Staff Training for the Governance section

Contents

1. Introduction

The following guidance document details the roles and responsibilities for ensuring staff training for the Joint Research Management Office (JRMO) Governance Section. For the purpose of this guidance, the Governance Section consists of the following teams:

- Good Clinical Practice (GCP) and Compliance
- Research Governance and Performance
- Queen Mary Ethics of Research
- Clinical Research Audit

All Governance Section members must have and maintain individual training folders (set up as per *Standard Operating Procedure (SOP) 34b JRMO Staff Training*).

Note that the training of Operations Managers is not in the scope of this document and is the responsibility of their direct line manager.

The Governance Section has agreed minimum standards and good practice. These are outlined below.

1.1 Induction

Line Managers should ensure that they are available for the first two weeks of a new staff member within the JRMO. Attendance in the office should be encourage during this time and should where possible and appropriated be full time (If a Line Manager is not able to do this, they should arrange others to be available and discuss reasons with Research Governance Operations Manager.

JRMO SOP 34b Associated Document 1 Induction Checklist should be used alongside the *JRMO Handbook*, *training matrix* and this document. All new staff members will be required to complete training for their individual roles as stipulated in this document.

Line manager should:

- where possible work with the Office Manager prior to the person starting to ensure logistics are in place (such as laptop, email and SharePoint access etc).
- dedicate time to sit with the new starter to not only flag where SOPs etc are found but to discuss in detail each process the person will be doing. Shadowing of current staff is encouraged.
- ensure that the new starter feels they can ask questions at any point and feels enabled to flag if they are unsure or have not received or understood training.
- arrange (or initiating) meetings with other Governance Section key staff as well as external JRMO, Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) wide stakeholders. As a minimum all Governance Section staff should meet with the:
    - Research Governance Operations Manager
    - Team Leaders from the other 2 Governance Sections
    - Research Information Lead (to arrange EDGE log in and training)

- JRMO Quality Assurance (QA) Manager (for orientation and explanation to the Quality Management System (QMS), training files and JRMO Documentation)

Many teams use a simple word document to diaries training and meetings in the first 2-4 weeks.

Examples of previous staff meeting programs can be obtains by request for team leaders

1.2 Dedicated training time

Apart from the induction period the Governance Section feels ongoing training and development is important. The responsibility lies with the staff member to ensure they are up to date with any mandatory training (both organisational and JRMO such as SOPs).

Line mangers can agree up to 2.5 hours a month for the staff member to ensure this is up to date.

1.3 Training courses

Only when mandatory training and training files are up to date will any request for a course be considered (this is the responsibility of the staff member to evidence). Request for attendance to a course, should be accompanied by a written explanation of:

- why the staff member wishes to attend the course,
- how it will benefit them on their current role and development,
- how its sits within their appraisal or probation objective (or not with reasoning)
- how it will advance the sections work.
- effect on work and workload and
- a full estimate of cost should be provided.

Requests will be considered on a case-by-case basis.

Line managers should discuss with their Team Leaders where necessary. Team leaders can agree attendance to course where of up to two days and where there is no cost. For courses longer than two days in length or where there is a cost this should be agreed with the Research Governance Operations Manager.

Staff should be aware they may be asked to feedback to the section after attending a course and may be asked to become the section champion or SOP author following attendance – this will be discussed prior to attending the course.

Staff should request permission from their Line Manager prior to booking on to any course (even Barts Health or Queen Mary).

1.4 Line managers and staff one to ones

Staff should have the opportunity to have at least 1 organised one-to-one per month. These meetings should be private, and content will depend on individuals and needs. They can be structured or informal, topics can include workload, special projects, staff wellbeing, training needs and records a and well as regularly touching base on appraisal or probation aims and objectives.

1.5 Staff Handover (Annual leave, changing roles and leavers).

Staff are requested to keep their work up to date including updating any systems in use to document (e.g. workflows in EDGE, spreadsheets, or QMERC system). Email and correspondence should be filed in shared folders in real time.

A meeting should be arranged to discuss handover in person and may include line mangers if appropriate

2. Research Governance Operations Manager:

It is the responsibility of the Research Governance Operations Manager to arrange the induction and training of all new Team Leaders and the Clinical Research Auditor. Induction and training for new-team managers should be proportional to the level of experience they have.

2.1 Research Support & Development Manager

- Familiarising with all relevant SOPs in particular those related to sponsorship (*SOPs 9, 11a, 11b, 12a, 12b, 13a, 13b*) and QMERC Process and procedure (*SOP 15*).
- Shadowing the review and approval of a sponsorship application.
- Observing a QMERC Review Panel meeting, attending a QMERC Main Committee.
- GCP training as per *SOP 34b JRMO staff training and induction*
- Research ethics/ research integrity training (UKRIO etc) on how to conduct ethical reviews.
- Become familiar with the Queen Mary policies on Research Ethics and Research Integrity.
- Ensure agreed external/internal reading, training and SOPs are reviewed as per training matrix.

2.2 JRMO Clinical Research Auditor

Where possible an external auditor course should be attended. If a course is not attended the Research Governance Operations Manager should document to confirm they are aware that the staff member is suitably trained to perform the requested audit.

- Familiarise themselves with the departmental SOPs
- GCP training as per *SOP 34b JRMO staff training and induction*
- Familiarising will all relevant Barts Health and Queen Mary policies (including but not limited to JRMO Policy and data protection or IG policies)
- Training of Local Portfolio Management System; EDGE (read the EDGE Guidance and attend training) and training on ReDA
- Ensure agreed external/internal reading, training and SOPs are reviewed as per training matrix.

2.3 Research Governance & Performance Manager

- Familiarise themselves with the departmental SOPs and JRMO Research Management Policy
- GCP training as per *SOP 34b JRMO staff training and induction*
- Shadow staff within the team to get an understanding of what each team member does and understand the workloads
- Shadow Sponsorship meetings
- Undertake training for the BBR Redcap application
- Train on undertaking final quality assurance step for sponsorships studies and Trust Authorisations for Hosted studies
- Ensure agreed external/internal reading, training and SOPs are reviewed as per training matrix.
- Shadow the Research Information Lead and understand the key departmental objectives and reporting systems
- Training of Local Portfolio Management System; EDGE (read the EDGE Guidance and attend training) and any other system that is used by the team
- Training and understanding and NIHR reporting requirements.
- Shadow the Clinical Research Auditor for a minimum of two audits.
- Attend meetings with the Research Governance Operations Manager as a deputy.
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2.4 Senior GCP & Governance Managers

- Familiarise themselves with the departmental SOPs
- GCP and other relevant training as per *SOP 34b JRMO staff training and induction*
- Familiarising with all relevant Barts Health and Queen Mary policies (including but not limited to JRMO Policy and data protection or IG policies)
- Studies prior to being allocated to them. Where possible a handover should be performed with the allocated monitor and existing GCP & Governance Manager and/or Research Governance Operations Manager.
- SUSAR (Suspected Unexpected Serious Adverse Reaction) reporting procedures (in accordance with *SOPs 26 Pharmacovigilance and safety reporting series*). SUSAR reports should be reviewed by the existing GCP & Governance Managers and/or Research Governance Operations Manager before submission to the MHRA, until it is

agreed that the new GCP & Governance Managers is competent to complete SUSARs autonomously.
- Shadow at least one Kick-off meeting and Final governance meeting prior to chairing the meetings in person.
- Should ensure first risk assessments be reviewed by an existing GCP & Governance Manager or Research Governance Operations Manager prior to distribution to the research team, until it is agreed by the existing GCP & Governance Managers or Research Governance Operations Manager that the new GCP & Governance Manager is competent to complete risk assessments autonomously
- Training of Local Portfolio Management System; EDGE (read the EDGE Guidance and attend training) and training on REDA

3. Research Governance & Performance Team

The Research Governance & Performance Manager (Or direct line manager) is responsible for the induction and training of the following team members:

3.1 Data and AI Research Governance Lead

- Familiarise themselves with the departmental SOPs, policies and procedures
- GCP and other relevant training as per *SOP 34b JRMO staff training and induction*
- Training on SOP 9, 10, 11a, 11b, 12a, 12b, 13a, 13b for sponsorship review and capacity and capability reviews. Sponsorship/C&C reviews will be conducted with line manager/another GO until competent in reviewing independently.
- Be specifically trained on and shadow work related to amendments, Risk Assessment, Peer Review, Research Passport, and research access to Barts Health NHS Trust
- Train on managing the Amendment inbox and the Research Governance inbox
- Shadow the Clinical Auditor on a sponsored study audit
- Attend meetings with Research Governance and Performance Manager as a deputy
- Shadow the Research Information Lead and understand the key departmental objectives and reporting systems
- Attend appropriate management course to support with HR and line management responsibility (as per agreed probation objectives)
- Introductory meetings with necessary Governance section/Data precision medicine board colleagues
- Familiarize and become expert at NIHR reporting requirements.
- Training on EDGE (Local portfolio Management system, ODP and all IT systems used by the department
- Become an expert, lead trainer and lead admin for the LPMS
- Understanding the support requirement by the Operations Manager and the Governance and Performance Manager
- Understanding the need of running and compiling departmental reports
- Attend managing workload/project management training as this role expect high level of project management

3.2 Senior/Research Management and Governance Officers

- Familiarise themselves with the departmental SOPs
- GCP and other relevant training as per SOP 34b JRMO staff training and induction
- Training on SOP 9, 10, 11a 11b, 12a, 12b, 13a, 13b for sponsorship review and capacity and capability reviews. Sponsorship/C&C reviews will be conducted with line manager/another Research Management and Governance Officers (RM & GO) until the RM & GO is competent in reviewing independently. Specific training will be provided on processes involved in reviews e.g., risk assessment, peer review
- Progress and training needs will be discussed as part of one-to-one meetings and probation review
- Ensure agreed external/internal Reading, training and SOPs are reviewed as per training matrix.
- Be specifically trained on and shadow work related to amendments, Risk Assessment, Research Passport and research access to Barts Health NHS Trust
- Train on managing the Amendment inbox and the Research Governance inbox
- Training of Local Portfolio Management System; EDGE (read the EDGE Guidance and attend training) and any other system that is used by the team
- Shadow the Clinical Auditor on a sponsored study audit
- Senior RM & GO only: Attend meetings with Research Governance and Performance Manager as a deputy
- Senior RM & GO only: Shadow the Research Information Lead and understand the key departmental objectives and reporting systems
- Senior RM & GO only: Attend appropriate management course to support with HR and line management responsibility (as per agreed probation objectives)

3.3 Research Information Lead

The below list is not limited to but involves a varied tasks that might require training or support for on the job which therefore requires the post holder to request to line manager to provide/direct to training providers to assist on the job.

- Introductory meetings with necessary Governance section colleagues
- Familiarise themselves on the departmental SOPs and read relevant SOP relating to the role
- GCP and other relevant training as per *SOP 34b JRMO staff training and induction*
- Familiarize and become expert at NIHR reporting requirements.
- Training on EDGE (Local portfolio Management system, ODP and all IT systems used by the department
- Deputise for the Data and AI Research Governance Lead an all aspects of the LPMS.
- Shadow colleagues at the local CRN to better understand reporting
- Understanding the support requirement by the Operations Manager and the Governance and Performance Manager

- Observe the Governance Officer to understand the processes and the road map of a study approval
- Understanding the need of running and compiling Joint Clinical Research Board (JCRB) report, Data cleaning reports, Study set up reports and departmental reports
- Attend managing workload/project management training as this role expect high level of project management
  Understand the requirement of Pre-Award and Post-Award finance departments and their reporting needs.

3.4 Governance Administrator

- Familiarise themselves with the departmental SOPs
- GCP and other relevant training as per *SOP 34b JRMO staff training and induction*
- Training on managing inbox, dealing with and replying to various queries, triaging to the correct departments/individuals.
- Training on the following processes: SOP18 study closure and APR's.
- Administrative duties for clinicaltrials.gov registration

4. GCP & Compliance Team

The Senior GCP & Governance manager (Or direct line manager) is responsible for the induction and training of the following team members:

4.1 GCP and Governance manager

New GCP & Governance Managers should be trained on:

- Familiarise themselves with the departmental SOPs
- GCP and other training as per *SOP 34b JRMO staff training and induction*
- Studies prior to being allocated to them. Where possible a handover should be performed with the allocated monitor and existing GCP & Governance Manager and/or Research Governance Operations Manager.
- SUSAR reporting procedures (in accordance with *SOP 26 Pharmacovigilance and safety reporting series*). SUSAR reports should be reviewed by the existing GCP & Governance Managers and/or Research Governance Operations Manager before submission to the MHRA, until it is agreed that the new GCP & Governance Managers is competent to complete SUSARs autonomously.
- Shadow at least one Kick-off meeting and Final Governance meeting prior to chairing the meetings in person.
- Should ensure first risk assessments be reviewed by an existing GCP & Governance Manager or Research Governance Operations Manager prior to distribution to the research team, until it is agreed by the existing GCP & Governance Managers or Research Governance Operations Manager that the new GCP & Governance Manager is competent to complete risk assessments autonomously

4.2 QA Manager

- Familiarise themselves with the departmental SOPs
- GCP and other relevant training as per *SOP 34b JRMO staff training and induction*
- Attend external course as per training need of individual
- For first SOP release the Senior GCP and Governance manager should shadow the full process and release steps.
- Full training in the process and management of non-compliances.
- Attend a QMS and non-compliance meeting prior to chairing or leading
- Internal review process training to include drafting of the schedule
- Shadow members of the Governance Section as applicable to level of training needs of individual

4.3 Clinical Trials Monitors

Induction and training for new Clinical Trial Monitors should be proportional to the level of experience they have. Training needs should be discussed with the GCP & Governance Managers /Line manager.

- New Monitors should be trained in each trial prior to being allocated to them. Where possible a handover should be performed with the allocated GCP & Governance Manager and existing monitor.
- New monitors should receive specific training on current monitoring tools and processes (*see SOP 28 Monitoring*). As a minimum, the Monitor should shadow an experienced monitor on at least one visit (consider type of monitoring activity e.g., site, pharmacy, laboratory etc.) and perform one accompanied visit prior to any solo visits. Progress and training needs will be discussed as part of one-to-one meetings and probation review. This should continue until agreed by the Senior GCP & Governance Managers or Research Governance Operations Manager that the monitor is competent to conduct a monitoring visit autonomously.
- Attend a Kick off and Final Governance meeting

4.4 Clinical Trials facilitator

- Familiarise themselves with the departmental SOPs
- GCP and other relevant training as per *SOP 34b JRMO staff training and induction*
- Undergoing CPD (system and email) training from CPD team
- Attend a refresher and full GCP or governance course prior to taking over management of courses
- Attend a Sponsor Oversight Group (SOG) meeting, prior to preparing papers and minute a SOG with GCP & Governance manager prior to taking over as admin lead.

5. Research Support & Development Manager

The Research Support & Development Manager is responsible for the induction and training of the following team members:

5.1 Senior/Queen Mary Research Ethics Facilitator

- Observe one (preferably two) Review Panel meetings before leading on coordinating a Panel meeting
- Introductory meetings with all necessary colleagues in Governance section
- Understand the basics of NHS approvals and where there may be overlap, in order to recognise when studies may require dual review (QM ethics review + sponsorship)
- Meet with the QMERC Chair and Deputy Chair
- Observe how applications are prepared and circulated to QMERC Panel members
- Observe the preparation and coordination of a Main QMERC meeting before leading on one
- Be trained in the shared Research Ethics generic mailbox and e-filing
- Become familiar with the Queen Mary policies on Research Ethics and Research Integrity
- Learn to navigate, correspond, make comments, review and issue approvals within 'QMEthics' system