

30/06/2020

Dr Daniel Meyerkort  
Sent via email: daniel@perthortho.com.au

Dear Dr Meyerkort,

**RE: A Randomised Control Trial of a Low Carbohydrate versus Standard Habitual Diet for the Management of Perioperative Glycaemic Control in Hip and Knee Replacement (2010)**

The Ramsay Health Care WA|SA Human Research Ethics Committee (RHC WA|SA HREC) has granted ethical approval to the above project. The sites for which ethical oversight will be provided by the RHC WA|SA HREC include:

Study Site	Site Principal Investigator
Hollywood Private Hospital	Dr Daniel Meyerkort

The RHC WA|SA HREC provides **ethical approval** for all RHC facilities in WA and SA. **Please note that site-specific approval must be granted before you commence your project at any RHC site.**

Your project approval number is indicated above; please quote this number in all correspondence to the RHC WA|SA HREC.

The documents approved as part of this submission include:

Document	Version	Date
Study Protocol	1.3	19/06/20
HREA – DM02953	1	24/10/19
PICF	1.3	19/06/20

This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2007), updated 2018. The Committee's continuing approval is subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RHC WA|SA HREC of any event, including new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial /evolving safety profile of the trial, or which may indicate the need for amendments to the trial protocol/documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found on the RHC research website\*.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with RHC WA|SA HREC policy and procedures. These instructions can be found on the RHC research website\*.
- The Coordinating Principal Investigator will report to the RHC WA|SA HREC annually in the specified format and notify the HREC when the project is completed at all sites.
- The Coordinating Principal Investigator will notify the RHC WA|SA HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.

- The Coordinating Principal Investigator will notify the RHC WA|SA HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found on the RHC research website\*.
- The Coordinating Principal Investigator will notify the RHC WA|SA HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- The Coordinating Principal Investigator will notify the RHC WA|SA HREC if the project does not commence within six months of approval.

Your approval is initially for four years from date of approval; after this period, you may be asked to apply for an extension or re-apply. You are also required to notify the Committee promptly of any changes in your contact details.

A copy of this ethical approval letter should be presented when required as official confirmation of the approval of the RHC WA|SA HREC

**This letter constitutes ethical approval only.** This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO (or delegate) of the Facility where the research is to be conducted.

Should you have any queries about the RHC WA|SA HREC's consideration of your project please contact the Executive Officer. The RHC WA|SA HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the RHC Research website or from the Executive Officer.

The RHC WA|SA HREC wishes you every success in your research.

Yours sincerely



A/Prof Paul Porter

Chairperson, Ramsay Health Care WA | SA HREC

RHC WA|SA HREC contact details:

Joanna Brisbane, Executive Officer

RamsayHREC.WA-SA@ramsayhealth.com.au

\*website: [www.ramsayhealth.com.au/Research/Research-Ethics](http://www.ramsayhealth.com.au/Research/Research-Ethics)