Clinical Research Remote Audit

Study Title			
Name of person completing remote-audit:		**Research Team Role:**	
Chief Investigator:			
Study Type:			
Start Date:	DD/MM/YYYY	**Planned End Date:**	DD/MM/YYYY
Signature:		**Date:**	DD/MM/YYYY

Area of Audit	Question	Response			Comments
Version Control					
	Where appropriate please identify the current version number and date for the following:	Version	Date		
1	Participant Information Sheet				
	Minor				
	Parent/ Guardian				
	Adult				
	Staff				
	Other (please specify)				
	Consent Form				
	Minor				
	Parent/ Guardian				
	Adult				
	Staff				
	Other (please specify)				
	Protocol				
2	Is the current version of the PIS referenced in the consent form?	Yes	No	NA	
Data Protection					
1	Who has access to confidential and participant identifiable data?				
2	Do any participant identifiable data get transferred out side of GCU?	Yes	No	NA	
3	If YES, what methods are used to transfer this				

	information – both paper and electronic formats				
4	What measures are put in place for each transfer method to ensure protection of information?				
5	Has confidentiality and data protection been fully discussed with potential participants?	Yes	No	NA	
6	Has this discussion been recorded on the consent form?	Yes	No	NA	
7	What systems are in place to store study materials within the dept./team/locality to comply with data protection and GCP standards?				
8	How long will participant identifiable data be stored at the end of the study?				
Site File					
1	Where is the study site file held				
2	Who has responsibility for maintaining this?				
4	Has the Delegation log been signed by all study team members?	Yes	No	NA	
5	Do all study team members hold up to date GCP certification?	Yes	No	NA	
Consent					
1	Do the consent forms require initials for each statement?	Yes	No	NA	
2	Have all participants completed a Consent Form prior to engaging in any research specific activity?	Yes	No	NA	
3	Has the Informed Consent process been recorded including	Yes	No	NA	

	questions asked and outcome?				
4	Has "willingness to continue" been recorded (where appropriate)	Yes	No	NA	
5	Have you had to re consent anyone onto the study? (If Yes please give reasons)	Yes	No	NA	
Performance Management					
1	What are the target figures for the study?				
2	Do you feel that you will meet the target figures in the required amount of time?	Yes	No	NA	
3	If No, have contingency plans for study data been discussed?	Yes	No	NA	
Research Site/Teams					
1	Which other services/localities are supporting this study?				
2	Do you/Have you had regular contact with the teams?	Yes	No	NA	
3	Have you had regular contact with the PI?	Yes	No	NA	
Archiving					
1	Who is responsible for Archiving the study information?				
2	How long will study information be stored for and where?				
Documentation					
1	Were all approvals received prior to commencement of research activities?	Yes	No	NA	
2	Do all research team members have current access permissions such as letters of access/honorary contracts/employment contracts?	Yes	No	NA	

3	Have annual progress reports been sent to the NHS REC?	Yes	No	NA	
Training					
1	Have all team members received adequate training for the appropriate delegated study duties?	Yes	No	NA	
2	Who would you contact regarding any GCP related queries?				
3	Have you ever had any GCP queries? And if so were they resolved?	Yes	No	NA	
Safety Reporting					
1	Do you have a copy or have access to the safety reporting SOP for your study?	Yes	No	NA	
2	Do you know what study related (S)AE/R's require reporting?	Yes	No	NA	
3	Are you confident in how to report adverse events for your study?	Yes	No	NA	
4	Have any (S)AE/R's been reported since commencement of the study?	Yes	No	NA	
5	Have these been reported in accordance to protocol and SOP?	Yes	No	NA	
6	Have any study related procedures or information been amended due to the Safety reporting?	Yes	No	NA	
Integrity					
1	In your opinion do you believe that the study is being conducted in accordance with the relevant frameworks/legal & ethical legislation/SOPs?	Yes	No	NA	
2	Are you aware of any incidences of fraud or	Yes	No	NA	

	misconduct in relation to the conduct of your study? (If yes, please refer to the Trust Research SOP)				
3	Are you aware of any complaints or concerns raised by study participants about the conduct of the study?	Yes	No	NA	