



23 September 2020

Associate Professor Michelle Dowsey
Department of Surgery
St Vincent's Hospital Melbourne

Dear A/Prof Dowsey,

Project ID: 62902

St Vincent's Local Reference Number: LRR 069/20

Study Title: 'Development and evaluation of informed consent procedures for recruitment into a placebo-controlled surgical trial'

Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research 2007 (updated July 2018)*

This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Research Involving Humans 2007 (updated July 2018), and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

Approval Date: 23 September 2020

Ethical approval is given for this research project to be conducted at the following sites:

- St Vincent's Hospital Melbourne – VIC

This approval will be ratified by St Vincent's Hospital (Melbourne) HREC at the next meeting.

Approved documents

The following documents have been reviewed and approved:

Document	Version	Date
Victorian Specific Module (VSM)	-	22 Sep 2020
Research Protocol	1.0	16 Apr 2020
Surgeon Consent – Contact Private Patients	1.0	14 Apr 2020
Verbal Consent Script	1.0	07 Apr 2020

PICF – Patient Group 1	1.0	13 Apr 2020
ASD Animation Video Final	-	-
Video Consent – Animation Script	1.0	14 Apr 2020
Video Consent – Patient Outcome Measures Questionnaire	1.0	03 Feb 2020
Written Consent – Control	2.0	04 May 2020
Oxford Shoulder Score (OSS) – English (UK)	-	1998
Therapeutic Misconception Scale	-	-
SVHM Orthopaedic Post Surgery Form	-	-
Study Budget	-	-

Acknowledged Documents

Document	Version	Date
HREA - HREC/62902/SVHM-2020-234308(v3)	-	23 Sep 2020
Letter of Support – Head of Department	-	16 Mar 2020
CV – Samantha Bunzli	-	-
GCP – Samantha Bunzli	-	02 Mar 2020
CV – Peter Choong	-	-
GCP – Peter Choong	-	15 Sep 2018
CV – Michelle Dowsey	-	-
GCP – Michelle Dowsey	-	15 Aug 2020
CV – Elizabeth Nelson	-	-
GCP – Elizabeth Nelson	-	28 Aug 2018
CV – Cade Shadbolt	-	-
GCP – Cade Shadbolt	-	29 Apr 2019

Governance approval is given for this research project to be conducted at St Vincent’s Hospital Melbourne

Terms of approval:

1. It is the responsibility of the Principal Researcher to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as specified in the application.
2. The Principal Researcher is to notify the Research Governance Unit of all significant safety issues in accordance with the NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods (including all updates).
3. Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
4. Amendments to the approved project: Changes to any aspect of the project require the submission of a Request for Amendment to the Low Risk Research Sub-committee and must not begin without written approval. Substantial variations may require a new application.
5. Future correspondence: Please quote the reference number and project title above in any further correspondence.
6. **An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the 01 May each year for the duration of the project.**

Continuation of ethics approval is contingent on submission of an annual report. Failure to comply with this requirement may result in suspension of the project by the HREC.

7. Final report: A Final Report must be provided at the conclusion of the project.
8. Monitoring: Projects may be subject to an audit or any other form of monitoring by the Research Governance Unit at any time.

We wish you well with your project.

Yours sincerely,



Lauren Barina
Low Risk & QA Officer
Research Governance Unit
St Vincent's Hospital Melbourne