

14 April 2021

Human Research Ethics Committee

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Core Members

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MBBS FRACP FRCPA
Member with current experience
in the professional care of humans

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Member who performs a pastoral
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Expert knowledge in medical
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Dr Vivian Chiu
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knowledge in clinical psychology

Dr Gail Ross-Adjie
BN MClInNurs PhD
Community member with current
experience as a nurse researcher

Dr Evan Bayliss
MBBS FRACP
Community member with expert
knowledge in oncology

Dr Ai Tran
Rheumatologist,
Wexford Medical Centre,
29/3 Barry Marshall Parade,
MURDOCH WA 6150

Dear Dr Tran,

Re: (RESCUE): Response to COVID-19 vaccination in immunosuppressed patients with autoimmune disease

(Our ref: 1809)

Thank you for forwarding the above study for review by the St John of God Health Care (SJGHC) Human Research Ethics Committee ("the Committee").

I am pleased to advise that the Committee at the meeting on 14 April 2021 has granted ethical approval of your study as satisfying the ethical requirements under the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) ("the National Statement").

The study approval period is from 14 April 2021 to 14 April 2022. Should an extension of this timeframe be required, you must seek continued approval from the Committee before the expiry of this time period.

In accordance with NHMRC guidelines, the Participating Site/ Principal Investigator is responsible for:

1. Notification to the HREC of any adverse events or unexpected outcomes that may affect the continuing ethical acceptability of the study;
2. The submission of any proposed amendments to the study or previously-approved documents;
3. The submission of an six-month progress report for the duration of the study which is due on the anniversary of HREC approval;
4. Reporting of all protocol deviations to the sponsor (if applicable) and all serious breaches reported to the HREC (preferably via the sponsor), together with details of the procedure(s) put in place to ensure the deviation or serious breach does not recur;
5. Notification and reason for ceasing the study prior to its expected date of completion (if applicable);
6. The submission of a final report and translation of results (including publications) upon completion of the study.

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The following documents have been reviewed and approved:

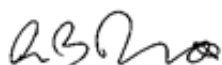
Title	Version	Date
Protocol RESCUE	1.1	
PICF RESCUE	1.0	05-Apr-21
Declaration of Interest_Ai Tran and Nik Ding		06-Apr-21
Ai Tran CV 2020		

You are reminded that this letter constitutes ethical approval only. You must not commence this research at SJGHC until separate authorisation in writing has been obtained.

Final approval for this study to be conducted at St John of God Murdoch Hospital and Dr Ai Tran's Private Rooms is subject to receipt of a fully signed Participating Site Operational Approval form (PSOA). Once this has been received by the SJGHC Ethics Office, you will be advised of final study approval in writing.

I wish you well with your research.

Yours sincerely,



Clinical Professor Dr Simon Dimmitt

Chairman

St John of God Health Care Human Research Ethics Committee

cc. Nik.DING@svha.org.au

cc. Alexis Cranfield and Sarah-Jayne Powell, SJG Murdoch Hospital