

**FORMAT FOR SUBMISSION OF PROJECTS FOR CLEARANCE BY ETHICS
COMMITTEE OF S-VYASA**

1. Title of the Study		
2. Name of Investigators / co-Investigators with designation and division	Signatures	No. of Projects already with Investigator
2.1	2.1	
2.2	2.2	
2.3	2.3	
2.4	2.4	
2.5 (Expand if there are more co-investigators)	2.5	
3. Objectives of the study	3.1	
	3.2	
	3.3	
	3.4	
	3.5	
4. Justification for conduct of this study		
5. Methodology		
5.1. SAMPLE SIZE and the BASIS (Kindly indicate the relevant statistical assumptions and way in which the sample size has been obtained)		
5.2. Inclusion criteria	a)	
	b)	
	c)	
	d)	
5.3. Exclusion criteria	a)	
	b)	
	c)	
	d)	
5.4. Control(s)		
5.5. Study design		
5.6. Assessment		
5.7. Investigations related to projects		
5.8 Permission to use copyrighted Questionnaire/proforma		

5.9 Others		
6.a.) Methods adopted for standardization of the proposed intervention/ treatment protocol		
6.b.) Standard therapy/ Primary Intervention		
7. Plans to withdraw standard therapy during conduct of research (Underline the option)	Yes/No	Remarks:
8. Plan for provision of coverage of medical risk (s) during the study period		
9. How you will maintain confidentiality of subject?		
10.a) Total Budget (Approx. in INR)		
10.b) Who will bear the cost of investigation/drugs/intervention (Highlight the option)	1. Subjects 2. Investigator 3. Private Funding 4. Other Agencies (Name)_____	
11. Participant Informed Consent Form (Underline the options if you have attached)	<ul style="list-style-type: none"> • Attached English version • Attached Local language version • <i>Certified that Local language version is a true translation of English version</i> 	
12. Conflict of interest for any other Investigator(s) (if yes, please explain in brief)	Yes/No	Explanation (if Yes)
12.a) Is there a financial conflict of interest?		
12.b) I or my immediate family members own or control shares of the concerned company		
12.c) I or my immediate family members have a proprietary interest in the product that I have contracted to test		
12.d) I or my immediate family members have a financial interest in the sponsoring company or product being studied		
12.e) I or my immediate family members have received material/other benefit from the sponsoring company		
13. Has work on this project started? (Underline the option)	Yes/No (Please enclose a separate certificate to this effect).	
14. Attached documents (if any) (Underline the option)	14.1 Covering letter, through proper channel.	(Yes/No)
	14.2 Copy of the detailed protocol is mandatory.	(Yes/No)

	14.3 Brief CV of all the Investigators (including No. of projects with Principal Investigator)	(Yes/No)
	14.4 Undertaking that the study shall be done in accordance with ICMR and GCP guidelines	(Yes/No)
	14.5 In case of multicentre study, IEC clearance of other centres must be provided	(Yes/No)
	14.6 Definite undertaking as to who will bear the expenditure of injury related to the project	(Yes/No)
	14.7 In case an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)	(Yes/No)
	14.8 Permission as mentioned in column 5.8	(Yes/No)
	14.9 Certificate /undertaking as mentioned in column 13	(Yes/No)
	14.10 Others	(Yes/No)
15. In case of clinical trials CTRI status		
16. Are Vulnerable subjects included? Please state Yes or No against Each item (Underline the option)		
Pregnant women Yes/No	Terminally ill Yes/No	Special Groups Yes/No
Children (below 18 years) Yes/No	Seriously ill Yes/No	Students Yes/No
Elderly (60 years and above) Yes/No	Service providers Yes/No	Physically Challenged Yes/No
Foetuses Yes/No	Economically Backward Yes/No	Captives Yes/No
Prisoners Yes/No	Socioeconomically disadvantaged individuals Yes/No	Institutionalized Yes/No
Destitute Yes/No	Mentally challenged Yes/No	Armed Forces Yes/No
Individuals with Cognitive or Intellectual Disabilities Yes/No	Individuals with limited literacy or language proficiency Yes/No	Ethnic or racial minorities Yes/No

Refugees and Displaced Persons Yes/No	Homeless Individuals Yes/No	Communicable disorders Yes/No
Sexual and Gender Minorities Yes/No		
Others (Specify)		
17. Has the study been reviewed by the (Comprehensive Project Evaluation Board) CPEB? Yes/No (Underline the option)		
CPEB Number:		
CPEB Risk Category:		
18. Nature of the Project: 1. BSc 2. MSc 3. PhD 4. MD 5. BNYS 6. Faculty Project 7. Funded Project (Underline the option)		