NNUH Sponsor Green Light Checklist

Study Short Title:		**Site:**	
Local Ref:		**PI:**	

Date of Study Approvals & Permissions	
HRA Approval:	
REC Approval:	
Clinical Trials Authorisation (CTA) / Notification of No Objection (NoNO):	

I confirm that all the conditions applicable to the above REC, HRA and MHRA approvals have been checked and met prior to activation of the site:	
Name:	
Job title:	
Signature:	
Date:	

The following steps must be completed before activating a Site:

Acknowledgement: Based on the Site Activation Green Light Checklist provided by Norwich Clinical Trials Unit

Initial Set Up	Date	Initials	Notes
Initial interest received from site (if relevant)			
Protocol version & Summary of Drug Arrangements (SoDA) sent to site (if applicable)			
Confirmation of receipt of protocol and signed SoDA (if applicable) at NNUH			

Acknowledgement: Based on the Site Activation Green Light Checklist provided by Norwich Clinical Trials Unit

Initial Set Up	Date	Initials	Notes
Initial interest received from site (if relevant)			
Site Feasibility Form template sent to site (if applicable)			
Risk assessment completed			

Assessment of Site Suitability	Date	Initials	Notes
Site history of non-compliance checked (if relevant)			
Completed Site Feasibility Form returned to NNUH			
Site suitability assessed and recorded on Site Assessment Report			
Site has infrastructure, facilities, and patient catchment to take part in the trial			

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Initial Set Up	Date	Initials	Notes
Initial interest received from site (if relevant)			
PI CV received at NNUH (signed, dated & with evidence of *current GCP training or GCP certificate) *updated as per SOP002			

Site Specific Approvals & Contracts	Date	Initials	Notes
HRA Pack / Site set up documents sent to Site from NNUH e.g. Protocol, Patient Information Sheet etc			
Confirmation of receipt of site set up documents received at NNUH and checked for confirmation of correct versions received			
Site added to Part C of IRAS form or amendment submitted to add new site			
R&D confirmation of capacity and capability received, and checked for: • Cover for all participating sites (with the same PI) within Trust/Health Board • Any unusual requirements			
Signed Site Agreement or other contracting document, returned and filed at NNUH			

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Documentation	Date	Initials	Notes
Investigator Site File (ISF) set up			
Staff training log in place and training records available			
Procedures for unblinding (including “emergency unblinding”) provided to Sites (if applicable)			
Procedures for randomization in place (if applicable)			
Details of logistical arrangements received e.g. collection of IMP between site staff and pharmacy/pharmacies obtained (if applicable)			
Trial specific prescription(s) reviewed (if applicable)			
If applicable, pharmacy site file set up			
If applicable, laboratory site file set up			
If study specific SOPs are to be developed, confirm these are available			
Clear arrangements for monitoring and completed monitoring plan in place			

Site Initiation	Date	Initials	Notes
Site Initiation visit has been carried out			
Confirm Delegate Lists from site initiation visit have been received at NNUH and filed in the Site File			
Site Initiation Checklist & Report finalised and all actions completed			
Site Initiation Visit report reviewed and approved			

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Checklist reviewed by Sponsor Representative or Delegate		
Name:		
Signature:		
Date:		
Sponsor Green Light	**Date**	**I**
Sponsor has issued green light letter to PI		

Site Activation	
Date of Site Activation Letter:	
Date Site Activation letter emailed/sent to PI:	
Name of NNUH staff who sent Site Activation letter:	
Key site staff copied into Site Activation Letter: *(must include main Research Nurse contact and Lead Pharmacist at Pharmacy – if applicable)*	

If site setup abandoned:

	Date	Initials	Notes
Site informed that set up abandoned			
Name of staff who informed site:			
Reason site setup not completed:	***Please give details of concerns that could pose a future risk***		

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