



Bendigo Health Care Group Human Research Ethics Committee

ETHICS APPROVAL

Prof Irene Blackberry
PO Box 821
Wondonga
Vic, 3689

28 June 2019

Dear Prof Blackberry,

Project Title Improving Detection of Patient Complexity in the Community (ImPaCt)
Project ID 54227
Review Reference LNR/54227/BHCG-2019-179128(v2)
Local Reference Number LNR/19/BHCG/54227 - *please use in all correspondence*

I am pleased to advise that the above project has received ethical approval from Bendigo Health Care Group Human Research Ethics Committee (HREC). Please note that the expiry date for this approval is **31 December 2019**.

The HREC confirms that your proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* (2007). 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).

Participating Sites

Ethical approval for this project applies at the following site(s): Bendigo Health.

Site	State/Territory
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Approved Documents

The following documents have been reviewed and approved:

Document Type	File Name	Date	Version
Other	letter of support for ImPaCt JH	11/06/2019	1
Curriculum vitae	CV 2019 JBoak	12/06/2019	10
Evidence of professional registration	JB registration AHPRA	12/06/2019	1
Curriculum vitae	Brief CV_T Rasekaba	13/06/2019	1
Curriculum vitae	Curriculum Vitae Irene Blackberry	13/06/2019	1
Questionnaire	ImPaCt survey 1 V2	25/06/2019	2

Questionnaire	ImPaCt survey 2 V2	25/06/2019	2
Questionnaire	ImPaCt survey 3 & 4 V2	25/06/2019	2
Participant information and consent form	ImPaCt Appendix 1 Staff information and consent v4	27/06/2019	4
Protocol	ImPaCt Research Protocol JBOAK V17	26/06/2019	17
Other	Response letter	26/06/2019	1

Research Governance Authorisation

The associated site specific assessment (SSA) has also satisfied Bendigo Health's research governance requirements, meaning this project can commence at this site.

Conditions of Ethics Approval

1. You are required to submit to the HREC:
 - An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the scheduled date. Failure to comply with this requirement may result in suspension of the project by the HREC.
 - A comprehensive Final Report upon completion of the project.
2. Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
3. Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016).
4. Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
5. Notify the reviewing HREC of the failure to commence the research project within 12 months of the HREC approval date or if a decision is taken to end the research project at any of the sites prior to the expected date of completion.
6. Notify the reviewing HREC of any matters which may impact the conduct of the research project.
7. If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency *Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes'* Radiation Protection series Publication No.8 (May 2005) (ARPANSA Code).
8. The HREC, authorising institution and/or their delegate(s) may conduct an audit of the research project at any time.

Waiver of the Requirement for Consent

The request for a waiver of consent for the collection/use/disclosure of health information as per the protocol (listed above) is approved. The HREC agrees that the request to waive consent meets the criteria set out in the *National Statement on Ethical Conduct in Human Research* (2007) and the *Health Records Act 2001* (Vic).

Yours sincerely,



Ms Sally McCarthy
Research Manager
Bendigo Health