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 on 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 Sponsored by: Cambridge University Hospitals NHS Foundation Trust (CUH) or CUH jointly with the University of Cambridge 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

3.2. Abbreviations

Abbreviation	Meaning
CI	Chief Investigator
CTC	Clinical Trial Coordinator
CCTU	Cambridge Clinical Trials Unit
CTO	Clinical Trials Officer
PIS	Patient Information Sheet
PI	Principal Investigator
PID	Patient Identification Card

TMF	Trial Master File

4. Undertaken by

CCTU staff, Chief Investigators (CI) and Principal Investigators (PI) or their trial team as delegated within the Trust, 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)

6. Summary of Significant Changes

Clarification of the arrangements and responsibilities for conducting out of hours medical cover test at participating sites

Clarity on filing requirement for the results of test calls

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 Officer (CTO) designated by the Cambridge Clinical Trials Unit (CCTU) is responsible for testing the trial specific out of hours medical cover arrangements for Addenbrooke's Hospital as the lead site prior to initiation of the trial

The responsibility transfers to the Principal Investigator (PI) at Addenbrooke's Hospital during the course of the trial (refer to section 7.5)

For Participating sites the Principal Investigator (PI) or staff delegated by the PI is responsible for arranging and testing the out of hours medical cover arrangements and for ensuring that any changes to the out of hours medical cover arrangements are tested prior to implementation

Under certain circumstances when participating site staff are not able to provide the documentation confirming the outcomes of the test and site activation is likely to be delayed as a result, it is recommended that the CTC can conduct the test for that site.

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 (PID) Card

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

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 Addenbrooke's Hospital as the Lead Site

For Type A trials:

Using standard care, this test will not be conducted.

For all other trials:

- Each out of hour's phone number provided on the patient documents should be tested prior to recruitment of the first patient
- The test calls should be made outside of normal working hours (Monday to Friday 5.30pm – 9am, weekends and bank holidays)
- The test caller (see section 7.1 for who this should be) is responsible for making the telephone call(s) using the telephone numbers provided on the PID Card and PIS/GP letter as appropriate
- 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 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 trial related documentation including patient medical records

  - Call back is not within the pre-determined time limit (as defined by the departments own policy)
- The outcome of the test call(s) should be recorded in a trial level file note and provided to the CI/CTC for filing in the TMF. A copy of the file note and Addenbrooke's site PIS& Patient ID card containing the emergency telephone number (s) should be filed in the 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

7.4. Testing the Out of Hours Medical Cover Arrangements at Participating Sites

- For all trials (except Type A) testing the out of hours medical cover arrangements must be performed at all participating sites and the outcome of the test appropriately documented prior to site activation
- The procedure for testing Out of Hours Medical Cover Arrangements at the lead Site (section 7.3) should be followed for each participating site within the trial
- Each out of hours phone number provided on the site level patient documents should be tested prior to recruitment of the first patient at that site
- The outcome of the test call(s) should be recorded in a trial level file note and filed in the Investigator Site File together with the relevant site level patient documents and confirmation provided to the CI/CTC for filing in the TMF

7.5. 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 successfully tested by the appropriate person as listed in section 7.1 prior to implementation
- The outcome of the test call should be recorded in a trial level file note and filed in the Investigator Site File together with updated site level patient documents and confirmation provided to the CI/CTC for filing in the TMF
- 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

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.

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