Greater Manchester Mental Health NHS Foundation Trust

RD SOP 14 Trust Sponsorship of Research

Improving Lives
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<th>Title of Standard Operating Procedure:</th>
<th>RDSOP14 Trust Sponsorship of Research</th>
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<td>To define who the sponsor of a research study should be and how to ensure sponsorship is agreed in writing.</td>
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<th>Minimum Monitoring Requirement</th>
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<th>Responsible Individual(s)</th>
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1. Introduction

The Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments set out specific requirements for the sponsorship of investigational medicinal products in clinical trials.

The Department of Health UK Policy Framework for Health and Social Care Research (2017) requires that all research conducted in the NHS must have an identified Sponsor or co-Sponsors. The Sponsor assumes overall responsibility for the study and may also be the funding organisation.

2. Purpose

To define who the sponsor of a research study should be and how to ensure sponsorship is agreed in writing.

3. Roles and Responsibilities

3.1 Duties within the organisation

It is the responsibility of the Research & Innovation Office 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 ensure up-to-date SOPs are filed in the Investigator Site File and are available to research staff, and 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.

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 R & I Office prior to starting the study.

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

The Research & Innovation Office is responsible for managing Trust R & I SOPs including their approval, dissemination and archiving. All Trust R & I SOPs must be made available via Q-Pulse and published on the Trust website.
3.2 Specific to this SOP

In accordance with this SOP, it is the responsibility of all researchers to ensure that the appropriate Sponsor is selected and requested to accept this role.

The Sponsor is defined as such on Research Ethics applications and Clinical Trial Authorisations to the Medicines & Healthcare products Regulatory Authority (MHRA), and all documents associated with the study.

4. Procedure for Defining/Assigning a Sponsor

It should be noted, the IRAS form Section A64-1 identifies the status of the Sponsor (e.g. NHS Organisation, Academic, Pharmaceutical Company, Medical Device Industry, Local Authority, Social Care Provider) and gives contact details for the Sponsor. Part D of the IRAS form, D2 is the Sponsor Declaration, once this has been authorised electronically it confirms the organisation who are taking on the role of Sponsor and confirms their responsibilities (see Appendix 1).

Sponsorship must be assigned/ secured as follows with an accompanying letter (if appropriate), electronically signed IRAS Declaration form or Agreement to define responsibilities:

4.1 Non-Commercial multi-centre studies (led by other Centres)

These studies will be sponsored by either the funder or the Lead Centre. Confirmation is provided in the IRAS form section D2. If a letter is provided to the Research Ethics Committee a copy must also be made available to the R & I Office prior to obtaining Trust confirmation of capacity and capability to conduct the study.

CTIMP’s – additionally/alternatively it is mandatory that a Sponsor Agreement be put in place between the Sponsor and the Trust to ensure responsibilities are outlined clearly. Sponsors may initiate Sponsor Agreements for non CTIMP multi-centre studies also.

See RDSOP13 Contract Management & RDSOP3 Definition and delegation of responsibilities.

4.2 Non-Commercial studies (led by University of Manchester)

Non-CTIMP Studies - led by a University of Manchester (UoM) employee, and/or is a Postgraduate Student research study, will be Sponsored by the UoM. When the student is an employee of GMMH but is supervised through UoM, UoM will still be the Sponsor.

CTIMP’s - led by UoM employee may be co-Sponsored by the UoM and GMMH. Governance arrangements have already been agreed between the two organisations.
in the Memorandum of Understanding on the partnership and joint working arrangements for Research Governance (May 2008).

4.3 Non-Commercial studies (led by GMMH)

These studies could be Sponsored by the Funder, but if the Funder refuses, GMMH will accept this role if the study is led by a GMMH employee (subject to the results of a risk analysis).

4.4 Postgraduate Student Studies (Initiated by the Commercial Company)

The student must seek Sponsorship from the associated University. If the University refuses to accept this role then:

If the student is employed by GMMH, GMMH will accept Sponsorship if appropriate, with confirmation that the Academic Supervisor will peer review the protocol for the study.

If the student is not employed by GMMH, then the student’s employer must take on Sponsorship.

4.5 Commercial Contracted Studies (Initiated by the Commercial Company)

These studies must be Sponsored by the Commercial Company and a formal Contract be agreed with GMMH. See RDSOP13 Contracts Management.

4.6 Investigator led, commercially funded studies

The Sponsor for these studies is decided on the same basis as sections above, relating to the employing organisation of the investigator.

5. Process to gain Trust Sponsorship of Research

If a suitable sponsor cannot be found, The Chief Investigator should approach the Head of R & I Office as soon as possible to request Trust sponsorship of their study. All relevant minimum document set should be provided: peer reviewed protocol and independent review comments in support of the proposal; completed IRAS form; GMMH Recruitment Plan; Evidence of Funding or exemption justification.

The Head of R & I Office will review the documentation and communicate any changes required to the researcher. Once all final documents are available and queries have been answered, R & I will forward CI/PI Agreement outlining responsibilities (SOP
appendix 2). Once signed and available to R & I it will be forwarded together with the full application pack to the Head of R & I who will make a sponsorship decision within 14 working days. The decision will be confirmed in writing.

The Head of R & I Office may then be named on the IRAS form as Sponsor at 64-1 and will authorise the form when requested to do so.

All amendments and accompanying documentation should also be submitted to the Head of R & I Office as Sponsor prior to submitting to the REC/HRA for approval.

Risk proportionate approach will be applied to sponsor oversight. Oversight strategy including monitoring arrangements and ongoing researcher responsibilities will be defined once study has been approved by the REC/HRA and other regulatory bodies as required.

The Head of R & I Office may delegate some or all sponsor responsibilities to another person and this should be documented.
### References and Bibliography


UK Policy Framework for Health and Social Care Research v3.3 updated March 2018  