

Protocol Number:

Date (D/M/Y):

Principal Investigator (Name and Designation)

Protocol version and date:

Reviewer's name with Designation:

Sl.No	Particulars	Indication (Yes-No)		Comments
1.	Objectives of the Study			
2.	Background and Rationale			
3.	Methodology			
4.	Study Design and Sample size			
5.	Inclusion Criteria			
6.	Exclusion Criteria			
7.	Voluntary, Non-Coercive Recruitment of Participants			
8.	Is Travel Allowance Mentioned in ICD?			
9.	Are Qualifications and experience of the Principal Investigator appropriate?			
10.	Facilities and infrastructure of Participating Site			
11.	Involvement of Local Researchers and Institution in the Protocol Design, Analysis and Dissemination of Results			
12.	Risk-benefit analysis			
13.	Benefit to Local Communities			
14.	Are blood/tissue samples sent abroad?			
15.	CTRI Document			
16.	Final Clinical Trial Agreement & Budget Sheet			
17.	Insurance Policy(Study/site Specific)			
18.	DCGI submission letter			
19.	DCGI Approval Letter			
20.	Statement for protection of rights and interests of Vulnerable Participants. If yes. Please refer SOP for Research involving Vulnerable Population/Annexure			
a.	Children (up to 18 years);	Yes	No	NA
b.	Students, employees or residents, subordinates, defense service personnel require special considerations			
c.	Genetic research			
d.	Terminally ill patients			

e.	Women special situations- Pregnant or lactating women			
f.	Tribal and marginalized communities			
g.	Economically and socially disadvantaged			
21.	Research on human Genetics and research (if applicable)			
a.	Types of Consent Broad consent _____ Tiered Consent _____ Specific consent ____ Delayed consent ____			
b.	Bionabking facilities and SOPs			
c.	Data transfer certificate or material transfer Agreement-DTA-MTA			
d.	Types of samples as per ICMR guidelines-2017			
e.	Anonymous or unidentifiable			
	Anonymous			
	Identifiable			

List of additional documents required (if applicable)

IEC office use only	
Reviewer name signature and date	
Member Secretary/Chairperson signature with date	