

**ANNEXURE 4**

**Institutional Ethics Committee, B. J. Medical College & Civil Hospital  
Proposal Assessment Form for IEC Members**

Protocol Number:		Date (D/M/Y)	
Protocol Title:			
Principal Investigator:			
Co-Investigator/s:			
Department/s:			
No of participants at the site		No of study site(s):	

**Mark and comment on whatever items applicable to the study:**

1	Objectives of the study a) Clear            b) Unclear	What should be improved?
2	Is the Methodology well written and understandable? a) Yes            b) No	Comment:
3	What should be improved?	
3a	Background information and data a) Sufficient    b) Insufficient	Comment:
3b	Risks and Benefits Assessment a) Acceptable   b) Unacceptable	Comment:
3c	Inclusion Criteria a) Appropriate   b) Inappropriate	Comment:
3d	Exclusion Criteria a) Appropriate   b) Inappropriate	Comment:

## The Institutional Ethics Committee

### B. J. Medical College & Civil Hospital, Ahmedabad

3e	Assessment parameters a) Appropriate b) Inappropriate	
3f	Discontinuation and Withdrawal criteria a) Appropriate b) Inappropriate	Comment:
3g	Recording and analysis of results a) Appropriate b) Inappropriate	
4	Involvement of vulnerable participants: a) Yes b) No	Comment:
5	Sample size appropriate to achieve the objective/s? a) Yes b) No	Comment:
6	Control Arms (placebo, if any) a) Yes b) No	Comment:
7	Are qualification & experience of the Participating investigators appropriate? a) Yes b) No	Comment:
8	Disclosure or declaration of potential Conflicts of Interest a) Yes b) No c) NA	Comment:
9	Facilities and infrastructure of participating sites a) Appropriate b) Inappropriate	Comment:
10	Benefit to local communities? a) Yes b) No c) NA	Comment:
11	Availability of similar study/results a) Yes b) No	Comment:
12	Are blood/tissue samples sent abroad? a) Yes b) No	Comment:
13	Are procedures for obtaining Audio-visual informed consent appropriate? a) Yes b) No	Comment:

**The Institutional Ethics Committee**  
**B. J. Medical College & Civil Hospital, Ahmedabad**

14	Contents and language of the Informed Consent Document (ICD): a) Clear                      b) Unclear	Comment:
15	Contact person for participants mentioned? a) Yes                      b) No	Comment:
16	Privacy & confidentiality maintained? a) Yes                      b) No	Comment:
17	Has provision been made for compensation for participation? a) Yes                      b) No	Comment:
18	Is the compensation for participation? a) Appropriate      b) Inappropriate	Comment:
19	Has provision been made for treatment for study/related injuries? a) Yes                      b) No	Comment:
20	Is the provision for compensation for study/related injuries? a) Appropriate      b) Inappropriate	Comment:

Reviewer's Signature with date: