SRI VENKATESWARA DENTAL COLLEGE, CHENNAI

FORMAT OF PROPOSAL TO SUBMIT TO RESEARCH COMMITTEE/ETHICS COMMITTEE

(Fill as applicable)

1. The face page

(carrying the title of the proposal with signatures of the investigators)

2. Brief summary/ lay summary

3. Clear research objectives and end points (if applicable);

4. Background with rationale of why a human study is needed to answer the research question **(for excempt review kindly write the background and skip to No: 16)**

5. Justification of inclusion/exclusion of vulnerable populations;

6. Justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld, justification for the same;

7. Procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. AV recording if Applicable; informed consent for stored samples;

8. Eligibility criteria and participant recruitment procedures;

9. Plan to maintain the privacy and confidentiality of the study participants;

10. For research involving more than minimal risk, an account of management of risk or injury;

11. Proposed compensation, reimbursement of incidental expenses and management Of research related injury/illness during and after research period;

12. Provision of ancillary care for unrelated illness during the duration of research;

13. An account of storage and maintenance of all data collected during the trial; and

14. Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/identity.

15. Ethical considerations and safeguards for protection of participants.

16. Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures (if any), statistical analysis, expected outcomes, clinical and public significance (if any).

17. Duration of the study

18.Funding and expenditure details

19. Conflicts of interest

20. Any other information deemed relevant to the study.