Annexure 12
AX 12/ SOP 05-A/V 7
Site Assessment Checklist

IEC No. of the Project: …………………………………………..

Title of Study: …….

……….

……….

Principal Investigator (Name, Designation & Affiliation): …………………………………………………………………………

………..

		State Y (Yes) or N (No)	If No, Comment
1.	**Patient Population**		
	1. Do you have access to the desired participants pool? If no direct access, is the collaborating department providing access?		
	2. Will you need to recruit patients from external sources? If so, will sponsor /CRO provide funding?		
	3. Is the proposed enrollment goal for a given period realistic?		
	4. Will enrollment compete with other studies seeking the same patients?		
	5. Is Patient Charter of Rights of Participants in research available and displayed at the site, including English and vernacular languages		
	6. Is Participant's Request/ Complaint Record form drop box available?		
	7. Are services/ investigations available (e.g., lab, radiology-accreditation) to meet the protocol requirements present Are these laboratories accredited		
	8. Are necessary equipment /instruments (availability, validation and calibration) required for protocol execution present at site?		
	9. Does protocol execution require dedicated internet/phone/fax facilities If yes, are they available at the site?		

	-eCRF - patient monitoring (eg phone call)		
2.	**Procedures**		
	1. Are the study visits frequent? (more than those in clinical practice for a given disease)		
	2. Are the procedures during each visit difficult and time consuming? If yes measures taken to minimize patient risk at the site		
3.	**Study Team**		
	1. Does the study require special study team members with additional expertise?		
	2. In case study visits are complex, do they present scheduling difficulties for the team?		
	3. How many study team members will be required /participant / visit?		
	4. In case of unavailability of any protocol required equipment / procedures willsponsor / CRO provide it If yes: permanent / rental for the trial period		
4.	**Trial Procedure**		
	1. Is adequate space available?		
	2. Does the site have dedicated with restricted access area for - Investigational product (IP) storage / - Mention IP accountability		
	3. IP storage room has a facility to record temperature/ humidity 24*7		
	4. Will electronic or remote data retrieval systems be used? If so, will the sponsor/CRO provide training?		
	5. Does the site have dedicated computer, printer, cupboard, stationary for storage of study documents		

Name and Signature of the PI & Date: …………………………………………………………………………….

IEC office use only:

Date of the physical site assessment: ________________ Time in __________ Time out________

Assessment performed by

Name of IEC member:

1. ……………………………………………………………………………
2. ……………………………………………………………………………
3. ……………………………………………………………………………

Type of facilities: ………………………………………………………

Confirmation of all items in AX 12/ SOP 05-A addendum, Site Assessment Checklist Yes __ No__ if no list the deficiencies

1. ………………………………………………………………………..
2. ………………………………………………………………………..
3. ………………………………………………………………………..

Interaction with clinical trial members at the site:

Name of the trial team members	**Query asked**	**Reply provided**
PI		
Co-I 1		
Co-I 2		
Co-I 3		
CRC1		
CRC2		
CRC3		
Lab Technician		
Any other trial team member		

Date and signature of the monitors:

1. ……………………………………………………………….
2. ……………………………………………………………….
3. ……………………………………………………………….