Delegation of Responsibilities

NOTES:

(1) This document accompanies the SOP on Applying for NBT Sponsorship (RI/QMS/SOP/007).

(2) The UK Policy Framework for Health and Social Care Research (2017) requires all research staff to be aware of their responsibilities. Where any responsibilities in the table below are delegated to an individual other than indicated, this must be recorded in a 'Delegation of Responsibilities Log' (see RI/QMS/SOP/007d).

(3) Where a different delegation of Sponsor responsibilities has been contractually agreed elsewhere (e.g. in a collaboration agreement or similar), that delegation will take precedent over the delegation outlined in this document. In such cases, the CI must seek confirmation of their delegated roles and responsibilities prior to the trial commencing.

(4) In the case of a single-centre project, the Chief Investigator (CI) and Principal Investigator (PI) will be the same person.

(5) Accountabilities are not delegable. Where there is only a symbol for accountability, responsibility will lie also.

KEY:	●ACCOUNTABLE	⦿ RESPONSIBLE	
Activity	Responsibility		
	NBT R&I	CI	PI
Regulatory Approvals			
Perform trial risk assessment prior to any regulatory approvals being sought	●		
Sponsorship authorisation of any IRAS applications (or Sponsor signature on any other regulatory application)	●		
Prepare and submit HRA application (including REC application)		●	
Obtain HRA approval (including REC approval)	●	⦿	
Prepare and submit application for MHRA Clinical Trials Authorisation (for CTIMPs) or Notice of No Objection (for Device Trials)		●	
Obtain MHRA Clinical Trials Authorisation (for CTIMPs) or Notice of No Objection (for Device Trials)	●	⦿	
Prepare approval applications from other relevant bodies (e.g. ARSAC, HTA)		●	
Obtain approvals from other relevant bodies (e.g. ARSAC, HTA)	●	⦿	
Obtain a EudraCT reference	●	⦿	
Register trial with appropriate registration scheme (e.g. clinicaltrials.gov, ISRCTN, UKCRN Portfolio)	●	⦿	

Ensure no participants are recruited until all necessary approvals have been received		●	
Finances, Contracts and Insurance			
Secure funding	●	⦿	
Ensure adequate funding is in place	●		
Administer funding	●		
Manage and maintain records of trial finances		●	
Ensure appropriate contractual arrangements and technical agreements are in place	●		
Ensure insurance/indemnity arrangements in place to cover liabilities	●		
Study Documents and Procedures			
Develop ethically, scientifically and statistically sound research protocol		●	
Ensure protocol has undergone independent scientific and statistical review and is compliant with applicable regulations	●	⦿	
Prepare Participant Information Sheet(s) (PIS), Consent Form(s) (CF) and other documents including, where applicable, consent for obtaining human tissue, medical data or other material		●	
Identify Reference Safety Information (RSI) for the trial (e.g. Prepare the Investigator's Brochure (IB) or obtain Summary of Product Characteristics (SmPC).	●	⦿	
Review RSI annually and update where relevant	●	⦿	
Design of case report forms and database		●	
Ensure a robust randomization process in in place	●	⦿	
Develop trial-specific procedural documents		●	⦿
Approve trial-specific procedural documents	●		
Setting up Sites			
Identify appropriate trial sites and a suitably qualified PI at each site		●	
Obtain Sponsor authorisation for the number and location of participating sites		●	
Conduct preliminary assessment of site suitability	●	⦿	
Obtain REC permission to include each NHS site involved	●	⦿	
Provide sites with the relevant documentation to enable sites to assess, arrange, and confirm local capability and capacity at the relevant timepoints in accordance with HRA requirements	●	⦿	
Ensure adequate facilities, resources and support are available to conduct the trial at the trial site		●	⦿
Obtain relevant authorisations from support departments at each site, in accordance with the policies and procedures at each site		●	⦿
Obtain written confirmation from each trial site of their capability and capacity to support the trial	●	⦿	
Conduct a site initiation visit at each site	●	⦿	
Issue Sponsor greenlight to recruit	●		
Pharmacy / IMP (CTIMPs only)			
Identify supply of Investigational Medicinal Product(s) (IMPs)	●	⦿	
Ensure IMP is provided imported, and labelled in accordance with applicable legislation	●	⦿	

Completion of pharmacy manual at the lead site		⦿	
Assess feasibility at pharmacy department of participating sites		●	⦿
Ensure adequate supply of IMP to sites on an ongoing basis	●	⦿	
Set up pharmacy site file within the pharmacy at each site		●	⦿
Identify storage arrangements for IMP and ensure appropriate temperature monitoring is in place		●	⦿
QP certification and release of IMP	●	⦿	
Ensure Investigational Medicinal Product (IMP) not used for any purposes other than trial and in strict accordance with the Protocol	●	⦿	⦿
Assure accountability records are maintained	●	⦿	
Ensure procedures are in place for emergency unblinding of the randomisation code (including out of hours if applicable)	●	⦿	⦿
Ensure system is in place regarding destruction/return of IMP	●	⦿	
Study Team			
Ensure research team are appropriately qualified by education and experience to undertake their role(s) and they have current substantive or honorary employment contracts in place (or arrange letters of access or research passports as necessary)	●	⦿	⦿
Ensure students and new researchers are adequately supervised	●	⦿	⦿
Ensure core research team members have completed ICH GCP training according to NBT policy	●	⦿	⦿
Train all relevant staff in the use of trial-specific standard operating procedures		●	⦿
Put and keep in place arrangements to allow all research staff to conduct the trial in accordance with the Protocol and any agreed contract			●
Notify employers/managers of research staff members' participation in the research		●	⦿
Study Delivery and Conduct			
Ensure the trial is conducted in accordance with ICH GCP and that applicable legislation is followed at all times	●	⦿	⦿
Ensure the rights, safety, dignity and well-being of participants are protected and that they receive appropriate medical care whilst participating in the trial	●	⦿	⦿
Ensure informed consent is taken for each participant in accordance with Protocol and approved patient-related documentation		●	⦿
Maintain trial documentation in accordance with regulatory requirements and ICH GCP		●	⦿
Ensure Trial Master File (TMF) is complete, accurate and legible	●	⦿	
Ensure Investigator Site File (ISF) and documentation are complete, accurate and legible		●	⦿
Inform, where practicable, health or social care professionals if their patient is a participant in the trial		●	⦿
Maintain a record of patient recruitment and report recruitment to the R&I office in line with Trust policy		●	
Ensure trial data are collected in accordance with the Protocol and ensure integrity and confidentiality of all data collected		●	⦿

Ensure all data and documentation are available for monitoring, audit or inspection and that appropriate consent has been provided by the Participant		●	◉
Ensure trial is managed, monitored and reported as agreed in the protocol	●	◉	◉
Undertake monitoring in accordance with study monitoring plan for assurance that the trial is being conducted according to the principles of GCP and appropriate legislation	●		
Report to Sponsor on trial progress, via trial management meetings		●	
Report all suspected breaches of protocol, ICH GCP and research misconduct and fraud to the Sponsor		●	◉
Report suspected breaches to the regulatory authorities, as necessary	●		
Ensure all protocol amendments are agreed and authorised by the Sponsor prior to submission for approval and implementation		●	
Sponsorship authorisation of any IRAS amendment applications (or Sponsor signature on any other regulatory application)	●		
Prepare and submit notification of amendments to the HRA (including ethics) and MHRA as necessary		●	
Obtain amendment approval from ethics and MHRA as necessary	●	◉	
Arrange amendments and/or extensions with the funder as necessary (following discussion with R&I)	●	◉	
Update all participating sites regarding amendments and submit to relevant R&I departments regarding amendment dates and version changes	●	◉	
Safety Recording and Reporting			
Maintain a copy of the Sponsor's safety reporting SOP in the site files		●	◉
Establish a Trial Management Group or applicable other system for maintaining oversight of all reported SAEs	●	◉	
Maintain detailed records of all Adverse Events (AE) as specified in the Protocol and in accordance with the regulatory requirements	●	◉	◉
Report adverse events as specified in the Protocol and regulatory requirements	●	◉	◉
Notify sites of relevant safety information on an ongoing basis	●	◉	
Ensure all Serious Adverse Events (SAE) other than those specified in Protocol as not requiring immediate reporting are recorded, assessed and reported in line with the regulatory requirements and Trust policy	●	◉	◉
Code SAEs	●	◉	
Ensure all SAEs are reviewed by an appropriate committee for monitoring trial safety (if applicable)	●	◉	
Ensure that all Suspected Unexpected Serious Adverse Reactions (SUSARs) are recorded, assessed and reported to the Sponsor immediately	●	◉	◉
Ensure that all Suspected Unexpected Serious Adverse	●		

Reactions (SUSARs) are recorded, assessed and reported to authorities in accordance with the regulatory requirements and Trust policy, within required timelines			
Promptly inform the MHRA, REC, R&I office and investigators at all sites of any urgent safety measures taken to protect participants	●	⦿	⦿
Ensure all investigators are, at all times, in possession of the current relevant safety information for the trial including any SUSARS that have occurred in relation to the IMP	●	⦿	
Issue reminders that DSURs, Annual Safety Reports and progress reports are due	●		
Ensure DSURs, Annual Safety Reports (ASRs) and progress reports are submitted to the MHRA and REC within the required timescales and copies provided to the R&I office	●	⦿	⦿
Maintain a record of patient recruitment and report recruitment to the R&I office in line with Trust policy		●	⦿
Study Completion			
Notify regulatory authority(ies) and relevant REC of Trial if suspended or terminates early	●	⦿	
Notify regulatory authority(ies) of the end of the Trial	●	⦿	
Ensure all trial records are archived appropriately on conclusion of the Trial and retained in accordance with regulatory requirements and protocol	●	⦿	
Ensure appropriate analysis of data		●	
Initiate and coordinate review and submission of abstracts, posters and publications	●	⦿	
Ensure all publications are sent to sponsor for review and comment prior to submission		●	