Attachment-2 Template for EC monitoring checklist

Clinical trial monitoring checklist for review of clinical research studies

Study Number		**Name of Department**	
Study Title			
Name, address and contact details of site			
Date of study initiation		**Date of EC approval**	
Date of monitoring visit		**Name of EC monitors**	
Opening meeting Conducted	Yes ☐ / No ☐		
	Members present during meeting are:		
	Name of EC monitors:	Name of Site members:	

1. Type for monitoring :

a) Routine :- Yes/NO (Please tick mark suitable option**)**

b) For cause (state reason) – Yes/No (Please tick mark suitable option)
(If yes then select applicable below option)

i) High number of protocol violation/deviation ii) Large number of SAE reporting

iii) Any significant non-compliance issues iv) High drop-out rate of study participant

v) Complaint from participants, any person vi) Vulnerable population

vii) Very low number of SAEs reported in comparison to other participating sites in a study.

viii) Large number of ongoing studies at the same timeframe by a particular investigator

x) Non-compliance to reporting requirements as per EC SOPs or Indian Clinical trial regulations/ guidelines

xi) Other (Specify):

b) Remote monitoring: Yes/No (Please tick mark suitable option)

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2. Last EC monitoring done, if any:	Yes ☐ Date of last visit: DD/MMM/YYYY	No ☐

3. Vulnerable population involved (Tick applicable box)	**1.** Pregnant women	☐	6. Illiterate	☐
	2. Children	☐	7. Handicapped	☐
	3. Elderly	☐	8. Economically & socially backward	☐
	4. Terminally ill	☐	9. Any Other	☐
	5. Fetus	☐		

4. Study Status (Tick applicable box):

1. Ongoing ☐ 2. *Completed ☐ 3.Enrollment Completed ☐

4. Follow-up, extension study ☐ 5. Suspended ☐ 6. Terminated ☐

In case of the response to the above question is option 5 or 6, kindly provide reason/s: ----------

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*Completed means last patient last visit of study

5. Recruitment status of study participants (Mention details):

1. Total participants to be recruited: ____
2. Screened: ____
3. Enrolled: ____
4. Discontinued (with reason): ____
5. Withdrawn (with reason):____
6. Screen Failures: ____
7. Completed: ____
8. Active: ____

Comments (if any):

6. Site Facility visit done: Yes ☐ / No ☐

Comments (if any):

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7. Informed Consent Process:

1. Type of consent taken:		
a) Consent- Oral		Yes ☐ / No ☐
b) Written		Yes ☐ / No ☐
c) Audio visual		Yes ☐ / No ☐
Comments (if any):		
Consent documents are checked for: _____ subjects *(Mention subject no.)*	Sub. No. XX, XX etc.	
Check following in case of audio-visual (AV) consent-		
1. Whether recording is conducted in a room conducive to recording (Good light, noise free, privacy ensured)?		Yes ☐ / No ☐ / NA ☐
Comments (if any):		
2. Whether information is given to the study participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded?		Yes ☐ / No ☐ / NA ☐
AV recordings are checked for: _____ subjects *(Mention subject no.)*		Sub. No. XX, XX etc.
Comments (if any):		
3. Are all AV recorded CDs are appropriately labelled and stored in password protected laptop/ desktop computer and/ or hard drive?		Yes ☐ / No ☐ / NA ☐
Comments (if any):		
Checkpoint for consent process of children:		
1. Are provisions made to obtain the assent of children of 7 years and above (where appropriate)?		Yes ☐ / No ☐ / NA ☐
Comments (if any):		
2. Type of assent taken: (Mention details): a. Oral assent		Yes ☐ / No ☐ / NA ☐
Comments (if any):		
3. Assent documents are checked for: _____ children *(Mention total subject no.)*		Sub. No. XX, XX etc.

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Comments (if any):	
4. Are provisions available at site to obtain assent process of children less than 7 years of age (where appropriate)?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
5. Are provisions made to protect participants' privacy and the confidentiality of information regarding consent procedures?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
6. Consent from parents /LAR is taken?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
7. Is consent of both parents necessary?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
Checkpoint for consent process of pregnant women:	
1. Is the woman's consent or the consent of her legally authorized representative obtained in accordance with the informed consent provisions?	Yes ☐ / No ☐ / NA
Comments (if any):	
2. Is the woman or her legally authorized representative, as appropriate, fully informed regarding the reasonably foreseeable impact of the research on the	Yes ☐ / No ☐ / NA
Comments (if any):	
General checkpoint for consent document and consent process	
1. Is the recent version of ICD used for consent is after EC approval?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
2. Whether ICF is signed and dated by subject and by PI?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
3. Whether copy of patient information sheet was given to patient?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
4. Are source notes of Informed consent process maintained?	Yes ☐ / No ☐ / NA ☐

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Comments (if any):	
5. Whether any of the informed consent process was observed by EC monitor during monitoring process?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
6. Is there process for obtaining, documenting, recording and maintaining source notes of re-consent process if there are any amendments in ICD?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
7. Are all steps taken to ensure privacy and confidentiality of vulnerable participants?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
8. Is Informed Consent process well documented and there is no undue coercion or incentive for participation?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
9. Whether in case of illiterate subjects or illiterate representative of a subject, there are signature and details of an impartial witness?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
10. Whether witness/ signature is being personally dated (If applicable)?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
11. Whether re-consenting is done in case of any changes in ICF, if any?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
8. <u>Checkpoints related to site master file:</u>	
1. Are all investigator meeting related documents compiled in file?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
Is recent EC approved version of protocol used? Mention protocol version no. and date:_____	Yes ☐ / No ☐ / NA ☐

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Comments (if any):	
2. Have the subsequent protocol amendments been approved by DCGI? Mention approval dates:	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
3. Are all regulatory application and approval documents compiled in file i.e. study approval, CTRI registration, financial disclosure?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
4. Are the present study team members as per the list approved by the IEC:	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
5. Whether study contact details of site staff (PI, Co-Investigator/sub-Investigator and CRC) are present?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
6. Whether Sponsor contact details are present?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
7. Whether CV, GCP, eCRF training certificate, study document training certificate and MRC of PI are present?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
8. Whether CV, GCP, study document training certificate and MRC of co-investigators/sub-investigators/study physicians are present?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
9. Whether CV, GCP, eCRF training, study document training certificate (If applicable) of other site staff are present?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
10. Are delegation log of site staff /study team are present? And Whether they are performing their duties as per delegation log?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
11. Are all version of informed consent documents compiled in file?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
12. Are all translated and back translated documents compiled in file with translation certificates?	Yes ☐ / No ☐ / NA ☐

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Comments (if any):	
13. Whether informed consent has been obtained from each subject prior to participation of the subject in study?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
14. Whether inclusion and exclusion criteria followed during eligibility check?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
15. Any adverse events found and reported in CRF?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
16. Is CRF up to date and data in CRF corresponds to the source documents (Source file of participant):	Yes ☐ / No ☐ / NA ☐
Comment:	
17. Whether all SAE are reported to EC within timelines specified by NDCT rules 2019?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
18. Are there any SAE? If yes, mention number of SAE occurred at site: _____	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
19. Mention the criteria of SAE reported: Death And/or Other than Death	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
20. Whether reported SAEs are related to clinical trial:	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
21. If related, compensation has been paid as per timelines specified by licensing authority?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
22. Are there emergency facilities available to handle any emergency situation?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
23. Last monitoring /auditing of the site by sponsor/CRO done if any:	Yes ☐ / No ☐ / NA ☐

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Date of last monitoring/auditing _____ Follow-up report of monitoring/auditing sent to site_____	
Comments (if any):	
24. Are all monitoring/auditing related reports and communication filed in site file?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
25. Whether lab test/investigations are done from accredited lab? Mention accreditation validity date:	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
26. Whether adequate quantity of drug received/dispensed/destroyed with adequate storage conditions along with IP shipment documents?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
27. Are IP storage area are locked or under access control provision?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
28. Whether adequate record of quantity of test drug received, dispensed, drug accountability log is maintained?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
29. Is IP code breaking process available at site and is documented in study manual in case of blinded study?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
30. Are investigation product containers appropriately labelled? Mention expiry date of IP:	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
31. Are all Interactive Web/Voice Response System Manual (IWRS/IVRS), IP manual, IP logs and forms, & Related documents Communication filed in site file?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
32. Are electronic or hand-written temperature logs available for investigational products?	Yes ☐ / No ☐ / NA ☐

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Comments (if any):	
33. Are there any violation/deviation/non-compliance of protocol? If yes then whether the same is notified to EC, sponsor and regulatory authority or not?	Yes ☐ / No ☐ / NA ☐ Yes ☐ / No ☐ / NA ☐
Comments (if any):	
34. Whether travel allowance/reimbursement given to the participant for each visit? a) How much is the travel reimbursement amount as per ICF? Rs. _____ b) Is Visit schedule of participant followed as per protocol?	Yes ☐ / No ☐ / NA ☐ Yes ☐ / No ☐ / NA ☐ Yes ☐ / No ☐ / NA ☐
Comments (if any):	
35. Is insurance valid: Validity period: _____	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
36. Are site SOPs available (Investigator and site)?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
37. In case of vaccines, is a spillage SOP available and the study team trained to handle such an incidence?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
38. Are there any new information available that changes risk-benefit analysis reported to EC?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
39. Are source files of all subjects available and are in proper condition to ensure completeness, legibility, accessibility of the documents	Yes ☐ / No ☐ / NA ☐
40. Source notes are checked for: _____ subjects *(Mention subject no.)*	Sub. No. XX, XX etc.
Comments (if any):	
41. Does interaction with PI and study team members happens on regular basis to confirm proper understanding of study activity and uniformity as per	Yes ☐ / No ☐ / NA ☐

protocol?	
Comments (if any):	
42. Whether any participant recruitment process like advertisement, letter, poster, notices were followed?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
43. Are all study specific logs and forms like screening and enrolment log, subject identification log, site visit log, PD log are compiled in file?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
44. Whether site has submitted CSR notification to EC after study completion? *(Applicable for only completed studies)*	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
45. Whether site maintains all communications with sponsor, EC and Licensing Authority?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
46. Is adequate space available for document retention and documents are maintained properly for the period as specified?	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
47. Whether the archival access controlled or restricted to authorized personnel.	Yes ☐ / No ☐ / NA ☐
Comments (if any):	
48. Is electronic data processing is done by authorized person?	Yes ☐ / No ☐ / NA
Comments (if any):	

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49. Whether list of authorized persons to make changes is maintained	Yes ☐ / No ☐ / NA
Comments (if any):	
50. How well are the participants protected? Good ☐ Fair ☐ Not Good ☐	
Comments (if any):	
51. Any other remarks:	
52. Final remarks by EC monitors:	

	Name	**Sign and Date** **(DD-MMM-YYYY)**
Checklist filled by*: **(EC Monitor-1)**		
Checklist filled by: **(EC Monitor-2)**		
Checklist filled by: **(EC Monitor-3)**		

**Details of EC monitors can be added or removed as per requirement.*