Health and Disability Ethics Committees
Ministry of Health
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18 November 2016

Mr Hassan Mohamed Ahmed
Department of Oral Rehabilitation, University of Otago
310 Great King St
North Dunedin
Dunedin 9054

Dear Mr Mohamed Ahmed

Re:	**Ethics ref:**	**16/CEN/174**
	Study title:	Feasibility study of a chlorhexidine-modified glass ionomer cement used as a restorative material for root caries lesions.

I am pleased to advise that this application has been *approved* by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.
The Committee found this to be a well prepared application and look forward to its results. Thank you for your submission.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Central Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your **next progress report** is due by **17 November 2017.**

Participant access to ACC

The Central Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Mrs Helen Walker
Chairperson
Central Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
CV for CI: Principal investigator	word 97-2003	16 September 2016
CVs for other Investigators: other researcher	word 97-2003	16 September 2016
CVs for other Investigators: other researcher	word 97-2003	16 September 2016
CV for CI: Principal investigator	word 97-2003	16 September 2016
CVs for other Investigators: other researcher	word 97-2003	16 September 2016
CVs for other Investigators: other researcher	word 97-2003	16 September 2016
Survey/questionnaire: Operator assessment sheet	microsoft word document	18 September 2016
Survey/questionnaire: participants' questionnaire.	microsoft word document	18 September 2016
Evidence of scientific review: Scientific peer review Thompson	word 2016	21 October 2016
Evidence of scientific review: Scientific peer review Nick	word 2016	21 October 2016
PIS/CF: Participant information sheet	Word 2016	04 October 2016
PIS/CF: Participant information sheet	Word 2016	04 October 2016
Protocol: Study Protocol	PDF	24 October 2016
CVs for other Investigators	Word 2016	24 October 2016
Application		

Appendix B
Statement of compliance and list of members

Statement of compliance

The Central Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008712) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	30/07/2015	30/07/2018
Dr Melissa Cragg	Non-lay (observational studies)	30/07/2015	30/07/2018
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Cordelia Thomas	Lay (ethical/moral reasoning)	19/05/2014	19/05/2017

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz