

**Notification of Expedited Approval**

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To Chief Investigator or Project Supervisor:	<b>Conjoint Professor Parker Magin</b>
Cc Co-investigators / Research Students:	<b>Doctor Liz Holliday Professor Billie Bonevski Associate Professor Christopher Etherton-Beer Associate Professor Stephen Barnett Conjoint Associate Professor Adrian Dunlop Associate Professor Sarah Hilmer Dr Laura Deckx Conjoint Professor Josh Davis Mrs Kim Pinkerton Miss Amanda Tapley Mr Nigel Catzikiris Ms Katie Mulquiney Doctor Emma Pappalardo Doctor Jenny Presser Mrs Debbie Quain Ms Irena Patsan Ms Jasmine De Giovanni Ms Dominica Moad Dr Simon Morgan Dr Rohan Kerr Professor Neil Spike Professor Mieke Van Driel Doctor Andrew Davey Doctor Simon Holliday Doctor Rachel Turner Ms Nashwa Najib</b>
Re Protocol:	<b>Registrar Clinical Encounters in Training (ReCenT) Project- Using Longitudinal Patient Encounter Data to Enhance General Practice Training</b>
Date:	<b>18-Apr-2018</b>
Reference No:	<b>H-2009-0323</b>

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Thank you for your **Response to Conditional Approval (minor amendments)** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to a variation to the above protocol.

Variation for:

1. FUSION is an annual three-day training program presented by the Registered Training Organisation, GP Synergy, to help meet the educational needs of Term 1 and Term 2 General Practice (GP) registrars. Approximately 540 GP registrars will be invited to attend FUSION 2018. The goal of the Fusion workshop sessions assessment is to evaluate two of the educational sessions being presented: i) GP registrars' evaluation and deprescribing of inappropriate medicines in the elderly, ii) Approaches to management of anxiety and insomnia. The aim of the two educational sessions is to facilitate deprescribing of potentially inappropriate medications if, in the particular patient, they are evaluated as being more likely to cause harm than benefit, and better management of anxiety and insomnia through safe prescribing practices and the promotion of non-pharmacological alternative therapies.

Evaluation of the educational program changes will involve the following:

A. Quantitative evaluations of change in GP registrars' behaviour regarding prescribing, deprescribing and referral behaviour as measured by ReCEnT data. Data for this analysis will be collected during the six-monthly rounds of ReCEnT data collection.

B. Quantitative evaluations of change in GP registrars' attitudes and knowledge regarding prescribing, deprescribing and other management, including referral, behaviour, as measured by questionnaire responses to clinical vignettes. Pre- and post-educational intervention questionnaires will elicit participants' medication management responses to a number of general practice vignettes (clinical scenarios) involving polypharmacy in older patients or anxiety or insomnia. These clinical vignettes will be designed to reflect situations where prescribing, deprescribing and or referral behaviour are either recommended or not warranted, consistent with current research.

Participants can choose to complete an online version or a paper-based version of the questionnaire. Completion of the questionnaire will be taken as informed consent to participate. Information Statements and questionnaires/ links to electronic questionnaires will be mailed/ emailed to registrars by the project co-ordinator, with a follow-up email reminder 2 weeks later. An identical process will be used for the post-workshop questionnaire, two months post-workshop.

We would also like to include a tea / coffee bag in the mailed information package and invite registrars to enjoy a 'cuppa' while completing the questionnaire.

C. A qualitative evaluation for each educational intervention (deprescribing in older patients; and pharmacological/non-pharmacological approaches to management of anxiety and insomnia) of: a) GP registrars' and supervisors' opinions on how the educational intervention worked well and how it could improve; and b) how GP registrars' practices have changed and barriers to / facilitators of such change. A small subset (approximately 20-30) of the GP registrars and supervisors who took part in each educational session will be required for this part of the evaluation. The interviews will be conducted by telephone or Skype. The interview questions will explore participants' experiences of the educational material, which aspects were acceptable and feasible and how the educational material has influenced their prescribing, deprescribing and patient management practices (for inappropriate medicines in older patients and for anxiety and depression, respectively). Among other purposes, it will identify aspects of the material which require iteration (the list of themes to be explored is attached to this submission). The qualitative phase will employ a theoretical framework of thematic analysis. A researcher (to be appointed) will conduct the interviews.

2. Addition of the following people to the research team: Billie Bonevski; Liz Holliday; Adrian Dunlop; Sarah Hilmer; Christopher Etherton-Beer; and Stephen Barnett.

- Electronic Invitation for Pre-post Questionnaire (v2, submitted 05/04/2018)
- Electronic Information Statement for Pre-post Questionnaire (v2, dated 04/04/2018)
- Hard Copy Invitation for Pre-post Questionnaire (v2, submitted 05/04/2018)
- Hard Copy Information Statement for Pre-post Questionnaire (v2, dated 04/04/2018)
- Pre-workshop Clinical Vignette Questions (v2, dated 04/04/2018)
- Post-workshop Clinical Vignette Questions (v1, dated 14/03/2018)
- Invitation and Consent Form for Qualitative Interviews (v1, dated 13/02/2018)
- Information Statement for Qualitative Interviews (v2, dated 04/04/2018)
- Qualitative Interview Questions (v1, dated 13/02/2018)

Your submission was considered under **Expedited** review by the Ethics Administrator.

I am pleased to advise that the decision on your submission is **Approved** effective **18-Apr-2018**.

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request.

Associate Professor Helen Warren-Forward  
**Chair, Human Research Ethics Committee**

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***Linked University of Newcastle administered funding:***

Funding body	Funding project title	First named investigator	Grant Ref
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