# C:\Users\ammartin\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Word\UOM-Pos3D_S_Sm.jpgConsent Form

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

## ***Project:* Evaluation of Efficacy of Dentifrices with Different Forms of Fluoride and/or other Agents to Remineralize Enamel and Dentine Subsurface Lesions in A Double-Blind Randomized *In Situ* Clinical Trial. HREC ID# 1955501**

**Responsible Researcher:** Professor E.C. Reynolds

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

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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 ability of different toothpaste formulations 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 in this project I will be required to do the following:
6. wear an upper removable denture-like appliance, with sterilized pieces of human teeth attached, for 24 hours a day for 14 consecutive days (treatment period);
7. complete five treatment periods with a one-week rest from the study between each treatment period;
8. only remove the appliance whenever eating or drinking and, in the morning and at night, when cleaning my teeth and appliance and participating in sporting activities;
9. four times each day during each treatment period, when wearing the appliance, rinse with a sugar solution for one minute then wait 40 minutes before rinsing with a toothpaste slurry for one minute;
10. on weekends store the sugar solutions and toothpaste slurries in a refrigerator and allow them to warm to room temperature before rinsing with them;
11. provide a total of 15 saliva samples over the five treatment periods; one sample on three separate weekdays during each treatment period immediately after rinsing with toothpaste slurry;
12. receive a dental examination, without x-rays of my teeth being taken, prior to and after each treatment period by a qualified dentist on the research team.
13. 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 (other than the sugar solutions and allocated toothpaste slurries at the specified times), consume any antibacterial lozenges or chew any gum products.
14. 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.
15. 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.
16. I understand that the data from this research will be stored at the University of Melbourne for 15 years post publication before being destroyed.
17. 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.
18. I understand that after I sign and return this consent form, it will be retained by the researcher.

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| **Participant Signature:** |  | **Date:** |  |