# LTHT / UoL CTIMP Sponsorship

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## Distribution & Storage:

### Distribution to:

Investigators and all members of research teams conducting or assisting with a CTIMP trial sponsored by the University of Leeds or Leeds Teaching Hospital NHS Trust.

### Location of document:

**Paper:** QA Department, Room 5, Research and Innovation Centre, St James’ University Hospital

**Electronic:**

- [http://www.leedsth.nhs.uk/research/information-for-researchers/key-documents](http://www.leedsth.nhs.uk/research/information-for-researchers/key-documents)
- [http://lthweb.leedsth.nhs.uk/sites/research-and-development/resources/Sponsored%20CTIMPs%20%20Quality%20Assurance%20](http://lthweb.leedsth.nhs.uk/sites/research-and-development/resources/Sponsored%20CTIMPs%20%20Quality%20Assurance%20)

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Section A: Introduction

1. This Standard Operating Procedure (SOP) outlines the process for accepting Sponsorship of Clinical Trials of Investigational Medicinal Products (CTIMPs) on behalf of the Leeds Teaching Hospitals NHS Trust (LTHT) and the University of Leeds (UoL).

2. The SOP was developed to ensure that the process is standardised between both organisations.

3. The aim of the SOP is to ensure that CTIMPs have incorporated aspects that follow relevant guidelines (e.g. the National Research Ethics Committee (REC), Health Research Authority (HRA), Good Clinical Practice (GCP), The Medicines for Human Use (Clinical Trials) Regulations 2004, European Commission Directives (e.g. 2001/20/EC) plus any subsequent amendments).

Section B: Applicability

1. This SOP is applicable to the UoL/LTHT Joint Quality Assurance (QA) department and any member of staff within the LTHT Research & Innovation (R&I) Department, the UoL Faculty of Medicine & Health Research Office (or other UoL faculty research offices who may be involved in the approval process), and UoL Secretariat staff.

Section C: LTHT / UoL Acceptable of CTIMP Sponsorship

1. General Principles for Sponsoring CTIMP’s

1.1 The employing organisation of the Chief Investigator (CI) will act as the Sponsoring organisation for any investigator initiated “in house”, single site trial. Any deviation to this agreement on a trial specific basis must be documented in writing and endorsed by both Sponsor Representatives.

1.2 Regardless of trial Sponsor (LTHT or UoL), the Joint Sponsor QA office are responsible for the setup, approval and oversight of all Sponsored CTIMPS.

1.3 Sponsoring CTIMPs must be a considered decision based on trial risk, investigator experience and resource. The Sponsor reserves the right to decline Sponsorship at any point in the trial set up process.

1.4 As a condition of Sponsorship, multi-site CTIMPs Sponsored by either organisation must be managed by a Clinical Trials Research Unit (CTRU) (where the trial fits with the academic priorities of the institute or another academic UK trials unit subject to a trial specific agreement) or a Clinical Research Organisation (CRO) (subject to a third party agreement).
1.5 The Sponsor QA review process must be consistent across all trials and at a minimum must include a review of the essential documents listed on the “CTC01: Researcher Checklist – LTHT / UoL Sponsored CTIMP” checklist.

1.6 CTIMPs managed by the University of Leeds CTRU must also follow the guidance outlined in “CTGN35: LTHT / UoL Sponsor Process Instructions for CTRU”.

1.7 Sponsor oversight of the trial set up process must be recorded on “CTC12: QC Record for UoL / LTHT accepting CTIMP Sponsorship”, and the electronic “QA Review and Approval Tracker” located on the QA department’s internet IT system (I:Drive).

1.8 The Sponsor review process consists of four distinct stages:
   i. Sponsor Acknowledgement of Grant Application (where applicable)
   ii. Sponsor Authorisation for HRA submission
   iii. Sponsor Authorisation for Medicines and Healthcare products Regulatory Agency (MHRA) submission
   iv. Confirmation of Sponsorship

1.9 Confirmation of Sponsorship must be endorsed by the Sponsor Representative (R&I Director for LTHT Sponsored CTIMPs, and Head of Research Integrity and Governance for UoL Sponsored CTIMPs).

2. QA Review of Grant Applications – Assessing Trial Risk

2.1 Where a grant application for a potential CTIMP requires a Sponsor signature / support, the applicant must submit the draft grant application and “Risk Assessment Form A (CTT04)” to the Sponsor QA team for review.

2.2 The QA Manager (or delegate) conducts a “light touch review” of the application to confirm the trial risks are within the normal realms of Sponsorship, specifically focusing on the following risk areas:
   - Healthy volunteers, pregnant women, research in prison population, persons under the age of 18
   - CTIMPs involving advanced therapy
   - CI experience / research team experience
   - Research team resource (e.g. admin and nursing support)
   - Licensing status of the Investigational Medicinal Product(s) (IMP’s) and phase of the trial
   - International sites
   - Emergency research
   - Any uncertainty regarding the fit with UK regulations
Please note: For Leeds CTRU managed trials, the CTRU QA team and operations director will conduct the initial risk assessment and liaise with Sponsor QA as per “CTGN35: LTHT / UoL Sponsor Process Instructions for CTRU”.

2.3 Should concerns be flagged under one of the risk categories above, Sponsor signature will not be provided until the QA Manager has had the opportunity to discuss and agree Sponsorship in principle with the appropriate Sponsor representative (R&I Director for LTHT Sponsored CTIMPs and Head of Research Integrity and Governance for UoL).

2.4 Further information may be requested via email to support the decision making process. Such correspondence must be maintained within the Sponsor oversight file.

2.5 Should a single site trial be classed as early phase and taking place solely within LTHT, the research team should be directed to the Leeds Clinical Research Facility for further discussion / risk assessment.

2.6 Once the review of the grant application is complete, and the Sponsor representative is content with the initial perceived risks of the trial, the Sponsor QA office will issue the “CTL01a Sponsor Acknowledgement of Grant Application” letter (template available on the department I:Drive).

2.7 The grant application must be logged on the electronic “QA Review and Approval Tracker” on I:Drive and a copy of the acknowledgement letter must be uploaded to the EDGE database and filed within the Sponsor oversight files (both paper and electronic).

2.8 Any changes to the grant application which may alter the details captured on the Risk Assessment Form must be communicated to the Sponsor QA office in real time.

2.9 Any grant application submitted by a UoL or LTHT employee for a CTIMP trial which has not had QA review cannot be guaranteed to obtain organisational sponsorship.

Please note: Should a trial have no associated grant application, the risks listed in section 2.2 must be considered during the preparation for submission to the HRA (see below), and escalated to the Sponsor Representative as appropriate.

3. Preparing for the Health Research Authority (HRA) Submission

3.1 Once the QA team are made aware of a new CTIMP, or a successful grant application (where applicable), the QA manager (or delegate) will arrange a face to face meeting with the CI (or delegate) to discuss the trial design, sponsorship review process and proposed timelines.
3.2 If the trial has no associated grant application, and the research team have not previously approached QA to discuss the trial design and risks, researchers will be asked to complete and return ‘Risk Assessment Form A (CTT04A)’ in advance of the meeting. The QA Manager (or delegate) is responsible for reviewing the perceived risks of the trial and escalating any initial concerns to the Sponsor Representative.

3.3 During the new trial meeting, the QA Manager (or delegate) will introduce the “CTC01: Researcher Checklist – LTHT / UoL Sponsored CTIMPs” checklist and provide training on the Sponsor review process, stages and approximate timelines for review.

3.4 For Leeds CTRU managed trials, this initial meeting will be held with the Head of Trial Management for the trial (or nominee) approximately two weeks before the submission of the document pack to QA. Please see “CTGN35: LTHT / UoL Sponsor Process Instructions for CTRU” for specific CTRU considerations.

3.5 Throughout the meeting, the QA Manager will seek to obtain as much information as possible regarding the trial design, endpoints, phase, drug supply, third party involvement and projected timelines and answer any questions the researcher may have at this stage.

3.6 A summary of the meeting and any actions agreed / details of next steps must be circulated to the researcher(s) following the meeting and filed within the Sponsor oversight file.

3.7 Following the introductory meeting, the CI (or delegate) must collate the initial submission pack (as per CTC01 checklist / CTGN35 as applicable) and submit to the QA Manager (or delegate) for review.

3.8 To minimise version control difficulties and pre-live amendments, it is recommended that researchers should apply for HRA approval prior to MHRA submission. Parallel submissions should only be considered when timelines are strict and the research team are particularly experienced in trial coordination.

3.9 QA can liaise with the researchers and provide support with the completion of the documents by directing researchers to where SOPs / work instructions / templates are located on the R&I website.

3.10 For protocol development, investigators should be directed to the HRA CTIMP protocol template for completion. Sponsor specific requirements regarding Pharmacovigilance and deviation reporting can be lifted from the relevant researcher facing SOPs.

3.11 Follow up meetings can be arranged (at the discretion of the QA Manager or delegate) to review progress and provide additional support, however the QA team are not to be considered part of the trial team and are not permitted to author any trial documents.
4. QA Review of the HRA Submission Pack

4.1 Following the receipt of a complete submission pack (see CTC01 checklist part B) the QA manager (or delegate) will commence review of the documentation, checking for compliance with the clinical trial regulations / Sponsor SOPs and for consistency across all of the documentation provided.

4.2 For single site trials, the QA Manger or delegate must conduct a full review of the trial Protocol, Patient Information Sheet / Informed Consent Form (ICF) and Integrated Research Application System (IRAS) application form (and any other associated documents), checking the content is consistent across documents and is in line with our Sponsor SOPs and Quality Management System. This review is documented on a “CTT39: QA Review of a CTIMP” form, with any recommended changes / findings communicated to the Investigator / research team via email.

   Note: For CTRU managed trials, depending on the volume of queries, the QA Manager (or delegate) may choose to communicate their initial QA review by email only.

4.3 Draft IMP and third party agreements must be provided in the initial document pack (see CTC01 part B). Agreements must only be finalised once the QA review of the associated protocol is complete.

4.4 During the document review process, the QA manager (or named delegate), may seek additional assistance from the Sponsor Representative, LTHT Pharmacy team, Clinical Academics or R&I Medical Experts. This will be documented via email for audit trail purposes.

4.5 The process of managing the acceptance of sponsorship must be recorded on “CTC12: QC Record for UoL / LTHT Accepting CTIMP Sponsorship” and the “QA Review and Approval Tracker” in real time. Supporting email correspondence must also be maintained in the Sponsor oversight file and the departmental I:Drive.

4.6 The investigator team must respond in writing, evidencing the changes made by providing tracked changed versions of the documents using Microsoft Word.

5. Sponsor Authorisation for HRA Submission

5.1 The QA manager (or delegate) is required to check all requested changes to the documentation have been implemented before issuing the “CTL01b Sponsor Authorisation for HRA Submission” letter. A template for this letter is available on I:Drive.

5.2 Once the QA Manager (or delegate) has confirmed the document pack is complete and all queries have been addressed, an email to the Sponsor Representative (or delegate) requesting IRAS authorisation / signature is issued.
5.3 The CI, or their delegate, is responsible for submitting the final document set to the HRA / REC and booking the CTIMP into an appropriate REC review meeting. Sponsor QA are not required to attend such meetings.

5.4 The QA team must be sent copies of all correspondence, including cover letters, approvals and response to requests for further information in real time to enable Sponsor oversight of any required changes.

5.5 For single site trials, once Sponsor Authorisation for HRA submission has been granted, the QA Manager (or delegate) should recap the next stage of the Sponsor approval process with the research team. This should include the introduction of Data Management Plans and Trial Specific Monitoring Plans which are required later in the approval process. Please refer to Sections 7 and 8 for further details.

5.6 Once REC approval is received, the trial must be added to the QA Master Trials List by the QA Portfolio Coordinator (or delegate) with all applicable information available at this stage populated in the relevant fields.

Please note: Pharmacy approval is not required at this stage for a CTRU led, multi-site trial unless LTHT are acting as a central pharmacy and supplying IMP to sites.

6. Sponsor Authorisation for MHRA Submission

6.1 QA will support the CI, or their delegate, as required in the review of relevant documentation in preparation of the submission to the MHRA.

6.2 Following the receipt of a complete submission pack (see CTC01 checklist Part C), the QA Manager (or delegate) will review the documentation for consistency and compliance with Sponsor processes and the previous HRA submission. This review must be evidenced in writing (via email or a second “CTT39: QA Review of a CTIMP” form).

6.3 As part of this review, the Reference Safety Information (RSI) for use in the trial must be clarified and recorded on the CTC12 Checklist. Researchers must also be directed to include details of the RSI on the accompanying cover letter to the MHRA (as per MHRA guidance).

6.4 For single site trials, researchers must not be authorised to submit their application to the MHRA until the LTHT Pharmacy clinical trial lead has had the opportunity to review the MHRA form and supporting paperwork. Once reviewed, the Pharmacy lead will provide confirmation of their support for the submission in writing.
6.5 Once the document pack has been reviewed, all queries have been addressed, and the Pharmacy approval is in place, QA will provide the “**CTL02: Sponsor Authorisation for MHRA Submission**” letter and request the Sponsor Representative’s signature on the Clinical Trial Application.

6.6 The CI, or their delegate, is responsible for submitting the final document set to the MHRA via the Common European Submission Portal (CESP). Access to the system can be arranged via the QA Portfolio Coordinator (or delegate).

6.7 The CI (or delegate) must share all MHRA correspondence with the QA office in real time, and any re-submissions following a ‘Grounds for Non-acceptance’ must be authorised by the QA office before resubmission.

6.8 MHRA approval must be forwarded to QA in real time and, when received, the trial must be added to the QA Master Trials List (if REC approval has not already been received) and all relevant fields updated.

7. **Data Management Considerations**

7.1 From October 2017, no single site LTHT or UoL Sponsored trial can be approved for Sponsorship until a Data Management Plan is constructed and agreed by both the CI (or delegate) and Sponsor QA.

7.2 Data Management Plans (DMPs) are not required to be finalised until the “**Confirmation of Sponsorship**” stage of set up, however researchers should be briefed on this requirement and forwarded on a copy of the SOP “**QCRES 07 - Researcher Guide to Data Management**” and associated template for completion once a protocol has been finalised.

7.3 The QA Manager is permitted to delegate the review of DMPs to the QA Regulatory and Governance Affairs Officer and / or QA Clinical Trials Monitor as deemed appropriate.

7.4 This review must include a sense check of the trials Source Data Location Sheet and paper Case Report Form (CRF) templates (if applicable). The reviewer must cross check the content against the approved trial protocol and communicate any required changes back to the research team in writing.

7.5 If any data points are intended to be recorded directly on the CRF (with no supporting source in the medical notes), this must be detailed in both the approved protocol DMP along with a supporting rationale for this method of data collection.
### 7.6
If an electronic database or CRF is detailed within the protocol or DMP, the QA team must have sight of the supporting validation paperwork, including evidence of quality control checks by the research team, **prior** to issuing confirmation of Sponsorship.

*Note*: **QA are not required to review DMPs, CRFs or databases for trials managed by a CTRU / CRO**

### 8. Trial Specific Monitoring Plans

8.1 From 1st October 2017, Trial Specific Monitoring Plans became a mandatory requirement and must be in place prior to Confirmation of Sponsorship.

8.2 The QA Monitoring team are responsible for completing the initial **"CTT62_Trial Specific Monitoring Plan"** template (with assistance from the QA Manager or delegate) before forwarding to the research team for comment. Templates are located on the departmental i:Drive.

8.3 The monitoring plan must document both internal monitoring / QC checks planned by the research team, and the formal monitoring to be conducted by Sponsor QA.

8.4 The trial specific monitoring plan must be agreed and signed by the QA Manager (or delegate) and CI (or delegate) prior to the issue of confirmation of Sponsorship.

*Note*: **Trial specific monitoring plans as described above are not applicable for CTRU / CRO managed trials. CTGN35 instead requests a copy of the CTRU’s Risk Mitigation and Monitoring Plan as part of the review process.**

### 9. Confirmation of Sponsorship

9.1 Once REC, HRA and MHRA approvals are in place, the research team must apply for a “Confirmation of Sponsorship” letter to be issued before the trial can commence recruiting at any trial site.

9.2 Following the receipt of a **complete** submission pack (see CTC01 checklist part D) the QA Manager (or delegate) will commence their review, checking for compliance with the clinical trial regulations / Sponsor SOPs and for consistency across all of the documentation provided.

9.3 The majority of documents will have already been reviewed in draft form throughout the earlier stages of Sponsor review, however as a significant time may have passed between reviews, this is an opportunity for the QA team to undertake a full quality check on the Sponsor oversight file to confirm all documentation is complete and auditable.
9.4 For single site, non CTRU led trials, the Sponsor QA Manager (or delegate) is required to conduct a Sponsor initiation visit prior to issuing the “Confirmation of Sponsorship” letter. This visit should be arranged upon receipt of a complete CTC01 Part D submission pack.

9.5 The initiation visit should be scheduled for a time after the Sponsor QA / LTHT R&I “handover meeting” date, with the aim to prevent delays between confirmation of Sponsorship and LTHT Confirmation of Capacity and Capability (CCC) Approval (please see Section 10 for further details of the R&I handover process).

9.6 The QA manager (or delegate) must use template “CTT41 LTHT / UoL Initiation Visit” both as an agenda for the meeting and as the formal visit write up. Any key discussions must be documented on the template and returned to the research team for signature following the visit.

9.7 Throughout the visit, any outstanding actions will be logged and summarised on the initiation visit report. Only once all actions are complete can the “CTL03 Confirmation of Sponsorship” letter be issued.

9.8 Once Confirmation of sponsorship is issued, it is the QA Portfolio Coordinator’s (or delegate’s) responsibility to ensure this information is correctly entered on the QA Master Trials List, and the timelines for all key trial events (e.g. the planned end date) are populated correctly. All fields on the Master Trials List which are populated using a fixed data point (a data point which will not change throughout the lifetime of the trial) must also be finalised at this stage and access to the trial on EudraCT should also be requested for future end of trial reporting purposes (please see LTU_QM_04 LTHT / UoL Sponsor Notification of the End of a CTIMP for further information).

10. LTHT Confirmation of Capacity and Capability

10.1 From 2016, the Sponsor QA office no longer processes R&I approval / CCC on behalf of LTHT. Instead, a formal handover meeting between Sponsor QA and the core LTHT R&I function (usually the R&I Coordinator) must be arranged in preparation for “Confirmation of Sponsorship”.

10.2 The QA Manager, or delegate leading the QA review for the trial, must contact the LTHT R&I contact to request a “handover meeting”. This should be scheduled once the initial approvals (REC / MHRA/HRA) have been received, and be in advance of the Sponsor initiation visit.

10.3 In advance of the handover meeting, the QA administrator or delegate should prepare the R&I mandated “Local Information Pack” and complete a draft of the required template email located on I:\Drive \ResearchQA\4_DOCUMENTS\5. Templates\Email Templates\ 2019 template RI Handover email .oft
10.4 The QA Manager (or delegate) should provide the R&I Coordinator with an overview of the trial, the local approvals obtained to date and current status of set up.

10.5 The R&I Coordinator will advise if any further local approvals or additional documentation is required and provide an estimated timeline for CCC approval.

10.6 Obtaining local approvals (with the exception of those listed on CTC01 (e.g. Pharmacy / Clinical Service Unit / Feasibility) is the responsibility of the participating site and research team, however the Sponsor QA team can request the additional documents on R&I's behalf during or in preparation of the initiation visit.

10.7 A trial is only permitted to open to recruitment in LTHT once both confirmation of Sponsorship and R&I CCC approval are in place.

Note: An R&I handover meeting is not required for CTU / CRO managed trials. The CTU / CRO will liaise with LTHT R&I directly, as LTHT will not be the only site the trial team are working with.

11. Use of External Trials Unit / Clinical Research Units

11.1 Multi-site trials can only be accepted for Sponsorship if they are managed via a CTRU or an external CRO.

11.2 For Leeds CTRU led trials, a Memorandum of Understanding between the Sponsor and the CTRU is in place, describing the break down for responsibilities for the management of the study. This is supported by the guidance note “CTGN35 LTHT / UoL Sponsor Process Instructions for CTRU (CTIMPS only)”, detailing the steps that need to be taken by the CTRU and Sponsor to approve and manage this activity.

11.3 Should an external trials unit be supporting a LTHT / UoL CTIMP, the QA team should where possible mirror the delegated duties / responsibilities in place with Leeds CTRU, to prevent split processes across the Sponsored portfolio.

11.4 Delegated duties should be clearly outlined in the Trial Management Agreement and be reviewed and approved by the Sponsor Representative and / or QA Manager as part of the set up process.

11.5 Additional due diligence assessments will be required for external trials units, often including a visit to the unit to review their systems, process and quality management systems. This review should be documented on the “CTC21 Third Party Provider Checklist for CTIMPS” (template available on I:Drive) and filed within the Sponsor Oversight Files.

11.6 Where a trials unit have not worked with an LTHT / UoL Sponsored CTIMP before, additional work instructions may be required to detail Pharmacovigilance, Protocol Deviation and Serious Breach
Reporting Arrangements. Where possible, the procedures agreed should mirror our arrangements with Leeds CTRU to prevent split processes across the portfolio.

12. Administration Considerations

12.1 The QA Manager (or delegate) is supported by the QA Assistant throughout the Sponsor review process.

12.2 The QA Assistant (or delegate) is responsible for maintaining the complete audit trail for trials in set up, including but not limited to:

- Assigning the R&I / Sponsor Number for the trial, detailed in “CTGN45_A QA Guide to EDGE”
- Collating document packs for QA Manager review
- Constructing and maintaining the electronic and paper Sponsor oversight file, detailed in “CTGN38_LTHT_UoL Sponsor Oversight File Contents”
- Ensuring all documentation is filed in line with the “CTGN38_LTHT_UoL Sponsor Oversight File Contents” and “CTGN46_LTHT_UoL Naming Convention for Electronic Filing”.
- Assisting the Sponsor Representative with contract review and signature.
- Maintaining the EDGE Record as detailed in “CTGN45_A QA Guide to EDGE”
- Managing the CESP submission portal
- Transferring the trial details to the electronic “QA Master Trials List” held on I:Drive once the first approval (REC or MHRA) is received.
- Transferring the trial details to the “QA Annual Reporting Tracker” once the first approval (REC or MHRA) is received, as detailed in “CTGN47_Annual Report Submission Tracking and Reminding Process”
- Performing a final quality check on of the document pack and signing the CTC12 checklist.
Section D: References

MHRA Good Clinical Practice Guide 2012
QCRE_07 Researchers Guide to Data Management
CTC01 Researchers Checklist for UoL / LTHT Sponsored CTIMPs
CTGN35 LTHT / UoL Sponsor Process Instructions for CTRU (CTIMPs only)
CTGN38 LTHT / UoL Sponsor Oversight File Contents
CTGN46 Naming Conventions for Electronic Filing
CTGN47 Annual Report Submission Tracking and Reminding Process

Section E: Acronyms

CESP Common European Submission Portal
CI Chief Investigator
CRF Case Report Form
CRO Clinical Research Organisation
CTIMP Clinical Trial of an Investigational Medicinal Product
CTRU Clinical Trial Research Unit
DMP Data Management Plan
GCP Good Clinical Practice
HRA Health Research Authority
ICF Informed Consent Form
IRAS Integrated Research Application System
LTHT Leeds Teaching Hospitals NHS Trust
MHRA Medicines and Healthcare Products Regulatory Agency
QA Quality Assurance
R&I Research and Innovation
REC Research Ethics Committee
RSI Reference Safety Information
SOP Standard Operation Procedure
UK United Kingdom
UoL University of Leeds
### Section F: Previous versions of Document

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