

September 19, 2022

Assoc. Professor Philip Beale
Concord Repatriation General Hospital
Hospital Road
Concord NSW 2139

Dear Assoc. Professor Beale,

Re: Application No: 2022-04-420

Study Title: The safety and tolerability of Annona muricata leaf product in people living with cancer.[REGIS Application ID:2020/ETH00536]

Application Type: NEW

Type of Review: FULLBOARD

Name of the Documents Submitted & Approved: Attachments

Safety Review Charter_V2_July 2022_Clean
The National PICF project- Interventional for Self - Part A July 2018
Participant Information Sheet and Consent Form _V5_CLEAN_29th August 2022
FACIT-Fatigue
FACT;McGill Body Image Scale # Head & Neck (FACT-MBIS)
FACT-Brain (version4)
FACT-G
Functional Assessment of Cancer Therapy # Bladder
Functional Assessment of Cancer Therapy # Breast
Functional Assessment of Cancer Therapy # Central Nervous System
Functional Assessment of Cancer Therapy # Cervix
Functional Assessment of Cancer Therapy # Colorectal
Functional Assessment of Cancer Therapy # Endometrial
Functional Assessment of Cancer Therapy # Esophageal
Functional Assessment of Cancer Therapy # Gastric
Functional Assessment of Cancer Therapy # Hepatobiliary
Functional Assessment of Cancer Therapy # Leukemia
Functional Assessment of Cancer Therapy # Lung
Functional Assessment of Cancer Therapy # Lymphoma
Functional Assessment of Cancer Therapy # Melanoma
Functional Assessment of Cancer Therapy # Multiple Myeloma
Functional Assessment of Cancer Therapy # Nasopharyngeal
Functional Assessment of Cancer Therapy # Ovarian
Functional Assessment of Cancer Therapy # Prostate
Functional Assessment of Cancer Therapy # Vulva
Investigator Brochure_V3_July 2022_Cln

Clinical Trial Protocol Manuscript_V13_ July 2022_Clean version
Standard Mini-mental statement examination tool
Participant Dosing Diary V3_CLEAN_29th August 2022

Includes:

Receipt of the following documents has been noted:

Certificate of Analysis Swansons Graviola

Good Manufacturing Practice Certificate_UST Mfg.LLC

Good Manufacturing Practice Certificate_Swansons

Max International GMP Certificate

PB CV 2021 October

Serious_Adverse_Event Form_V3

2020_ETH00536 v1_05 - v1_06 Changes

Date of Meeting: May 11, 2022

Date of Approval: September 19, 2022

Period of Approval: September 19, 2022 - September 19, 2023

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. For clarity, the 'Date of Meeting' is a system-generated field. Please only take note of the 'Date of Approval' and 'Period of Approval' as relevant.

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 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 before 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 (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



Barry Chatterton

Chair, Committee D

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.