



Date: 3 July 2014

**Human Research Ethics Committee :-
Meeting held on: 22 May 2014**

Protocol: "The impact of patient-centered dental open educational resources (DOER) on enhancing a shared clinical decision-making and improving health care outcomes."

Research Ethics Committee

Level 3, Hanson Institute

Tel: (08) 8222 4139

Fax: (08) 8222 3035

Email: rah.ethics@health.sa.gov.au

TO WHOM IT MAY CONCERN

Please be advised of the above Protocol approval by the Royal Adelaide Hospital Research Ethics Committee. It is the policy of both the RAH Research Ethics Committee & Investigational Drug Subcommittee that the names of the regular members of these Committees are not released.

The general makeup of the Committees is as listed below (effective at the above Meeting review date):

Research Ethics Committee

Male – Chairperson, Hospital Scientist employee Royal Adelaide Hospital
Female – One Qualified Lawyer
Male – One Layman
Female – One Laywoman
Female – One Laywoman, Philosophy, University of Adelaide
Male – One Minister of Religion
Male – One Counselling Professional.
Female – One Nurse, employee Royal Adelaide Hospital
Male – Clinician, Graduate of Medicine, employee SA Pathology
Male – Clinician, Graduate of Medicine, employee SA Pathology
Male – Clinician, Graduate of Medicine, employee SA Pathology
Male – Clinician, Graduate of Medicine, retired employee SA Pathology
Female – Clinician, Graduate of Medicine, employee Royal Adelaide Hospital
Female – Clinician, Graduate of Medicine, employee Royal Adelaide Hospital
Female – Clinician, Graduate of Medicine, employee Royal Adelaide Hospital
Male – Clinician, Graduate of Medicine, employee Royal Adelaide Hospital
Male – Clinician, Graduate of Medicine, employee Royal Adelaide Hospital
Male – Clinician, Graduate of Medicine, employee Royal Adelaide Hospital

Investigational Drug Subcommittee

Chairperson - Senior Staff Specialist in Clinical Pharmacology, Royal Adelaide Hospital.
Three senior members of the University of Adelaide, Department of Clinical Pharmacology.
Two members of the Royal Adelaide Hospital, Pharmacy Department.
Three members of the Royal Adelaide Hospital, Clinical Pharmacology.
Chairman, Research Ethics Committee.

The REC composition is in accord with the guidelines for Institutional Ethics Committee composition as set out in the NHMRC National Statement on Ethical Conduct in Human Research (2007).

The committee is serviced by me (undersigned) in my role as Executive Officer.
Proxy members have been appointed to assure that there is full representation at all meetings.

Please be advised that no Investigators of the abovementioned study were present at either the Investigational Drugs Subcommittee Meeting or the Research Ethics Committee Meeting, at the time of discussion or recommendations.

The Hospital's Research Ethics Committee is governed by the NHMRC National Statement on Ethical Conduct in Human Research (2007).

Yours sincerely,

**Mrs Heather O'Dea
Executive Officer, RESEARCH ETHICS COMMITTEE**



Approval Date: 3 July 2014

Dr K Hanna
PhD Candidate
Australian Research Centre for Population Oral Health
School of Dentistry
UNIVERSITY of ADELAIDE

Dear Dr Hanna,

HREC reference number: HREC/14/RAH/160

Project Title: **“The impact of patient-centered dental open educational resources (DOER) on enhancing a shared clinical decision-making and improving health care outcomes.”**

RAH Protocol No: 140514.

Chief Investigator: A/Prof David Brennan

Thank you for submitting the above project for ethical and scientific review. This project was first considered by the Royal Adelaide Hospital Human Research Ethics Committee at its meeting held on 22 May 2014.

I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research*. The documents reviewed and approved include:

- **NEAF Application: AU/1/F3A7115 Sites covered by this approval:**
 - **Royal Adelaide Hospital**
 - **East Adelaide Oral and Maxiofacial Clinic**
- **Protocol: Adelaide 2013**
- **Patient Information Sheet, Version 3, 3 July 2014**
- **Consent Form, 18 April 2014**
- **Clinicians Information Sheet, 18 April 2014**
- **Introduction Letter, 19 April 2014**
- **Baseline Patient Education Survey, 3 July 2014**
 - **Clinicians' Survey, 3 July 2014**
 - **Pre-consultation Patient Education Survey, 3 July 2014**
 - **Follow-up Patient Education Survey, 3 July 2014**
- **RAH Policy: Audit and Quality Assurance, Version 1.1, 12 January 2014**
- **Contacts for Information on Project & Independent Complaints Procedure, 18 April 2014**
- **Semi Structured Interview Form, 19 April 2014**

Please quote the RAH Protocol Number allocated to your study on all future correspondence.

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

- For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
- Adequate record-keeping is important. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years.
- You must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
 - (a) serious or unexpected adverse events which warrant protocol change or notification to research participants,
 - (b) changes to the protocol,
 - (c) premature termination of the study

- The Committee must be notified within 72 hours of any serious adverse event occurring at this site.
- Approval is valid for **5 years** from the date of this letter, after which an extension must be applied for. Investigators are responsible for providing an annual review to the RAH REC Executive Officer each anniversary of the above approval date, within 10 working days, using the Annual Review Form available at: <http://www.rah.sa.gov.au/rec/index.php>
- The REC must be advised with a report or in writing within 30 days of completion.

Should you have any queries about the HREC's consideration of your project, please contact Mrs Heather O'Dea on 08 8222 4139, or rah.ethics@health.sa.gov.au .

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a SA Health site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

This Committee is constituted in accordance with the NHMRC's *National Statement on the Ethical Conduct of Human Research* (2007).

The HREC wishes you every success in your research.

Yours sincerely,



**A/Prof A Thornton
CHAIRMAN
RESEARCH ETHICS COMMITTEE**