

## **Monash University Human Research Ethics Committee**

## **Approval Certificate**

This is to certify that the project below was considered by the Monash University Human Research Ethics Committee. The Committee was satisfied that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and has granted approval.

**Project ID:** 22340

Project Title: A statewide Pragmatic Cluster Randomised Controlled Trial of Vaxcards: a tool for education and reward for vaccination.

**Chief Investigator:** Dr Dan Epstein **Approval Date:** 31/10/2019 **Expiry Date:** 31/10/2024

## Terms of approval - failure to comply with the terms below is in breach of your approval and the Australian Code for the Responsible Conduct of Research.

- 1. The Chief Investigator is responsible for ensuring that permission letters are obtained, if relevant, before any data collection can occur at the specified organisation.
- 2. Approval is only valid whilst you hold a position at Monash University.
- 3. It is responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
- 4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
- 5. The Explanatory Statement must be on Monash letterhead and the Monash University complaints clause must include your project number.
- 6. Amendments to approved projects including changes to personnel must not commence without written approval from MUHREC.
- 7. Annual Report continued approval of this project is dependent on the submission of an Annual Report.
- 8. Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected completion date.
- 9. Monitoring project may be subject to an audit or any other form of monitoring by MUHREC at any time.
- 10. Retention and storage of data The Chief Investigator is responsible for the storage and retention of the original data pertaining to the project for a minimum period of five years.

Kind Regards,

Professor Nip Thomson

Chair, MUHREC

CC: Dr Chris Barton, Dr Joanne Enticott

## List of approved documents:

Document Type	File Name	Date	Version
Supporting Documentation	vaxcards questionaire	14/10/2019	1
Supporting Documentation	VICblank sample and exclusion flow	14/10/2019	1
Supporting Documentation	Parent email from school for questionaire	14/10/2019	1
Supporting Documentation	Student email from school for questionaire	14/10/2019	1
Supporting Documentation	Vaxcards Explanatory Statement 2	14/10/2019	1
Supporting Documentation	ExecSummaryRiskProfile(1)	14/10/2019	1
Supporting Documentation	RCT handout	14/10/2019	1
Supporting Documentation	Parent email from school for questionaire	14/10/2019	1
Supporting Documentation	Student email from school for questionaire	14/10/2019	1
Explanatory Statement	Vaxcards Explanatory Statement 2	14/10/2019	1
Consent Form	Student email from school for questionaire	14/10/2019	1
Consent Form	Parent email from school for questionaire	14/10/2019	1
Questionnaires / Surveys	vaxcards questionaire	14/10/2019	1

30/10/2019

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