

24-Apr-19

Dr. Ashish Diwan
St George Private Hospital
Suite 16, Level 5
Sydney/Kogarah NSW 2217

Dear Dr. Diwan,

Re: Application No: 2018-05-387

Study Title: A Multi-centre, Randomised, Single-Blinded, Twelve-Month Follow-Up Trial to Evaluate the Safety and Effectiveness of the Kunovus Disc Device for the Preservation of Lumbar Disc Form and Function in Patients Undergoing Microdiscectomy for Sciatica due to Lumbar Disc Herniation

Application Type: NEW

Type of Review: FULLBOARD

Name of the Documents Submitted & Approved: Attachments

PROM-Oswestry Disability Index
PROM-Numerical Rating Scale
PROM SF36
Spine Service_Letter to the GPs_(v1.1)_11Feb'19
Kunovus Pty Ltd. - Aus-KDD-MDP-002 - Australia - Certificate
Kunovus System - Investigator's Brochure_(v1.2)_11Feb'19_CLEAN
Radiation Physicists Report
Kangaroo biomechanics_KDD_Sabet et al 2011
NuCore 5 year follow-up data
NucORE_Berlemann_EurSpine2009
Restoration of compressive load characteristics_Strange et al 2010
Histological Examination_KDD_11Feb'19
Mechanical Testing KDD_11Feb'19
AuDi - PISCF_STG site_(v1.3)_14Mar'19_CLEAN
PI Signed Protocol Signature Page Version 1.5 dated 201900222
AuDi - Clinical Trial Protocol (v1.5)_11Feb'19_CLEAN
AuDi - Surgical Training Manual (v 1.1)_11Feb'19
AuDi - Participant Diary Card_(v1.1)_31Aug'18
AuDi - Patient ID Cards (v1.2)_14March2019_CLEAN

Date of Meeting: 21-Nov-18

Date of Approval: 24-Apr-19

Period of Approval: 24-Apr-19 - 24-Dec-20

Thank you for submitting the above mentioned application.

The Bellberry Human Research Ethics Committee (HREC) reviewed this study in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates as at 2018) (National Statement) on the above meeting date.

This Bellberry HREC is constituted and operates in accordance with the National Statement.

I wish to advise that the Bellberry Human Research Ethics Committee has approved this project and that the application meets the requirements of the National Statement subject to the conditions mentioned below.

CONDITIONS:-

- **THAT YOU ACKNOWLEDGE YOUR AGREEMENT TO THE UNDER MENTIONED CONDITIONS BY SIGNING AND RETURNING A COPY OF THIS LETTER, PRIOR TO THE COMMENCEMENT OF THE RESEARCH. THE SIGNED LETTER CAN BE EMAILED TO BELLBERRY@BELLBERRY.COM.AU OR POSTED TO THE ABOVE ADDRESS.**
- The data collected for the purpose of this research project cannot be used for any other purpose without the approval of the Bellberry Human Research Ethics Committee. Requests to use this data for other purposes must be made in the form of a formal research proposal.
- All research data, including electronic data is to be stored by the Principal Investigator for 15 years after the research has been completed or after the last contact, whichever is the later. Data must be recorded in a durable and appropriately referenced form and comply with relevant privacy protocols.
- That copies of all completed consent forms and any other data used in this research may be inspected at any time by representatives of the Bellberry Human Research Ethics Committee.
- That a report on the progress of the research will be made to the Bellberry Human Research Ethics Committee on **24-Apr-20** or on completion of the trial (if sooner) and then annually for the duration of the trial. This report is to indicate whether any ethical problems or complications have arisen, particularly side effects of drugs used or any other factor which may result in the investigation not producing any result as distinct from the anticipated result.
- That you will notify the Bellberry Human Research Ethics Committee of any changes that may be required within the research proposal.
- Bellberry Human Research Ethics Committee approval is conditional upon your meeting any statutory obligations that you may have in relation to this project.
- Adverse Event reporting should be reported to the Bellberry Human Research Ethics Committee as per the monitoring guidelines posted on the website www.bellberry.com.au.
- Any extension to the initial approval period is to be requested in an application via the eProtocol system together with the inclusion of a progress report.
- That you will provide a copy of the Sponsor's final report when this becomes available.

Details of Ethics Committee:

It is the process of the Bellberry Human Research Ethics Committee not to disclose personal details of its reviewing members. This Project was considered by a Committee that fulfilled the requirements of the National Statement (2007) section 5.1.29 & 5.1.30. A member listing is available as an attachment in eProtocol. Please note that the Principal Investigator and Co-Investigators are not members of the Bellberry Human Research Ethics Committees and were not involved in the review of this study.

This study has been given the above reference number. Please remember to log on to eProtocol for all further correspondence with the Committee.

Please do not hesitate to contact me if further clarification is required.

Yours sincerely



Bellberry Limited
supporting research and ethics

B. Canny

Ben Canny

Chair, Committee G, HREC Code EC00458

BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

[Handwritten Signature] 28/05/2019

PRINCIPAL INVESTIGATOR SIGNATURE DATE

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