Greater Manchester Mental Health NHS Foundation Trust

RDSOP19 Financial Management of a Clinical Trial

Greater Manchester Mental Health NHS Foundation Trust

Improving Lives
<table>
<thead>
<tr>
<th>Title of Standard Operating Procedure:</th>
<th>RD SOP19 Financial management of a clinical trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Summary:</td>
<td>This SOP describes the procedures for the financial management of Clinical Trials conducted in the Trust.</td>
</tr>
<tr>
<td>Document Author:</td>
<td>Maxine Syme R &amp; I Pharmacist</td>
</tr>
<tr>
<td>Target Audience:</td>
<td>Trust-wide, Research Community, Internal and External Researchers</td>
</tr>
<tr>
<td>Consultation:</td>
<td>R &amp; I Committee</td>
</tr>
<tr>
<td>Approval Committee:</td>
<td>R &amp; I Committee</td>
</tr>
<tr>
<td>Cross Reference Document(s):</td>
<td>All Trust R &amp; I SOPs</td>
</tr>
<tr>
<td>Contact details for further information:</td>
<td>Maxine Syme: R &amp; I Pharmacist</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:Maxine.syme@gmmh.nhs.uk">Maxine.syme@gmmh.nhs.uk</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<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>
</tr>
</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 ........................................................................................................ 3
   4.1 Identification of the Trial Budget .................................................................................................... 4
   4.2 Managing the Budget throughout the trial to achieve financial balance ...................................... 4
   4.3 Any Adverse Financial Events to be reported appropriately ......................................................... 4
   4.4 Roles and Responsibilities ............................................................................................................ 4
5. Associated Trust Documents .............................................................................................................. 4
6. References and Bibliography ............................................................................................................... 5
1. Introduction

The Medicines for Human Use (Clinical Trials) Regulations 2004 and UK Policy Framework for Health and Social Care Research set out specific requirements for the financial management of clinical trials and other research studies. GCP requires that for any funded clinical trial, adequate resources should be available to support the planned investigation(s). The investigator should be able to demonstrate (eg. based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period. The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions. In addition, the financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

2. Purpose

This SOP describes the procedures for the financial management of Clinical Trials conducted in the Trust.

3. Roles and Responsibilities

3.1 Duties within the Organisation

It is the responsibility of the R & I 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 R & I 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 inform the R & I Office 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 R & I Office prior to starting the study.

4.1 Identification of the Trial Budget

It is important that the R & I Office is involved as early as possible in identifying the trial budget; they will assist researchers in grant preparation and costings for studies. At the contracting stage a financial trial budget will have been agreed and approved. This will have set out the expected costs which must reflect the complete cost of the trial and include investigator time, investigations etc. and Trust overhead recovery. An account with a designated cost code will be established for each study. The contract will also stipulate the agreed time points for invoicing the commercial sponsor (see also RDSOP13: Contracts).

4.2 Managing the budget throughout the trial to achieve financial balance

The Trust R & I Accountant will provide monthly budget statements to report expenditure and income received to date. Any unexpected variances from the plan will need to be flagged up with her/him as soon as possible and the cause investigated.

4.3 Any adverse financial events to be reported appropriately

If an adverse financial event (unexpected cost/ trial overspending etc) is identified then this must be reported to the R & I Office as soon as possible (if the amount is significant, then this should be reported immediately to the R & I Office). If necessary, the Trial Steering Group may need to be alerted. This will allow corrective action to be taken promptly. Corrective action could be to approach the commercial sponsor / funder for the revised budget to be agreed, or to reappraise the costs of delivering the trial and making appropriate changes.

4.4 Roles and Responsibilities

The CI or local PI must ensure that they are aware of their responsibilities in managing the trial's finances and that they comply with Trust's Standing Financial Instructions (see https://newintranet/Policies/gmmh-policies/financial/Pages/Standard-Financial-Instructions.aspx - only available on GMMH intranet). If a study is adopted to the NIHR Portfolio, the R & I Office will assist researchers in applying for NIHR Service Support Costs from the LCRN and Excess Treatment Costs. For non-portfolio studies, it is the responsibility of the CI or local PI to ensure that service support costs and excess treatment costs are met via either the research funder or, where agreed, by the Trust.

5. Associated Trust Documents

RDSOP13: Contracts Management
6. References and Bibliography


UK Policy Framework for Health and Social Care Research v3.3 07/11/17