# Standard Operating Procedure CCTU/SOP039

# Set up and Activation of Participating Sites for Cambridge Sponsored CCTU Led Clinical Trials

## 1. Scope

This SOP applies to Cambridge Sponsored or CCTU Led Clinical Trials.

This SOP does not apply to international trials.

## 2. Purpose

This SOP describes the process of setting up and activation of participating sites (PS) in accordance with Good Clinical Practice (GCP), CCTU procedures 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<br>or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT); or CPFT jointly with UoC |
| Clinical Trial of an Investigational Medicinal Product (CTIMP) | An investigation in human subjects which is intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products. Identify any adverse reactions or study the absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/or efficacy of those products. This definition includes pharmacokinetic studies. |
| Devolved Nation | Scotland, Wales, and Northern Ireland |
| Investigator Site File | The investigator site file (ISF) contains trial and participating site specific essential documents and is located at the participating site and maintained by the local Principal Investigator (PI) and local research team. |
| Modifications | A modification (formerly amendment) is any change to an approved trial, categorised as substantial, an important detail, or minor, depending on its impact on participant safety, rights, or data reliability, requiring different levels of review and approval from regulatory bodies. |

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| Multi-centre Trial | A clinical trial conducted according to a single protocol but at more than one participating site, and therefore, carried out by more than one investigator. |
| Non-CTIMP | A research study in humans that does not involve an investigational medicinal product (IMP) and does not fall in the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004. Non-CTIMPs can include observational studies, interventional studies, randomised controlled studies, and device studies. |
| Participating Site | Referred to in the regulations as a 'Trial Location' currently defined as: a hospital, health centre, surgery or wider healthcare setting, or facility or premises at or from which a clinical trial, or any part of such a trial, is conducted. For the purposes of CCTU SOPs, Forms and Templates, this does not include Participants homes. |
| Participating Site Activation | The point at which a participating site is opened for recruitment. |
| Site Information File | The site information file (SIF) is a sub-section of the TMF and contains Sponsor essential documents relating to an individual participating site. |

## 3.2. Abbreviations

| Abbreviation | Meaning |
|---|---|
| CCTU | Cambridge Clinical Trials Unit |
| CI | Chief Investigator |
| CPFT | Cambridgeshire & Peterborough NHS Foundation Trust |
| CTA | Clinical Trials Authorisation |
| CTC | Clinical Trial Coordinator |
| CTIMP | Clinical Trial of an Investigational Medicinal Product |
| CTO | Clinical Trial Officer |
| CUH | Cambridge University Hospitals NHS Foundation Trust |
| CV | Curriculum Vitae |
| GCP | Good Clinical Practice |
| GP | General Practitioner |
| HRA | Health Research Authority |
| HSC | Health and Social Care |
| IB | Investigator's Brochure |
| ICF | Informed Consent Form |
| IMP | Investigational Medicinal Product |
| IRAS | Integrated Research Application System |
| ISF | Investigator Site File |
| LIP | Local Information Pack |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| OID | Organisation Information Document |
| PI | Principal Investigator |
| PIS | Participant Information Sheet |
| PS | Participating Site |

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|---|---|
| PSA | Participating Site Agreement |
| PSF | Pharmacy Site File |
| REC | Research Ethics Committee |
| R&D | Research and Development |
| SmPC | Summary of Product Characteristics |
| SIF | Site Information File |
| SOP | Standard Operating Procedure |
| SoE/SoECat | Schedule of Events/Schedule of Events Cost Attribution Template |
| TMF | Trial Master File |
| UoC | University of Cambridge |

# 4. Undertaken by

Principal Investigators (PIs), Clinical Trial Coordinators (CTCs), and other delegated members of the coordinating and participating site trial teams

# 5. Items Required

- CCTU/SOP081 Identification and Feasibility Assessment of Participating Sites for Cambridge Sponsored CCTU Led Clinical Trials
- R&D/SOP005 Management of Contracts for Research Projects
- Participating Site Agreement (PSA) from Trust R&D
- CCTU/SOP024 Initiation Meeting for CTIMPs
- CCTU/SOP076 Initiation Meeting for CCTU led Non CTIMPs
- CCTU/SOP015 TMF and Site File Essential Document Management
- CCTU/SOP071 Selection of Laboratories for Analysis of Research Samples
- CCTU/TPL058 Delegation of Roles and Responsibilities and Signature Log (Delegation Log)
- CCTU/FRM051 Trial Specific Training Record
- CCTU/TPL087 Out of Hours Test File Note
- CCTU/TPL066 Pharmacy Manual template
- CCTU/FRM064 Participating Site Activation Checklist
- CCTU/FRM086 Participating Site Initiation Form
- CCTU/TPL028 Participating Site Activation Letter

# 6. Summary of Significant Changes

Clarification that for CTIMPs, the Participating Site Activation Checklist template CCTU/FRM064 must be created for the trial and reviewed by a Clinical Trial Officer (CTO) in the Regulatory Team prior to the set-up and activation of the first participating site.

Updates in relation to the new Clinical Trial Regulations 2025

# 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 Authority (MHRA) websites for any further information or clarification.

## 7.1. Identification and Feasibility Assessment of Participating Sites

- Refer to CCTU/SOP081 Identification and Feasibility Assessment of Participating Sites for Cambridge Sponsored CCTU Led Clinical Trials

## 7.2. Setting up NHS Participating Sites in England and the Devolved Nations

- The participating site must be listed on the initial HRA/Research Ethics Committee (REC) and Clinical Trials Authorisation (CTA) application forms. Additional participating sites can only added via the modification process
- Following submission to REC/MHRA/HRA, trial-related documents can be sent to the participating site to begin their set-up process
- Prior to setting up any participating sites and sending the LIP, ensure the Participating Site Activation Checklist (CCTU/FRM064) template is prepared and approved by a Clinical Trial Officer (CTO) in the Regulatory team. This will help ensure it contains/covers all of the documentation required to be provided to, and received from the participating site (as per trial Protocol and Risk Assessment), prior to activation.
- The Local Information Pack (LIP) will be sent to the relevant department for the participating site. Refer to the IRAS guidance by the CTC.

**NOTE:**

- Selection confirmation of a participating site received by site R&D will trigger their locally reportable timeline to recruit their first participant. The CTC should discuss this with the participating site R&D department and research team prior to this email and the submission of the LIP
- The LIP will typically include the following (always check IRAS guidance for updates):
    - Copy of the submitted IRAS Form
    - Submitted protocol
    - Submitted participant information sheet (PIS) and informed consent form (ICF) (without local logos/ headers)
    - Relevant NHS model agreement
    - Completed Organisation Information Document (OID)
    - Schedule of Events (SoE)/Schedule of Events Cost Attribution Template (SoECAT)
    - A copy of HRA Initial Assessment Letter (if one is issued)
    - A copy of the HRA Approval Letter and final documents
    - Any other documents to support the set up and delivery of the trial
- The relevant approval letters together with any revised trial documents will also be sent to the participating site (PI, local research team, local R&D office and local Research Delivery Network (where relevant) by the CTC
- The participating site will confirm their capacity and capability to deliver the trial by exchanging signed agreements and/or agreeing the OID

## 7.3. Setting up non-NHS/HSC Participating sites

(e.g. University or GP surgeries)

- For CTIMPs:
  - All non-NHS/Health and Social Care (HSC) participating sites should be listed in the appropriate section of the IRAS form
  - A non-NHS/HSC participating site assessment form should be completed and submitted for all non-NHS/HSC participating sites
  - Additional documentation should be included with the application, including the following (always refer to the IRAS guidance for updates):
    - Short CV for PI
    - Evidence of insurance or indemnity (if required)
    - Local versions of documents (if significantly different to the main version)
- For all other study types:
  - All non-NHS/HSC participating sites should be listed in the appropriate section of the IRAS form, and no additional documents/forms are needed.

## 7.4. Participating Site Agreement

A Participating Site Agreement (PSA) between the Sponsor and each participating site will be issued, signed and filed. Refer to R&D/SOP005 Management of Contracts for Research Projects.

- The draft agreement should be sent to the R&D department of the participating site for their review before signatures are obtained
- If the R&D department of a participating site has any issues with the PSA, this must be resolved between the solicitors and/or contract managers of the Sponsor and the PS R&D department
- For CTIMPs: A pharmacy appendix to the PSA will also be completed and signed by the participating site Pharmacy Department

## 7.5. Participating Site File Preparation

- For each participating site, the CTC will prepare an ISF (and for CTIMPs, a Pharmacy Site File). Refer to CCTU/SOP015 TMF and Site File Essential Document Management
- These files are sent to the participating site prior to the
- initiation visit as they contain trial and participating site related essential documents
- The CTC will prepare and maintain a Site Information File (SIF) for each participating site, as a part of the Trial Master File (TMF)
- Any updated trial related documentation sent to participating site are filed in the ISF (and/or PSF as appropriate) by participating site staff

## 7.6. Documents Managed by Participating Site(s)

- The participating site(s) must complete:

  - The Delegation of Roles and Responsibilities and Signature log CCTU/TPL058 (also referred to as 'delegation log')
  - Trial Specific Training Log CCTU/FRM051
  - All participant documentation (PIS, ICF, GP letter, etc.) with participating site specific logos/contact details (as required) and send copies to the CTC for checking and filing in the SIF
- The PI must sign and date the delegation log to confirm staff suitability for their delegated responsibilities
- The completed delegation log, CV and GCP certificates for all participating site staff will be filed in the ISF at the participating site

During the course of the trial participating site staff are responsible for:

  - Keeping the delegation log up to date
  - Keeping the out of hours contacts up to date
  - Keeping CVs and GCP certificates for participating site staff up to date in accordance with their local policy
  - Keeping training records up to date

Sending to the CTC updated copies of:

  - Updated out of hours contacts so the test can be repeated
  - The updated delegation log
  - Updated training records
  - Current or updated GCP and CV evidence for the PI only

## 7.7. Laboratory and Pharmacy Documents

The participating site must provide the CTC with:

- Accreditation documents for the laboratories that the participating site will be using for the trial, with their normal reference ranges
- A lab questionnaire for non-accredited laboratories refer to CCTU/SOP071 Selection of Laboratories for Analysis of Research Samples
- Copies of local SOPs (e.g. pharmacy) and policies that differ from those described in the trial protocol

## 7.8. Drug/IMP Supply System (if applicable)

The Sponsor's Clinical Trials Pharmacist (Oncology or Central Pharmacy) will be involved in the preparation of the trial specific drug/IMP management guidelines known as the pharmacy manual. Refer to CCTU/TPL066. This must cover as a minimum the following topics:

- Procedures for drug supply/ordering
- Instructions for drug storage
- Instructions for preparation and administration of drug
- Drug labelling (if relevant)
- Procedure for temperature deviations
- Quarantine procedure
- Drug accountability and form completion
- Drug destruction instructions
- List of pharmacy forms provided by the Sponsor

- Pharmacy staff training requirements
- Electronic-prescribing (if relevant)

The trials pharmacy at the participating site will be responsible for receipt, storage and accountability of the drug and for issuing the green light for the drug to be used at the participating site.

The CTC will supply participating sites the following as required:

- Trial specific drug/IMP management guidelines (pharmacy manual)
- The current Investigator's Brochure (IB) and/or Summary of Product Characteristics (SmPC) for the medicinal product(s) to be used (for pharmacy IMP management purposes)
- Trial specific prescriptions and forms for drug/IMP accountability (the participating site may use their own versions, but a copy must be provided by the participating site to the CTC and approved prior to use)
- Delegation log, participant log etc. for the Pharmacy Site File

## 7.9. Local Service Agreements

Local resources and/or agreements should be in place in good time before participating site initiation to avoid delays in activation.

The CTC should remind PIs at participating sites that they must liaise with local service departments involved in trial specific procedures (e.g. radiology, pharmacy, laboratories) as soon as the participating site start-up process commences.

## 7.10. Participating Site Initiation

Participating Site initiation can only take place:

- After the lead participating site has been activated
- Before the participating site is activated

The participating site initiation process is described in detail in:

- CCTU/SOP024 Initiation Meeting for CTIMPs
- CCTU/SOP076 Initiation Meeting for CCTU led Non CTIMPs

## 7.11. Participating Site Activation all trials

After the lead participating site has been activated, approved participating sites can be activated when:

- The local R&D department has provided the fully executed PSA and confirmation of their capacity and capability

- Participating Site initiation has been completed and the CCTU/FRM086 Participating Site Initiation Form completed and signed

The CTC will:

- Check that the Participating Site Activation Checklist CCTU/FRM064 has been completed and signed, and copies of all participating site related documentation have been received
- Ensure that the participating site PI is aware that he/she must provide relevant protocol training to all new staff joining the trial team after the

participating site initiation and that the Trial Specific Training Log CCTU/FRM051 is updated

- Perform out of hours testing
    - Complete the Out of Hours Test File Note CCTU/TPL087 for the SIF and provide a copy to the participating site for the ISF

Additional procedures for CTIMPs:

- Ensure the Participating Site Activation Checklist CCTU/FRM064 has been completed and signed, and sent to the CCTU regulatory team for review and authorisation before participating site activation
- The CTC has authorised the release of IMP to the participating site (if applicable)
- The participating site pharmacy has given the green light for the IMP to be used
- Arrangements for IMP receipt, storage and accountability are in place

Confirm that the participating site is open to screening and recruitment by issuing the activation letter CCTU/TPL028 to:

- The participating site
- Other relevant parties (e.g. randomisation office, contracted service providers)

- Participating sites to inform lead participating site once first participant has been recruited.

### 7.12. Addition of Participating Sites

Further participating sites not included in the original IRAS application must be identified and processed according to CCTU/SOP081 Identification and Feasibility Assessment of Participating Sites for Cambridge Sponsored CCTU Led Clinical Trials

## 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.

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, UKSI 2025/538

ICH E6(R3) Guideline for Good Clinical Practice

HRA website: www.hra.nhs.uk

IRAS website: https://www.myresearchproject.org.uk/

## 10. Associated Documents

CCTU/SOP041 Green Light Procedure for IMP Release

CCTU/SOP005 Test of Out of Hours Medical Cover Arrangements

## 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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