YENEPOYA ETHICS COMMITTEE 2
-2 Floor
Yenepoya Dental College
yec2@yenepoya.edu.in
Ext. Phone Number – 2063

YEC2/Ann2B/SOP06/v1

Checklist for Protocol Submission to Yenepoya Ethics Committee 2 for clearance

Please tick in appropriate cells. Submit a duly completed and signed copy of the checklist to the YEC2 after SRB approval along with the protocol

No	Document			Yes	No	Reason for "No"	YEC 2 Secretariat to confirm
1	Letter to Member Secretary Yenepoya Ethics Committee 2 requesting ethical clearance						
2	Project proposal – 1 hard copy						
3	Project proposal – soft copy sent by e-mail to yec2@yenepoya.edu.in *(Please note that there should be no discrepancy between the hard copy and the soft copy submitted)*						
4	Brief signed copy of Curriculum Vitae (CV) of ALL Investigators (including PI, Co-PI, Guide) not more than two pages focusing on research activities and research training						
5	Fee for review (not applicable for YU students/faculty)						
6	Approval of Scientific Review Board (SRB) *(Please note that the Principal Investigator (PI) and the guides are responsible to ensure that there is no discrepancy between the hard copy and the soft copy of the protocol submitted to the YEC2 and that approved by the SRB)*						
7	Detailed Protocol						
	a	Title					
	b	Objectives and hypothesis (research question)					
	c	Background					
	d	Justification / Need for the study					
	e	Review of literature					
No	**Document**			**Yes**	**No**	**Reason for "No"**	**YEC2 Secretariat to confirm**
	f	Detailed methodology					
		i	Study design: Prospective/Retrospective Observational/Interventional/etc				

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		ii	Site (s) of study *(Attach permission letters from concerned authorities if the study is to be conducted outside the ambit of Yenepoya University or provide a copy of the MoU)*				
		iii	Sample size: (with justification)				
		iv	Sampling technique				
		v	Inclusion criteria (if any)				
		vi	Exclusion criteria (if any)				
		vii	Randomization (if any)				
		viii	Details of clinical examination (if any) *(attach **anonymised** clinical data collection pro forma)*				
		ix	Details of questionnaire (if any)*(attach anonymised questionnaire wherever necessary with translation)*				
		x	Details on discontinuation/withdrawal of participant from study criteria (Example: Occurrence of complications or non compliance by the participant)				
		xi	Vulnerable participant (Example: Children, pregnant women, Psychiatric illness etc.) (if yes, provide justification)				
		xii	Use of placebo (if yes, provide justification)				
		xiii	Details of investigations (if any) and how the sample will be obtained and processed				
No	**Document**			**Yes**	**No**	**Reason for "No"**	**YEC 2 Secretariat to confirm**
		xiv	Whether samples will be sent outside the institution /processed abroad *(Provide permission letter from concerned authority)*				
		xv	Details on how samples will be destroyed				
		xvi	Details on whether the data/samples/tissues are likely to be shared				

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		xvii	Details of data tabulation and statistical methods to be employed				
	f	Time line					
	g	Budget/Expenditure and how the finances will be met (Name of the sponsor, budget allocated and justification)					
	h	Expected outcome/benefit to participants, investigators, institution and society					
8.	Ethical Issues						
	a	Recruitment of participants will start only after the ethical clearance					
	b.	Protection of vulnerable participants					
	c.	Disposal of tissue samples					
	d.	Maintenance of privacy of participants					
	e.	Maintenance of confidentiality of data					
	f.	Sharing of samples/data					
	g	Compensation to participants					
	h.	Ensuring standard of care to participants					
	i.	Redacting of MRD files/Radiographic material/histopathology slides/blood and tissue samples					
No	**Document**			**Yes**	**No**	**Reason for "No"**	**YEC 2 Secretariat to confirm**
9	Informed consent document in English						
	a.	Is the language simple and clear such that an eight standard student (English or vernacular) will find easy to understand					
	b	Whether contact person details are provided in the ICF					
	c	Whether the PG/PI has assured privacy of participants & confidentiality					
	d	Has the PG/PI mentioned compensation for time taken to participate					

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	e	Has the PG/PI mentioned how study-related injuries will be managed				
	f	Has the PG/PI mentioned how such study – related injuries will be Compensated				
	g	Has the PG/PI made specific mention of whether data will be shared and how				
	h	Has the PG/PI taken consent for publication				
	i	In case a participant is illiterate, has the PG/PI made provision for an independent witness to countersign				
6	Informed consent documents in Regional languages					
7	Participant Information Sheet on a separate sheet (English & Regional language)					
8	Any other Documents submitted (please fill reverse)					

DECLARATION BY THE PG STUDENT AND THE GUIDE /PRINCIPAL INVESTIGATOR

I, Dr. (Name of PG/PI) and my guide, Dr. (Name of the Guide) do hereby declare that this study will be carried out by the PG student and supervised by the guide upholding the concepts in the Declaration of Helsinki and simultaneously abiding by the latest ICMR guidelines(2017).

Place: Sign of PI:

Date: Sign & Seal of the Guide