Research Study Protocol Assessment Form for Reviewers

Samarth IEC Proposal ID No:		Date (D/M/Y):		
Protocol Title:				
Protocol version no. & date:				
IEC Member name:				
Need for the study (Check Background & Justification sections of protocol)				
		Yes	**No**	**Comment**
1	Background and justification - sufficient?			
2	Literature review – adequate?			
3	Need for human participants justified?			
4	Does the study contribute to development of local capacity for Research / Treatment?			
Scientific value (Check Methods section of protocol)				
5	Methodology – clear and well-described?			
6	Objectives of the study – clear?			
7	Study Design - appropriate?			
8	Is the use of placebo justified?			
9	Inclusion Criteria – appropriate?			
10	Exclusion Criteria – appropriate?			
11	Laboratory methods – clear, well defined and feasible?			
12	Follow-up procedures well defined?			
13	Are study end points well defined?			
14	Are unbiased assessments used?			
15	Sample size adequate?			
16	Statistical methods proposed – appropriate?			
17	Is there a provision for interim analysis in interventional studies?			
Fair subject selection (Check Methods section of protocol)				
18	Inclusion Criteria – appropriate?			
19	Exclusion Criteria – appropriate?			
20	Is the recruitment of			

	participants voluntary, non-coercive?			
21	Is there an inducement for participation?			
22	Is participant deception avoided?			
Favourable risk-benefit ratio				
23	Risks and benefits assessment – acceptable?			
24	Are predictable risks minimized?			
25	Tests and procedures that are more than minimal risk cautiously used?			
26	Provision for medical/psychosocial support?			
27	Are participant discontinuation and withdrawal criteria appropriate?			
28	Provision for treatment of study-related injuries?			
29	Provision for compensation (where applicable)?			
30	Does the study benefit the individual?			
31	Does the study benefit the local community?			
Respect for human subjects				
32	Privacy and confidentiality ensured			
33	Are vulnerable populations involved?			
33.1	If yes, is it justifiable to conduct the study in that population?			
34	Are blood/ tissue samples sent abroad?			
34.1	If samples are sent, is it mentioned in the information and consent form?			
35	Is the fate of the samples once study is over mentioned?			
36	Is appropriate consent included for			

	storage of biological samples?			
Others				
37	Are facilities and infrastructure of Participating Sites appropriate?			
38	Is community consultation addressed if required?			
39	Is disclosure or declaration of potential Conflicts of Interest addressed?			
40	Is the PI adequately qualified to do the study?			
41	Are qualification and experience of the Participating Investigators appropriate?			
Comments:				
Decision: *Approved /Minor modification(s)/Major modification(s)/Rejected*				
Signature of the reviewer:				
Date (DD/MM/YY):				