Standard Operating Procedure CCTU/SOP081

Identification and Feasibility Assessment of Participating Sites for Cambridge Sponsored CCTU Led Clinical Trials

1. Scope

This standard operating procedure (SOP) applies to UK-wide multi-centre, Cambridge sponsored, CCTU led clinical trials.

This SOP does not apply to commercially sponsored trials or research sponsored by an external non-commercial organisation or international sites.

2. Purpose

This SOP describes the process of identifying suitable participating sites (PSs) to conduct Cambridge sponsored; CCTU led clinical trials in accordance with Good Clinical Practice (GCP) and applicable legislation.

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 UoC
Devolved Administration	Scotland, Wales, and Northern Ireland
Participating Site	The location(s) where trial related activities are conducted (referred to in this SOP as the site or PS)

3.2. Abbreviations

Abbreviation	Meaning
CCTU	Cambridge Clinical Trials Unit
CI	Chief Investigator
CPFT	Cambridgeshire & Peterborough NHS Foundation Trust
CTC	Clinical Trials Coordinator
CUH	Cambridge University Hospitals NHS Foundation Trust
DA	Devolved Administration

GCP	Good Clinical Practice
HRA	Health Research Authority
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare products Regulatory Agency
OID	Organisation Information Document
PI	Principal Investigator
PS	Participating Site
R&D	Research and Development
REC	Research Ethics Committee
RoIF	Registration of Interest/Feasibility Template
SOP	Standard Operating Procedure
TMF	Trial Master File
UoC	University of Cambridge

4. Undertaken by

Chief Investigators (CIs),
Principal Investigators (PIs) of potential sites
Clinical Trial Coordinators (CTCs)

5. Items Required

CCTU/TPL065 Registration of Interest/Feasibility Assessment Template

6. Summary of Significant Changes

New

7. Method

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

Refer to the Health Research Authority (HRA), Integrated Research Application System (IRAS), and/or the Medicines and Healthcare products Regulatory Agency (MHRA) websites for any further information or clarification.

7.1. Identification and Feasibility Assessment of any Participating Site

- PIs at potential sites that have been approached or have expressed an interest in participating in the trial will be asked to complete a registration of interest/feasibility assessment template (RoIF) (CCTU/TPL065) in order to establish their site's suitability
- The CI and CTC will review the completed RoIF to establish:
    - The ability of the site to identify a suitable number of potentially eligible participants
    - If the site has sufficient resources and staff with the relevant skills, expertise and time to conduct the trial procedures

  - If the site has appropriate equipment and facilities
  - If the site is participating in other clinical trials that are competing for the same trial population
  - If there are any financial implications or other factors that may affect the conduct of the trial at the site
- The CTC will inform the PI by email the outcome of the feasibility assessment. If the site is unsuitable to host the trial, the CTC will explain the reasons for the decision
- A copy of the completed RoIF and any related correspondence will be filed in the Trial Master File (TMF) for all decisions both accepted and declined

7.2. Accepted Sites

- A list of proposed participating sites including the PI name and qualifications will be included in the IRAS application forms for submission to HRA/Research Ethics Committee (REC) and MHRA
- The OID is an integrated form for use for both NHS and non NHS sites. The answer to the question within IRAS stating the participating sites to be included in the trial will determine whether the site is NHS or non NHS and generate the appropriate OID form

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"

HRA website

IRAS website

10. Associated Documents

CCTU/SOP039 Opening and Activation of Participating Sites

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.

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