Attachment –I **Template for EC monitoring Visit Agenda**

Study No.	
Study Title	
Name and Address of Site	
EC Monitoring visit date (s) DD-MMM-YYY (Follow date convention process as per institution/hospital)	
EC monitors Name (i.e. EC committee members (s) Name	
Visit scope (But not limited to...)	1) Site facility Visit i.e. screening, Consent room; Physical and medical examination room; sample collection, processing and storage room; investigational product storage room; other areas. 2) Meeting with Investigator and Site staff 3) Investigator Site Master File review 4) Audio-Video consent form review 5) Informed Consent Form review 6) Source document review 7) Investigational product accountability and handling 8) Study specific forms and log 9) Process of document management/handling at site 10) Site SOPs 11) Sample collection and processing activity 12) Sponsor and Regulatory communication 13) AE/SAE documentation (if any) 14) Protocol deviations (if any) 15) Others i.e. Archival area please specify_____

	Prepared By: **(By EC monitor)**	**Approved By:** **(By EC member secretary)**	**Acknowledged by:** **(By site investigator)**
Name			
Role of person			
Signature & Date			