

**HREC Committee Secretariat:**

**A/Prof Clement Loy**  
Medical Graduate – Neurologist

**Mrs Patricia Fa**  
Clinical Trials Pharmacist

**HREC Committee Members:**

**Ms Narelle Bell**  
Lawyer

**Dr Sangeetha Bobba**  
General Practitioner

**Sr Patricia Bolster RSM**  
Catholic Chaplain

**Mrs Therese Burke**  
Clinical Trial Coordinator

**Mr John Fisher**  
Lawyer

**A/Prof Anthony Harris**  
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**Mr John McLeod**  
Layman

**Mrs Janette Parry**  
Laywoman

**Mr John Shaw**  
Layman

**Dr Geoff Shead**  
Medical Graduate – Surgeon

**Dr Lynn Sinclair**  
Clinical Nurse Consultant

**Dr Howard Smith**  
Medical Graduate – Endocrinologist

**Ms Shane Waterton**  
Laywoman

**Ms Christine Wearne**  
Clinical Psychologist

HREC Ref: **(4266) AU RED HREC/15/WMEAD/143**  
SSA Ref: **AU RED SSA/15/WMEAD/161**

17 June 2015

Ms Katherine Maka  
Department of Physiotherapy  
Westmead Hospital

Dear Ms Maka

Project title: 'Video-game based exercise for older people with chronic low back pain. A pilot randomized controlled trial. The GAMEBACK Trial'

Thank you for your email dated 10 June 2015 addressing the matters raised in the HREC's letter dated 29 May 2015 following single ethical review of the above project at its meeting held on 26 May 2015.

This HREC has been accredited by the NSW Department of Health as a lead HREC to provide the single ethical and scientific review of proposals to conduct research within the NSW public health system. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

This proposal meets the requirements of the National Statement and I am pleased to advise that the HREC has now granted ethical approval of this **single site** research project to be conducted at:

- Westmead hospital, Chief Investigator Ms Katherine Maka

The following documentation has been reviewed and approved by the HREC:

- NEAF submission code AU/1/B04E14
- Protocol Version 1 dated 14 April 2015
- Participant Information and Consent Form Version 2 dated 10 June 2015
- Participation Assessment Booklet, version 1, dated 14 April 2015
- Initial Assessment, version 1, dated 14 April 2015
- Exercise Description, version 1, dated 14 April 2015
- Instructions for getting to the exercises, version 1, dated 14 April 2015
- Exercise Diary, version 1, dated 14 April 2015
- Recruitment Phone Script, version 2, dated 17 June 2015

**HUMAN RESEARCH ETHICS COMMITTEE**

Research Office, Level 2, REN Building  
Westmead Hospital, Hawkesbury & Darcy Roads, Westmead NSW 2145  
Telephone 02 9845 8183 Facsimile 02 9845 8352  
Email: [WSLHD-ResearchOffice@health.nsw.gov.au](mailto:WSLHD-ResearchOffice@health.nsw.gov.au)

**WESTERN SYDNEY LOCAL HEALTH DISTRICT**

ABN 48 702 394 764

WSLHD Office, Westmead Hospital Campus  
Institute Road, Westmead NSW 2145  
PO Box 574, Wentworthville NSW 2145  
Telephone 02 9845 5555

- HDMI compatibility form, version 1, dated 16 June 2015
- Recruitment Letter, version 1, dated 16 June 2015

Please note the following conditions of approval:

- The Chief Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- **For clinical trials of implantable medical devices only** – The Chief Investigator will confirm to the HREC that a process has been established for tracking the participant, with consent, for the lifetime of the device and will immediately report any device incidents to the Therapeutic Goods Administration (TGA).
- The Chief Investigator will immediately report any protocol deviation / violation, together with details of the procedure put in place to ensure the deviation / violation does not recur.
- The Chief Investigator will provide to the HREC in the specific format, proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, must be provided to the HREC to review in the specific format. Copies of all amendments when approved by the HREC must also be provided to the Research Governance Officer.
- The Chief Investigator must notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.
- The Chief Investigator must provide an annual report to the HREC and a final report at completion of the study, in the specified format. HREC approval is valid for 12 months from the date of final approval and continuation of the HREC approval beyond the initial 12 month approval period is contingent upon submission of an annual report each year. A copy of the Annual / Final Research Report Form can be obtained electronically from the Research Office on request.
- The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived including
  1. Discussion of relevant aspects of the project with investigators, at any time,
  2. Random inspection of research sites, data or consent documentation,
  3. Interview with research participants or other forms of feedback from them, and
  4. Request and review reports from independent agencies such as a Data Safety Monitoring Board.
- If your research project is an interventional trial, please ensure it is registered on one of the clinical trial registries, eg <http://www.actr.org.au>.
- It should be noted that compliance with the ethical guidelines is entirely the responsibility of the Chief Investigator.

**You are reminded that this letter constitutes *ethical approval only*. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. Copies of this letter, together with any approved documents as enumerated above, must be forwarded to all site investigators for submission to the relevant Research Governance Officer.**

Should you have any queries about the HREC's Terms of Reference, Standard Operating Procedures or membership, please contact the Acting Research Ethics Manager through the Research Office on 9845 8183 or emailing [kellie.hansen@health.nsw.gov.au](mailto:kellie.hansen@health.nsw.gov.au).

In all future correspondence concerning this study, please quote approval number **(4266) AU RED HREC/15/WMEAD/143**

The HREC wishes you every success in your research.

Yours sincerely



Mrs Kellie Hansen  
Research Ethics Manager  
WSLHD Research & Education Network

cc Ms Margaret Piper, Research Governance Officer

<b>Principal Investigator</b>	Ms Katherine Maka	
<b>Study Title</b>	Video-game based exercises for older people with chronic low back pain: A pilot randomized controlled trial: The GAMEBACK Trial	
<b>Please complete the boxes below and return a copy of <u>this page only</u> to the WSLHD Research Office:</b>		
<input type="checkbox"/> <i>I acknowledge and accept the conditions of ethical approval listed above</i>		
<input type="checkbox"/> <i>I will not commence this project at any site until separate written authorisation from the Chief Executive or delegate of that site has been obtained</i>		
<b>Chief Investigator</b> (Print Name)	<b>Signature</b>	<b>Date</b>