



Bendigo Health Human Research Ethics Committee

ETHICS APPROVAL FOR AMENDMENT

A/Prof Carina Chan
La Trobe University

Edwards Road, Flora Hill
Bendigo
3552

6 April 2023

Dear A/Prof Carina Chan,

Project Title	Imagine for better diabetes management
Project ID	80469
Review Reference	AM/80469/BH-2023-364269(v3)

I am pleased to advise that the amendment to the above project has received ethical approval from Bendigo Health Human Research Ethics Committee (HREC).

This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research* (2007), and all subsequent updates, and in accordance with the *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)*, the Health Privacy Principles described in the *Health Records Act 2001* (Vic) and Section 95A of the *Privacy Act 1988* (and subsequent Guidelines).

This amendment approval applies for all sites for which Bendigo Health HREC has issued ethical approval.

This amendment approval is subject to compliance with the conditions imposed by the reviewing HREC at the time of (a) the original ethics approval and (b) any amendment approvals prior to this.

Additional Sites

The amendment includes the addition of the NSW sites as described on the amendment form.

Research governance/site specific assessment (SSA) authorisation must be obtained by each participating site before the research project can commence at that site.

You are required to provide a copy of this letter, and all previous approval letters, to the principal investigator of each additional site. These documents must be included in the site research governance/SSA application.

Approved Documents

The following documents have been reviewed and approved:

Document Type	File Name	Date	Version
Protocol (Tracked)	Imagination Matters - Research Protocol_UPDATED_TRACKED_2023-03-31	31/03/2023	3
Protocol	Imagination Matters - Research Protocol_UPDATED_CLEAN_2023-03-31	31/03/2023	3
Other	Screening flyer advertisement - Imagine for Better Diabetes Management_w HREC number 2_TRACKED_20230331	31/03/2023	2
Other	Screening flyer advertisement - Imagine for Better Diabetes Management_w HREC number 2_CLEAN_20230331	31/03/2023	2
Curriculum vitae	CV_Simmons_updated_20230301	31/03/2023	1
Curriculum vitae	Milan Piya 2 page CV March 2023	31/03/2023	1
PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF- Imagine for better diabetes management - NSW_UPDATED_TRACKED_20230331	31/03/2023	1
PARTICIPANT INFORMATION AND CONSENT FORM (TRACKED)	PICF (eligible participants)- Imagine for better diabetes management - Bendigo Health_UPDATED_TRACKED_20230331	31/03/2023	3
Participant information and consent form	PICF- Imagine for better diabetes management - NSW_UPDATED_CLEAN_20230331	31/03/2023	1
Participant information and consent form	PICF (eligible participants)- Imagine for better diabetes management - Bendigo Health_UPDATED_CLEAN_20230331	31/03/2023	3

Research Governance Amendment

You are required to provide a copy of this amendment approval letter to the principal investigator of each site that is affected by the amendment and is covered by the Bendigo Health HREC approval. The principal investigator should provide a copy to their site research governance officer (RGO). An amendment to the site research governance/site specific assessment (SSA) authorisation may be required.

If any matters arise regarding conduct of the research at this site, please contact the RGO via email at researchoffice@bendigohealth.org.au or by phone on (03) 5454 6412

Yours sincerely,

Dr Merryn Davies

Bendigo Health