RDSOP03: Delegation and Oversight of Investigator Responsibilities in Research Studies

Greater Manchester Mental Health NHS Foundation Trust
<table>
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<th><strong>Title of Standard Operating Procedure:</strong></th>
<th>RDSOP03: Delegation and Oversight of Investigator Responsibilities in Research Studies</th>
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<td><strong>Document Summary:</strong></td>
<td>To outline the division and allocation of responsibilities within the research study team, and how they should be documented and overseen by a CI/PI</td>
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| **Target Audience:**                    | Trust-wide, Research Community, Internal and External Researchers |
| **Consultation:**                       | R & I Office, research community and R & I Committee members |
| **Approval Committee:**                 | R & I Committee |
| **Cross Reference Document(s):**        | Research Approval Policy  
All Trust R & I SOPs |
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<th><strong>Minimum Monitoring Requirement</strong></th>
<th><strong>Frequency</strong></th>
<th><strong>Process for monitoring</strong></th>
<th><strong>Evidence</strong></th>
<th><strong>Responsible Individual(s)</strong></th>
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1. Introduction

For a research study to be managed safely and effectively, it is essential that all staff involved are aware of the anticipated extent of their involvement and the limits to their authority. This is in line with the UK Policy Framework for Health and Social Care Research 2017: [https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/).

International Conference on Harmonisation Good Clinical Practice Guidelines (ICH GCP) define an investigator as "A person responsible for the conduct of the clinical trial at a trial site". The investigator is responsible for protecting the integrity, health and welfare of the research subjects.

The investigator must be:
- Qualified by education, training and experience
- Thoroughly familiar with the study protocol and any investigational product(s)
- Aware of, and compliant with Good Clinical Practice (GCP) and any applicable regulatory requirements pertaining to clinical trial conduct, e.g. Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments; Department of Health Research Governance Framework

The investigator, who has overall responsibility for the conduct of a study, either at single or multiple sites, is termed the Chief Investigator (CI). Each site involved in a study will have a local Principal Investigator (PI) who has responsibility for the conduct of the study at that site. The PI at a particular site may also be the CI of the study. If a team of investigators conducts a trial at a site, the investigator responsible for leading the team is the PI and other investigators are referred to as co-investigators.

The sponsor may delegate certain duties and responsibilities to both the CI and PI who in turn may delegate those responsibilities to other individuals or teams. However as the CI and PI both remain responsible they must maintain oversight and document evidence of their oversight throughout the duration of the study.

2. Purpose

To outline the division and allocation of responsibilities and how they should be documented. To describe the responsibilities of Chief and Principal Investigators in relation to oversight of research sponsored and hosted by the GMMH.
3. Roles and Responsibilities

3.1 Duties within the organisation

It is the responsibility of the Research & Innovation Office team (or proxy) to make Trust R & I SOPs available to all research active staff on the Internet and Intranet.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that researchers and research active staff know where to access SOPs. A file note should be present in the TMF/ISF to indicate the location of the SOPs.

It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example those of a commercial sponsor. If there is significant conflict between the external SOP and the Trust R & I SOP it is the responsibility of the CI or PI to resolve these with the Research Office prior to starting the study.

It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

3.2 Specific to this SOP

For all research studies (CTIMPs and other research) hosted or sponsored by the Trust, the PI/CI will be required to sign a list of duties delegated to him/ her by the Trust, and to confirm that all members of staff listed on the Delegation of Duties log are authorised to work on the trial, after HRA approval is given. A Template Delegation of Duties Log is available from the R & I Office.

For all GMMH sponsored studies that involve other sites a Sponsor Agreement. The CI or a delegated individual will be required to initiate this with the Research Office and the Principal Investigator at the other site.

For all studies sponsored by other organisations, there must be a delegation of duties to the Trust and to the local PI. This is incorporated within the Organisational Information Document (OID) or in an Appendix to the national model Sponsor Agreement if this has been used. See http://www.ukcrc.org/regulationgovernance/model-agreements/ for example model agreements.

The PI, co-investigator(s) if applicable and any assigned research practitioner (e.g. research nurse, practitioner, officer or co-ordinator) responsible for the trial must discuss and agree on the study requirements, the delegation of duties and the investigator oversight arrangements.
4. Procedure

4.1 When

Individual study related duties and functions must be defined, agreed, allocated and documented prior to the initiation of a trial. This includes a plan for oversight of delegated duties by the CI/PI. Discussions will be conducted with a representative from the R&I team present.

The delegation of tasks will depend on the qualifications and experience of the individuals in the team, and may vary from study to study.

This should occur before any trial procedures are performed i.e.

- At the feasibility stage- discussions with CI/PI will commence in the GMMH Initiation Meeting. Outcomes of discussions will need to be agreed with the research team and documented.
- During the set up and approval process- GMMH C&C will be issued once R&I are satisfied that delegation is documented and oversight plan is in place. For sponsored studies Green Light process will confirm CI/PI delegation and oversight process.
- At the site initiation visit for commercial trials- commercial sponsors will confirm and arrange for Delegation Log sign off.

In addition to study related duties, research team may be delegated by the CI/PI to help manage the study.

The PI can nominate an appropriately experienced and qualified person, e.g. a Research Nurse, Clinical Study Officer, Project Manager to assist in the management of the study at the investigational site. Tasks would have to be discussed and agreed with the member of the team before delegation is complete.

The allocation of research related tasks and study management tasks to appropriately qualified persons should be recorded either in a combined Delegation of Duties Log or in two separate Logs.

4.2 Level and Delegation of Responsibility

Study duties will vary depending on whether the investigator is the CI for the study, if it is sponsored by the Trust, or if they are a PI/ CI for a trial not sponsored by the Trust.

In summary, these responsibilities normally include:

- Ensuring the welfare and medical care of trial subjects
• Ensuring that only appropriately qualified personnel with a current license to practice, assess eligibility and make medical decisions on behalf of participants in drug trials
• Ensuring appropriate arrangements are in place to maintain communication with regulatory authorities, the sponsor and the host organisation - obtaining approvals, mandatory reporting (safety, deviations, breaches, progress reports, amendments), alerting R&I to any progress issues e.g. termination of the trial, urgent safety measures or other issues
• Conduct of the study in compliance with the protocol with active management of its progress in a Trial Management Committee or other relevant forum
• Risk management
• In RCTs randomisation management and oversight of the process
• Oversight of investigators at research sites
• Correct informed consent procedures
• Administration and management of storage of investigational product as appropriate in liaison with the Trust research pharmacist
• Safety and incident reporting e.g. Adverse Events and Serious Adverse Events, DATIX
• Oversight of PARIS entries
• Oversight of research data and trial records. Management of TMF/ISF
• The accurate and timely completion of trial data
• Archiving and other close out activities
• Ensuring adequate resources are in place to conduct the research (funding, staffing, infrastructure)
• Staff training including GCP
• Ensuring appropriate contractual arrangements in place
• GDPR compliance & Inspection Readiness

If large numbers of clinical staff are involved in a routine part of the trial as part of their duties e.g. delivering a study drug over many weeks, it may be more practical to include the senior staff member responsible for their conduct in the log, e.g. ward sister, rather than every single staff member. This must be agreed with the sponsor and documented in the TMF/SIF.

This is an ongoing process as circumstances may change, e.g. different members of staff may become involved in the study.

Even if duties are delegated to research team, the CI or PI remain overall responsibility for all tasks as listed in the delegation of duties agreements with either the Trust or external Sponsor.
4.3 Delegation Log Document

Study tasks Delegation Log template will be provided by the study sponsor. Study management Delegation Log covering management functions will be shared by the GMMH R&I office where applicable.

The delegation of duties log must include correct details:

- List the names of all staff involved and outline which procedures have been delegated to them
- Include a start date and stop date for staff involvement. This needs to reflect study set up activities so the start date may be earlier as compared to study start date
- Be signed and dated by the CI or PI (whichever is based on site), and supplied to the sponsor if required
- Be signed by GMMH R&I (where management functions are delegated to research team)
- Be filed appropriately in the investigator site file. If archived by a sponsor, a copy must remain at the site
- Be copied to the R & I Office and appropriate pharmacies whenever it is updated

If the study has an external sponsor, they should be made aware of the planned division of tasks. Contact names and roles of other individuals involved in the trial (e.g. pharmacy, laboratory staff) should also be notified to the sponsor and kept in the investigator site file.

5. Documenting Oversight of Delegated Tasks

The CI/PI will frequently oversee the study and delegated tasks. It is important that oversight is clearly documented and evidenced which can be achieved by a variety of methods, including:

- Reviewing and signing/countersigning eligibility criteria in the CRFs
- Documenting review of laboratory tests and safety data
- Ensuring notes of meetings where decisions and discussions have taken place are filed in the TMF/ISF
- Countersigning entries in PARIS and completing progress notes records
- Reviewing events occurring in research context on DATIX
- Documenting review of study data and/or data queries
6. References and Bibliography

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UK Policy Framework for Health and Social Care Research


UKCRC Model Agreements:
http://www.ukcrc.org/regulation-governance/model-agreements/

Organisational Information Document: