

Austin Hospital

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AUSTIN HEALTH HUMAN RESEARCH ETHICS COMMITTEE
ETHICAL APPROVAL

Dr Jason Trubiano

20 May 2019

Dear Dr Jason Trubiano,

HREC Reference Number: HREC/50791/Austin-2019

Austin Health SITE REFERENCE Number: ND 50791/2019

Project Title: Australian registry for Severe Cutaneous Adverse Reactions

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). 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), 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: 20/05/2019

Ethical approval for this project applies at the following sites:

Site
Alfred Health
Austin Health
Campbelltown Hospital
Eastern Health
Fiona Stanley Hospital
Peter MacCallum Cancer Centre
Institute for Immunology and Infectious Diseases
Monash Health
Nepean Hospital
Sir Charles Gairdner Hospital



St Vincent's Hospital Sydney
St Vincent's Hospital Melbourne
Royal Adelaide Hospital
Royal Brisbane Hospital
Royal Hobart Hospital
Royal Melbourne Hospital

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
HREA (HREC/50791/Austin-2019-173253)	3	3 May 2019
VSM (VSM/50791/Austin-2019-173255)	1	3 May 2019
Protocol including: <ul style="list-style-type: none"> Appendix 1: Drug Allergy Testing Concentrations Appendix 2: Case Report Form Appendix 3: Follow up patient survey 	4	3 May 2019
Master Participant Information Sheet/Consent Form	2	3 May 2019
Master Participant Information Sheet/Consent Form (Person Responsible)	2	3 May 2019

Noted Document	Version	Date
Western Australia Specific Module (WASM)	1.0	8 May 2019
NSW Privacy Form	-	-
Study Budget	1	9 January 2019

Governance Authorisation:

Governance Authorisation is required at each site participating in the study before the research project can commence at that site.

You are required to provide a copy of this HREC approval letter to the principal investigator for each site covered by this ethics approval for inclusion in the site-specific assessment application.

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.
- **If your project involves radiation:**
 - **It is your responsibility to ensure the research is added to the site Management Licence issued by Department of Human Services – Radiation Safety Section prior to study commencement should it be required (check your Medical Physicist Report). The site RGO must be notified when the research has been added to the licence.**
 - **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).**

Please note: Template forms for reporting Amendments, Adverse events, Annual/Final reports, etc. can be accessed from: <https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials>.

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

Yours sincerely,

Alyaa Mohamed
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