

Standard Operating Procedure CCTU/S0054

CCTU Funding and Collaboration Process

1. Scope

This SOP applies to CCTU staff and trial teams involved in initial contact with investigators who wish to run clinical research projects with the CCTU.

2. Purpose

This SOP describes the collaboration procedure between the CCTU and an investigator when starting a new clinical research project. This includes assisting with costing, preparation of a funding application and filing of study information

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 |
| Sponsor | An individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial |
| Externally Sponsored | Sponsored by any other Trust, University or academic Organisation outside the CUH or UoC remit. |
| Clinical Research Project | Clinical research involving human participants conducted as an observational or interventional study, investigating the efficacy, tolerability, feasibility, sensitivity or safety of a medical device, CTIMP or non-CTIMP. |

3.2. Abbreviations

| Abbreviation | Meaning |
|--------------|---------------------------------------|
| CI | Chief Investigator |
| CRL | Collaborative Research Letter |
| CTC | Clinical Trials Coordinator |
| GO | Grants Officer (CCTU Grants Officer) |

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| CTIMP | Clinical Trial of an Investigational Medicinal Product |
| CUH | Cambridge University Hospitals NHS Foundation Trust |
| DM | Data Manager |
| DMC | Data Monitoring Committee |
| FTE | Full Time Equivalent |
| IMP | Investigational Medicinal Product |
| MHRA | Medicines and Healthcare Products Regulatory Agency |
| NIHR | National Institute for Health Research |
| OTR | Office of Translational Research |
| R&D | Research and Development |
| RCT | Randomised controlled trial |
| RDS | Research Design Service |
| ReDA | Research Database Application |
| SoECAT | Schedule of Events Cost Attribution Tool |
| SOP | Standard Operating Procedure |
| TMG | Trial Monitoring Group |
| TSC | Trial Steering Committee |
| UoC | University of Cambridge |

4. Undertaken by

The CCTU Senior Management Team, CI and/or trial team members as appropriate.

5. Items Required

CCTU Costing Tool
CCTU/INF014 CCTU Funding and Collaboration Flow Diagram
CCTU/FRM083 CCTU Collaboration Request Form
CCTU/SOP045 Use of Vendors
CCTU/GD027 ReDA User Guide
R&D/POL003 International Studies Policy
CCTU Collaborative Research Letter
CCTU Support letter

6. Summary of Significant Changes

The Collaboration enquiry form is no longer used

7. Method

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

The processes are described in CCTU/INF014 CCTU Funding and Collaboration Flow Diagram

7.1. Initial contact with CCTU

- CIs wishing to collaborate with the CCTU will be asked to complete the CCTU Collaboration Request Form(CCTU/FRM083) available from the CCTU website and email it to cctu@addenbrookes.nhs.uk
- Collaboration enquiries may also be sent to the CCTU via the East of England Research Design Service (RDS) or a CCTU theme
- If the recipient(s) of a collaboration enquiry within the RDS or CCTU themes (except the CCTU core theme) judge the details of collaboration to be beyond the remit of the service or theme, the enquiry will be forwarded to the GO for review
- If the GO receives a collaboration enquiry beyond the remit of the CCTU core theme but within the remit of another CCTU theme or partner (e.g. RDS; OTR), the inquiry will be forwarded to the theme or partner
- If the relevant CCTU theme or partner intends to collaborate they will contact the enquiring CI directly to arrange an initial meeting
- A copy of all completed CCTU collaboration forms, detailing studies which fall within the remit of the CCTU core theme, should be sent to the GO to keep track of overall CCTU activity

7.2. Initial meeting with CCTU

- Members of the CCTU senior management team and if appropriate the RDS will be invited as appropriate to attend initial meetings with CIs
- The Clinical Trials Manager may delegate an experienced CTC to attend an initial meeting
- During initial meetings, the proposed study will be discussed in detail with emphasis on:
 - Study rationale
 - Intervention(s) and investigative product(s)
 - Research design, aim(s) and objectives
 - Participant recruitment strategy, target and duration
 - Number, spread and function of participating sites
 - Funding requirements, application deadlines and CCTU resources
 - Status, availability and supply chain of IMP, non-IMP or Device
 - Data capture, entry and management requirements
 - Funder requirements and necessary policies i.e. R&D/POL003 International Studies Policy if participating sites are international
 - Outcome dissemination strategy (i.e. publication interests)

7.3. Follow-up after initial meeting

- The GO will prepare and review a summary of all application-related meetings with the CCTU Operations Director
- The GO will also review details of proposed studies with the CCTU senior management team on a weekly basis, emphasising on:
 - Information gathered from meetings with CIs or their points of contact

- Timelines associated with proposed funding applications
- Progress made regarding the development of funding applications
- Concerns associated with proposed funding applications
- The GO may arrange additional meetings between the enquiring CI and member of the CCTU senior management team or their delegates as appropriate and in keeping with CCTU/INFO14
- Factors considered in the decision whether to collaborate with the enquiring CI to manage the project include:
 - Quality, scope and clinical relevance of proposed research
 - Proposed funding body and fit with the CCTU remit
 - Capacity and expertise within the CCTU
- If the CCTU is unable to collaborate the enquiring CI will be directed to other suitable partners or CTUs
- If the CCTU is able to collaborate the GO will provide the CI with relevant advice to allow for timely submissions of funding applications

7.4. Record Keeping/Filing

- If the proposed study/project is accepted by the CCTU, the GO will assign it a CCTU number and new ReDA entry (see CCTU/GD027)
- Delegates in the relevant CCTU Theme and/or the Regulatory Team will be subsequently responsible for completing/updating information in ReDA
- If the funding application is rejected the ReDA entry will be archived, unless there is clear documented communication from the CI indicating the application will be re-submitted in response to another funding call
- When a study is proposed, the GO will generate a study-specific electronic folder within the CCTU network drive in the folder titled "Proposed Studies". The folder may contain:
 - Email correspondences
 - Approved and accepted CCTU costing
 - Funding applications submitted at each funding stage
 - Letters of import associated with the application i.e. from the funder(s), sponsor(s) or CCTU
- The GO will also generate a study-specific hardcopy folder which will be stored in a lockable filing cabinet. Documents may be added to the folder by members of the CCTU senior management team as appropriate
- If a funding application is unsuccessful or withdrawn the folder associated, with the study in the "Proposed Studies" folder, will be archived unless there is communication from the CI indicating the application will be re-submitted in response to another funding call
- If a previously unsuccessful application is successful in response to another funding call, files associated with the application will be differentiated within a specific study folder in the "Proposed Studies" folder of the CCTU network-drive:
 - Files associated with the successful funding application will remain in a designated study folder within the "Proposed Studies" folder
 - Files associated with the unsuccessful funding application(s) will be archived within the "Proposed Studies" folder

- The GO, CCTU senior management team and appropriate trial team members may save files associated with funded studies using the CCTU filing template for the Finance, Proposed Studies and Study Files folders as appropriate

7.5. Costing

The GO will generate research-costs using the CCTU Costing Tool. The research-costs are direct-costs to the CCTU and may include but may not be limited to:

- Senior Trial Oversight
- Trial Coordination
- Database Programming
- Data Management
- Statistical Analyses
- Economic Analyses
- Administration Support
- Randomisation
- Regulatory Oversight

Considering the complexity of the trial, the GO will cost the FTE and determine the band-level for the following CCTU staff as appropriate:

- Coordinator: CRF design and IMP supply chain management, number of sites to open/close, participant recruitment target, potential for adverse events; duration and location(s) (e.g. UK vs. International); site monitoring requirements i.e. type of site monitoring (e.g. Onsite vs. Offsite), number of CRFs and TMFs to archive, involvement in meetings i.e. TMGs and time to update ReDA
- Database Programmer: Database set-up, database validation if applicable, number of variables to establish and validate; syntax coding requirements; database design amendments and database locking
- Data Manager: The anticipated burden of data queries; the number of participants, measures and endpoint all of which correspond with time required for data entry, size and complexity of dataset to be securely shared with a statistician for interim and end of trial analysis
- Data Entry Clerk: The number of participants, measures and endpoint which correspond with data entry time
- Statistician: Statistical design and analyses (e.g. interim and final); sample size, number of variables to validate; involvement in meetings i.e. DMCs and TMGs
- Health Economist: Economic analyses to generate specific economic outputs
- Clinical Trial Administrator: The number of CRFs and TMFs to archive; invoicing schedule
- Sponsor Regulatory Team (clinical trials officer, clinical trials monitor and PV officer): Involvement of the Team is mandatory for CTIMPs. Potential for adverse events; the complexity and potential issues of trial governance

- The GO will send the research-costs to the CCTU Operations Director for review and approval
- Once approved, the GO will send the research-costs to the CI or their point of contact, who may agree with or negotiate the costs
- This costing review and approval process will be repeated until an approved CCTU cost is agreed in principle by the CI
- CIs are responsible for all other costs associated with their clinical research study
- The GO may advise CIs to contact the relevant Sponsor's Finance Department for further advice on cost attributions
- If the CI has secured funding prior to approaching the CCTU for support, details of the collaboration must be agreed with the CCTU before CCTU staff start work on the study

7.6. Funding Application

- It is the responsibility of the GO to assist CIs who approach the CCTU for support to obtain grant funding where appropriate
- The GO may identify suitable funding calls and may approach CIs with relevant expertise to develop a funding application
- If a CI has approached the CCTU for assistance, the GO will work with the CI to identify suitable funding streams and will assist in preparing the funding application by:
 - Editing and commenting on proposal versions shared by the CI, until a final version is complete
 - Advising on the completion of the SoECAT
 - Preparing a signed CCTU support letter and any other CCTU letters which may strengthen the funding application
 - Seeking advice from the CCTU senior management team on the clinical and statistical relevance of the study design and assisting the CI to incorporate this advice into the application
- The GO must review the final draft funding application prior to submission to the funding body and must retain a copy of the final application
- The GO will advise CIs to include CCTU senior management staff as co-applicants as appropriate
- The GO will report the funding stage submission deadline and timelines of the funding application decision to the CCTU senior management team

7.7. Funding Application Outcome

The GO will track funding application outcomes and will request a copy of the funding award and/or rejection letter from the CI, if not provided

Once the outcome is known, the GO will inform the CCTU senior management team

The relevant legal team (CUH or University or other) will obtain the relevant contracts to review proposed timelines and mile stones in collaboration with the CCTU

7.8. Collaborative Research Letter (CRL)

- When the relevant legal team has prepared funding contracts associated with a clinical research project and contracts have been signed by all necessary parties, the CCTU Administrator will generate a CRL using the template in ReDA. The CRL will detail all:
 - CCTU responsibilities
 - Agreed timelines, payment schedule and invoicing details
 - The CCTU costing which should be attached
- The draft CRL should be reviewed by the GO and then sent to CIs for signed agreement
- The final CRL agreed between CCTU and CI will be printed twice and signed by both parties; the CI and the CCTU Director or designee
- One will be retained by the CI and the other by the CCTU Administrator, who will set-up the agreed invoicing schedule

7.9. Start of the collaboration

- CCTU staff will officially start working on the set-up phase once the CRL and all funding agreements are signed
- New members of CCTU staff may need to be employed - this applies mainly to study specific CTCs and DMs - to support the collaboration
- Existing CCTU staff may be assigned additional study-specific responsibility by relevant members of the CCTU senior management team
- A clinical research project is considered an active clinical trial once a participating site opens and recruitment can begin
- The trial will remain active until the final site has been closed

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"

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

HRA website

NIHR website

10. Associated Documents

CCTU initial contact flowchart (CCTU/INF014)
CCTU/SOP047 CTIMP Start Up Procedure for Trial Teams

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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