Informed Consent Form

Melbourne Dental School, Faculty of Medicine, Dentistry and Health Sciences

Project: A comparison of casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) prepared using microbial or porcine trypsin/chymotrypsin to remineralize subsurface enamel lesions *in situ*.

HREC # 20842

Responsible Researcher: Professor E.C. Reynolds

Additional Researchers: Dr P. Shen, Dr G.D. Walker, Dr Y. Yuan, Dr J. Fernando, Mrs C. Reynolds, Mr G.G. Adams

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 ability of two different chewing gums to repair early tooth decay.
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. I understand that 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 and chew gum for the first 20 minutes wearing the appliance each time, for two 10 consecutive-weekday treatment periods.
   b) wear the appliance for a total of 53 hours and 20 minutes and chew gum for a total of 26 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) 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 six weeks (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 (supplied) 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: ____/_____/____