

05-Feb-20

**Mr. Camdon Fary**  
**Epworth Foundation t/a Epworth HealthCare**  
**166 Gipps St**  
**East Melbourne Victoria 3002**

Dear Mr. Fary,

**Re: Application No:** 2019-09-822-AA

**Study Title:** A Prospective Multicenter Longitudinal Cohort Study of the mymobility Platform

**Application Type:** NEW

**Type of Review:** FULLBOARD

**Name of the Documents Submitted & Approved: Attachments**

2019.11.29 mymobility Recruitment Flyer  
mymo-Card Insert-smaller-091018 (2)  
Instructions to View mymobility Exercise Routines-AUS  
Site Approval Form FINAL Signed  
Cover letter for e-consent substudy  
mymobility Informed Consent Questions - Knowledge and satisfaction check  
PICF\_Epworth\_21Jan2020\_V1\_Clean\_Zimmer\_mymobility  
mymobility Multi-Care Pathway v1.8-AUS Prep  
mymobility PKA Specific Education 11.10.18  
mymobility THA Specific Education 11.10.18  
mymobility TKA Specific Education 11.10.18  
PROTOCOL\_CLU2018-13CH mymobility Clinical Study 11\_Jun\_2019\_Final  
Statement of Compliance Signed by Mr Fary  
updated e-Consent Protocol v1.2 05Jan2020 CLEAN UPDATED

**Includes:**

EQ-5D-5L Worksheet Version 1  
HOOS Jr Worksheet Version 1  
KOOS Jr Worksheet Version 1  
Patient Questionnaire 1\_Worksheet Version 3  
Patient Questionnaire 2\_Worksheet Version 2  
Patient Questionnaire 3\_Worksheet Version 2  
APPENDIX A\_All Source Worksheets 2019.08.05  
APPENDIX B\_CLU2018-13CH\_Study Logs  
mymobility clinical study brochure prints\_2159.2-US-en-REV1118  
CLU2018-13CH\_PISCF\_Master\_11Nov2019\_V3\_CLEAN

The Committee notes the insurance Certificate of Currency valid to 1 July 2020, and the following document:  
- mymobility VSM 21Nov2019



Please note the clarification for the meeting date below. The original study was reviewed at the Bellberry Human Research Committee meeting held on 30 October 2019. This site has been approved by the Bellberry Human Research Committee on the date listed below.

**Date of Meeting:** 06-Nov-19

**Date of Approval:** 05-Feb-20

**Period of Approval:** 05-Feb-20 - 05-Feb-23

Thank you for submitting the above mentioned application.

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 as at 2018) (National Statement) on the above meeting date.

This Bellberry HREC is constituted and operates in accordance with the National Statement.

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:-**

- **THAT YOU ACKNOWLEDGE YOUR AGREEMENT TO THE UNDER MENTIONED CONDITIONS BY SIGNING AND RETURNING A COPY OF THIS LETTER, PRIOR TO THE COMMENCEMENT OF THE RESEARCH. THE SIGNED LETTER CAN BE EMAILED TO BELLBERRY@BELLBERRY.COM.AU OR POSTED TO THE ABOVE ADDRESS.**
- The data collected for the purpose of this research project cannot be used for any other purpose without the approval of the Bellberry 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.
- That copies of all completed consent forms and any other data used in this research may be inspected at any time by representatives of the Bellberry Human Research Ethics Committee.
- That a report on the progress of the research will be made to the Bellberry Human Research Ethics Committee on **05-Feb-21** or on completion of the trial (if sooner) and then annually for the duration of the trial. This report is to indicate whether any ethical problems or complications have arisen, particularly side effects of drugs used or any other factor which may result in the investigation not producing any result as distinct from the anticipated result.
- That you will notify the Bellberry Human Research Ethics Committee of any changes that may be required within the research proposal.
- Bellberry Human Research Ethics Committee approval is conditional upon your meeting any statutory obligations that you may have in relation to this project.
- Adverse Event reporting should be reported to the Bellberry Human Research Ethics Committee as per the monitoring guidelines posted on the website [www.bellberry.com.au](http://www.bellberry.com.au).
- Any extension to the initial approval period is to be requested in an application via the eProtocol system together with the inclusion of a progress report.
- That you will provide a copy of the Sponsor's final report when this becomes available.

**Details of Ethics Committee:**

It is the process of the Bellberry Human Research Ethics Committee not to disclose personal details of its reviewing members. This



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Project was considered by a Committee that fulfilled the requirements of the National Statement (2007) section 5.1.29 & 5.1.30. A member listing is available as an attachment in eProtocol. Please note that the Principal Investigator and Co-Investigators are not members of the Bellberry Human Research Ethics Committees and were not involved in the review of 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

**Brian Stoffell**

**Chair, Committee A, HREC Code EC00372**

**BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE**

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**PRINCIPAL INVESTIGATOR SIGNATURE DATE**

e-protocol