

**Annexure 7**

***Letter to IEC Members requesting Initial Review with study assessment form***

Dear member,

The next meeting of the IEC will be held on XXX at XXX in XXXX.

Please note that the package of research proposals is to be circulated in the following order. You are requested to review the same preferably within 5 working days of receiving the package. Please review the protocol and related documents as per the guidelines attached with Annex 1 and provide your comments below and fill the study assessment form (for primary reviewers only) provided with the package (AX 02/SOP 7A/VI). Kindly confirm your availability for the meeting.

<b>Name of Member</b>	<b>Date of Receipt</b>	<b>Signature</b>	<b>Attending meeting (Y/N)</b>

Protocol Number : (as per IEC records)		Date of receipt at IEC office after review by member (DD/MM/YY):	
Protocol Title :			
Name of the Principal Investigator		Designation	Department
Name of the Reviewer:			

**Comments:**

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**Study Assessment Form to be used by the Primary Reviewer**

Protocol Number :	Date (DD/MM/YY):
Protocol Title :	
Principal Investigator:	
Department :	
No. of Participants at the site:	No. of Study site(s):

**Mark and comment on whatever items are applicable to the study.**

1	Objectives of the Study <input type="checkbox"/> clear <input type="checkbox"/> unclear	What should be improved?
2	Need for Human Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
3	Methodology: <input type="checkbox"/> clear <input type="checkbox"/> unclear	What should be improved?
4a	Background Information and Data <input type="checkbox"/> sufficient <input type="checkbox"/> insufficient	Comments:
4b	Risks and Benefits Assessment <input type="checkbox"/> acceptable <input type="checkbox"/> unacceptable	Comments:
4c	Inclusion Criteria <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate	Comments:
4d	Exclusion Criteria <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate	Comments:
4e	Discontinuation and Withdrawal Criteria <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate	Comments:
5	Involvement of Vulnerable Participants: <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
6	Voluntary, Non-Coercive	Comments:
	Recruitment of Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	
7	Sufficient number of participants? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
8	Control Arms (placebo, if any) <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
9	Are Qualifications and experience of the Participating Investigators appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
10	Disclosure or Declaration of Potential Conflicts of Interest <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
11	Facilities and infrastructure of Participating Sites <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	Comments:

12	Community Consultation: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA	Comments:
13	Benefit to Local Communities <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
14	Contribution to development of local capacity for research and treatment <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
15	Availability of similar Study / Results: <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
16	Are blood/tissue samples sent abroad? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
17	Are procedures for obtaining Informed Consent appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
18	Contents of the Informed Consent Document: <input type="checkbox"/> clear <input type="checkbox"/> unclear	Comments:
19	Language of the Informed Consent Document: <input type="checkbox"/> clear <input type="checkbox"/> unclear	Comments:
20	Contact Persons for Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
21	Privacy & Confidentiality <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:
22	Inducement for Participation <input type="checkbox"/> Unlikely <input type="checkbox"/> Likely	Comments:
23	Provision for Compensation for Participation <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate	Comments:
24	Provision for Treatment for Study-Related Injuries <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate	Comments:
25	Provision for Compensation for Study Related Injuries <input type="checkbox"/> appropriate <input type="checkbox"/> inappropriate	Comments:

Reviewer's Signature with date: \_\_\_\_\_