

22 June 2020

A/Prof Paul Porter
C/- Ms Joanna Brisbane

Via email to: BrisbaneJ@ramsayhealth.com.au
Cc: paul.porter@curtin.edu.au

Dear A/Professor Porter,

HREC Reference number: 2020-005

Project Title: An evaluation of the clinical utility and acceptability of maternally-administered foetal heart rate monitoring using a remote medical-grade device. The HeraBEAT Trial.

Study Protocol number: N/A

The Ramsay Health Care NSW | VIC HREC has granted ethical approval to the above project on 22 June 2020, following satisfactory response from researchers after the HREC meeting held on 2 June 2020.

The sites for which ethical oversight will be provided by the Ramsay Health Care NSW | VIC HREC include:

Study Site	Site Principal Investigator
Joondalup Health Campus	A/Prof Paul Porter

The RHC NSW | VIC HREC provides **ethical approval** for all RHC facilities in NSW and VIC. Please note that site-specific **Research Governance approval** must be granted before you commence your project at any RHC site.

Your project approval number is indicated above; please quote this number in all correspondence to the RHC NSW | VIC HREC.

The documents approved as part of this submission include:

Document	Version	Date
01 - 2020-005 Ethics Submission - Antenatal Monitoring	-	-
02 - JB03631_Output Form_v1	1	-
03 - JB03631_The HeraBEAT Study PROTOCOL V1.0 12 May 2020_v1	1	12 May 2020
04 - JB03631_Antenatal monitoring PICF_v1.0_120520_v1	1	12 May 2020
05 - CV_PorterP	-	-

This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2007). updated 2018 The Committee's continuing approval is subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RHC NSW | VIC HREC of any event, including new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial /evolving safety profile of the trial, or which may indicate the need for amendments to the trial protocol/documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at <http://www.ramsayhealth.com.au/Research/Research-Ethics>.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with RHC NSW | VIC HREC policy and procedures. These instructions can be found at <http://www.ramsayhealth.com.au/Research/Research-Ethics>.
- The Coordinating Principal Investigator will report to the RHC NSW | VIC HREC annually in the specified format and notify the HREC when the project is completed at all sites.
- The Coordinating Principal Investigator will notify the RHC NSW | VIC HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the RHC NSW | VIC HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at <http://www.ramsayhealth.com.au/Research/Research-Ethics>.
- The Coordinating Principal Investigator will notify the RHC NSW | VIC HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- The Coordinating Principal Investigator will notify the RHC NSW | VIC HREC if the project does not commence within six months of approval.

Your approval is initially for four years from date of approval; after this period, you may be asked to apply for an extension or re-apply. You are also required to notify the Committee promptly of any changes in your contact details.

A copy of this ethical approval letter should be presented when required as official confirmation of the approval of the RHC NSW | VIC HREC.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO (or delegate) of the Facility where the research is to be conducted.

Should you have any queries about the RHC NSW | VIC HREC's consideration of your project please contact RHC NSW | VIC HREC Ethics Secretary via 02 9433 3854 or RamsayHREC.NSW-VIC@ramsayhealth.com.au. The RHC NSW | VIC HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available upon request.

The RHC NSW | VIC HREC wishes you every success in your research.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Mitchell', written in a cursive style.

Professor Philip Mitchell
Chairperson - Ramsay Health Care NSW | VIC HREC