SOP 410 Appendix 1 Site Initiation Visit Checklist

Item	Action	Comments/Confirmation
1	Site initiation visit date: Time: Location: Agenda issued:	
2	Roles and Responsibilities: • Delegation of responsibilities log in place (sponsor and co-sponsor / staff delegation log)	
3	Check all approvals are in place: • Confirmation of Capacity and Capability (main site) • Ethics • Confirmation of Capacity and Capability (local site) • Health Research Authority (HRA) Approval • Medicines and Healthcare Products Regulatory Agency (MHRA) authorisations (if appropriate) • Contract for funding (if appropriate) • Drug supply Agreement (if appropriate) • Laboratory Agreement (if appropriate) • Technical Agreement (if appropriate)	
4	TMF / ISF contents and set up **See SOP 305 Creating and Maintaining a Trial Master File for guidance**	

Item	Action	Comments/Confirmation

5	Training requirements:
	
	• Study aims
	• Time Frames
	• Trial procedures
	• Delegation log requirements
	• Study outcomes
	• Inclusion/Exclusion
	• Recruitment Targets
	• Data handling
	• Case Report Form's (CRF) / Electronic data capture systems
	• Monitoring plan and visits (draft) (as agreed with Sponsor) including plans for close. See **SOP 335 Research Project Closure (including procedure for project suspension or early termination)**
	• Trial Specific SOPs or Working Practice Documents (if used)
	• Safety reporting procedures
	• Pharmacy procedures (for IMPs)
	  ○ Labelling
	  ○ Receipt
	  ○ Storage
	  ○ Prescriptions
	  ○ Product recall
	  ○ Destruction
	• Laboratory procedures (if appropriate)
	• Other departments (e.g. Radiology)
	• Contact details for local site and study lead site
	• Staff training log /Training records, see **SOP 505 Creating and Maintaining Training Records**	

6	Site initiation report completed	

This checklist is for guidance purposes and should be adapted to the requirements of the study