

## **INSTITUTIONAL ETHICS COMMITTEE (IEC)**

Seth G. S. Medical College and KEM Hospital, Mumbai.

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

Principal Investigator (Name, Designation & Affiliation):	
Title of Study:	
IEC No. of the Project:	

			State Y (Yes)	If No, Comment
			or N (No)	
•	Pat	tient 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) t o 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?		



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-eCRF			
<ol> <li>Are the study visits frequencies</li> </ol>	ent? (more than those in clinical		
practice for a given disea	se)		
2. Are the procedures durin	each visit difficult and time		
consuming?			
f yes measures taken to mini	nize patient risk at the site		
Study Team			
<ol> <li>Does the study require sp</li> </ol>	ecial study team members with		
additional expertise?			
<ol><li>In case study visits are co</li></ol>	mplex, do they present scheduling		
difficulties for the team?			
B. How many study team m	mbers will be required /participant		
/ visit?			
I. In case of unavailability of	f any protocol required		
equipment / procedures	willsponsor / CRO provide it		
f yes: permanent / rental for	the trial period		
Trial Procedure			
I. Is adequate space availab	e?		
2. Does the site have ded	cated with restricted access area		
for			
- Investigational product	IP) storage /		
- Mention IP accountabili	y		
3. IP storage room has a fac	lity 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 dedica	ed computer, printer, cupboard,		
1 2 2 3 3 2 2 1 1 2 2 3 3 2 2	<ul> <li>Procedures</li> <li>1. Are the study visits freque practice for a given diseas</li> <li>2. Are the procedures during consuming?</li> <li>If yes measures taken to minin</li> <li>Study Team</li> <li>1. Does the study require speadditional expertise?</li> <li>2. In case study visits are condifficulties for the team?</li> <li>3. How many study team means / visit?</li> <li>4. In case of unavailability or equipment / procedures</li> <li>If yes: permanent / rental for the team?</li> <li>1. Is adequate space availability or equipment / not procedures</li> <li>1. Is adequate space availability or environment / rental for the team?</li> <li>3. How many study team means / visit?</li> <li>4. In case of unavailability or equipment / procedures</li> <li>If yes: permanent / rental for the team?</li> <li>1. Is adequate space availability or environment / rental for the team?</li> <li>3. IP storage room has a facing humidity 24*7</li> <li>4. Will electronic or remote so, will the sponsor/CRO procedure</li> <li>5. Does the site have dedicated to the sponsor/CRO procedure</li> </ul>	<ol> <li>Are the study visits frequent? (more than those in clinical practice for a given disease)</li> <li>Are the procedures during each visit difficult and time consuming?</li> <li>If yes measures taken to minimize patient risk at the site</li> <li>Study Team</li> <li>Does the study require special study team members with additional expertise?</li> <li>In case study visits are complex, do they present scheduling difficulties for the team?</li> <li>How many study team members will be required /participant / visit?</li> <li>In case of unavailability of any protocol required equipment / procedures willsponsor / CRO provide it</li> <li>If yes: permanent / rental for the trial period</li> <li>Trial Procedure</li> <li>Is adequate space available?</li> <li>Does the site have dedicated with restricted access area for         <ul> <li>Investigational product (IP) storage /</li> <li>Mention IP accountability</li> <li>IP storage room has a facility to record temperature/ humidity 24*7</li> </ul> </li> <li>Will electronic or remote data retrieval systems be used? If so, will the sponsor/CRO provide training?</li> </ol>	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?       1.         If yes measures taken to minimize patient risk at the site       5.         Study Team       1.         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       1.         Trial Procedure       1.         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,

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



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IEC	IEC office use only:				
Da	Date of the physical site assessment: Time in Time out				
As	sessment performed by				
Na	me of IEC member:				
1.					
2.					
3.					
Ту	pe 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-l 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. .....