

Ethics Application H6837

9469

Project title: Do we need a lateral cephalometric radiograph to diagnose malocclusions?

Principal Investigator: Karadeniz, Carmen

Start: 02-Dec-16 **End:** 31-Dec-17 **Approved:** 03-Feb-17

Termination Dates	Notes	Date Approved
31-Dec-17	No extensions recorded	

Research participants	9469
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1	Karadeniz, Carmen	Staff	P	02-Dec-16 to 31-Dec-17
2	Roberts, Sophie	Student	C	02-Dec-16 to 31-Dec-17
3	Currell, Scott	Student	C	02-Dec-16 to 31-Dec-17
4	Meredith, Neil	Staff	C	02-Dec-16 to 31-Dec-17
5	Esterman, Adrian	Staff	C	02-Dec-16 to 31-Dec-17

Amendment History	Date requested
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04-Apr-17

The Principal Investigator requested to make the following amendments to the study:

04-Apr-17

1. Aim- To determine if there is any change in the diagnosis when orthodontists are presented with a typical orthodontic case, with or without a lateral cephalometric radiograph.
2. Aim- To determine if there is a difference in treatment planning decision-making when orthodontists are presented with a typical orthodontic case, with or without a lateral cephalometric radiograph
3. Participant numbers- The number of participants has been estimated as 270. 135 males and 135 females.
4. Changes in protocol: Recruitment of Participants

First, we will seek approval to circulate invitations to participate in our research from the following dental organizations internal member's mailing list:

- Australian Health Practitioners Regulation Agency (AHPRA)
- Australian Society of Orthodontists (ASO)
- Australian Orthodontic Board (AOB) websites.

If approval is not granted:

- The contact details (i.e. names) of the potential participants (all Australian registered orthodontists) will be attained from the Australian Health Practitioner Regulation Agency (AHPRA), Australian Society of Orthodontists (ASO); and, Australian Orthodontic Board (AOB) public database.
- Participants may be contacted by email or by phone (from their dental practice's websites)
- Alternatively, participants may be contacted in person at orthodontic conferences/meetings. Those interested will receive the questionnaire by email or by post according to their personal preference.

5.. Changes to methodology

The content of the questionnaire remains as per the previous ethics submission; however, the methodology has changed. There will be only one (1) questionnaire (survey) in this study. This questionnaire will be prepared in an online format via a web-based survey generator.

6. Study Design

-A Panel of Experts will provide the "correct" Diagnosis and Treatment Plan. Firstly, the Head of Orthodontics at each of the six Australian Dental Council accredited universities (University of Adelaide, University of Melbourne, University of Sydney, University of Western Australia, University of Queensland and University of Otago) will be contacted, requesting their participation in the study. If they agree to participate, they will receive one questionnaire containing 5 selected cases, with complete records including lateral cephalometric radiograph. Their responses would create, what is deemed by an esteemed panel of experts, the correct diagnosis and treatment plan.

7. Participants allocation

The Orthodontists who are willing to join this study then be randomly allocated into two groups. One control group and one intervention group. Those in the control group will receive a random orthodontic case, with all diagnostic material, including a lateral cephalometric radiograph. Whereas those in the intervention will receive the same random sample without the lateral cephalometric radiograph.

Provisos	Date	Assessed by	Assessment
December 2016	14-Dec-16	Meeting	Conditional Approval

~email
The HREC deems that the photographic records have not been de-identified sufficiently. Please

provide a more sufficient means/way for the photographs to be used in the study in a de-identified format.

Please clarify if patients have consented to having their photographs shared for use in this way or only consented to their patient records.

Please provide the 'clinical images and the use of personal mobile devices' form again in a clearer format as the copy that was provided is very hard to read.

The National Statement states that research that has merit is 'conducted using facilities and resources appropriate for the research'. It is expected that adequate resources will be available for this research project. Resources include: finances, equipment/ facilities and in-kind support. As per section 6 please confirm the funding/resources required for this study.

As per the two students listed on the ethics application please confirm if this study will contribute to a qualification for them or are they on the project as research assistants.

December 2016	14-Dec-16	Meeting	Pending
		Pending	
February 2017	03-Feb-17	Meeting	Approved

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