**Austin Hospital**

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# AUSTIN HEALTH HUMAN RESEARCH ETHICS COMMITTEE

## ETHICAL APPROVAL

A/Prof. Jason Trubiano,
Department of Infectious Diseases, Austin Health

29 April 2020

Dear A/Prof. Jason Trubiano,

**HREC Reference Number:** HREC/59438/Austin-2020

**Austin Health Project Number:** DT 59438/2020

**Project Title:** Oral penicillin provocation in low risk penicillin allergies - ORACLE Study.

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I am pleased to advise that the above project has **received ethical approval** from the Austin Health Human Research Ethics Committee (HREC). The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007, updated 2018). This 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), 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).

**HREC Approval Date:** 29 April 2020

**Ethical approval for this project applies at the following sites:**

| Site |
|---|
| Austin Health |

**Approved Documents:**

The following documents have been reviewed and approved:

| Document | Version | Date |
|---|---|---|
| Ethics Cover Letter & Checklist | - | 24 January 2020 |
| HREA | 2 | 25 March 2020 |



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| Victorian Specific Module (VSM) | 1 | 27 January 2020 |
| Protocol | 4 | 26 February 2020 |
| Participant Information Sheet/Consent Form -Self | 3 | 20 March 2020 |
| Participant Information Sheet/Consent Form – Person Responsible | 3 | 20 March 2020 |

**Conditions of Ethics Approval:**

- 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 approval anniversary. 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.
- 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.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products November 2016*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters, which may affect the conduct of the project.

The HREC may conduct an audit of the project at any time.

Yours sincerely,

Priyanka Sathe

Digitally signed
by Priyanka Sathe
Date: 2020.04.29
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**Priyanka Sathe**
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