



**ST VINCENT'S
HOSPITAL**
MELBOURNE

A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

**St Vincent's Hospital
(Melbourne) Limited**
ABN 22 052 110 755

41 Victoria Parade Fitzroy VIC 3065
PO Box 2900 Fitzroy VIC 3065

Telephone 03 9231 2211
Facsimile 03 9231 3399
www.svhm.org.au

19 November 2020 (Revised)

Associate Professor Elif Ekinci
Department of Medicine
Austin Health

Dear A/Prof Ekinci,

Project ID: 62605
St Vincent's HREC Ref: HREC 188/20

Title: 'FlashGM Study - Can Flash Glucose Monitoring (FlashGM) improve glucose management in Indigenous Australians with type 2 diabetes? A randomised controlled trial'

I am pleased to advise that the above project has received **Ethical approval** from the St Vincent's Hospital Melbourne Human Research Ethics Committee (HREC)

HREC Approval Date: 19 November 2020

This HREC is accredited by the Office of Health and Medical Research under the single ethical review system. The HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007, updated 2018).

Ethical approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992*, the *National Statement on Ethical Conduct in Human Research 2007 (Including all updates)* and the *Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2018)*.

Ethical approval is given for this research project to be conducted at the following sites:

- Rumbalara Aboriginal Co-Operative – VIC
- Goulburn Valley Health – VIC
- Austin Health – VIC
- Apunipima Aboriginal Co-Operative – QLD
- Wuchopperen Aboriginal Co-Operative – QLD
- Maari Ma Aboriginal Corporation – NSW
- St Vincent's Hospital Melbourne – VIC

The research team is required to inform the HREC of the participant sites when available and sites will need to be listed in the Annual Progress Report.

Approved documents

The following documents have been reviewed and approved:

Document	Version	Date
Victorian Specific Module (VSM)	1.1	24 Sep 2020
Protocol	1.1	24 Sep 2020
Master PICF – Governance Evaluation	1.1	24 Sep 2020
Master PICF – Patient Population	1.1	24 Sep 2020
Final Interview – Qualitative Component	1.1	24 Sep 2020
Modified Glucose Monitoring Satisfaction Survey	1.0	18 Aug 2020
Mayi Kuwayu Research Assistant Script	1.0	05 Nov 2020
EQ-5D-5L Health Questionnaire – English (UK)	-	2009
Governance Evaluation – Email Invitation to Stakeholders	1.0	18 Aug 2020
Governance Evaluation – Script and Interview Questions	1.0	18 Aug 2020
Governance Evaluation – Audio Consent Script	1.0	18 Aug 2020
User Manual – FreeStyle LibreLink	-	02 Mar 2018
User Manual – FreeStyle LibrePro	-	23 Sep 2016
Certificate of Participation – PPT	1.1	24 Sep 2020
Certificate of Participation – Word	1.1	24 Sep 2020
Budget	1.1	24 Sep 2020
CTN – Clinical Trial CT-2020-CTN-00912-1 v3 Draft	-	-
Certificate of Currency (covering 31 Oct 2019 – 31 Oct 2020)	-	23 Oct 2019

Acknowledged Documents

Document	Version	Date
HREA - HREC/62605/SVHM-2020-241432(v3)	-	18 Nov 2020
FDA Approval – FreeStyle Libre Pro Flash Glucose Monitoring System	-	23 Sep 2016
FDA Approval – FreeStyle Libre 14 Day Flash Glucose Monitoring System	-	23 Jul 2018
FDA – Summary of Safety and Effectiveness Data (SSED) – PMA P160030	-	-
TGA – Public Summary – FreeStyle Libre Flash Glucose Monitoring System Sensor	-	03 Oct 2018
TGA – Public Summary – FreeStyle Libre Pro Flash Glucose Monitoring System Sensor	-	20 Dec 2015
Sponsorship Letter – University of Melbourne	-	-
Final Ethical Approval – Austin Health HREC	-	23 Jun 2020
Final Ethical Approval – GV Health	-	31 Oct 2017
NHMRC – Funding Approval	-	-
Letter of Support – Wuchopperen Health Services Limited	-	24 Feb 2020

Letter of Support – Maari Ma Health Aboriginal Corporation	-	14 Jul 2020
Letter of Support – Rumbalara Aboriginal Co-Operative	-	26 Feb 2020
Letter of Support – Torres and Cape Hospital and Health Service	-	20 Jun 2017
Letter of Support – Goulburn Valley Health	-	05 Oct 2020
Letter of Support – Apunipima Cape York Health Council	-	15 Jun 2020
Letter of Support – NACCHO	-	21 Sep 2020
CV – Elif Ekinci		
GCP – Elif Ekinci	-	22 Jul 2019
CV – Tracey Hearn		
GCP – Tracey Hearn	-	18 Jun 2019
CV – Sharon Atkinson-Briggs		
GCP – Sharon Atkinson-Briggs	-	19 May 2020
CV – Sandra Eades		
CV – Stephen Twigg		
GCP – Stephen Twigg	-	22 Jan 2018
CV – Megan Freund		
CV – David O’Neal		
CV – Sabine Braat		
GCP – Sabine Braat	-	19 Feb 2019
CV – David Story		
GCP – David Story	-	26 Mar 2019
CV – Alex Brown	-	-
CV – Anna McLean	-	-
CV – Ashim Sinha	-	-
CV – Audrey Eer		
GCP – Audrey Eer	-	04 Mar 2018
CV – Jeffrey Zajac	-	-
GCP – Jeffrey Zajac	-	12 Jul 2020
CV – John Furler		
GCP – John Furler	-	18 May 2020
CV – Mariam Hachem		
GCP – Mariam Hachem	-	25 Sep 2018
CV – Philip Clarke		
CV – Richard O’Brien		
CV – Daniel Duke		
CV – Donna Rumbiolo		
GCP – Donna Rumbiolo	-	07 May 2020
CV – An Duy Tran		
CV – Luke Burchill		
GCP – Luke Burchill	-	06 Dec 2018

Project ID: 62605
St Vincent’s HREC: 188/20

Please quote these numbers on all Correspondence

Approval is subject to:

- **An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the 01 May each year for the duration of the project. Continuation of ethics approval is contingent on submission of an annual report. Failure to comply with this requirement may result in suspension of the project by the HREC.**
- The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement on Ethical Conduct in Human Research 2007 (including all updates)
- The Principal Researcher is to notify the Research Governance Unit of all significant safety issues in accordance with the *NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods (including all updates)*.
- Submit an Annual Safety Report for the duration of the project.
- Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
- Notification and reasons for ceasing the project prior to its expected date of completion;
- Submit to the reviewing HREC for approval of any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s, Investigator Brochure and other study materials.
- Submission of reviewing HREC approval for any proposed modifications to the project.
- Submission of a final report and papers published on completion of project.
- Projects may be subject to an audit or any other form of monitoring by the Research Governance Unit at any time.

The HREC wishes you and your colleagues every success in your research.

Yours sincerely,

Lauren Barina
Administrative Officer
Research Governance Unit
St Vincent's Hospital Melbourne