
Human Research Ethics Committee - Approval to Conduct Experimentation on Humans

Project Title: Phase 1 D_Bhydroxyburate Safety Profile Clinical Trial

Chief Investigator(s): Dr Janet Schloss

Co-Investigator(s): N/A

HREC Approval Number: 20190815-JS-1

Duration of ethical clearance: 15/08/2022

Thank you for submitting the above research project for Reciprocal Approval. This project was considered by a standing committee of the Endeavour College of Natural Health Human Research Ethics Committee (HREC) (EC00358) and approved on 15 August 2019.

I am pleased to advise you that the above research project meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) – Updated 2018 and ethical approval for this research project has been granted and is subject to the following conditions being met:

Conditions of approval

- The Committee suggested that dosages be staggered per patient to minimise risk. If you agree with this suggestion, please ensure this is reflected in your protocol documentation.
- Further reporting is required on symptoms for a period of 6 weeks after participation. Please ensure this is reflected in your participant case diaries, Protocol, HREA, and PICF via track changes and a clean version.

Should you have any queries about the HREC's consideration of your project please contact HREC@endeavour.edu.au.

The HREC wishes you every success in your research.

Kind regards,

Research Ethics and Governance Administrator

On behalf of the Endeavour Human Research Ethics Committee