

Consent Form



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

Project: Concealment of white spot lesions in enamel and occlusion of dentinal tubules following topical application of gels containing high concentrations of casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) with and without added fluoride in healthy adults, *in situ*. Ethics ID# 14357

Responsible Researcher: Professor E.C. Reynolds

Additional Researchers: Dr G.D. Walker (statistical analysis and laboratory aspects of the project), Dr P. Shen, Dr Y. Yuan, Dr J. Fernando, Mrs C. Reynolds (involved in all other clinical and/or laboratory aspects of this project).

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 abilities of two different gel formulations and a fluoride solution to repair early tooth decay and treat tooth sensitivity.
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, for 24 hours a day for four 14 consecutive-day treatment periods each starting on a Monday and finishing on the Sunday two weeks later;
 - b) complete the four treatment periods with a one-week rest from the study between each treatment period;
 - c) for three of the treatment periods:
 - (i) present to the research department at the Melbourne Dental School once a day on each weekday of the treatment period to remove my appliance from my mouth and give my appliance to the research team who will paint one of the two gels or the solution on the slabs on my appliance and apply some heat

to the gel or solution on the slabs in the laboratory with the appliance out of my mouth.

(ii) paint gel or solution, given to me by the research team on Fridays, on the slabs on my appliance once a day on the following Saturday and Sunday (without applying heat to the gel or solution), with the appliance out of my mouth, as instructed by the research team;

- d) for the remaining treatment period I will wear the appliance as for the other three treatment periods without having gel or solution painted on the slabs on my appliance;
 - e) during each treatment period only remove the appliance whenever eating or drinking (except water) and, in the morning and at night when cleaning my teeth and appliance, participating in sporting activities, and when the test gels and solution are being applied to the tooth slabs on my appliance;
 - f) provide two saliva samples during the screening procedure;
 - g) receive a dental examination, without x-rays of my teeth being taken or my gums being probed, as part of the screening procedure and prior to and after each treatment period by a qualified dentist on the research team.
7. I understand that during the entire study period, in addition to brushing my teeth with the supplied toothbrush and toothpaste, I will be able to perform other oral hygiene procedures such as flossing but will not be able to use any mouthrinses during the treatment periods.
8. I understand I will be given the option of having a standard professional fluoride treatment by a qualified dentist on the research team at the end of the study.
9. 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.
10. I understand that the data from this research will be stored at the University of Melbourne for 15 years post publication before being destroyed.
11. 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.
12. I understand that after I sign and return this consent form, it will be retained by the researcher.

Participant Signature: _____ **Date:** _____