Thursday, 19 December 2019

Prof Michael Nicholas
Northern Clinical School: Pain Mgt. Res. Inst.; Faculty of Medicine and Health
Email: michael.nicholas@sydney.edu.au

Dear Michael,

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.

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| **Protocol Number:** | **2019/976** |
| **Protocol Title:** | **Early Matched Care For Australia Post Employees With Work-related Injuries and at risk of delayed return to work.** |
| **Authorised Persons:** | **Nicholas Michael; Mittinty Manasi; Ianseen Melanie; Rae Natasha;** |
| **Approval Period:** | **19 December 2019 to 19 December 2023** |
| **First Annual Report Due:** | **19 December 2020** |

**Documents Approved:**

| Date Uploaded | Version Number | Document Name |
|---|---|---|
| 05/11/2019 | Version 1 | Information Sheet for GP |
| 05/11/2019 | Version 1 | APG and Pain Foundation Ltd Agreement |
| 05/11/2019 | Version 1 | Recruitment Flowchart |
| 05/11/2019 | Version 1 | Data Management Protocol |
| 05/11/2019 | Version 1 | Participant Consent Form Intervention State |
| 05/11/2019 | Version 1 | Participant Consent Form Control State |
| 17/12/2019 | Version 3 | CLEAN_Revised Participant Information Sheet Intervention Sta |
| 17/12/2019 | Version 3 | Revised Participant Information Sheet Intervention State |
| 13/08/2019 | Version 1 | Orbero Muculoskeletal Pain Screening Questionnaire |
| 05/11/2019 | Version 2 | Secondary Measures Questionnaire |
| 05/11/2019 | Version 1 | Recruitment/ Introduction by WRP for Intervention States |
| 05/11/2019 | Version 1 | Recruitment/ Introduction by WRP for Control States |
| 05/11/2019 | Version 1 | Study Protocol |

**Special Condition/s of Approval**

- It will be a condition of approval that registration of the Clinical Trial must be completed before the trial commences.

**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,

Glen Davis
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**Professor Glen Davis**
**Chair**
**Human Research Ethics Committee (HREC 2)**

*cc. Clinical Trial Governance*

THE UNIVERSITY OF SYDNEY

**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).**