RDSOP03: Definition and Delegation of Investigator Responsibilities for CTIMP’s

Greater Manchester Mental Health NHS Foundation Trust

Improving Lives
<table>
<thead>
<tr>
<th>Title of Standard Operating Procedure:</th>
<th>RDSOP03: Definition and Delegation of Investigator Responsibilities for CTIMP’s</th>
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</thead>
<tbody>
<tr>
<td>Document Summary:</td>
<td>To outline the division and allocation of responsibilities, clarify boundaries of responsibility within the research study team, and how they should be documented</td>
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<td>Target Audience:</td>
<td>Trust-wide, Research Community, Internal and External Researchers</td>
</tr>
<tr>
<td>Consultation:</td>
<td>R &amp; I Office, research community and R &amp; I Committee members</td>
</tr>
<tr>
<td>Approval Committee:</td>
<td>R &amp; I Committee</td>
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<tr>
<td>Cross Reference Document(s):</td>
<td>Research Approval Policy All Trust R &amp; I SOPs</td>
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<tr>
<th>Minimum Monitoring Requirement</th>
<th>Frequency</th>
<th>Process for monitoring</th>
<th>Evidence</th>
<th>Responsible Individual(s)</th>
<th>Response Committee(s)</th>
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</thead>
<tbody>
<tr>
<td>Review of SOP content</td>
<td>Annually</td>
<td>Review by Author, redraft, submission to R &amp; I Operational Group</td>
<td>Minutes of R &amp; I Operational Group</td>
<td>Head of R &amp; I Office</td>
<td>Research &amp; Innovation Committee</td>
</tr>
</tbody>
</table>
Contents

1. Introduction........................................................................................................................................3
2. Purpose...............................................................................................................................................3
3. Roles and Responsibilities ..................................................................................................................3
   3.1 Duties within the organisation.....................................................................................................4
   3.2 Specific to this SOP......................................................................................................................4
4. Procedure...........................................................................................................................................4
   4.1 When............................................................................................................................................4
   4.2 Level and Delegation of Responsibility.......................................................................................5
5. References and Bibliography ..............................................................................................................6
1. Introduction

For a Clinical Trial of an Investigational Medicinal Product (CTIMP) 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.

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.

2. Purpose

To outline the division and allocation of responsibilities, clarify boundaries of responsibility within the research study team, and how they should be documented.

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 working on Trust-approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R & I SOPs are available to research staff.

It is the responsibility of the study Chief Investigator or local Principal Investigator to inform the Research Support Co-ordinator of the names of all research staff involved.
on a study so that copies of SOPs can be distributed appropriately, and to ensure that up-to-date copies are filed in the Investigator Site file and are available to research staff.

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 Clinical Research Network or 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 CTIMPs Sponsored or Co-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, before HRA approval is given. A Template Delegation of Duties Log is available from the R & I Office.

For all CTIMPs Sponsored or co-sponsored by the Trust that involve other sites a Sponsor Agreement is required between the site and the Trust. The CI will be required to initiate this with the Research Office and the Principal Investigator at the other site.

For all CTIMPs Sponsored by other organisations, there must be a delegation of duties to the Trust and to the local PI. This is incorporated as an Appendix to the national model Sponsor Agreement if this has been used. See http://www.ukcrc.org/regulation-governance/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 and the delegation of duties.

4. Procedure

4.1 When

Individual trial related duties and functions must be defined, established, allocated and documented prior to the initiation of a trial. This may be conducted with a representative from the sponsor if appropriate.

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.
  • During the approval process
  • During the trial set up phase
  • At the site initiation visit

4.2 Level and Delegation Responsibility

The CI or PI has overall responsibility for all duties outlined in the delegation of duties agreement with either the Trust or external Sponsor. These duties will vary depending on whether the investigator is the CI for the study if it is sponsored/ co-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
  • Obtaining approval of and continued communication with regulatory bodies e.g. Ethics Committee, MHRA, Trust management
  • Conduct of the study in compliance with the protocol
  • Correct informed consent procedures
  • Administration and management of storage of investigational product as appropriate
  • Ensuring that local management needs are met
  • Safety reporting e.g. Adverse Events and Serious Adverse Events
  • The accurate and timely completion of trial data
  • Archiving

It is of paramount importance that the investigator in charge on site whether CI or PI, keep detailed records of all adverse events reported to them and that they report these to the sponsor, host institution and regulatory authorities appropriately (see RDSOP 8A Pharmacovigilance for Trust-Sponsored MHRA-regulated Clinical Trials; RDSOP 8B Pharmacovigilance for MHRA-regulated Clinical Trials not sponsored by the Trust). Any delegation associated with this procedure must be well documented and delegation must be made only to appropriately trained individuals.

The PI can nominate an appropriately experienced and qualified person, e.g. a Research Nurse, to assist in the management of the study at the investigational site. The allocation of tasks to appropriately qualified persons should be recorded in the Delegation of Duties Log with specimen signatures and the initials of all involved.

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.

Some trial related responsibilities may also be delegated to appropriately qualified personnel according to local practice. This must be documented on the Delegation of
Duties Log and signed and dated by the PI. Tasks commonly associated with clinical research team roles are listed in the Delegation of Duties Log.

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

The delegation of duties log must:
- List the names of all staff involved and outline which procedures have been delegated to them
- Be signed and dated by the CI or PI (whichever is based on site), and supplied to the sponsor if required
- 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. References and Bibliography

- International Conference on Harmonisation of Good Clinical Practice 1996

- UK policy framework for health and social care research (2017)


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