STANDARD OPERATING PROCEDURE 3: SITE INITIATION CHECKLIST.

SOP 3: Site Initiation Checklist.

The following items should be addressed when initiating a participating site into a multi-center trial.

I. Site Information

Site Name:		Date:	
Study Name:		Initiation Visit Method	□ On-site
Name of PI:			□ Teleconference
Conducted by:			□ Others: _____

II. Checklist

Sr. No	Content	Yes	No	NA
1.	**Contact details-**			
	A. Contact detail of Principal Investigator, Co- Investigator, Clinical Research Coordinator, Research Nurse etc.			
	B. Signed and dated CV, MRC, GCP certificate of PI, Co-I and other site research staff			
2.	**Agreements-**			
	A. Non - Disclosure Agreement (NDA) if yes, Date:			
	B. Clinical Study Agreement (CSA)/Clinical trial Agreement (CTA) if yes, Date:			
	C. Financial Disclosure Form (FDF) If Applicable if yes, Date:			
	D. Material Transfer Agreement if yes, Date:			
	Finance			
	A. Grant offer letter if yes, Date:			
	B. Payments of investigator sponsor from the funding body if yes, Date:			
	C. Accounts statement/ Utilization Certificate			
	D. Expense statement for Investigators Meeting			
	E. Payments to other sites			

3.	**Insurance-**			
	A. Insurance Policy			
	B. Other documents			
4.	**Ethics Committee-**			
	A. Composition of ethics committee, EC SOP			
	B. Submission letter/Notification			
	C. Approval letters if yes, Date:			
	D. Other communication			
5.	**Major Documents related to conducting of the trial**			
5.1	**Protocol**			
	A. Current approved protocol			
	B. Protocol Signature Page			
	C. Amendments (If Any)			
5.2	**Investigational Brochure (IB)**			
	A. Current approved Investigational Brochure			
	B. Amendments (If Any)			
5.3	**Informed Consent Form (ICF)**			
	A. Current EC approved version of ICF with translations in other vernacular languages			
	B. Assent form (if applicable)			
	C. Translation and Back translation certificates			
5.4	**Case Report Form (CRF)**			
	A. Current EC approved Case Report Form			
	B. Amendments (If Any)			
6.	**Subject details-**			
	A. Randomization log (templates)			
	B. Screening log (templates)			

	C. Subject identification code list (templates)			
	D. Note to Files (templates)			
7.	**Regulatory-**			
	A. Approval letter of (If applicable) • DCGI • HMSC • Import/Export License			
	B. CTRI registration			
8.	**Safety reporting-**			
	A. Blank Templates of • Adverse Event (AE) • Serious Adverse Event (SAE)			
	B. Copies of completed- • Serious Adverse Event (SAE) form • Serious Adverse Event (SAE) report as per table 5 of New Drug and Clinical Trial Rule 2019			
	C. Safety report (SAE)log (templates)			
	D. Annual safety report (separators attached)			
9.	**Research team training**			
	A. Duty delegation log and signature log			
	B. Study Specific Training Log			
10.	**Lab details**			
	A. Accreditation and certificates of local lab			
	B. Accreditation and certificates of central lab (if applicable)			
	C. Normal value/range for medical lab			
	D. Other validation (where required)			
11.	**Monitoring**			
	A. Feasibility report			
	B. Visit Confirmation letter/E-mail			
	C. Pre-trial Visit Report			
	D. Study monitoring plan (if applicable)			

	E. Site initiation visit (SIV) report (separators attached)			
	F. Monitoring visit log (templates)			
	G. Follow up letters/E-mail			
	H. Deviation/violation log			
	I. Close –out Visit Report			
	J. Audit certificate (if available)			
	K. Clinical Study report			
12.	**Investigational Medicinal Product (IMP)- (if Applicable)**			
	A. Manufacturing and authorization license			
	B. IMP Shipment record			
	C. IMP accountability log (templates and completed)			
	D. IMP order record			
	E. IMP Return Records / Forms			
	F. Temperature log (templates and completed copies)			
	G. Documentation of IMP destruction			
	H. IP labels/ package insert			
	I. Certificate of Analysis of the IP shipped			
13.	**Miscellaneous**			
	A. Investigator Meeting (IM) presentation, agenda including attendance sheet, minutes of the IM			
	B. MOMs of teleconference between NCG CRO and Sites or Investigator sponsor (separators attached)			
	C. Newsletters and any other communications			
	D. Recruitment advertisement, Patient Diary Card, Questionnaire with translations etc (If applicable)			
	E. SOP training should be completed for all study team members (training log)			