UNIVERSITY OF BIRMINGHAM

BCTU Birmingham Clinical Trials Unit

Date _____

Dear _____

You have approached us to collaborate on the _____ study.

The attached document outlines the suggested division of potential responsibilities between the University of Birmingham Clinical Trials Unit and yourself, the Chief Investigator (which includes staff associated with the study which you may be responsible for but external to the Birmingham Clinical Trials Unit).

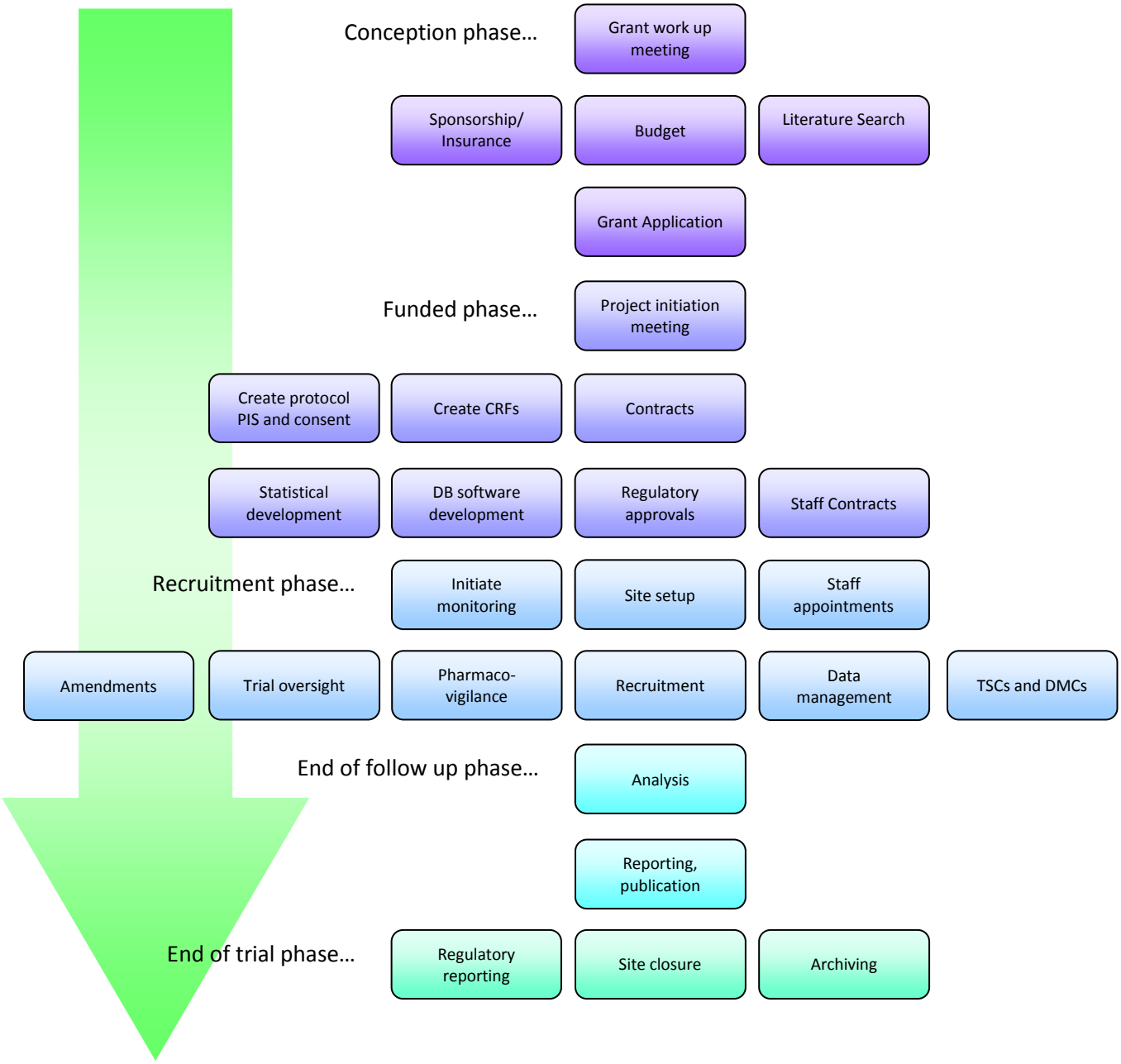
Before we agree to work with you we would like you to read through this document paying particular attention to < *insert as applicable* > and < *insert as applicable* >. These milestones will need to be finalised before progress can be made to the next phase of the study. If you would like to make any suggested modifications to these milestones then please let us know.

We look forward to working with you.

Professor Peter Brocklehurst (Director of the Birmingham Clinical Trials Unit)

Working as a Chief Investigator on a study run through the Birmingham Clinical Trial Unit

This document aims to provide an agreed basis for a practical division of responsibility between Birmingham Clinical Trials Unit and the Chief Investigator from conception of the study through to finalisation where full engagement between both parties has been agreed. Suggested responsibilities and timeframes (where appropriate) are outlined in the table below.



Milestones (in order)	CI/non BCTU	BCTU	Time-frames/important notes
Conception – BCTU agree to run study			
Grant work up meeting	Attend, facilitate	Arrange and Attend	At least three months prior to grant deadline
Agree publication policy including authorship listing	Agree	Agree	BCTU staff member to have prominent position on academic output
Literature Search	Prepare	Prepare (if required)	At least three months prior to grant deadline
Sponsorship/Insurance	Determine	Obtain confirmation	
Budget	Non BCTU costs (e.g. R&D, Trust)	Collate all groups budget estimates and create plan	Two weeks before deadline
Grant application	Input	Input	Completed at least a week before deadline
Funded			
Project Initiation Meeting	Attend	Arrange and Attend	ASAP
Contracts	Sign off	Organise	Variable time
Staff appointments	Organise local staff if required	Organise	Can only be made once contracts have been signed
Protocol, including PIS and consent forms	Input, review and approve	Input	CI overall responsibility. Funding not released until complete & Ethics approval in place
Case Report Forms (data collection)	Input into design. Provide example data, and ranges	Create, review and finalise	Database specification cannot start until CRF's are finalised
Database Application development	Input, review and feedback	Provide documentation, demo versions, review and finalise	Online randomisations can only start when system approved
Statistical development	Input if required	Analysis plan, DMC templates, analysis code	BCTU to finalise prior to first DMC
Regulatory approvals	Review and sign off	Make applications	Frequently funding not available until regulatory approval in place
Initiate independent monitoring (TSC/DMC)	Attend	Organise, input	Prior to recruitment starting
Recruitment			
Site setup	Input into site selection	Trust approvals, Clinical trial site agreements. Provision of site file and site initiation	Dependent on Trust R&D, sponsor and cooperation of local investigators
Recruitment	Encourage and engage with sites to promote participation	Randomisation service, data collection	Ongoing
Data management	Answer clinical queries (e.g. eligibility/CRFs)	Data entry, chasing, cleaning	Ongoing
Pharmacovigilance	Urgent reviews of SAEs	Monitoring and reporting	Ongoing
Reporting	Review, input and sign off	Create reports for ethics, regulatory, funders	Generally due on anniversary of funding/approvals
Amendments	Input, review and sign off	All necessary documentation	35 day limit on review
Trial oversight - TMG's	Attend, input and respond	Organise, attend, prepare reports	Typically monthly
Independent monitoring (TSC, DMC)	Attend, input and respond	Organise, attend, prepare reports	Typically every six months/annually
End of follow up			
Analysis	Review, clinical input, respond to data queries	Lock database, complete analysis	Typically at least 6 months from close of follow up
Reporting/publications	Writing	Writing	Up to another year depending on re-writes
End of Trial			
Site closure	Only if Local PI for site	Coordinate trial closedown with participating sites	
Regulatory reporting	Review reports	Writing	MREC, MHRA, R&D, Sponsor/funder
Archiving	Own site file storage	Data storage	Kept for a minimum 15 years