to demonstrate the date on which current roles and responsibilities have been agreed. A job description may not be required where roles and responsibilities are clearly defined elsewhere for the staff member.
* Where possible, it is recommended that a job description is also signed and dated by the staff member’s line manager.
* A job description is also recommended as a best practice for staff members working on non-CTIMPs and/or studies to demonstrate their assigned roles and responsibility related to the clinical research.

## Initial staff training

1. At the start of a new staff member’s employment the manager (or delegate), together with the staff member, will provide an induction and perform a training needs analysis. This will identify the training required to ensure the staff member is appropriately trained to undertake their tasks. Training needs will depend on the staff member’s prior education and experience. A training plan will be developed, including agreed timelines, to ensure training is provided in a timely fashion. The plan may include training on:
	* relevant documents from the QMS
	* relevant procedures and/or tasks for the clinical research
	* applicable regulations and/or standards (see the Clinical Research Quality Manual (UoB-CQM-POL-001)).
2. The manager (or delegate) will consider the appropriateness of mentorship provided by an experienced colleague.
3. The staff member will undertake the training as set out in the training needs analysis, and to the timelines agreed with the manager (or delegate).
4. The staff member will keep on file proof of up-to-date training (and competency where applicable). Examples of evidence of training/competency may be through:
* certificates of attendance
* Employee Training Record (UoB-TRN-QCD-002)
* Training Attendance Log (UoB-TRN-QCD-003)
* a signed statement for Laboratory Competencies (UoB-CRL-QCD-003)
* the [Performance and Development Review (PDR)](https://bham.sharepoint.com/sites/performanceprogression) report.

Note: if a PDR report is used as proof of training, the staff member should document their agreement to allow auditors/inspectors to review the document if needed. A PDR report may contain other private and confidential information that is not relevant to clinical research and therefore, where possible, it is recommended that evidence of training is captured elsewhere.

1. The manager (or delegate) will maintain oversight of the staff member’s initial training activities to ensure training was received in a timely fashion. The manager (or delegate) will also assess and confirm competency to perform a specific task/activity/procedure, where applicable.

## Ongoing training of staff

1. Following completion of the initial training, the staff member and manager (or delegate) will review any further training needs on an ongoing basis. This should be at least once per year, typically through the UoB PDR programme. Timelines for the training to be completed will be agreed (see steps 4 to 8) and further training may be required following:
* changes to applicable regulations and standards
* changes to the UoB QMS documents
* changes to the role of the staff member, whereby training on new tasks is required.
1. The staff members will undertake any [UoB mandatory training](https://bham.sharepoint.com/sites/POD/SitePages/Mandatory-Training.aspx), e.g. as requested by their Heads of College, following the set timelines for training. It is recommended that evidence of the UoB mandatory training is recorded locally, in additional to the record held on the UoB Core system.
2. The staff member will keep on file proof of training (and competency where applicable) as detailed in procedure step 7.

## Staff changes

1. Where a staff member changes their role, including where they remain working with the same manager, the procedure steps 4 to 11 will be followed.
2. Before a staff member leaves their post, the manager (or delegate) will ensure that the items listed below are retained on file. These items provide proof the staff member was appropriately qualified for the tasks they took on before they left their post.
* A signed and dated copy of an up-to-date job description for CTIMPs (recommended for non-CTIMP and studies).
* A signed and dated copy of their clinical research CV.
* Proof of relevant training.

# List of expected outputs

* Documented evidence per staff member that includes:
* a training plan identifying training needs (where appropriate)
* a signed and dated CV containing proof of relevant education and/or experience
* proof of training (and competency where applicable) as detailed in procedure step 7 above
* for CTIMPs, a signed and dated job description specifying the roles and responsibility assigned to the staff member.

# Related documents

* UoB-CQM-POL-001 Clinical Research Quality Manual
* UoB-CRL-QCD-003 Laboratory Competencies
* UoB-GCP-POL-001 UoB Principles of Good Clinical Practice (GCP) for Clinical Research
* UoB-TRN-QCD-001 Employee CV
* UoB-TRN-QCD-002 Employee Training Record
* UoB-TRN-QCD-003 Training Attendance Log

Access to the full UoB QMS for clinical research is available via the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx).

# References and frameworks

* CRCT training and workshops: <https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/training-and-workshops.aspx>
* HRA CV guidance: <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/>
* UoB Code of Practice for Research: <http://www.birmingham.ac.uk/Documents/university/legal/research.pdf>
* UoB mandatory training (requires UoB login): <https://bham.sharepoint.com/sites/POD/SitePages/Mandatory-Training.aspx>
* UoB PDRs (requires UoB login): <https://bham.sharepoint.com/sites/performanceprogression>

# Abbreviations and definitions

| Term | Description |
| --- | --- |
| CI | Chief investigator |
| CRCT | Clinical Research Compliance Team |
| Employee training record  | Record of any training sessions that relate to previous and current functions and that are relevant for the current post. |
| HRA | Health Research Authority |
| Manager | A person within the UoB who takes on line management responsibilities. This is typically an academic-related or support-staff function. For the purpose of this SOP, manager is used to define the role that has the responsibility for ensuring staff are trained. This may be the chief investigator (CI) or UoB lead for the clinical research project. For clinical research approved by a UoB research ethics committee (REC), the role of CI may be referred to as the principal investigator (PI), or the supervisor for postgraduate research students. See also ‘Chief Investigator (CI)’, ‘Principal Investigator (PI)’, and ‘UoB Lead’ in the Glossary of Terms. |
| PDR | Performance and development review |
| QMS | Quality management system |
| REC | Research ethics committee |
| SOP | Standard operating procedures |
| UoB | University of Birmingham |

See also the [Glossary of Terms](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/Glossary-of-Terms.aspx).