Rahbar College of Dentistry

Ethical Review Committee (ERC)
Research Ethics Review Evaluation Form

Application No: **Date:**

Title: _____

Principal Investigator: _____

Instruction for Reviewer:

Please write brief meaningful statements for each item, and indicate at the right column:

Y – Agree/ stated in the paper

N – Not agree or stated in the paper

R – Referral to an expert

NA – Not applicable/ Not necessary in the paper

	Is all the documentation provided?	
	Scientific importance and validity	
1	Will the study lead to improvements in human health and wellbeing?	
2	If this is an intervention study, can it be practically implemented?	
3	Are the objectives stated clearly?	
4	Do the sample size and statistical techniques have adequate power to produce reliable and valid results using the smallest number of research participants?	
	Reviewer's comment:	
	Assessment of Risks/Benefits	
1	Is the involvement of human participants necessary to obtain the required information of research project?	
2	Is the medical/psychological support for the participants adequate?	
3	Does the study site have adequate support staff, facilities and required emergency procedures?	
4	Have adequate provisions been made for safety monitoring and termination of the research project?	

5	There are no potential physical, psychological, social and legal risks to the participants.	
6	Is there any provision of periodic monitoring during and after research, regarding safety and long term impacts of intervention?	
	Reviewer's comment:	
	Respect for the dignity of the research participants	
	Informed consent	
1	Is the process for obtaining informed consent appropriate?	
2	Will refusal to participate be respected?	
3	Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?	
4	Do you approve the compensation offered?	
5	Will fresh informed consent be obtained if the procedures are changed during the re-search?	
6	Is there an opportunity for the participant to ask questions regarding the research?	
	Reviewer's comment:	
	Confidentiality	
1	Is the privacy of the research participant safe guarded?	
2	Are data/ biological specimen storage and disposal procedures adequate to protect participant confidentiality?	
	Reviewer's comment:	
	Rights of the participants	
1	Is the participant's right to unconditionally withdraw from the research at any time safeguarded?	
2	Is there provision for the participants to ask questions and register complaints?	
3	Is the research and intervention designed without discrimination on the basis of race, ethnicity, gender, religion?	
	Reviewer's comment:	
	Fair participant selection	
1	Has the study population been determined, primarily, based on the scientific goals of the study?	
2	Is the selection of participants appropriate so that risks are minimized and benefits are maximized?	

3	If there are more than one study group , then does any group feel embarrassed about the participants' selection?	
	Reviewer's comment:	
	Vulnerable group e.g. children, prisoners, pregnant women, handicapped, mentally disabled persons, minorities **(if applicable)**	
1	Can the research be equally well carried out in another, less vulnerable, group?	
2	Will the study result in new knowledge relevant to the health needs of this population?	
3	Will the subject's withdrawal from research due to refusal (dissent) be always upheld?	
4	Will the benefit of the research be made available to this group?	
	Reviewer's comment:	
	Externally sponsored research (if applicable)	
1	Is there a local co–investigator?	
2	Is the justification for the research to be carried out in Institution and not in the sponsoring country/institution adequate?	
3	Are the post-research benefits to RCoD acceptable?	
4	Are relevant local laws/regulations/guidelines of each country adhered to?	
5	Is the research responsive to cultural/social differences?	
6	If the data/biological materials are to be transferred overseas, is there adequate provision to safeguard the interests of the subjects and protect intellectual property rights?	
7	Are there any conflicts of interest? If Yes, provide details? Attach an Annexure	
8	Is there a written agreement between the collaborators?	
	Reviewer's comment:	
	Community based research (if applicable)	
1	Is the study relevant to the community needs?	
2	Is the study culturally acceptable?	
3	Does the research study in any way stigmatize the participants?	
4	Before commencement of the study, have the concerned community leaders and other key stakeholder been consulted to consent to design of the study?	
5	Is individual consent obtained?	
6	Is the privacy of the participants safeguarded?	

7	If the intervention is shown to be beneficial will the sponsor continue to provide it to participants after conclusion of the study?	
8	Will the intervention or product developed or knowledge generated be made available and affordable for the benefit of the population?	
9	Will the results of the research be made available to the concerned community leaders and other key stakeholders in the community?	
10	Are any conflicts of interest resolved?	
	Reviewer's comment:	
	Clinical trials (if applicable)	
1	If it is a multi-centre trial, are all centres following the same protocol?	
2	Is the clinical trial registered with a clinical trials registry?	
3	Is their sufficient justification for using a placebo control arm?	
4	Does the control group receive the standard therapy?	
5	Are all subject participants treated equally?	
	Reviewer's comment:	
	Biohazard Safety	
1	Are there any potential biohazards associated with the research such as exposure to infectious agents and toxins?	
2	Does the research complies with national and international biosafety regulations?	
3	Does the research adhere to institutional biosafety regulations?	
4	Are the participants adequately informed about the biohazards risks associated with the research?	
	Reviewer's comment:	

Overall Assessment / Action	
Approved: Acceptable in its present format.	
Minor Revisions	
Major Revisions	

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Research Ethics Review Evaluation Form

Reviewer's Disclosure of Personal Interests	
As a reviewer of this protocol, do you have any financial interest, paid consultancy, or share-holding in any of the stakeholders involved in this study?	
Please declare in this space all personal interests with this study:	

Name of the Reviewer: ……

Signature: ……

Date: ……

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Director Research and Development Cell, RCoD