STANDARD OPERATING PROCEDURE 2:

SCREENING A SITE FOR ELIGIBILITY.

SOP 2: Screening a site for eligibility.

Purpose

This SOP describes the procedure of site feasibility assessment to evaluate if a site is suitable for a given study conduct.

Scope

The SOP describes the process to be followed for creating a tool for site feasibility assessment and to review the completed assessment sheets. It will also be applicable for a site feasibility visit.

Applicable to Whom

This SOP is applicable to CRO team members (CRA / Project Manager) who would be assigned to create a tool for site feasibility assessment. CRA (Clinical Research Associate) may visit site for conducting the feasibility assessment (if applicable). A complete review of the assessment sheet must be done by a Sponsor- Investigator (S-I)/ PI/ HCC Executive Committee & the Project Managers.

Procedure

The site assessment process would be classified into following activities

(a) Creating a site feasibility questionnaire.

(b) Administering the feasibility questionnaire.

(c) Site Assessment Visit (SAV)

Note: CRO team can be contacted by S-I/any other HCC member to carry out the entire site assessment process or only a part of it.

(A) Creating a site feasibility questionnaire:

Sponsor-Investigator (SI) will contact CRO to create protocol specific site feasibility questionnaires, based on the feasibility questionnaire (FQ) template (Annexure 1)

Principal-Investigator (PI) / Project Manager (PM) will assign the task to CRA

Delegated CRA will be trained on the protocol by PI/S-I/PM and will create the feasibility questionnaire based on the study specific requirements

CRA will share the questionnaire with SI to finalize the same

(B) Administering the feasibility questionnaire:

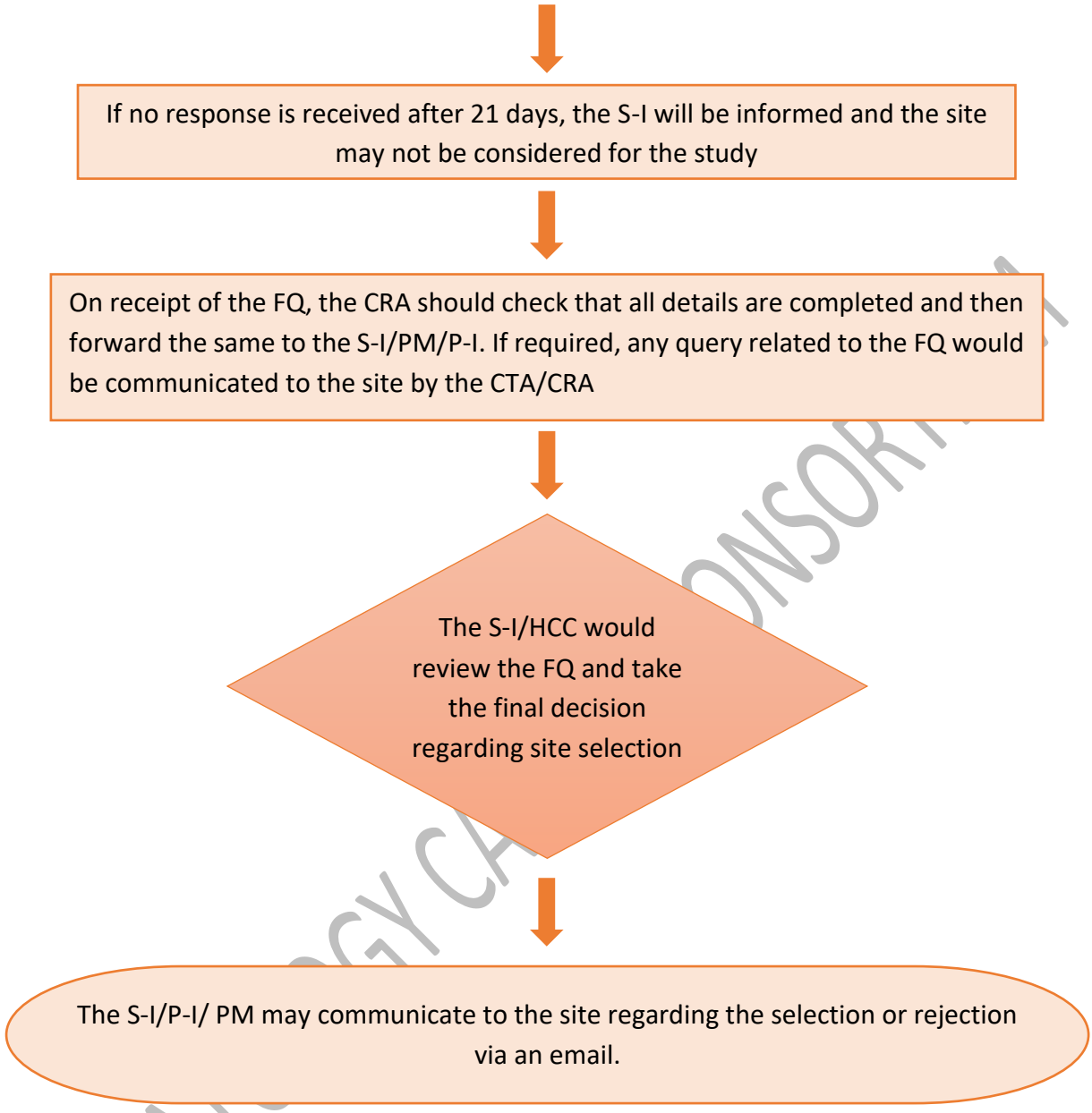
The CRA would request Sponsor-Investigator to provide the list of potential sites

The Non-Disclosure Agreement (NDA) would be sent to the sites by the CRA

After the receipt of the signed NDA, the CRA would send the FQ and the study synopsis/full Protocol soft copy to the sites as per the list provided by the Project Manager (PM)/P-I /Sponsor Investigator(S-I)

The site would be requested to send back the scanned copy of the filled FQ within **14-21 working days** from the day of receipt of the FQ by the site.

In case the site does not provide the FQ within 14 working days the CRA should follow-up through email/telephone. If required CRA may provide assistance to the site in the FQ completion process.



(C) Site Assessment Visit (SAV):

The approach to plan a SAV may be applicable to:

(a) New Institution
(b) Institutes with new research set up
(c) New Investigator
(d) High Intensity Studies

- The P-I/ PM should instruct the CRA to contact the selected sites for a suitable date of SAV after the evaluation of the FQ.

- The CRA should confirm with the site regarding the SAV date and would send a confirmation email (Annexure 2) with the agenda of the SAV to the site. The agenda would be reviewed and approved by the PM/P-I.

The activities during the SAV would comprise of any of the following but not limited to:

Sr. No.	Activities	Details
1.	Protocol Discussion	The following aspects of the Protocol detailed below but not limited to would be discussed: Study design Eligibility criteria Informed Consent process CRF Safety reporting Investigational Medicinal Product (IMP) Any Others.....
2.	Recruitment strategy	Access to target patient population- verification of database source Details of annual patient registration Expected monthly and annual recruitment target Any Others.....
3.	Ethics Committee set up	IEC registration IEC SOP IEC constitution and composition as per ICMR and New Drugs and Clinical Trial rules. frequency of meeting, Fees (if applicable) Any Others.....
4.	Assessment of resource and manpower	People: Qualification, experience, availability, of PI &Co-Investigators, Study Coordinators etc. Place: availability of space for the conduct of research activities, place for monitoring activity Time: Number of ongoing trials under the Investigator, personal supervision. Study Budget: cost of investigations, remuneration of staff appointed for the study etc. Other resources: Computer equipment, phone &fax etc. Any Others.....

5.	Facility tour, if possible	Local laboratory: accreditation, blood investigation facilities Drug storage and destruction facility Radiology: facilities available Sample storage facility: Blood sample and tissue storage Archival facility Any Others.....
6.	Others	Source documentation procedures Site SOPs etc

- During the site assessment visit, the SAV report (Annexure 3) should be filled by the CRA.
- The CRA should submit the SAV report to the PM/P-I for review and approval within 7-14 working days of the visit. The approved report (along with recommendation for site selection) will be shared with S-I for review and final decision.
- The PM//P-I should recommend on the site selection (only FQ based or FQ and SAV) based on the following criteria but not limited to:

(1) Clinical expertise of the Investigator	(2) Site staff (qualification & experience) and resource	(3) Site's access to potential study participants	(4) IEC set up
(5) Local Laboratory facility	(6) Radiology facilities	(7) Drug storage/Pharmacy and destruction facility	(8) Any others

- The S-I/PM/P-I should communicate to the site regarding the selection or rejection via an email.

Reference(s):

- New Drugs and Clinical Trial rules 2019.
- Indian GCP guidelines (2001)
- ICH GCP E6 (R2) guidelines (2016)
- https://globalhealthtrials.tghn.org/site.../Pre-Study_Site_Selection_Visit_Checklist

Annexure(s):

- Annexure 1-Feasibility questionnaire template
- Annexure 2-SAV confirmation email template
- Annexure 3-SAV Report template
- Annexure 4- Site assessment visit follow-up email template

Note: All the annexures can be customised as per the requirement of the study and/or as per discretion of CRA/PM//P-I.

Annexure 1 - Feasibility questionnaire template

Site Feasibility Questionnaire		
Sr. No.	**Feasibility criteria**	**Please fill in the details**
1	Name of site	
2	Contact details of the site	Address: Telephone: Fax: Email:
3	Type of site (Please tick)	○ Government hospital ○ Private hospital ○ Charitable Trust Hospital ○ Primary care physician ○ Other
4	Does the site/PI have standard operating procedures (SOPs)?	○ Yes ○ No
Comments (if any):		
Site Resources		
Research staff		
5	Details of the Principal Investigator	Name: Designation:
6	Credentials	○ MD ○ MS ○ MCh ○ PhD ○ DM ○ Other
7	Contact details of the Principal Investigator-	Address: Telephone: Fax: Email:
8	Contact details of the coordinating person (Investigator/CRC)?	Telephone: Email:

9	Number of ongoing interventional trials as a Principal Investigator	Number of ongoing trials:
10	Professional Experience of the PI (in years)	
11	Clinical Research Experience of the PI (in years)	
12	Does the PI have experience in global clinical trials?	○ Yes If Yes, please specify the phase of the trial: ○ Phase I ○ Phase II ○ Phase III ○ Investigator Initiated Study ○ Post Marketing Surveillance ○ No
13	How many clinical studies are currently ongoing under the PI's supervision?	
14	Research publications of the PI	○ Number of International publications- ○ Number of National publication-
15	Is the PI GCP Trained? (If yes, Mention the date of training, Name of Training/Certification Body)	○ Yes ○ No
16	Number of research staff and supportive staff	Number of Co-Investigators- Number of Study Coordinators- Any other (Study Nurse/Pharmacist etc.)- Please specify the number
17	Does the staff have experience with e-CRF?	○ Yes ○ No
18	Is the site staff (other than the PI) GCP trained?	○ Yes ○ No
Comments (if any):		
Laboratory details		
19	Is Local laboratory facility available?	○ Yes ○ If No, please specify the name of the laboratory whose services would be used.
20	Does the site have a sample processing facility (separation of serum & plasma)?	○ Yes ○ No ○ NA

	If yes, Give details	
21	Is the laboratory accredited?	○ NABL ○ CAP
22	Does the site have facility for Radiology Investigations?	○ Yes ○ No
23	Please tick facilities available	○ X-ray ○ CT scan ○ MRI ○ USG ○ Bone Scan ○ PET ○ ECG ○ 2D ECHO ○ Other (Please specify any additional investigational facilities in the comments section)
Comments (if any):		
Space and Facilities		
24	Does the site have space for storage of study related materials (lab kits)?	○ Yes ○ No
25	Does the site have separate rooms for Monitoring?	○ Yes ○ No
26	Does the site have infrastructure for storage of blood and tissue samples?	○ Yes ○ No
27	Does the site have space for Archival of data after completion of the trial? If yes, provide the details and procedures? If no, specify the location where documents will be stored?	○ Yes ○ No
28	Does the site have a dedicated space for study document storage?	○ Yes ○ No

29	Does the site have a dedicated Refrigerator for IP storage facility with temperature control?	○ Yes ○ No ○ NA
30	Does the site have Internet facility	○ Yes ○ No
	Comments (if any)	
Patient Recruitment Strategy		
31	What is the number of patients (per month) seen in the Hospital of particular indication involved in the trial?	
32	How does the site recruit patients?	○ Database ○ Referrals ○ Internet ○ Newsletters ○ Advertisements ○ Other
33	Besides English which other Vernacular ICDs/Patient related documents would be required?	
Protocol Specific (To be pre-filled by CRA/CTA before sending the FQ to site)		
34	Total sample size (all sites)	
35	Inclusion criteria	
36	Exclusion Criteria	
37	How many patients would fit the eligibility criteria of the trial? How many patients would the site /PI be able to recruit?	Patients eligible for trial per month: …… Patients to be recruited per month: ……
38	Have the PI conducted any clinical trials with similar indications?	○ Yes ○ No If yes, please state the number-

39	Are there any ongoing competing clinical trials for a similar indication?	○ Yes ○ No If, yes, please specify details (Sample Size, No. of patients enrolled till date, CTRI No etc)
Comments (if any):		
Ethics Committee		
40	Does the Institute have any Institutional Ethics Committee?	○ Yes ○ No
41	Kindly provide the contact details of EC administrator/ member secretary	IEC Contact person Address Telephone: Fax: Email:
42	a) Is the IEC registered with DCGI? b) Is the IEC registered with DHR (Department of health research, ICMR)? c) IS NABH assessment of IEC performed?	○ Yes ○ No If, yes, please mention the registration number and the validity period- ○ Yes ○ No If, yes, please mention the registration number and the validity period- ○ Yes ○ No If yes, please mention the accreditation number and the validity period-
43	Is the EC constituted as per the New drugs and CT rules/ ICMR?	○ Yes ○ No
44	Does IEC have a written SOP?	○ Yes ○ No
45	What is the frequency of IEC meetings? Please provide the dates of the previous and upcoming IEC meeting	
46	How many days prior to the meeting should the study documents be submitted?	

47	Is checklist for submission of documents for IEC review available	○ Yes ○ No
48	How many copies of documents are required for submission?	
49	How many days after the meetings will the approval letter be issued?	
50	EC fees (if any) for academic research studies	Initial review:…….. Amendments documents Review:…… Any other review fee:……
Comments (if any):		
Finance		
51	Does the site have any research specific account where study related payments can be made? I f Yes, please mention the mode of payment (cheque/fund transfer), PAN & GST details	
52	Admission Charges-	
53	Bed Charges-	○ General ward : ○ Semi-private ward : ○ Private ward :
54	ICU charges-	
55	Please specify the cost of Blood Investigations (Enclose the current schedule of charges/ Rate card)	Haematology: Biochemistry: Others:
56	Please specify the cost of radiology and other investigations (Enclose the current schedule of charges/ Rate card)	○ X-ray ○ CT scan ○ MRI ○ USG ○ Bone Scan ○ PET ○ ECG ○ 2D ECHO
Comments (if any):		

Annexure 2 - SAV confirmation email template

To,

{The Principal Investigator}

{Designation}

{Site details}

Reference : {Protocol Title and ID}

Dear {PI name}

Greetings!

Thank you for confirming your availability for the Site Assessment Visit (SAV) for the above-mentioned study.

As discussed, we would be conducting the SAV at your site on (date) and the duration of the visit would be of …… day/s. I would be accompanied by (designated person) during the visit.

Please revert in case of any queries regarding the visit.

Kindly find the enclosed SIV agenda for your reference.

I also request you to send the acknowledgement copy of this letter for our record.

Thank you for your cooperation and interest in the study. I look forward to meeting you during the visit.

Regards,

Yours sincerely,

Name of the CRA

Annexure 3 - SAV Report template

Study Title:

Name of CRA:

Date of visit:

Investigator Information	
Name of the Investigator	
Title/Department	
Site/Institution Name	
Address:	
Email :	
Telephone:	
Fax:	

Protocol Information :	
Protocol Title	
Protocol Version	
Protocol / Project Code	

Attendance of the Site Personnel during visit :		
Sr. No	**Name of the Personnel**	**Designation**

Sr. No	Activity	Yes	No	N/A
01	Did the Principal Investigator sign Confidentiality agreement?			
02	Has the feasibility Questionnaire been filled by site?			
03	I. Brief discussion on essential study documents: (a) Protocol (b) Study design and visit schedule (c) Eligibility criteria (d) Informed Consent Process (e) Source documentation (f) IP-storage, accountability, dispensing, return, destruction (g) Safety reporting (h) Concomitant medications (i) Paper/electronic CRF/Quality of Life forms II. Discussion on Monitoring frequency and expectation from site			
04	Were the cost of investigations/ other study related costs discussed?			
Comments:				
Manpower				
05	(a)Is the Principal Investigator (PI) qualified to conduct the trial? (b) Is updated CV available?			
06	Is the PI having the necessary facilities, time and support staff, to carry out the proposed research?			
07	(a)Is the Co- Investigator qualified to conduct the trial and have relevant experience? **(b)** Is updated CV available?			
08	Are the Investigators aware of and trained on ICH-GCP and Indian GCP guidelines? Also DCGI regulations/ICMR guidelines? (as per the requirements)			
09	(a)Is the Study Coordinator qualified to conduct the trial and have relevant experience? (b)Is updated CV available?			

10	Does the site have Standard operating procedure (SOP)?			
Comments:				
Recruitment strategy				
11	Was Time-line for target patient enrolment discussed?			
Comments: Please specify the monthly and annual target enrolment after verifying the details (database/other sources) of site's access to target patient population				
IRB/IEC Procedure:				
12	a) Is the IEC registered with DCGI? b) Is the IEC registered with ICMR (Department of health research)			
13	Is the IEC constituted as per New drugs and Clinical Trial rules?			
14	Does the IEC have SOPs?			
15	Was IRB/IEC meeting frequency & documents required for submission & time-lines discussed?			
16	Whether the IEC submission checklist was collected from the site?			
Comments				
Informed consent procedure				
17	Does the principal investigator/Co-Investigator administer the consent? Please specify			
18	a) Does the site require the ICD translations? If Yes specify the languages required…….. b) Is back translation required by IEC?			
19	Does the site have a dedicated room for AV recording of Consent process (if applicable)?			
Comments				
Facility/Resource Assessment:				
20	(a) Is there an accredited local laboratory available? (b) Normal laboratory ranges available?			

21	Does the site have facilities for radiology investigations?			
22	Does the site have an emergency treatment facility?			
23	Does the site have adequate beds for inpatient admission if required?			
24	Does the site have facilities of storage of blood and tissue samples?			
25	Is there an internet facility available at the trial site?			
26	Is Fax machine available at the trial site?			
27	Is Photocopier machine available?			
28	Is Printer/scanner available?			
29	Are adequate records maintained for Clinical supplies Inventory Tracking and Reporting?			
30	Adequate archival facility available at trial site?			
31	Does the site have space for study conduct and monitoring activity?			
Comments:				
Pharmacy				
32	Is Drug storage facility available?			
33	(a) Is Refrigerator (2°- 8°c) available for drug storage? (b) Is a deep freezer (-20° and/or -70°c) available for drug storage?			
34	Is thermo hygrometer and its calibration certificate available at the site? (if applicable)			
Comments:				
Access of the Source Document & Archiving assessment:				
35	How are source documents maintained at the site: (a)Electronic (b) Paper (c) Hybrid			
36	Will the NCG CRO Monitors/Auditor have Access to source documents and subject medical records?			

37	Does the Institute have some Medical Records retention and destruction policy? If yes, for how many years the medical records are retained?			
Comments:				

CRA comments about suitability of site for study:				
Site recommended	☐	Yes	☐	No
Recommended with conditions	☐	Yes	☐	No
Site not recommended	☐	Yes	☐	No
Please specify reason:				

Report reviewed and approved by:
Signature:
Date:

Annexure 4 - Site assessment visit follow up email template

To,

<The Principal Investigator name>
<Designation>
<Site details>

Reference: < Protocol Title and ID>

Dear <PI name>

Greetings!

I thank you and your staff for the cooperation extended during the site assessment visit held on <date>. I appreciate the time spared by you from your busy schedule for the visit.

The following were reviewed and discussed during the visit:

1. Study Protocol

2. Recruitment strategy
3. Ethics Committee set up
4. Site resource and manpower

Tour facilities were conducted at the following departments:

During the discussion it was agreed that the site would be able to enrol <number> of patients per month based on the eligibility criteria.

<If selected>we are pleased to inform you that your site has been considered for the conduct of the study. Requesting you to proceed with the Institutional Ethics Committee submission for approval of the study related documents

<If rejected> we regret to inform you that at present your site cannot be considered for the study. We look forward to working with you on other studies in future.

Please revert in case further information/assistance is required and kindly share the acknowledgement copy of the letter for our records.

Regards,

Yours sincerely,
Name of the CRA

Checklist of signed agreements that needs to be in place before proceeding for initiation of study.

1. Non – Disclosure Agreement
2. Grant offer letter
3. Authorship list