Bellberry Limited
supporting research and ethics

20-Aug-20

Professor Stephen Hall
Emeritus Research
Level 2, 1180 Toorak Road
CAMBERWELL VIC 3124

Dear Professor Hall,
Re: Application No: 2020-07-622
Study Title: PXR002: A Prospective, Randomised, Double Blind, placebo controlled, single dose, single site Phase I study to assess the safety and biological activity of a human non-autologous platelet derived Extracellular Vesicle therapy vs placebo on wound healing rate following skin punch biopsy in healthy volunteer adults.
Application Type: NEW
Type of Review: FULLBOARD

Name of the Documents Submitted & Approved: Attachments

The National PICF project- Interventional for Self - Part A July 2018

PXR002_PICF PLEXOVAL II_V2 dated 12 Aug 2020_Clean Copy

PLEXOVAL2 Investigator Brochure_v2 dated 12 Aug 20_Clean Copy

PLEXOVAL2 Protocol V2 dated 12 Aug 20_Clean Copy

Includes:
The Committee notes the following document:
2019.096 Exopharm Research project Progress Report Site Form

Date of Meeting: 29-Jul-20
Date of Approval: 20-Aug-20
Period of Approval: 20-Aug-20 - 20-Aug-21

Thank you for submitting the above-mentioned application.

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:-

- **This letter constitutes ethical and scientific approval only. You must not commence the research project at any site until your Research Governance Office/ Institution/Organisational delegate has granted their approval. Sites are responsible for ensuring there are executed indemnities, contracts, and appropriate insurance in place before the commencement of the study at the site. Sites are also responsible for ensuring their site-specific documents are based on the current Master approved documentation**.
- All changes to the approved study documentation must be submitted to Bellberry via an Amendment Form for review and approval prior to implementation.
- Safety reporting, Protocol Violations and Serious Breaches should be reported to the Bellberry Human Research Ethics Committee as per the monitoring guidelines posted on the website www.bellberry.com.au
- A progress report must be completed annually for the duration of the trial. The due date for all additional sites will fall in line with the lead sites original approval date. Submission of the progress report is to be within 30 days of the due date. Requests for an annual extension will be granted upon successful completion and noting of a progress report.
- A final report is due on completion of all closeout activities (clinical trials) or final reconciliation of study activities

e-protocol

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(non-clinical trials)The site must also provide a copy of the Sponsor's final report where there are study outcomes that the HREC should be aware of such as issues related to participant safety

- The Principal Investigator must inform the HREC, by way of an amendment, of the outcomes of any audit by a regulator or organisation/body.
- The data collected for the purpose of this research project cannot be used for any other purpose without the approval of a 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.
- Copies of all Master/Site specific documentation and any other data used in this research may be inspected at any time by representatives of the Bellberry Human Research Ethics Committee. This may be in the form of a Bellberry site monitoring visit or requested electronically via a desktop audit.
- Bellberry Human Research Ethics Committee approval is conditional upon your meeting any statutory and licensing obligations; data custodian or other organisational authorisations that you may have with this project.

Details of Ethics Committee:

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) on the above meeting date. Bellberry Human Research Ethics Committees do not disclose personal details of its reviewing members. A member listing is available as an attachment in eProtocol. Please note that the Principal Investigator and Co-Investigators were not members of the Bellberry Human Research Ethics Committee that reviewed 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

Jeffrey Karrasch

Chair, Committee E (NHMRC HREC Code: EC00450)
BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

Committee Name/NHMRC Codes: A/ EC00372; B/ EC00419; C/ EC00430; D/ EC00444;
E/ EC00450; F/ EC00455; G/ EC00458; H/ EC00459; I/ EC00468; J/ EC00469; K/ EC00470; L/ EC00471.

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