

Standard Operating Procedure R&D/SOP001

Delegation of Roles and Responsibilities for Trust Sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs)

1. Scope

For use when defining roles and responsibilities to the Sponsor, Chief Investigators and their trial teams for CTIMPs sponsored by CUH or jointly sponsored by CUH and the University of Cambridge

2. Purpose

This SOP outlines the delegations made by Cambridge University Hospitals NHS Foundation Trust (the Trust) when sponsoring, either solely or jointly with the University of Cambridge, a Clinical Trial of an Investigational Medicinal Product (CTIMP) within the meaning of the Medicines for Human use (Clinical trials) regulations 2004

3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

Common abbreviations and definitions can be found in CCTU/INF001 Common Abbreviations and Definitions.

3.1. Definitions

Term	Definition
Trust-Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH) or sponsored by CUH jointly with The University of Cambridge

3.2. Abbreviations

Abbreviation	Meaning
CCTU	Cambridge Clinical Trials Unit
CI	Chief Investigator
CTIMPs	Clinical Trials of Investigational Medicinal Product
PI	Principal Investigator
PIS	Participant Information Sheet
ICF	Informed Consent Form
CRF	Case Report Form

4. Undertaken by

This SOP should be used by staff in R&D, CCTU, Chief Investigators and Principal Investigators.

5. Items Required

CCTU documents required to carry out the activities described in this SOP are available on the Research and Development for Researchers Document Library.

http://www.cuh.org.uk/research/researchers/document_library.html

6. Summary of Significant Changes

Replaces R&D/S/004

7. Method

The following sections provide a description of the processes to be followed when implementing this document's procedures.

The following table outlines the statutory responsibilities delegated by the Sponsor to the CCTU and to the Chief Investigators of Trust sponsored CTIMPs. Any trial specific responsibilities will be detailed in relevant agreements/contracts with CIs.

Responsibility	CCTU	CI	Comments
Prior to start of trial			
Ensuring there are sufficient resources (Staff, facilities, finances) for the conduct of the trial		X	
Preparation of Protocol, PIS, ICF, CRF, data base and other study documents;		X	
Review of Protocol, PIS, ICF, CRF, data base and other study documents;	X		
Completion of submissions documents and make submissions to REC, MHRA, R&D and other relevant agencies		X	
Obtaining MHRA CTA approval		X	
Obtaining favourable opinion from Research Ethics Committee		X	
Review of the NHS Site Specific Assessment form for Addenbrooke's	X		Prior to Submission to R&D
Additional Approvals from other bodies eg NIGB, ARSAC if necessary		X	

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Responsibility	CCTU	CI	Comments
Discussions with clinical and other departments involved in the trial and obtaining relevant agreements/signatories e.g. Pharmacy, Radiology, Laboratories	X	X	Includes technical agreements related to IMP
Release of IMP – Regulatory Green Light.			Pharmacy procedure
During the trial			
Preparation and submission of amendments to MHRA, REC, R&D and other relevant agencies		X	
Review of amendments before they are sent to MHRA, REC and R&D and other relevant agencies	x		
Trial specific delegations within the Trial team(s) as defined at initiation according to local procedures		X	Must be documented locally
Maintenance of Trial Master File/Investigator Site File		X	Delegated to participating site
Maintenance of Sponsor File	X		
Reporting of Serious Adverse Events/SUSARs to Regulatory Authorities, REC and Sponsor (CCTU)		X	
Reporting of SUSARS to other Investigators		X	
Oversight of trial SAEs/SUSARS reporting	X		
Monitoring	X		
Management of IMP			As per Pharmacy SOP
Data Management and set-up of a clinical trial data base in a validated system.		X	
Submission of Annual Reports to Regulatory Authorities, REC, R&D and other participating sites		X	
Logging of ASRs	X		
Reporting of Serious Breaches to CCTU and sponsor		X	
Reporting of Serious Breaches of GCP to sponsor	X		Sponsor (R&D) will report to MHRA and REC
Urgent Safety Measures		X	

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End of the Trial	CCTU	CI	Comments
Notification of End of trial to MHRA, REC and R&D		X	
End of trial report to MHRA within one year of trial closure		X	
Reporting/Publication of the results of the trial		X	
Reports and publications		X	
Archiving of Trial Master File/Investigator Site File		X	Delegated to participating sites

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring compliance and Effectiveness

As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators

This process forms part of a quality management system. Documents are reviewed every two years

9. References

The Institute of Clinical Research, 2008, Abbreviations used in Clinical Trials.

10. Associated Documents

Referred to in section 5

11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

Review date	2 years (or earlier in light of new evidence) from approval date
Owning department:	CCTU QA
Supersedes:	R&D/S/004 Old style
Local reference:	R&D/SOP001 version 1