

ANNEXURE:01

AF/IEC/01/05/V7.1

Independent Consultant Review Report Form

Protocol Number:

Date (D/M/Y):

Name of Principal Investigator:

Independent consultant's Name:

Mark and comment on whatever items applicable to the study.

1.	Objectives of the Study <input type="checkbox"/> Clear <input type="checkbox"/> Unclear	
2.	Background and Rationale <input type="checkbox"/> Sufficient <input type="checkbox"/> insufficient	Comment:
3.	Methodology Clear <input type="checkbox"/> Unclear <input type="checkbox"/>	Comment
4.	Study Design and Sample size <input type="checkbox"/> Appropriate Inappropriate	Comment:
5.	Inclusion Criteria <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	Comment:
6.	Exclusion Criteria <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	Comment:
7.	Statement for protection of rights and interests of Vulnerable Participants <input type="checkbox"/> Clear <input type="checkbox"/> Unclear	Comment:
8.	Voluntary, Non-Coercive Recruitment of Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
9.	Are Qualifications and experience of the Principal Investigator appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
10.	Facilities and infrastructure of Participating Sites <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	Comment:
11.	Risk-benefit analysis <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
12.	Vulnerability assessment <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
13.	Benefit to Local Communities <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable	Comment: