From: no_reply@regis.health.nsw.gov.au
Subject: 2019/ETH09847: Application HREA - Approved
Date: 7 May 2019 at 08:26
To: adhwanesthesia@gmail.com, allanmolloy1@gmail.com
Cc: sarah.amos@health.nsw.gov.au, monique.macara@health.nsw.gov.au, harriet.price@health.nsw.gov.au

Date of Decision Notification: **07 May 2019**

Dear Andrew Weiss,

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2019/ETH09847: Optimising and personalising recovery after total knee replacement (TKR) utilising an internet based educational and medical record system that is based on "usual care"

Thank you for your letter, dated 6th May 2019, 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 HREC at its meeting held on 11th February 2019 **.** *This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER)*. 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*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the Committee at a***n out of session meeting held on the 6th of May 2019*** has granted ethical and scientific approval of the above ***multi centre project***. The HREC were satisfied that this project meets the requirements of the National Statement.

This project has been Approved to be conducted at the following sites:

1. Royal North Shore Hospital
2. Hornsby Ku-Ring-Gai Hospital
3. Ryde Hospital

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

- PSEQ Survey-2-15-APR-2019
- Protocol Tracked-2-01-APR-2019
- PROMIS 10 Survey-2-15-APR-2019
- PISCF Tracked-2-15-APR-2019
- PISCF Clean-2-15-APR-2019
- PCS Survey-2-15-APR-2019
- OKS Survey-2-15-APR-2019
- NSLHD_Primo-002 final 171218.pdf
- SUS Survey-2-15-APR-2019
- Medical Device confirmation
- KOOS Survey-2-15-APR-2019
- HREA
- DASS-21 Survey-2-15-APR-2019
- Consent Form-2-15-APR-2019
- letter of Invitation-2-15-APR-2019
- WOMAC assessment tool

Application Documents - The Human Research Ethics Application reviewed by the HREC was:
Version: 4
Date: 06 May 2019

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). The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of approval and expires on **6th of May 2024.** 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 to the Institution **at the anniversary date of the project** as well as a final study report at the completion of the project using the template available on the Research Office website.
- 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) 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 lifecycle.

Many thanks,
Sarah Amos ***Research Ethics Officer***
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