Thursday, 21 March 2019

Dr Trudy Rebbeck
Clinical and Rehabilitation Sciences; Faculty of Health Sciences
Email: trudy.rebbeck@sydney.edu.au

Dear Trudy,

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

After consideration of your response to the comments raised your project has been approved.

Protocol Number:	**2018/926**
Protocol Title:	**Implementation of a novel clinical PAthway of CarE for common musculoskeletal disorders in primary care (PACE Musc study).**
Sites Approved:	
Authorised Persons:	**Rebbeck Trudy; Cameron Ian; Evans Kerrie; Nicholas Michael; Refshauge Kathryn; Shaw Timothy (Tim); Simic Milena; Trevena Lyndal; Ferreira Paulo; Kang Kwangil; Moura Campos Carvalho Silva Ana Paula; Ferreira Manuela; Beales Darren; Bennell Kim; Boyle Eileen; Connelly Luke; Foster Nadine E; Hodges Paul W; Jull Gwendolen; Ritchie Carrie; Robins Sarah; Schwartz Kantarzhi Sarah; Sterling Michele;**
Approval Period:	**21 March 2019** to **21 March 2023**
First Annual Report Due:	**21 March 2020**

Documents Approved:

Date Uploaded	Version Number	Document Name
06/03/2019	Version 2	Appendix A_hospital recruitment letter_FINAL
14/02/2019	Version 2	PACE Musc Baseline_Questionnaire_Patients_FINAL_REVISED_FEB2
14/02/2019	Version 2	PCF Patient_PACE Musc_REVISED_FEB2019_Cleancopy
14/02/2019	Version 2	PIS prim care HCP_REVISED_FEB2019_Cleancopy
14/02/2019	Version 2	PIS_Specialist_FINAL_REVISED_FEB2019_Cleancopy
19/11/2018	Version 1	CV template
16/11/2018	Version 1	Budget
16/11/2018	Version 1	Protocol
16/11/2018	Version 2	Patient Participant Information Statement
16/11/2018	Version 1	Telephone screening questionnaire
16/11/2018	Version 1	Advertising Flyer
16/11/2018	Version 1	Primary HCP Participant Consent Form
16/11/2018	Version 1	Specialist Participant Consent Form
16/11/2018	Version 1	Primary HCP Information letter_usual care
16/11/2018	Version 1	Primary HCP Information letter_low risk
16/11/2018	Version 1	Primary HCP Information letter_high risk
16/11/2018	Version 1	Safety Report Form

Special Conditions of Approval for Clinical Trials

- **This letter constitutes ethical approval only.** This project cannot proceed at any site until the necessary research governance authorisation is obtained. If your study is sponsored by the University or is to be conducted on a University of Sydney site you may need to comply with additional University governance requirements prior to commencing. Please contact the Clinical Trials Governance Office at clinical-trials.research@sydney.edu.au

- Clinical Trials must be registered on a clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE). For trials conducted in Australia or New Zealand registration should be on the Australian New Zealand Clinical Trial Registry before recruitment of the first subject (http://www.anzctr.org.au/).

Condition/s of Approval

- Research must be conducted according to the approved proposal.
- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
  - Serious or unexpected adverse events (which should be reported within 72 hours).
  - Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).
- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.
- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Data and primary materials must be retained and stored in accordance with the relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures and governance requirements.
- The Ethics Office may conduct audits on approved projects.
- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

Please contact the Ethics Office should you require further information or clarification.

Sincerely,

Helen Mitchell

Dr Helen Mitchell
Chair
Human Research Ethics Committee (HREC 1)

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007) and the NHMRC's Australian Code for the Responsible Conduct of Research (2007).