DIRECTORATE OF RESEARCH AND INNOVATION

Document Number: GOSH/ICH/SOP/R/002	Version Number: 03
Title: Training Requirements for Staff Participating in Clinical Research	
Effective Date:	*06-Jul-2021*

	Name	Position
Authored by:	Beth Reeves and Ilyas Ali	QA Manager R&I and Clinical Trial Manager
Approved by:	Vanshree Patel	Head of Governance, Clinical Trials and Contracts

1. Scope

This SOP is applicable to

- All Research & Innovation (R&I) Directorate staff
- All Great Ormond Street Hospital for Children (GOSH) or UCL Great Ormond Street Institute of Child Health (ICH) staff working on clinical research. This includes studies where GOSH/ICH are the Sponsor or where there is an external Sponsor (hosted studies).

Further to the requirements listed in this SOP, personnel must also comply with:

- Any additional study-specific requirements mandated by the PI, Sponsor or R&I.
- Any additional study-specific training mandated by the PI, Sponsor and/or R&D (evidence to be recorded in the Investigator Site File).
- Any additional professional training mandated by the employer (evidence to be recorded using the appropriate employer system, e.g. GOLD for GOSH staff).

2. Purpose

The purpose of this SOP is to describe the training record requirements for R&I Directorate staff and research staff, including the requirements for study delegation logs.

3. Definitions/Abbreviations

Clinical Research – As per UK Framework for Health and Social Care Research and HRA/MRC 'Is my study research?' tool.

CRF – Clinical Research Facility

Delegation Terms

Leading – Being in charge of either the delivery of the study at a site (i.e. the PI) or the delivery of a particular function or activity at a site with oversight from the PI (e.g. a pharmacist may lead on the management of investigational medicinal product).

Delivering with and without freedom to act – Describes how an individual is able to act in the context of delivering the study. Where individuals are acting wholly under written instructions, and would escalate anything which falls outside of these for action by someone else, they are delivering *without* freedom to act (e.g. radiologists following a scanning protocol). Where they would be expected to use their more detailed knowledge of the study, GCP and other standards to act beyond the instructions, they are delivering *with* freedom to act. This is specific to study delivery (i.e. is different to an individual's freedom to act as a professional within their role).

R&I Directorate staff and staff employed specifically to deliver research must be said to be delivering with freedom to act (unless agreed with R&I Senior Management).

GCP – Good Clinical Practice

PI – Principal Investigator

Q-Pulse – An electronic document management system

NIHR – National Institute for Health Research

4. Responsibilities

Duties may be delegated but the responsibility always remains with those listed.

4.1 All staff are responsible for:

- Ensuring that their training is up to date and maintaining their own training records (see Appendix for details).
- Uploading training record on Q-Pulse/Investigator Site File (ISF)

4.2 The study Principal Investigator (PI) is responsible for:

- All PIs must read all SOPs accessed via GOSHWeb/request a copy from the R&D team and record all applicable SOPs as read and acknowledge on the log.
- Ensuring that the study team are appropriately trained, qualified and experienced to perform their delegated duties throughout the study and that the delegation log is maintained (see section 5.3).
- Ensuring that the R&D office is aware of any changes to PI or Sub-Investigators.

4.3 A study function or activity delivery lead is responsible for:

- Ensuring that any study team member allocated a function or activity are appropriately trained, qualified and experienced to perform their allocated duties throughout the study and that the authorised persons record is maintained (see section 5.3).

4.4 R&I Division line managers are responsible for:

- Requesting a Q-Pulse user account for their direct reports.
- Ensuring that their direct report(s) are appropriately trained, qualified and experienced to perform their role.
- Ensuring that the Q-Pulse training records of the staff they are responsible for are reviewed for completeness at least annually (usually during their PDR).

4.5 Q-Pulse Administrators are responsible for

- Creating and archiving user accounts on Q-Pulse and providing Q-Pulse training for staff as appropriate.

5. Procedure

5.1 Staff Research Training Record Requirements

A principle of Good Clinical Practice (GCP) is that each individual involved in conducting research shall be qualified by education, training and experience to perform their tasks. Records of training are essential documents as they demonstrate that the research has been performed in accordance with GCP.

Appropriate research training records must be maintained and retained for all R&I Directorate staff and all research staff. The minimum requirements for staff research training records are the research competencies (see Appendix).

Training records must be kept in a designated secure storage area and must be accessible for inspection or audit at all times.

For R&I Directorate staff; Q-Pulse is the designated storage area for staff research training records. Additional records of role and/or therapeutic area and/or study-specific training may also be kept in the staff member's Q-Pulse training record.

Superseded documents must be kept for as long as necessary to support the historical reconstruction of the study(ies) the staff member is involved in.

The standard Trust specific training is recorded on the GOLD LMS (internal learning system) and any research specific training record is kept in Q-Pulse or ISF.

The electronic medical record training is accessible using tip sheets found in GOSHWeb which are specific to task for specific roles.

5.2 Written Procedures

New or amended written procedures will be disseminated to all relevant R&I Directorate staff and PIs (based on the Written Procedure Matrix). Staff must acknowledge that they have read and understood the content of the written procedure that has been distributed to them.

The PI is responsible for ensuring that study staff are aware of and appropriately trained in the Sponsor's and site's written procedures related to the study conduct. The PI can access all SOPs via R&I website.

5.3 Study Specific Training and Delegation Logs/Authorised Persons Records

Individuals who are leading on delivery of the study (i.e. the PI) or a function or activity may allocate activities to others but must ensure that the members of staff are appropriately qualified, trained and experienced to do the allocated activities.

Study specific training must be documented in the site file using a 'Study Specific Training Record' (see section 6 or use equivalent provided by the Sponsor).

All staff involved in the delivery of a study must be identifiable in order to provide appropriate audit trails and enable the reconstruction of the study.

In order to demonstrate that the lead has authorised appropriately trained and qualified individuals to undertake certain study related tasks, a log must be used. This document may be combined with a staff signature log, but should clearly state the name of the person, their role and the activities they are allocated by the lead, as well as being signed and dated by the lead prior to the activity being undertaken by the individual. It is not acceptable for the lead to simply sign off the log at the end of the study. All staff performing study specific tasks must be on the log, irrespective of length of involvement.

The delegation log is a live document and must list all individuals involved in study conduct.

In exceptional circumstances/pandemic, the delegation log can be electronically signed off via email. This possible where this is clearly demonstrated via training and acceptability agreed by both PI and member of study team. Thecorrespondence must be filed in the training section of the ISF/TMF..

5.3.1 Delegation of Duties Log

Individuals who are leading or delivering with freedom to act are delegated study duties. They must complete the delegation of duties log, with oversight and agreement from the PI.

R&I Directorate staff and staff employed specifically to deliver research must be said to be delivering with freedom to act (unless agreed with R&I Senior Management) and must be listed on the delegation of duties log.

5.3.2 Authorised Persons Record

If the study involves individuals who are delivering a function or activity without freedom to act, they could sign an authorised persons record (rather than the study delegation of duties log), with the oversight and agreement of the lead for that function or activity. This lead must have been delegated this duty by the PI and be on the delegation of duties log.

If this process is used, the authorised persons record and related training records may be held in the location of the function or activity (rather than in the site file) to be accessible by those staff. A note to file must be filed in the site file to document that these essential documents are held in a different location. Once the study is closed, the authorised persons record and training documents must be consolidated with the site file OR (if held centrally for the duration of archive) a note to file added to the site file to document that these are held in a different location for archive.

The decision making regarding the use of the authorised persons record must be document in the site file.

For note to file templates, see section 6.

If staff have a question regarding the appropriate use of delegation of duties logs (or authorised persons records) then they should contact Research Governance (Research.Governance@gosh.nhs.uk). Information is also available on the NIHR Delegation & Training Decision Aid.

5.4 Change to Training Records or Delegation Log/Authorised Persons Record

5.4.1 Change of Name

An individual may change their name during the course of employment and/or during a study (e.g. due to a change in marital status or during gender transition). The training records and any delegation logs/authorised persons records must reflect the new name.

	Option 1 (most suitable option unless name change is sensitive or private)	**Option 2** (may be more suitable if the name change is sensitive or private)
Training Records (Either individual's or in the site file)	Training done before the name change does not need to be redone (unless it is due) and is kept in the 'old' name. Training done after the name change would be in the 'new' name. A note must be added to the record(s) to link the two names (including the date the name changed). For note to file templates, see section 6.	Treat as if the records before and after the name change are for different people. Training done before the name change must be kept for historic reconstruction and show the 'old' name. Training done after the name change would be in the 'new' name. Training may need to be redone to make sure the records

		under the 'new' name are complete. No note to link the two names is required.
Delegation Logs and Authorised Person Records	End date must be added for the entry with the 'old' name and a new entry added with the 'new' name. If space allows, a note should be added to the log to show the two names are for the same person. A file note must be added to the site file(s) to link the two names (including the date the name changed). For note to file templates, see section 6.	End date must be added for the entry with the 'old' name and a new entry added with the 'new' name. No note to link the two names is required.

5.4.2 Change of Allocated Duties for a Study

An individual's allocated duties may change during a study (e.g. due to a change in professional role or change in study role). In this case, the delegation of duties log or authorised person record must be updated.

The log must be updated by adding an end date to the original entry and a new entry added showing the amended duties – there must only be one active entry per person on the log. The original entry must not be adjusted to amend the duties (this is because it must be documented that the lead has authorised the new duties). If space allows, a note should be added to the log to show the two entries are for the same person but that the duties have changed.

If additional training has been done to support the new duties this must be added to the study site file. An updated CV may also be needed.

A file note must be added to the site file to explain the change in allocated duties (and any supporting training done) and the two log entries. For note to file templates, see section 6.

Please note: the duties allocated must be based on the individual and their education, training, and experience, not their professional role.

5.5 Q-Pulse

5.5.1 Creation of User Accounts on Q-Pulse

Q-Pulse administrators will set up the Q-Pulse user account, assign the applicable competencies (see Appendix) and ensure the staff member is a Copyholder for the relevant written procedures (based on the Written Procedure Matrix). They will also provide Q-Pulse training.

5.5.2 Maintenance of the Q-Pulse Training Record

Each staff member must maintain and update the information held in their Q-Pulse training record and must complete the research competencies assigned to them within the designated timeframe.

The certificate of attendance must be included if available.

5.5.3 Written procedures

Staff members will be designated as 'Copyholders' for the written procedures that are relevant to their role (based on the Written Procedure Matrix).The relevant written procedures must be read, understood, and acknowledged by staff on Q-Pulse before they carry out the related activities, or within the designated timeframe, whichever is soonest.

5.5.4 Archiving the Q-Pulse Training Record File

If personnel leave, a Q-Pulse administrator will archive their account.

5.6 Support and Escalation

If a staff member has questions or queries they can ask for support from a more experienced colleague or their line manager. If the query is related to a specific study, then the study research nurse, PI and/or CRA may also be able to help.

If a staff member becomes aware of an issue or has any concerns then this must be escalated to the appropriate person(s) in a timely manner (see SOP/R/005 Reporting and Escalation for Research).

5.7 Compliance

5.7.1 R&I Division Staff

Within 2 months of personnel starting work in R&I Division, their Line Manager will complete a review of the post holder's training records to confirm compliance with this SOP. This review is recorded in Q-Pulse. The Line Manager will also review the training record for completeness at least once annually, usually as part of the PDR meeting as per Appendix 1.

Q-Pulse will notify users when training or document acknowledgement is due. If tasks are not completed in the required timeframe, Q-Pulse will issue reminders and notify the staff member's line manager.

5.7.2 Research Staff

The PI/Line Manager will review study staff research training to confirm compliance with this SOP as part of the study delegation.

Joint R&D office will review PI training to confirm compliance with this SOP during governance checks.

5.7.3 General

Training and delegation records will be reviewed during routine monitoring/audit.

Systematic or persistent failure to comply with the study procedures and/or this SOP will be seen as non-compliance to GCP and must be bought to the attention of the Head of Governance, Clinical Trials and Contracts who will decide the appropriate action.

6. Related Documents

- GOSH/ICH/SD/R/001: Written Procedure Matrix
- GOSH/ICH/TMP/R/003: Study Specific Training Record – Group
- GOSH/ICH/TMP/R/004: Study Specific Training Record – Individual
- SOP read and acknowledgement record template
-
- Template: Delegation of Responsibilities and Signature Log (for studies sponsored or co-sponsored by GOSH/ICH)
- GOSH/ICH/TMP/R/005: File note template. File note templates are also available for essential documents that are routinely held outside of the TMF at GOSH, see GOSH/ICH/TMP/R/005*x* (where '*x*' is a different letter for each template)

7. References

- NIHR Delegation & Training Decision Aid.

8. Appendices

APPENDIX 1: Core Research Competencies – to be completed by all R&I Division Staff and all GOSH/ICH Research Staff (unless otherwise stated). Additional training

may be required/recommended by the Joint R&D office during governance checks depending on the study type (e.g. Human Tissue Act, Advanced Therapy, Consent, etc.)

Staff Research Training Record	Renewal period
Job description - R&I Directorate Staff only Dated and signed by post holder and line manager	As required
Dated and signed CV A research CV Template is available on the HRA website. Signature must be wet ink or a validated electronic signature (a pasted image of a signature or a typed name converted to a hand writing font are not acceptable).	At least every 2 years
GCP Training If applicable based on the NIHR Delegation & Training Decision Aid. GCP Training is mandatory for all R&I Directorate staff. Must include clear reference to framework used in the training (e.g. UK legislation, EU directives etc.) GOSH based NIHR GCP course dates are circulated by the Joint R&D Office via R&I Newsletter and GOSH Newsletter. Visit 'NIHR CRN Learn' for NIHR GCP course registration.	At least every 2 years
Any department specific training	N/A

APPENDIX 2: CRF Competencies

Staff Research Training Record	Renewal period
CRF Local Induction for Visiting Researchers (non-CRF staff working in the CRF) A completed checklist, signed and dated by the post holder and relevant CRF Study Nurse (or delegate), must be filed on Q-pulse.	N/A
Emergency Scenario Training – CRF clinical staff only Additional to scenarios conducted as part of life support certification	At least annually