GENVASC
Site Initiation Checklist

The purpose of this document is to provide the lead site (NIHR LCBRU) with a system for performing standardised study initiation visits.

Instructions for use:
Fill in the participating site information and the names of the attendees
Some areas may need to be discussed in detail and others require only verification
Mark the appropriate boxes with 'YES' 'NO' or 'N/A' as appropriate
Add any action items or comments as required
Items verified prior to the site initiation visit should be marked with an asterisk (**)
On completion, sign and date the checklist and file in the site file.

Site Information	
Name of Participating Site:	
Study No: UHL 107325 REC 12/EM/0208	Initiation Visit Method:
Date of initiation:	On site Yes No
Conducted by:	Other (Specify)……..
Lead site personnel present:	Title
Study site personnel present:	Title

If additional study site personnel present record on separate attendance List

Item Discussed/Verified	Yes	No	N/A	Actions/Comments
Background/Purpose of Study				
Study objectives				
Study procedures				
Study practice pack and ISA				
Communication				
Study contacts				

Billing process				
Site Personnel/Record Keeping				
CV and study training/GCP certificates				
Safe storage of site file				
Deviation from protocol Work Instruction				
Deviation Log				
Work Instructions and SOP'S				
Consenting at the first point of contact				
Un-witnessed consent				
SystMone/EMIS				
Sampling process				
Ordering of consumables				
Study Material				
Version controlling				
Participant information leaflets: Full Abbreviated				
Consent Forms: Witnessed Un-witnessed				
Withdrawal Form				
GP Letter				
Advert				
Sample Bag Labels				
Source Documentation				
Filing of original consent forms				
Training Materials				
Study specific training				
Correspondence				
Study related correspondence/Amendments				

Monitoring				
Monitoring visits				
Additional Comments				

Site Initiation Checklist completed by:	Date: