

# **Human Research Ethics Committee**

Level 1, 556 Wellington Street
PERTH WA 6000
PO Box 5753, St Georges Terrace
PERTH WA 6831
T: (08) 6116 0542
E: ethics@sjog.org.au

## **Core Members**

Clin Prof Dr Simon Dimmitt

BMedSc (Hons) MBBS FRACP FCSANZ

Chair

# Dr Ben Carnley MBBS FRACP FRCPA

Member with knowledge of, and current experience in the professional care, counselling or treatment of people

## Ms Wendy Meggison LLB (Hons) MA RN RM

Member who is a qualified Lawyer and where possible is not engaged to advise the institution

# Dr Janie Brown BNurs MEd PhD

Member with current research experience that is relevant to research proposals considered by the Committee

#### Ms Suzanne Lawrence BA(Psvch)

Member who brings a broader community or consumer perspective and has no paid affiliation with the institution

# Mr Hamish Milne BA (Hons) MPhil MBA GAICD FAIM

Member who brings a broader community or consumer perspective and has no paid affiliation with the institution

## Dr Tasnuva Kabir PhD MSc MBBS

Member with current research experience that is relevant to research proposals considered by the Committee

#### Fr Joe Parkinson STL PhD

Pool member who performs a pastoral care role in the community

# Other Members

## Prof Sally Sandover BSc MPH

Community member with expert knowledge in medical education

#### Dr Vivian Chiu PhD BPsych BSc BComm

Community member with expert knowledge in clinical psychology

#### Dr Gail Ross-Adjie BN MClinNurs PhD

Pool member with current experience as a nurse researcher

# Dr Evan Bayliss MBBS FRACE

Community member with expert knowledge in oncology

Ms Angel Ching St John of God Berwick Hospital 75 Kangan Drive Berwick VIC 3806

Dear Ms Ching,

# Re: The effectiveness of an education session prior to elective hip or knee replacement surgery in hospital length of stay at St John of God Berwick Hospital (Our ref: 2223)

Thank you for your email reply of 19 September 2024, addressing the queries raised by the St John of God Health Care (SJGHC) Human Research Ethics Committee ("the Committee"), and attaching amended study documentation. Your reply has been reviewed by the Committee out of session.

I am pleased to confirm ethics approval of your "low risk" study as satisfying the ethical requirements under the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (NHMRC, 2023)* ("the National Statement"). This ethics approval follows an expedited review process for lower risk research as per section 5.1.12 of the National Statement.

The study approval period is from 24 September 2024 to 28 December 2025. Should an extension of this timeframe be required, you must seek continued approval from the Committee before the expiry of this time period.

In accordance with NHMRC guidelines, the Participating Site/ Principal Investigator is responsible for:

- 1. Notification to the HREC of any adverse events or unexpected outcomes that may affect the continuing ethical acceptability of the study;
- 2. The submission of any proposed amendments to the study or previously-approved documents;
- 3. The submission of an annual progress report for the duration of the study which is due on the anniversary of HREC approval;
- 4. Reporting of all protocol deviations to the sponsor (if applicable) and all serious breaches reported to the HREC (preferably via the sponsor), together with details of the procedure(s) put in place to ensure the deviation or serious breach does not recur;
- 5. Notification and reason for ceasing the study prior to its expected date of completion (if applicable);
- 6. The submission of a final report and translation of results (including publications) upon completion of the study.

The following documents have been reviewed and approved:

Title	Version	Date
Research Proposal	2	19/09/2024
Appendix 1 Patient Information Statement and Consent Form	2	19/09/2024
Appendix 2 Hip Surgery Phase 1 Exercises	2	19/09/2024
Appendix 3 Knee Replacement Phase 1 Exercises	2	19/09/2024

# **REMINDER:**

As per section 3.1.7 of the National Statement, you are required to register your clinical trial with a public registry (eg ANZCTR) before recruitment of the first participant. Please advise the SJGHC Ethics Office of the name of the registry and the trial registration number when this is known if you have not done so already.

# **PLEASE NOTE:**

This letter constitutes ethics approval only. You must not commence this research at SJGHC until separate authorisation in writing has been obtained. Final institutional approval for this "clinical trial" to be conducted at St John of God Berwick Hospital ("the participating site") is subject to receipt of the fully signed Participating Site Operational Approval form (PSOA) and confirmation from SJG Legal that SJGHC agrees to act as Sponsor of this clinical trial. The SJGHC Ethics Office is already in receipt of the PSOA, so once we have also received the SJG Legal confirmation, you will be advised in writing of final institutional approval.

I wish you well with your research.

Yours sincerely,

250no

Clinical Professor Dr Simon Dimmitt

Chairman

St John of God Health Care Human Research Ethics Committee

cc. Lisa Norman, CEO, SJG Berwick Hospital;

cc. Research Governance, SJGHC