Dear Dr Philip Austin,

Thank you for submitting the following Human Research Ethics Application (HREA) for review:
**2019/ETH12454 - Virtual reality for the treatment of people with cancer-related pain.**

Thank you for your letter, dated 09 March 2020 responding to the Northern Sydney Local Health District HREC’s request for additional information/modification for the above project, which was first considered by the Full HREC held on 10 February 2020.

The application was assessed as a **Greater than low risk study.**

I am pleased to advise that the HREC at a meeting of its Executive has granted ethical and scientific approval of the above **single centre project on 11 March 2020**. The Executive were satisfied that this project meets the requirements of the *National Statement on Ethical Conduct in Human Research, 2007 (updated 2018)*.

This project has been Approved to be conducted at the following sites:
Greenwich Hospital under the auspices of HammondCare.

The following documentation was reviewed and is included in this approval:

* Protocol, Version 1.1, Dated 16 March 2020
* Recruitment Flyer/Brochure, Version 1.0, Dated 08 May 2019.
* Master Consent Form, Version 1.1, Dated 09 March 2020
* Master Participant Information Sheet, Version 1.0, Dated 17 December 2019
* Participant Information Sheet/Consent, Version 1.1, Dated 09 March 2020
* Case Report Form, No Version, Dated 07 July 2009
* Semi-structured interview questions, No Version, Dated 09 March 2020.
* Modified Brief Pain Inventory (Items 1-5)
* iGroup Presence Questionnaire (IPQ), No Version, 09 March 2020

The following documentation was noted by the Committee:

* Depression Anxiety and Stress Scale (DASS-21)
* Edmonton Symptom Assessment System (ESAS)
* Australian-Modified Karnofsky Performance Scale

The Human Research Ethics Application reviewed by the HREC was:
Version: 4
Date: 24 February 2020

[Application Documents](https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fregis2.health.nsw.gov.au%2Fapi%2FApplicationDecision%2FDownloadAttachments%3Ftoken%3D526315e4-f6ad-4b56-b342-d319b026e7a9&data=02%7C01%7Cpaustin%40hammond.com.au%7C55cc18f2ba6e4b688a8c08d7c9e8d6ba%7Cba16567c026d478d957e68bdf3db5530%7C0%7C0%7C637199874245950606&sdata=sSeNyhTam5xsg5uyVzctQ0FcRucFquX2eY6otRdjvWs%3D&reserved=0) - (**Please note: Due to security reasons, this link will only be active for 14 days**.)

**This email constitutes ethical and scientific approval only.**

This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution under whose auspices the research will be conducted at that site.

**This HREC is constituted and operates in accordance with the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council. No HREC members with a conflict of interest were present for review of this project.**

Please note the following conditions of approval:

* HREC approval is valid for **5 years** from the date of approval and expires on**11 March 2025.** The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
* The Co-ordinating Investigator will provide an annual progress report **at the anniversary date of the project** as well as a final study report at the completion of the project within the Research Ethics and Governance Information System (REGIS).
* The Co-ordinating 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 and any complaints made by study participants regarding the conduct of the study.
* Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review, in the specified format.
* The HREC will be notified, giving reasons, if the project is discontinued before the expected date of completion.
* Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a university course are advised to contact the relevant university HREC regarding any additional requirements for the project.

 Please note it is the responsibility of the sponsor or the co-ordinating investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trial Registry [www.anzctr.org.au](https://aus01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.anzctr.org.au%2F&data=02%7C01%7Cpaustin%40hammond.com.au%7C55cc18f2ba6e4b688a8c08d7c9e8d6ba%7Cba16567c026d478d957e68bdf3db5530%7C0%7C0%7C637199874245960597&sdata=dgis83BLcpgjhZ%2BJiBm2syWrvorjjwVYMonD1ahds%2F8%3D&reserved=0)) if applicable.Please contact us if you would like to discuss any aspects of this process further, as per the contact details below.

We look forward to managing this application with you throughout the project life-cycle.

Kind regards,
Vanessa

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