Annexure 1: Research funded by foreign agencies/companies

		Applicable		Section in Protocol & page
		Yes	**No**	
1.	Justification for conducting the study in Sri Lanka	☐	☐	
2.	Relevance of the study to Sri Lanka	☐	☐	
3.	Post research benefits to Sri Lanka	☐	☐	
4.	The steps taken to mitigate effects on the environment and on cultural and social customs, practices, and taboos in Sri Lanka	☐	☐	
5.	The sharing of rights to intellectual property	☐	☐	
6.	The fate of data and biological samples including whether they will be transferred abroad and what will happen to them after the conclusion of the study	☐	☐	
7.	How the results of research will be conveyed to relevant authorities in Sri Lanka	☐	☐	
8.	The agreement between the sponsor/funding agency and the investigator	☐	☐	Please Attach
9.	The materials transfer agreement, if biological material is to be transferred abroad	☐	☐	Please Attach

Annexure 2: Clinical trials

		Applicable		Section in Protocol & page
		Yes	No	
1	What phase clinical trial is being conducted?	☐	☐	
2	Is it a multicentre trial? If yes, list the other trial sites	☐	☐	
3.	Justification for withdrawing any therapy from participants to prepare them for the trial	☐	☐	
4.	Justification for withholding standard therapy from trial participants (e.g. control group)	☐	☐	
5.	Justification for providing care which is not the standard of care	☐	☐	
6.	Procedure for dealing with adverse events	☐	☐	
7.	Procedure for reporting adverse events	☐	☐	
6.	Measures in place for management of trial related injuries	☐	☐	
7.	Provisions for safety monitoring	☐	☐	
8.	Provisions/criteria for termination of the trial	☐	☐	
9.	Provisions for making the trial drugs and therapeutic measures available to participants after the trial if found to be effective	☐	☐	
10	Details of data Safety Monitoring Board	☐	☐	If applicable, please provide details below
	Name and Designation of Members			**Role**
11	Details of Indemnity and Insurance coverage for participants, investigators and ethics committee	☐	☐	If applicable, please provide details below
12	If Patient recruitment is not taking place in foreign collaborating institution	☐	☐	If YES, please explain why
13	Are the participants paid?	☐	☐	If YES, amount of money per participant per

				visit
14	Are the investigators paid?	☐	☐	If YES, by whom and the amount
15	Is the clinical trial registered with a clinical trials registry?	Yes ☐		No ☐
	If Yes			
	Name of register			
	Registration No.			
16	Has this protocol been approved by the Subcommittee on Clinical Trials (SCOT) of the Ministry of Health, Sri Lanka.	Yes ☐		No ☐
	If Yes			
	Approval No.			

Please attach following documents (if applicable):

Ethics approval from the sponsoring country or country of the overseas principal investigator

Curriculum vitae of all members of the DSMB

Related documentary evidence

Annexure 3: Community based research

		Applicable		Section in Protocol & page
		Yes	No	
1.	The impact and relevance of the research on the community in which it is to be carried out	☐	☐	
2.	The steps taken to consult with the concerned community during the design of the research	☐	☐	
3.	The procedure used to obtain community consent	☐	☐	
4.	The contribution to capacity building of the community	☐	☐	
5.	The procedure for making available results of research to the community	☐	☐	

Annexure 4: Establishment and maintenance of research database

		Applicable		Section in Protocol & page
		Yes	No	
1.	A list of data collected	☐	☐	
2.	Method of data collection	☐	☐	
3.	Type of the research projects to be undertaken	☐	☐	
4.	Procedure to obtain consent from patients for use of data	☐	☐	
5.	Data management process (including governance structure)	☐	☐	
6.	The methods employed to ensure data security	☐	☐	
7.	Procedure for amendment and termination	☐	☐	
8	Data collection and/or follow-up period	☐	☐	