Date : 26/07/2018

To: The Monash Higher Research Ethics Committee

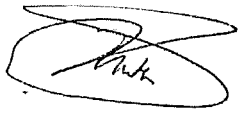
Re: Amendment of protocol for **HREC/17/MonH/180** study entitled " **Investigating The Utility Of A Novel Fetal Heart Rate Monitoring Device In Measuring Fetal Heart Rate Patterns**"

Dear HREC Committee,

Thank you for your time and effort in considering the amendment to the following study protocol. The following project requires an amendment due to the unforeseen issues with signal acquisition encountered in data collection thus far. Primarily, the issue lies with the large amount of electrical interference or noise which was encountered in the fetal monitoring unit which required correcting for. As such, the investigators deem it necessary to investigate the best positioning of electrodes for the device given the lack of evidence in available literature at present. We have thereby updated the study protocol and PICF to illustrate these changes. We have asked for allowances to recruit from 24 weeks of gestation as signal quality is better at lower gestations and to compare signals as well. In addition, a quick bedside ultrasound will be done pre procedure to determine the fetal back as it is theorised to impact on signal quality but studies are yet to demonstrate this in the literature. A ultrasound for use has already been negotiated with the Department of Obstetrics and Gynaecology which will not impact workflow in the unit. The ultrasound will take approximately 5 minutes and will be done by Dr Vinayak Smith.

We hope you find the following changes to be acceptable and welcome any further queries on the issue.

Your sincerely



Dr Vinayak Smith

PhD Candidate- Monash University

MonashHealth

Correspondence and attachments reviewed and approved by Dr James Doery, Deputy Chair, HREC
Site Specific Authorisation to proceed with amendment at Monash Health (Yes) No N/A

Signed:

Date: 26-7-2018

Forward electronic copy of Site Specific PICF for barcoding to Research@monashhealth.org.: (Yes) No

Amendment Request Form

For an amendment to an ethically approved research project, submit the completed form to the reviewing Human Research Ethics Committee (HREC).

An amendment must not be implemented at a site until HREC approval has been given and (if applicable) Site Specific Assessment (SSA) amendment has been authorised.

Research Project

HREC reference number	HREC/17/MonH/180	**HREC approval date**	28 April 2017
Local reference number	17-0000-027A	**Date of this form**	26 July 2018
Project title	Investigating The Utility Of A Novel Fetal Heart Rate Monitoring Device In Measuring Fetal Heart Rate Patterns		
Sponsor	BIORITHM Pte Ltd	**Sponsor telephone**	+6590472160
Sponsor contact (Aus)	Enter text	**Sponsor email**	Enter text
Sponsor billing address	Enter text		
Coordinating Principal Investigator (CPI) for project	Dr Vinayak Smith		
CPI email	Vinayak.smith@monash.edu		
Study coordinator name	Dr Vinayak Smith	**Study coordinator email**	Vinayak.smith@monash.edu

Amendment

Did a commercial sponsor initiate the amendment?	No
Amendment category	Amend protocol
Amendment category 2 ***(if applicable)***	Select one
Amendment category 3 ***(if applicable)***	Select one
Description of changes	The study protocol has also been amended in view of the issue encountered with signal acquisition to ascertain the best electrode position to collect fetal ecg signal. This has expanded the study to have 2 phases. The first will include testing electrode orientation with patients to evaluate the signal based criteria for NIFECG acquisition. For this phase , we would like to recruit women from 24 weeks as data quality is higher from that gestation and perform a mobile bedside ultrasound prior to application of electrodes.
Reason for changes	This was due to the unforeseen level of signal noise encountered during the first phase of the trail. As such the device components had to be increasingly shielded to prevent the signal interruption and a better orientation of the electrodes need to be determined to optimise fetal ECG acquisition. The bedside ultrasound will help delineate the fetal position and its effect on signal quality. A ultrasound for use has already been negotiated with the Department of Obsterics and Gynaecology which will not impact workflow in the unit. The ultrasound will take approximately 5 minutes and will be done by Dr Vinayak Smith.
Do the changes raise any ethical issues?	No
Do the changes raise any privacy (including data linkage) issues?	No

MonashHealth
Correspondence and attachments reviewed and approved by Dr James Doery, Deputy Chair, HREC
Site Specific Authorisation to proceed with amendment at Monash Health (Yes) No N/A
Signed:
Date: 26-7-2018
Forward electronic copy of Site Specific PICF for barcoding to Research@monashhealth.org : Yes / No

If Yes, provide description of ethical and/or privacy issues	Enter text
Does the amendment include additional/different drugs/devices or involve a new indication for any drug/device other than that approved in the original application?	No

Participating Sites

Does the amendment affect all sites approved by the reviewing HREC?	Yes
If No, list affected sites	Enter text

An amendment to an ethically approved research project may also impact research governance/Site Specific Assessment (SSA). The Research Governance Officer (RGO)at each affected site must be notified of the amendment by the site PI, in order to determine if research governance/SSA amendment is required.

Supporting Departments

Does the amendment impact the type or frequency of service provided by a supporting department at participating sites?	No
If Yes, list department(s)	Enter text

Supporting departments may include: Anaesthesia, Anatomical pathology, Cardiology or ECG, Chemical pathology, Clinical immunology, Clinical pharmacology, EEG or EMG, Emergency, Endocrinology, Haematology, Health information, Interpreter services, Medical staff, Molecular biology, Nuclear medicine, Nursing services, Occupational therapy, Ophthalmology, Pharmacy, Physiotherapy, Radiology, Social work, Speech pathology, Tissue typing.

Amended Documents

Document title ***(include version number, if applicable)***	**Version Date**
Study Protocol v 5.0	26072018
PICF v3.0	26 July 2018
Enter text	Select date
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Declaration

To be completed by the Sponsor/CRO, or the Coordinating Principal Investigator (CPI) for a multi-site project, or the Principal Investigator (PI) for a single-site project.

The information provided in this report is complete and correct. The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved). The project is being