# Informed Consent Form

## Melbourne Dental School, Faculty of Medicine, Dentistry & Health Sciences, The University of Melbourne

***Project:* Evaluation of the ability of sugar free chewing gum containing 5mg and 10 mg casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) to remineralize enamel subsurface lesions in a human *in situ* model**

## **HREC # 24896**

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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 chewing with three sugar free gums containing 0mg, 5mg and 10mg CPP-ACP (Recaldent®; a major milk protein casein, combined with calcium and phosphate).
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 chewing sugar free gums for 20 minutes (while wearing the appliance each time), for three 14 consecutive-day treatment periods.

b) wear the appliance for a total of 112 hours over the three treatment periods;

c) have a one-week rest from the study between 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.

1. I understand that during the entire study period of eight weeks of the three 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, 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.
2. 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.
3. I understand that the data from this research will be stored at the University of Melbourne for 15 years post publication before being destroyed.
4. 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.
5. 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:** |  |