Informed Consent Form

Melbourne Dental School

Faculty of Medicine, Dentistry & Health Sciences

Project: **Evaluation of the ability of stannous fluoride and CPP-ACP-containing oral care products to promote remineralisation of enamel subsurface lesions in a double-blind randomised *in situ* clinical trial.**

HREC # 23287

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Name of Participant: _____

1. I consent to participate in this project, the details of which have been explained to me, and I have been provided with a written plain language statement to keep.

2. I understand that the purpose of this research is to investigate the remineralisation (repair) of early decay-like lesions in tooth after rinsing with two toothpaste slurries containing (i) a major milk protein casein, combined with calcium and phosphate called CPP-ACP and stannous (tin) fluoride; and (ii) stannous fluoride alone.

3. I understand that my participation in this project is for research purposes only.

4. I acknowledge that the possible effects of participating in this research project have been explained to my satisfaction.

5. I understand that I will be required to adhere to all infection control procedures as described in the "Infection Control Protocol for Participants" given to me.

6. In this project I will be required to do the following:

a) wear an upper removable denture-like appliance, with sterilized pieces of human teeth attached, four times a day for 40 minutes each time after rinsing with toothpaste slurries for 60 seconds (while wearing the appliance each time), for two 14 consecutive-weekday treatment periods.
b) wear the appliance for a total of 74 hours and 40 minutes over the two treatment periods;
c) complete the two treatment periods with a one-week rest from the study between the two treatment periods;
d) not eat or drink anything (including water) when wearing the appliance;
e) provide two saliva samples, one at rest and one while chewing sugar-free gum, for two minutes each during the screening procedure;
f) provide a total of three post-rinse saliva samples during each treatment period; a saliva sample will be collected after the first rinse of the tooth crème/paste slurry on three different weekdays during each treatment period.;
g) receive a dental examination, without x-rays of my teeth being taken or my gums being probed, as part of the screening procedure by a qualified dentist on the research team.

7. I understand that during the entire study period of five weeks of the two treatment periods as well as for one week prior to the first treatment period commencing (first washout period) and during the one-week rest period between treatment periods (second washout period), I will brush my teeth twice a day with a toothbrush and only with the supplied standard fluoride toothpaste but otherwise will be able to perform all my normal oral hygiene procedures.

8. I understand that my participation is voluntary and that I am free to withdraw from this project anytime without explanation or prejudice and to withdraw any unprocessed data that I have provided.

9. I understand that the data from this research will be stored at the University of Melbourne for 15 years post publication before being destroyed.

10. I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements; my data will be password protected and accessible only by the named researchers.

11. I understand that after I sign and return this consent form, it will be retained by the researcher.

Participant Signature: _____ **Date:** _____