

ANNEXURE: 01

AF/IEC/01/19/V7.1

Checklist for IEC members Monitoring Visit

Monitoring Visit DATE & TIME	PROTOCOL NO.	PI's Name & Qualification

Study status: Enrolling/Follow up/Data cleaning

1	Subject Details:	
a	Total Enrolled :	
b	Nos. on-going:	
c	Nos. completed:	
d	Nos. dropout:	
2	Subject Interview (if planned):	
a	Awareness of the study:	Y/N
b	Awareness of the rights:	Y/N
c	Satisfied with the process	Y/N
3	Appropriate Protocol facilities (as required by the protocol and regulations) :	Y/N
4	Study protocol and related documents:	
a	Use of recent (EC approved) version of protocol	Y/N
b	Use of recent (EC approved) version of informed consent document	Y/N
c	Informed consent process complete(including source documentation)	Y/N
d	Is the delegation proper (as respect to qualification and experience)	Y/N
e	SAE reporting timely and complete (if any)	Y/N
5	Investigational product:	
a	Logs upto date	Y/N
b	Safekeeping with controlled access and temperature maintenance	Y/N
c	Clear delegation	Y/N
6	Ethical concerns:	

a	Grievance handling explained and the same documented	Y/N
b	Subject/s remuneration done as due	Y/N
7	Comments (if any) :	
8	Corrective action by PI on the IEC monitoring findings	Y/N

REPORT ON INSPECTION OF CLINICAL TRIALS BY EC MEMBERS

I. SUMMARY:

Key Dates	Subject Enrollment Status	Latest Versions & Date	Key Team Members Name & Qualification, GCP Trng etc.
EC Approval: Study Initiation: First-Subject Screened On:	Screened: Randomized: Withdrawn /Dropout: Ongoing:	Protocol: ICF: IB:	Co-Investigator: Sub-Investigator: Coordinator:

Documents Reviewed:

- Investigator’s undertaking_____
- Signed Informed Consents *: _____
- Source Documents *: _____
- Monitoring/ auditing reports:_____
- Investigational Product use, storage & reconciliation records: _____
- Delegation of Responsibilities Log: _____
- Subject Enrolment Log (equitable distribution):_____
- Clinical trial Agreement, Indemnity & Insurance: _____
- Payments to Subjects*: _____
- Investigator’s File & Communications file:_____
- EC Protocol File:_____

II. FINDINGS:

III. SUGGESTIONS:

EC MEMBERS

SIGNATURES: