

Human Ethics Application Approval

Ms Hilary Young

Human Research Ethics Officer
Office of Research Ethics and Integrity
Research, Innovation & Commercialisation
Level 5, Alan Gilbert Building, 161 Barry Street, Carlton
The University of Melbourne, Victoria 3010 Australia
T: (03) 8344 8595
E: hilary.young@unimelb.edu.au

Date: 12/03/2021

ATTENTION: Professor Eric Reynolds

5110 - Melbourne Dental School

The University of Melbourne

Research Application

Reference Number: 2021-14357-14877-4

Project Title: Concealment of enamel white spots and occlusion of dentinal tubules after application of gels containing casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) with and without fluoride, in situ

Dear Professor Reynolds,

I am pleased to advise that the STEM 1 Committee has **approved** the amendment to the above application on the basis that it meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). Please see overleaf, *Summary Details for the Approved Human Ethics Project and Conditions of Approval*. It is your responsibility to ensure that all people associated with the Project are made aware of what has been approved.

Desk-based elements of your project and face-to-face research can commence now, as can data collection that can be conducted online or via telephone, subject to necessary approvals or amendments to ethics applications.

Please consult the COVID-19 website for research guidance, FAQ and updates. <https://staff.unimelb.edu.au/covid-19-response/research-activity>

If you have any queries on these matters, or require additional information, please contact me using the details below. Please quote the ethics ID number and the title of the Project in any future correspondence.

Yours sincerely,

Ms Hilary Young

Human Research Ethics Officer

Summary Details for the Approved Human Ethics Project

Project Title:	Concealment of enamel white spots and occlusion of dentinal tubules after application of gels containing casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) with and without fluoride, in situ
Reference Number:	2021-14357-14877-4
Approval Date:	20 October 2020
Expiry Date:	20 October 2025
Responsible Human Ethics Committee	STEMM 1

Project Supervisor Prof Eric Reynolds
 Other Investigators Dr Glenn Walker, Dr Yi Yuan, Dr James Fernando, Ms Coralie Reynolds, Dr Peiyan Shen
 External Investigators

Documents table:

Document Type	File Name	Date	Version
Other	2057412.1 approval letter		Oct 2020
Other	2057412.1 response to HESC		Oct 2020
Consent form	2020_02_18 Consent form for extracted teeth	18/02/2020	13
Recruitment materials	2020_02_18 Consent form for extracted teeth	18/02/2020	13
Recruitment materials	intraoral exam (5)	07/07/2020	1
Recruitment materials	INSTRuforsaliv1 (6)	07/07/2020	1
Questionnaire(s) and/or survey instrument(s)		15/07/2020	
Consent form		15/07/2020	
Consent form		15/07/2020	
Consent form		20/08/2020	
Recruitment materials	Ethics App 2057412 Infection Control Protocol for Participants	20/08/2020	1
Plain Language Statement (PLS)	Ethics App 2057412 Infection Control Protocol for Participants	20/08/2020	1
Questionnaire(s) and/or survey instrument(s)	2021_02_16 Med Q_V3	16/02/2021	3
Recruitment materials	2021_02_16 Med Q_V3	16/02/2021	3
Consent form	2021_02_24 Consent form for Participants_V2	24/02/2021	2
Recruitment materials	2021_02_24 Advertisement_V3	24/02/2021	3
Recruitment materials	2021_02_24 Consent form for Participants_V2	24/02/2021	2
Recruitment materials	2021_02_24 PLS_V4	24/02/2021	4
Plain Language Statement (PLS)	2021_02_24 PLS_V4	24/02/2021	4
Recruitment materials	2021_02_24 Advertisement_V3	24/02/2021	3
Recruitment materials	2021_02_24 Consent form for Participants_V2	24/02/2021	2
Recruitment materials	2021_02_24 Advertisement_V3	24/02/2021	3

Conditions of Approval:

Research projects are normally approved to the anniversary date of the approval. Projects may be renewed yearly for up to a total of three years upon receipt of a satisfactory annual report. If a project is to continue beyond three years, two optional extensions of one year each (3+1+1) will need to be applied for. Anything beyond 5 years will need a new application to be submitted.

Please note that the following conditions apply to your approval. Failure to abide by these conditions may result in suspension or discontinuation of approval and/or disciplinary action.

- Limit of Approval:** Approval is limited strictly to the research as submitted in your Project application.
- Variation to Project:** Any subsequent variations or modifications you might wish to make to the Project must be notified formally to the Committee for further consideration and approval. If the Committee considers that the proposed changes are significant, you may be required to submit a new application for approval of the revised Project.
- Incidents or adverse effects:** Researchers must report immediately to the Committee anything which might affect the ethical acceptance of the protocol including adverse effects on participants or unforeseen events that might affect continued ethical acceptability of the Project. Failure to do so may result in suspension or cancellation of approval.
- Monitoring:** All projects are subject to monitoring at any time by the Committee.
- Annual Report:** Please be aware that the Committee requires that researchers submit an annual report on each of their projects at the end of the year, or at the conclusion of a project if it continues for less than this time. Failure to submit an annual report will mean that ethics approval will lapse.
- Auditing:** All projects may be subject to audit by members of the Committee.

