

STANDARD OPERATING PROCEDURE

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Pre- Study Procedures

R&D/S/014/1.0

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Approved By:

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Date

Effective Date:

Review date:

Copy Number:

Pre-study Procedures**1. PURPOSE AND SCOPE**

To describe the role of R&D in the procedure for setting up a CTIMP research study. Prior to the start of a clinical trial it is important that all regulatory, research governance and GCP requirements of the trial are met and that Investigator's are fully informed of their responsibilities.

This SOP describes the role of R&D in the CTIMP approval process and the start up procedures for investigators.

2. ASSOCIATED DOCUMENTS

Study Start Up Pack
SOP R&D/S/013 Review and Approval of Protocols and Amendments
Template R&D/T/013a - Pre-study start up meeting template
R&D Governance Procedures User Manual

3. APPLICABILITY

Applies to the R&D department and all Chief Investigators (CI) running clinical research sponsored by Cambridge University Hospitals NHS Foundation Trust or jointly sponsored by CUHFT and the University of Cambridge, where the CI is based on this site.

Applies to Clinical Trials of Investigational Medicinal Products (CTIMPS) only.

4. PROCEDURES**4.1 REGULATORY, ETHICS and R&D APPROVALS**

4.1.1 The Chief Investigator (CI) is delegated the responsibility for obtaining the approval from MHRA and the Research Ethics Committee for each clinical trial. As part of their responsibilities they are required to send the confirmation of these approvals to the R&D Office.

4.1.2 Upon receipt of the required documentation, the R&D Officer should review the documents and check against Governance Procedures. The details of the checks should be entered onto ReDA and any queries should be raised with the CI/trials co-ordinator. More details of the approval process is detailed in the Research Governance User Manual.

4.1.3 The Trust can either be the sole sponsor or joint sponsor with the University of Cambridge. For CTIMPs involving Addenbrooke's patients, their data or tissue, staff or facilities, approval from the R&D Office is required before any Clinical Trial can commence. Approval can only be given once all the governance checks have been performed.

4.1.4 An R&D Officer should sign the sponsor declaration page and when all governance checks are completed, a Trust sponsor letter will be printed along with the R&D Approval letter signed by the R&D Manager.

4.1.5 If there are concerns with an application i.e. it has no peer review or indemnity issues, the R&D Officer should explain why sponsorship can not be finalised and detail how the problem can be resolved.

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4.2 PRE-STUDY PROCEDURES

The following processes should be performed before the study starts. The order is not important:

- 4.2.1 **Protocol Review** - the Clinical Trial Manager (CTM) or designee should review the study protocol. The objective of this review is to check that the protocol is consistent with the requirements of GCP, the study and local policies. Evidence of CTM or designee review will be either through email documentation or the CTM will sign and date the front page copy of the protocol to be placed in R&D files.
- 4.2.2 **Risk Assessment**- the CTM or designee will conduct a risk assessment of the study (see criteria in Section 4.2 R&D/S/011) to highlight any issues which may require additional monitoring or more oversight by the Trust. This assessment should be documented.
- 4.2.3 **Pre-study start up meetings** – the objective of these is to inform and discuss with site staff the study, regulatory compliance and R&D requirements. Minutes of these meetings should be maintained.
- 4.2.4 **Start-up pack** – this contains useful information and guidance for research staff in managing a clinical trial from start-up to close down and can be given to research personnel during the start-up process.
- 4.2.5 **Study Specific Queries** – where researchers have specific queries about a forthcoming trial they should be directed to submit this enquiry to the R&D Enquiries e-mail account. An R&D Officer, with input from the CTM or designee should answer the query. This helps to raise the awareness of R&D staff who may be involved in the study.
- 4.2.6 **Monitoring Plan** – an appropriate monitoring plan (see Section 4.4 of SOP R&D/S/011) should be developed for each study. This should take into account the outcome of the risk assessments. The plan should be discussed with monitors and approved by the CTM.
- 4.2.7 **Peer Review** -The scientific quality of the study should be reviewed by an external expert in this field and by someone who is not involved in the study. This can be from external Funders, Charities, Internal Trust Committees such as the Scientific Advisory Board (SAB), the R&D Oncology Committee Meeting, Wolfson Research Advisory Committee or by the Trust Research Advisory Committee (which is organised by an R&D Officer).
- 4.3.8 **Agreements/Contracts** - For CTIMP studies contracts/agreements should be put in place. The R&D Solicitor and/or Contracts Manager will review and negotiate contracts and agreements. SOP R&D/S/008 gives further detail.

5. ILLUSTRATIONS/APPENDICES

APPENDIX 1 – Pre-study Start Up start up meeting template

6. CHANGES SINCE LAST VERSION

Description of changes	
<i>Section Ref:</i> NA	<i>Brief description of change</i> First Version of SOP

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APPENDIX 1 – PRE-STUDY START UP MEETING TEMPLATE - EXAMPLE

Study Initiation meeting:**Study:****Present: Research team:–****R&D:**

Topics	Chief Investigator:
IMP	
Eudract ref. REC ref.	
Point of Contact:	
Scale of Research:	
Patient & Site Numbers:	
Investigator clinical research experience	
Study Resources	
Monitoring arrangements	
Trial dates	
Funding	
Contracts	
Protocol Risk assessment:	
R&D approval	
Sponsorship	
Ethics	
MHRA Clinical Trials Authorisation Amendments & letters Annual safety reports End of trial notification End of trial report	
Information & personal data	
PIS & Consent forms	
Delegation Log	

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<p>Adverse Event Reporting</p>	
<p>Out of hours cover and emergency medical provision 24/7 provision & contact testing of emergency procedures</p>	
<p>Pharmacy issues Drug supply contracts Placebos; labelling; storage, dispensing; accountability Randomisation Codes</p>	
<p>Teams Trial team Trial steering committee Independent Data Monitoring and Safety Committee (DMC)</p>	
<p>Training GCP training records All trial staff MUST have GCP training</p>	
<p>Computerised systems Validation process Reconciliation of data bases Back-ups</p>	
<p>Medical Notes Alert Sheet</p>	
<p>Archiving Provision, space, costs</p>	
<p>Sub-contracting For example: Statistics randomisation Trial co-ordination Sample analysis & storage</p>	<p>All samples will be held at Addenbrooke's. No 3rd party laboratories will be used.</p>
<p>Signed and agreed: Version 6 March 2009</p>	<p>The above reflects the discussions at the set-up/monitoring meeting</p> <p>Signed by Chief Investigator/Trials Co-ordinator</p> <p>..... Date:</p>

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	Signed by R&D Clinical Trials Manager/ Representative of Sponsor Date:
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The above reflects discussion at the pre-study start up meeting on: