ANNEXURE: 02 **(AF/IEC/02/06/V7.3)**

Study Assessment Form for New Protocol

Protocol Number: Date (D/M/Y):

Name of Principal Investigator:

Reviewer's name with Designation:

Mark and comment on whatever items applicable to the study.

Sl.No	Particulars	Comments
1.	Objectives of the Study ☐ Clear ☐ Unclear	
2.	Background and Rationale ☐ Sufficient ☐ insufficient	
3.	Methodology ☐ Clear ☐ Unclear	
4.	Study Design and Sample size ☐ Appropriate ☐Inappropriate	
5.	Inclusion Criteria ☐ Appropriate ☐Inappropriate	
6.	Exclusion Criteria ☐ Appropriate ☐Inappropriate	
7.	Statement for protection of rights and interests of Vulnerable Participants ☐ Clear ☐Unclear	
8.	Voluntary, Non-Coercive Recruitment of Participants ☐ Yes ☐ No	
9.	Are Qualifications and experience of the Principal Investigator appropriate? ☐ Yes ☐ No	
10.	Facilities and infrastructure of Participating Sites ☐ Appropriate ☐ Inappropriate	
11.	Involvement of Local Researchers and Institution in the Protocol Design, Analysis and dissemination of Results ☐ Yes ☐ No	
12.	Risk-benefit analysis ☐ Yes ☐ No	
13.	Vulnerability assessment ☐ Yes ☐ No	
14.	Benefit to Local Communities ☐ Yes ☐ No ☐ Not applicable	
15.	Are blood/tissue samples sent abroad? ☐ Yes ☐ No	

16.	CTRI No/Document ☐ Yes ☐ No	
17.	Final Clinical Trial Aggrement ☐ Yes ☐ No	
18.	Insurance Policy(Study Specifc) ☐ Yes ☐ No	
19.	DCGI submission letter/Approval Letter ☐Yes ☐ No	
Participant Information Sheet and Informed Consent Documents		
Sl. No	**Points**	**Comments**
1.	Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐No	
2.	Contents of the Informed Consent Documents Translation and backatranlation certificates ☐ Clear ☐Unclear	
3.	Language of the Informed Consent Document: Kannada, Hindi, English and Marathi ☐ Clear ☐Unclear	
4.	Risks/ inconveniences mentioned clearly ☐ Yes ☐ No	
5.	Period of storage of biological samples ☐ Yes ☐ No	
6.	Are possible benefits mentioned ☐ Yes ☐ No	
7.	Patient dairy and information sheet (PIS) ☐ Yes ☐ No	
8.	Privacy & Confidentiality ☐ Yes ☐ No	
9.	Provision for Medical / Psychosocial Support/Trial related injuries ☐ Appropriate ☐Inappropriate	
10.	Provision for Compensation per subjects in ICFs-TA(INR)/ ☐ Appropriate ☐Inappropriate	

List of additional documents required (if applicable)

Reviewer Signature