

11-Sep-19

Dr. Marc Russo
Genesis Research Services Pty Ltd
220 Denison Street
Broadmeadow NSW 2292

Dear Dr. Russo,

Re: Application No: 2019-08-686

Study Title: A Prospective, Multicentre Study of Low Dose Targeted Drug Delivery (TDD) for Chronic Back Pain Patients who have Failed Spinal Cord Stimulation.

Application Type: NEW

Type of Review: FULLBOARD

Name of the Documents Submitted & Approved: Attachments

AXXON - Multi-Centre Research Compliance Agreement
BERWICK - Multi-Centre Research Compliance Agreement
FRANKSTON - Multi-Centre Research Compliance Agreement
GRS2018-006 STUDY MANAGEMENT PLAN .v3
HPC - Multi-Centre Research Compliance Agreement
GRS2018-006 Protocol Signature Page MRUSSO 26Jun2019
BPI-SF_English-24h_Original_CURRENT
PDF_Australia (English) EQ-5D-5L Paper Self complete v1.0 (ID 24736)
SF-36 RAND 1.0
GRS2018-006 MASTER PICF Rev E - 3 SEP 2019 - Clean
PROTOCOL_GRS2018-006_MDT_TDD V0.5 Clean

Includes:

- GRS2018-006 CTN - 6TH AUG 2019
- 2.2 8591 Catheter Passer Technical Manual Global M938409A001
- 2.2 A810 EN Manual M968017A Rev D (003)
- 8551 Refill Kit
- 8637 Indications, Drug Stability, and Emergency Procedures
- 8637 SynchroMed II Programmable Pumps Implant Manual
- 8780 Ascenda Intrathecal Catheter with an 86cm Spinal Segment Implant Manual
- 8835 MyPTM Physician Manual
- ANZ4751-032018 TDD Pain Control Workflow Brochure-LR
- 2019 01 21 COC LIAB expiring 30 November 2019

Date of Meeting: 21-Aug-19

Date of Approval: 11-Sep-19

Period of Approval: 11-Sep-19 - 11-Sep-21

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 **11-Sep-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



Brian Stoffell

Chair, Committee A, TGA Code: EC00372

BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

PRINCIPAL INVESTIGATOR SIGNATURE DATE