



Audit Checklist

1. Location

Campus:	Audit Date:
College / School / Department:	Auditor:
Building / Area:	Audit assessment team members:
Accountable Manager:	

2. Evaluation

Signature of Auditor:	Date:
Signature of Accountable Manager:	Date:

Detail Sheet

Mark Completion of each Activity/Action as per Functional Area			
Organization and Personnel			
	Yes/No	Risk	Comments
▪ Review of LinCTU SOP/ Policy documents			
▪ Documentation of training			
▪ Documentation of training on research specific processes			
▪ General research training requirements including GCP			
▪ Procedures to re-validate mandatory staff training after a certain time period? If yes, please record the frequency of revalidation in the comments section.			
Access Management			

<ul style="list-style-type: none"> ▪ Teams group ▪ Role Specific access to internal and external members ▪ Castor EDC 			
SOP Compliance training			
<ul style="list-style-type: none"> ▪ Ensure Project specific trainings is completed according to the training modules in eTAL (electronic Training attendance log) 			
<ul style="list-style-type: none"> ▪ Ensure training materials and SOP are available to all team members via website 			
Data Monitoring Checklist			
<ul style="list-style-type: none"> ▪ File/system access kept up to date 			
<ul style="list-style-type: none"> ▪ Database information recorded and stored appropriately 			
<ul style="list-style-type: none"> ▪ Copies of data monitoring reports to be filed in TMF 			
<ul style="list-style-type: none"> ▪ Copies of any regular data monitoring correspondence/ Consort Charts/ missing data and data query lists/ progress reports to be filed in TMF 			
LinCTU Study			
<ul style="list-style-type: none"> ▪ All functional leads should ensure the Project Team is kept aware of ongoing timelines and any changes as they occur 			

<ul style="list-style-type: none"> Review transfer of obligations, timelines, scope of study and address any deficiencies or changes 			
<ul style="list-style-type: none"> Ensure all responsibilities and taken by appropriate staff is in writing and saved/filed accordingly 			
<ul style="list-style-type: none"> Review study contract and financial metrics for risk, out of scope, overburn and under specific. Document if applicable 			
<ul style="list-style-type: none"> Complete a review of services supported by LinCTU 			
LinCTU Trial information			
<ul style="list-style-type: none"> Staff list and delegation log of LinCTU Studies 			
<ul style="list-style-type: none"> Staff CVs, training info, SOP Compliance 			
<ul style="list-style-type: none"> Risk Assessment 			
<ul style="list-style-type: none"> Trial registration evidence 			
<ul style="list-style-type: none"> Link to trial/study website 			
<ul style="list-style-type: none"> Protocol, CRF, copy of template participant information sheet(s) and copy of template participant consent forms(s) 			
<ul style="list-style-type: none"> Copies of site-specific participant information sheet(s), copy of site- specific participant consent form(s) 			
<ul style="list-style-type: none"> Copies of completed consent forms and Review of completed screening records (if we have agreed to monitor this on behalf of the sponsor or CI) 			

<ul style="list-style-type: none"> ▪ Review of completed screening records (if we have agreed to monitor this on behalf of the sponsor or CI) 			
<ul style="list-style-type: none"> ▪ Review of completed adverse event records (if we have agreed to monitor this on behalf of the sponsor or CI) 			
<ul style="list-style-type: none"> ▪ Regulatory approvals (Ethics, NHS R&D, Sponsorship letter, ARSAC approval etc) 			
<ul style="list-style-type: none"> ▪ Database information (e.g., data dictionary, documentation of database access and build process) 			
<ul style="list-style-type: none"> ▪ Check that eTMF is set up correctly and filing is up to date of all LinCTU studies. 			
<ul style="list-style-type: none"> ▪ Trial is listed on LinCTU Website with up-to-date information 			
<ul style="list-style-type: none"> ▪ Reports to ethics, regulatory bodies, and funders 			
<ul style="list-style-type: none"> ▪ File/system access check 			
<ul style="list-style-type: none"> ▪ Check that site file is set up correctly and filing is up to date 			