Standard Operating Procedure R&D/SOP001

Delegation of Roles and Responsibilities for Cambridge 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 Cambridge Sponsored CTIMPs

2. Purpose

This SOP outlines the delegations made by Cambridge University Hospitals NHS Foundation Trust (CUH) when sponsoring, either solely or jointly 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.

3.1. Definitions

Term	Definition
Cambridge Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH); or the University of Cambridge (UoC); or jointly by CUH and UoC or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge

3.2. Abbreviations

Abbreviation	Meaning
CCTU/RT	Cambridge Clinical Trials Unit Regulatory Team
CI	Chief Investigator
CRF	Case Report Form
CTIMPs	Clinical Trials of Investigational Medicinal Product
DSURs	Development Safety Update Reports
GCP	Good Clinical Practice
ICF	Informed Consent Form
IMP	Investigational Medicinal Product
HRA	Health Research Authority
MedDRA	Medical Dictionary for Regulatory Activities
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator

PIS	Participant Information Sheet
R&D	Research & Development
REC	Research Ethics Committee
SAEs	Serious Adverse Events
SoA	Statement of Activities
SoE	Schedule of Events
SUSARs	Suspected Unexpected Serious Adverse Reactions

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.

6. Summary of Significant Changes

Clarification on who is responsible for contacting the Regulatory Authorities with regulatory queries and expectations for Trial Committee attendance.

7. Method

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

Any trial specific responsibilities will be detailed in any of the below and agreed with the CIs:

- Any relevant agreements
- Contracts
- The Collaborative Research Letter

Note

Statutory responsibilities undertaken during the conduct of Cambridge Sponsored CTIMPs are delegated by the Sponsor to the:

- CCTU Regulatory Team and
- Chief Investigators

These responsibilities are detailed in the following table. For the purposes of this table CCTU/RT refers to the CCTU Regulatory Team

Responsibilities

At all stages prior to, during and post trial conduct	**CCTU RT**	**CI**	**Comments**
Communication with Regulatory Authorities (MHRA, REC, HRA) regarding regulatory/legislative/approval processes, procedures & guidance	X*		* Sponsor can authorise delegation to the CI on a trial by trial basis as appropriate.
Prior to the start of the trial	**CCTU RT**	**CI**	**Comments**
Ensuring there are sufficient resources (Staff, facilities, finances) for the conduct of the trial		X	
Preparation of Protocol, PIS, ICF, CRF, and other study documents		X	
Review of Protocol, all patient facing documents, IMP related documentation, IRAS/CRS, and other study documents as identified by the trial risk assessment	X		
Completion of submissions documents and make submissions to REC, MHRA, HRA, R&D and other relevant agencies		X	CCTU will make the on-line to the REC/HRA & MHRA
Obtaining MHRA approval		X	
Obtaining favourable opinion from REC & HRA		X	
Additional Approvals from other bodies e.g. ARSAC		X	
Conduct Trial Specific Sponsor Risk Assessment	X	X*	CI involvement in the RA process is essential and certain aspects are under their remit
CTIMP Quality Assurance	X		
Registration of Trial on publicly accessible website prior to FPFV		X	
Discussions with clinical and other departments involved in the trial, obtaining relevant agreements or signatories e.g. Pharmacy, Radiology, Labs	X	X	Includes technical agreements related to IMP
Set-up of a clinical trial database. To be built following CCTU SOPs*		X	*Any deviations from this process must be approved by the Sponsor up front
Release of IMP – Regulatory Green Light.			Pharmacy procedure
Lead site Activation	X		
During the trial	**CCTU RT**	**CI**	
Preparation and submission of amendments to MHRA, REC,HRA, R&D and other relevant agencies		X	
Review of amendments before submission to the MHRA, REC,HRA and R&D and other relevant agencies	X		

Trial specific delegations within the Trial team(s) as defined at the initiation meeting according to local procedures		X	Must be documented locally
Maintenance of Investigator Site File		X	Delegated to participating sites
Maintenance of Trial Master File		X	
Maintenance of Sponsor File	X		
MedDRA coding of safety events		X	
Reporting of Serious Adverse Events/SUSARs to Regulatory Authorities, REC and CCTU Regulatory team		X	
Reporting of SUSARS to other Investigators		X	
Oversight of SAE/SUSAR reporting	X		
Monitoring	X	X	Documented in the trial specific monitoring plan
Management of IMP			Refer to Pharmacy SOPs
Data Management (timely data entry, data queries and data cleaning)		X	
Submission of Annual Reports to Regulatory Authorities, REC, R&D and other participating sites		X	
Review and Submission of DSURs to MHRA	X		
Reporting Protocol non-Compliances to the CCTU Regulatory Team		X	PI Responsibility
Review and classification of reported protocol non-compliances	X		
Reporting Serious Breaches to the CCTU Regulatory Team		X	
Reporting Serious Breaches of GCP to R&D	X		Sponsor (R&D) will report to MHRA
Reporting Urgent Safety Measures to the sponsor & CCTU Regulatory Team and implementation		X	Sponsor (R&D) will report to MHRA
Attendance at TSC & DMC meetings (mandatory) in accordance with trial specific Committee Charters	X*	X	*Non voting sponsor representative at TSC
End of the Trial	**CCTU RT**	**CI**	**Comments**
Notification of End of trial to MHRA, REC and R&D		X	
Posting of trial data onto the EudraCT database within one year of trial closure		X	
Publication of the results. Follow the Consolidated Standards of Reporting Trials - CONSORT 2010 http://www.consort-statement.org/home/		X	
Necessary reports to funders and others		X	
Archiving of Investigator Site File		X	Delegated to participating sites
Archiving of Trial Master File		X	
Archiving of Sponsor File	X		

Full details of delegation and responsibilities are listed in the associated SOPs for individual processes.

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 and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

9. References

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

MHRA, Good Clinical Practice "Grey Guide"

10. Associated Documents

Medicines for Human Use (Clinical Trials) Regulations 2004

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
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