Standard Operating Procedure CCTU/SOP005

Test of Out of Hours Medical Cover Arrangements

1. Scope

This SOP applies to staff of the Cambridge Clinical Trials Unit (CCTU), Chief Investigators (CIs) and Principal Investigators (PIs) within the Trust (either as substantive employees or under an honorary contract) involved with, or working on Cambridge Sponsored Clinical Trials of Investigational Medicinal Products (CTIMPS). This SOP does not apply to commercially sponsored trials or trials sponsored by an external non-commercial organisation.

2. Purpose

The purpose of this SOP is to describe the process that must be followed to ensure that appropriate medical care and advice for trial related matters is available at all times, including outside of normal working hours.

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
Test Caller	A nominated individual, as stipulated in section 7.1, who calls the contact numbers out of hours to validate the process
Site Activation	The point at which a site is opened for recruitment

3.2. Abbreviations

Abbreviation	Meaning
CI	Chief Investigator
CTC	Clinical Trial Coordinator
CTIMPS	Clinical Trial of Investigational Medicinal Product
CCTU	Cambridge Clinical Trials Unit
CTO	Clinical Trials Officer
GP	General Practitioner
PIS	Patient Information Sheet
PI	Principal Investigator
ID	Identification Card

TMF	Trial Master File

4. Undertaken by

CCTU staff, Chief Investigators (CI) and Principal Investigators (PI) or delegated members of their trial team, working on Cambridge Sponsored CTIMPs.

5. Items Required

Site Specific Patient Information Sheet

Site Specific Patient Identification Card

Site Specific GP Letter (if containing out of hours contact details)

Out of Hours File note (CCTU/TPL087)

6. Summary of Significant Changes

Responsibility for the Lead site out of hours testing has transferred from the CTO to the CI/ delegated CTC.

7. Method

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

7.1. Responsibility

- The Chief Investigator (CI) is responsible for ensuring that all participating sites have adequate medical cover arrangements in place for their trial
- The Clinical Trials Coordinator (CTC) is responsible for testing the trial specific out of hours medical cover arrangements for the lead site prior to activation of the trial and at remaining participating sites as part of the site initiation activities
- The PI at each site is responsible for ensuring that the out of hours contact details provided to patients are suitable, correct and in compliance with their own Trust policies and procedures
    - Following site activation the Principal Investigator (PI) or staff delegated by the PI are responsible for arranging the continued out of hours medical cover and for ensuring that any changes to the out of hours medical cover arrangements are communicated to the CI/Trial Coordination team
    - A further out of hours test must be performed to test the new arrangements

7.2. Use of Appropriate Contact Details

7.2.1. All Trials

The out of hours (emergency) contact details must be present in both the Patient Information Sheet (PIS) and Patient Identification (ID) Card, and any other patient facing documents that may be relevant eg a Medication Diary.

Any updates to the out of hours contacts/procedures should be communicated to the CI/CTC to allow appropriate testing, the site-level patient facing documents should be updated in a timely manner and be provided to the CTC for inclusion in the TMF-SIF.

7.2.2. Type A Trials

Unblinded Type A trials:

Participants should be advised to follow standard care out of hours procedures, for example contacting 111 or 999 as appropriate in the PIS & Patient ID Card

Blinded Type A trials:

The requirements for emergency out of hours contact details will be stipulated in CCTUFRM021 – Risk Assessment Form for CTIMPs and appropriately provided in the PIS and Patient ID Card

7.3. Testing the Out of Hours Medical Cover Arrangements

For Type A trials:

Using standard care, this test will not be conducted.

For all other trials:

- Each out of hours phone number provided on the patient documents should be tested prior to site activation
- The test calls should be made outside of normal working hours - What defines 'Normal Working Hours must be determined by discussion with the site team since this could vary across hospitals/departments eg. If a units working hours are 8am to 8pm then the out of hours test would have to be performed outside of these hours
- The test caller (see section 7.1) is responsible for making the telephone call(s) using the telephone numbers provided on the patient facing documents eg Patient ID Card and PIS as appropriate

7.4. The call is considered successful

The call is considered successful if the test caller is able to contact either:

- A member of the trial team directly
- An on-call member of the department who is able to locate details of the protocol access patient records (in general terms) and provide suitable medical advice
- A pager service and receive a call back from an appropriate member of the trial team or on-call team within a pre-determined (as defined by the Trust's/departments own policy) time limit
- The contact is able to access the full latest version of the of the clinical trial protocol this must be determined by:
    - Asking the site contact to confirm the version of the clinical trial protocol they have access to
    - Asking the site contact to confirm how many pages there are in the protocol they are accessing

- Asking for specific details of a page of the protocol chosen at random by the caller

7.5. The call is considered unsuccessful

The call should be considered unsuccessful if the test caller is:

- Unable to make any contact on the telephone number (s) provided for any reason, including a wrong number or continuous ringing
- Unable to contact anyone on the telephone number provided with access, understanding or experience of the trial or current, approved trial related documentation
- Call back is not within the pre-determined time limit (as defined by the departments own policy)

7.6. Documentation

- The outcome of the test call(s) is recorded on the Out of Hours file note(CCTU/TPL087) and filed in the TMF and Sponsor file
- Any unsuccessful test calls should be documented in a trial specific file note and patients should not be recruited until successful test call(s) have been completed on all the telephone numbers provided to the patients
- For Participating Sites:
  - The Out of Hours Test File note (CCTU/TPL087) must be sent along with the Participating Site Activation Checklist (CCTU/FRM064) to the CCTU regulatory team for review before a participating site can be activated
- For the Lead Site:
  - The completed Out of Hours Test File must be sent to the regulatory team before the lead site can be activated

7.7. Updates to the Out of Hours Medical Cover Arrangements during the Trial

- Any changes to the out of hours telephone numbers or staff contact details during the trial must be updated in the appropriate documentation (eg PIS) and be forwarded by the site team to the trial coordination team
- An out of hours test should be performed by the CI/CTC
- The outcome of the test call should be recorded in a The Out of Hours Test File note (CCTU/TPL087) and filed in the TMF SIF with updated site level patient documents and copies provided to the PI for filing in the ISF
- All relevant patient documentation must be updated with the new contact details and provided to all active participants currently enrolled on the trial as a priority. This should be documented in the patient's medical notes
- If an out of hours test fails for a site that is open please discuss this with the CCTU regulatory team

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

CCTU/FRM021 – Risk Assessment Form for CTIMPs

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:	CCTU/SOP005 version 6
Local reference:	CCTU/SOP005 version 7