

Human Ethics Application Approval

ATTENTION: PROF Eric Reynolds

149 - Melbourne Dental School
140 - Medicine, Dentistry and Health Sciences
The University of Melbourne

Research Application

Reference Number: 2021-20842-20317-4

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

Dear PROF Eric Reynolds,

The Committee agreed to **approve** the amendment application on the basis that it meets the requirements of the National Statement on Ethical Conduct in Human Research (2007, Updated 2018). 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 Belinda Kelly

Research Ethics Officer

Human Ethics Team

Office of Research Ethics and Integrity | Research, Innovation & Commercialisation
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Summary Details for the Approved Human Ethics Project

Project Title:	A comparison of casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) prepared using microbial or porcine trypsin/chymotrypsin to remineralize subsurface enamel lesions in situ.
Reference Number:	2021-20842-20317-4
Approval Date:	03/08/2021
Expiry Date:	07/07/2024
Responsible Human Ethics Committee	STEMM 3
Project Supervisor	PROF Eric Reynolds
Other Investigators	DR Peiyang Shen, DR Glenn Walker, DR Yi Yuan, DR James Fernando, MS Coralie Reynolds, MR Geoffrey Adams

Documents table:

Document Type	File Name	Date	Version
Consent form	2020_02_18 Consent form for extracted teeth	18/02/2020	13
Other	Eric Reynolds RIOT Certificate (1)	26/11/2020	
Other	Peiyan Shen RIOT Certificate (1)	26/11/2020	
Other	James Fernando Riot Certificate (1)	26/11/2020	
Other	Glenn Walker RIOT Certificate (1)	26/11/2020	
Other	Yi Yuan RIOT Certificate (1)	26/11/2020	
Other	Coralie Reynolds RIOT Certificate (1)	26/11/2020	
Other	INSTRuforsaliv1 (6)	26/11/2020	
Other	Riot certificate Geoff Adams	26/11/2020	
Questionnaire(s) and/or survey instrument(s)	2021_04_19_MedicalHistoryQuestionnaire_V1	19/04/2021	1
Other	2021_04_19_ChewingDiary_V1 (1)	19/04/2021	1
Plain Language Statement (PLS)	2021_04_19_InfectionControlProtocol_v1	19/04/2021	1
Recruitment materials	2021_04_19_InfectionControlProtocol_v1	19/04/2021	1
Consent form	2021_04_22_InformedConsentForm_V1	22/04/2021	1
Recruitment materials	2021_04_22_InformedConsentForm_V1	22/04/2021	1
Consent form	2021_04_22_InformedConsentForm_V1	22/04/2021	1
Recruitment materials	2021_04_22_Advertisement_V1	22/04/2021	1
Consent form	2021_06_25 Consent form for extracted teeth v.14	25/06/2021	14
Recruitment materials	2021_06_28 PLS_V2	28/06/2021	2
Plain Language Statement (PLS)	2021_06_28 PLS_V2	28/06/2021	2
Recruitment materials	2021_07_23_Advertisement_V2	23/07/2021	2
Recruitment materials	2021_07_23_Advertisement_V2	23/07/2021	2

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 to the Project must be notified formally to the Committee for consideration and approval before they are implemented. If the Committee considers that the proposed changes are significant, you may be required to submit a new application.
- Incidents or adverse events:** Researchers must report immediately to the Committee anything that could affect the ethical acceptability of the project, including adverse effects on participants or unforeseen events. 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:** An annual report must be submitted each year on the anniversary of project approval, and at the conclusion of the project. Ethics approval will lapse if an annual report is not submitted.
- Auditing:** All projects are subject to audit by members of the Committee.