Checklist	Title	**Researcher Checklist for UoL / LTHT Sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs)**				
	Scope	Outlines the LTHT and UoL process for obtaining Sponsorship for a CTIMP				
	Version	**20.0**	Date	**29/10/2019**	WI ID	**CTC01**

Sponsor		**R&I Number**		**Chief Investigator**	
Trial Short Name					

INTRODUCTION:

This checklist outlines the stages and documentation required to obtain Leeds Teaching Hospital Trust (LTHT) or University of Leeds (UoL) Sponsorship for CTIMPs. Each stage requires the researcher to submit a core document set to the QA team for review and approval, prior to proceeding to the next step of the approval process. "Diagram A" provides an overview of the stages of approval, which should be used in conjunction with the tables below (listing the required documentation in checklist form) to aid a complete submission.

(Please note for CTRU led trials, set up will be arranged via direct liaison between the CTRU and the QA office in conjunction with this checklist and additional CTRU specific guidance (CTGN35). Researchers working on CTRU led trials should liaise directly with their CTRU contact in the first instance).

STAGE 1: SPONSOR ACKNOWLEDGEMENT OF GRANT APPLICATION:

PART A	**Documents required for Grant Application**			***Sent to QA*** ✓
	Document	***Version***	***Date***	
1	**CTT04A: Clinical Trial Risk Assessment Form (A)** (signed and dated by person completing the form)			
2	**Copy of Grant Application / Academic Summary**	NA		
3	**SoECAT (if required)**			

If the CTIMP is not linked to a grant application please proceed to Stage 2 / Part B.

- The Sponsor QA team do not review grant applications, but must be aware of all applications prior to submission and be content with the perceived risk to the organisation. In order for the risks to be assessed, a Sponsor number to be obtained and to permit Sponsor signature on the grant application, the above documents must be submitted to QA.
- QA will flag any immediate concerns based on the Risk Assessment Form to the research team, CSU / R&I lead and / or Head of Institute/School.
- Sponsor QA will issue a **"Sponsor Acknowledgement of Grant Application"** letter once any highlighted queries are satisfactorily resolved.
- Any changes to the grant application which may alter the details captured on the CTT04A Risk Assessment Form **must** be communicated to the QA Sponsor office in real time (please refer to diagram A - Stage 1).

Any grant application for an IMP trial which has been submitted without QA review, cannot be guaranteed to obtain organisational Sponsorship.

STAGE 2: SPONSOR AUTHORISATION FOR HEALTH RESEARCH AUTHORITY (HRA) SUBMISSION:

- QA review of the trial protocol and associated documentation will only commence following receipt of a **complete** "Part B" submission pack.
- Further review (and requests for additional documents) may be required at this stage. This will be communicated to the research team via email or by a formal QA review form.
- The **"Sponsor Authorisation for HRA Submission"** letter will only be issued once a complete "Part B" document pack is received and all initial review queries are resolved. The researcher may submit to the HRA at any time after receipt of the above authorisation letter.
- Following LTHT CSU feasibility review, the PI / CI must confirm all relevant local support departments (including R&I finance) have been contacted and approval discussions initiated.

The researcher must send all HRA / REC documentation including the completed application form, cover letter, approvals and any additional communication to the Sponsor QA office in real time. Any resubmissions must be communicated to QA PRIOR to submission.

PART B	**Documents required for initial QA review:**			**If N/A ✓**	***Sent to QA* ✓**
	Document	***Version***	***Date***		
3	**CTT04A: Clinical Trial Risk Assessment Form (A)** (signed and dated by person completing the form) **(NA if previously submitted during stage 1)**				
4	**Copy of at least 1 independent peer review** *(If peer reviewed as part of a grant application please provide grant application, reviewers comments and response / associated correspondence)*	NA			
5	**Evidence of Statistical Review**	NA			
6	**Draft of all trial related documents to be submitted to the HRA/REC e.g.:** • **Protocol** • **Patient Information Sheet (PIS) / Consent Form (CF)** • **GP Letter** • **Diary cards** • **Patient ID Cards** • **IRAS Form (for HRA / REC submission)** • **Any other trial documentation to be submitted**				

7	**Draft Third Party Agreements e.g. Investigational Medicinal Product (IMP) supply contracts / laboratory contracts / Draft CTRU Delegated Duties & Green Light Form**		
8	**Organisation Information Document (OID) (one for each site type)**		
9	**Draft Schedule of Events / Schedule of Events Cost Attribution Template (SOECAT) (one for each site type)**		
10	**Template model Non-Commercial Agreement (mNCA) (one for each site type)**		
11	**Clinical Service Unit (CSU) approval / Feasibility Assessment (applicable for single site trials only)**		
12	**GCP Training Certificate and CV for Chief Investigator (for single site trials GCP and CVs required for entire research team)**		

STAGE 3: SPONSOR AUTHORISATION FOR MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA) SUBMISSION:

- QA review of the MHRA application pack will only commence following receipt of a **complete** "Part C" submission pack, which must include all documentation pertaining to MHRA submission.
- Further review (and requests for additional documents) may be required at this stage. This will be communicated to the research team via email.
- The **"Sponsor Authorisation for MHRA submission"** letter will only be issued once a complete "Part C" document pack is received and all queries are resolved.
- The researcher may submit to the MHRA at any time after receipt of the above authorisation letter, a copy of which should be submitted with the application to the MHRA.

The researcher must send all MHRA related documentation including the completed application form, cover letter, approvals and any additional communication to the Sponsor QA office in real time. Any resubmissions must be communicated to QA PRIOR to submission.

PART C	Documents required for MHRA submission	If N/A ✓	*Sent to QA* ✓
13	**CTT04B: Clinical Trial Risk Assessment (B)** **(signed and dated by the person completing the forms)**		
14	**MHRA application form**		
15	**Copy of e-mail confirming EudraCT number**		
16	**Investigator Brochure (IB) / Summary of Product Characteristics (SmPC) / Investigational Medicinal Product Dossier (IMPD)**		
17	**Clinical Trial Labels**		
18	**QP Release / Manufacturers Authorisation (if applicable)**		
19	**Any further documentation you intend to submit to the MHRA**		
20	**LTHT Pharmacy Able to Support Letter (applicable for single site trials only - QA can help facilitate discussions with LTHT Pharmacy where required)**		

STAGE 4: CONFIRMATION OF SPONSORSHIP:

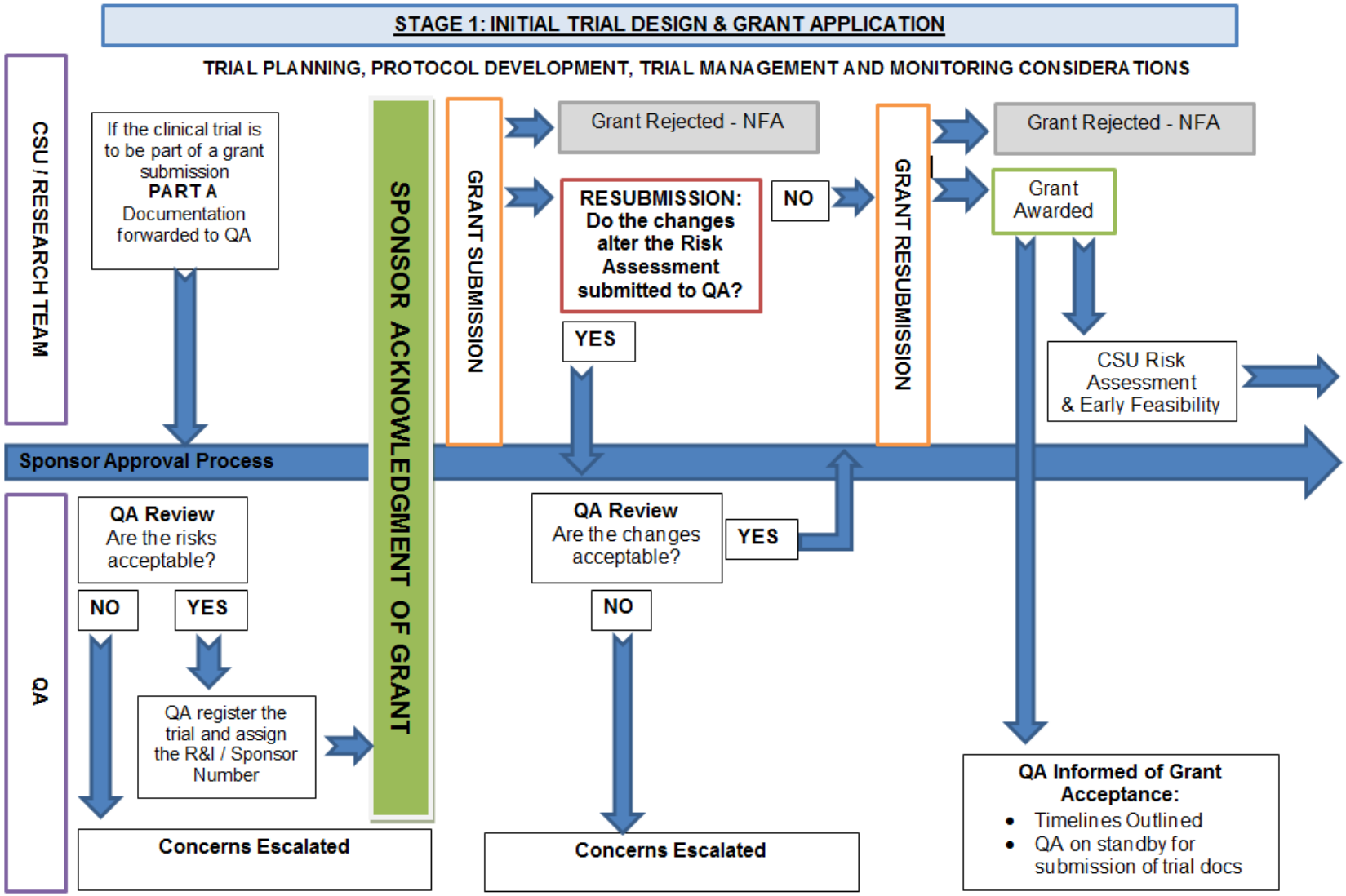
- Further review (and requests for additional documents) may be required. This will be communicated to the research team via email.
- The "Confirmation of Sponsorship" letter will only be issued once a complete part D document pack is received and all outstanding queries resolved.
- For single site LTHT or UoL Sponsored trials an initiation visit must take place prior to Confirmation of Sponsorship. This will be performed by the QA Manager or named delegate.
- If LTHT are a participating site local site approval will be arranged and confirmed by the main R&I office. For single site Sponsored trials the Sponsor QA team will formally hand over the trial to the R&I office once the Confirmation of Sponsorship letter is issued. The R&I point of contact will then liaise with the CI / PI / Research Team to confirm all locally required approvals are in place.

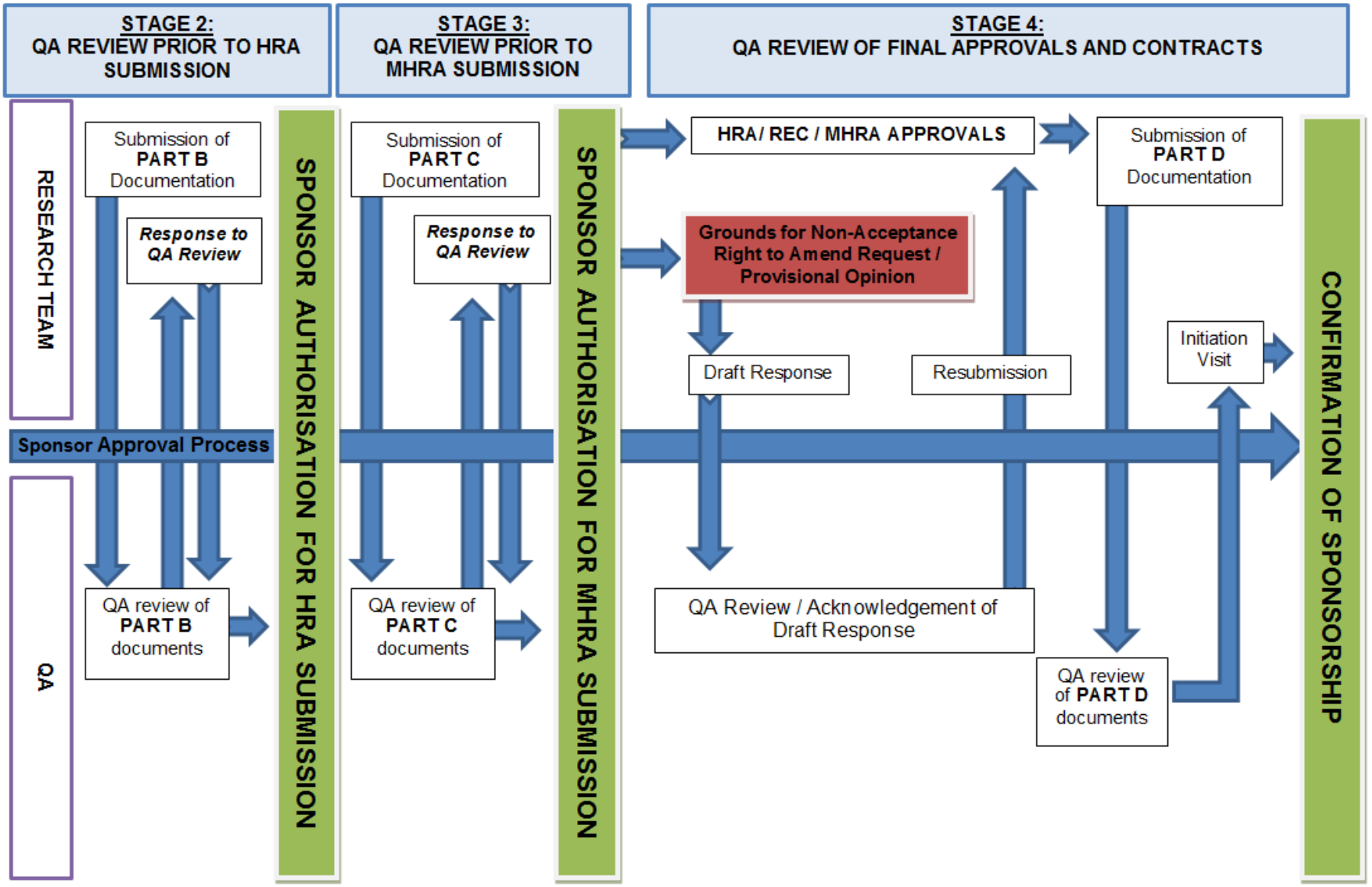
PART D	Documents required for **Confirmation of Sponsorship**	If N/A ✓	*Sent to QA* ✓
21	**Copies of all final HRA / REC & MHRA approved documents e.g. protocol, PIS, Consent Forms, diary cards etc.**		
22	**All HRA / REC correspondence e.g. completed application (fully signed), cover letters / response to any comments /approvals / amendments etc**		
23	**All MHRA correspondence e.g, completed application (fully signed), application covering letter, letter of receipt, resubmissions, approvals, amendments etc.**		
24	**Fully executed 3rd party funding / IMP supply contract / delegated duties / laboratory contracts / trial management agreements.**		
25	**Evidence of Registration on a Public data base (eg. ISRCTN, clinicaltrials.gov)**		
26	**Completed Data Management Plan (single site only, template to be provided by Sponsor QA).**		
27	**Trial Specific Monitoring Plan (single site only, template to be provided by Sponsor QA).**		

Note: For single site trials confirmation of Sponsorship will not be provided until an initiation visit, led by the QA team is performed.

For further information please contact: Louise Harris, QA Manager at Louise.Harris25@nhs.net

Diagram A - Overview of the Approval Process




STAGE 2:
QA REVIEW PRIOR TO HRA SUBMISSION
STAGE 3:
QA REVIEW PRIOR TO MHRA SUBMISSION
STAGE 4:
QA REVIEW OF FINAL APPROVALS AND CONTRACTS
RESEARCH TEAM
QA
Submission of PART B Documentation
Response to QA Review
Submission of PART C Documentation
Response to QA Review
Sponsor Approval Process
QA review of PART B documents
QA review of PART C documents
SPONSOR AUTHORISATION FOR HRA SUBMISSION
SPONSOR AUTHORISATION FOR MHRA SUBMISSION
HRA/ REC / MHRA APPROVALS
Grounds for Non-Acceptance Right to Amend Request / Provisional Opinion
Draft Response
Resubmission
Submission of PART D Documentation
Initiation Visit
QA Review / Acknowledgement of Draft Response
QA review of PART D documents
CONFIRMATION OF SPONSORSHIP