Research Support Services
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10 February 2023

A/Prof Alberta Hoi
Monash Health
Department of Rheumatology
246 Clayton Road
Clayton VIC 3168

Dear Researcher,

Study Title: Temporary Withholding of Immunosuppressant in Rheumatic diseases and Lupus (TWIRL) Study

ERM Reference Number: HREC/91163/MonH-2022-338637(v1)
Monash Health Reference: RES-22-0000-649A

The Monash Health HREC A reviewed the above application at the meeting held on 10 November 2022. In addition, the HREC is satisfied that the responses of 10 February 2023have sufficiently addressed all outstanding queries.

The HREC approved the above application on the basis of the information provided in the application form, protocol and supporting documentation.

This reviewing HREC is certified by the National Health and Medical Research Council under the National Certification Scheme, and is a Certified Reviewing HREC under the National Mutual Acceptance scheme.

Approval

The HREC approval is from 10 February 2023.

Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2018)*. The HREC has ethically approved this research according to the national Memorandum of Understanding for mutual acceptance of scientific and ethical review of multi-centre human research projects undertaken in public health organisations.

Approval is given for this research project to be conducted at the following sites and campuses:

- Monash Health

You must comply with the following conditions:

The Coordinating Principal Investigator is required to notify the HREC Executive Officer, Monash Health of:

1. Any change in protocol and the reason for that change together with an indication of ethical implications (if any).

2. Significant Safety Issues (SSIs) reported as either an Urgent Safety Measure (USM), an amendment, or as a temporary halt/early termination of the trial in accordance with the NHMRC safety monitoring and reporting guidelines as adopted by Monash Health. The local site Principal Investigator is also required to notify the Research Governance Office of any Suspected Unexpected Serious Adverse Reactions (SUSARs) that occur with a Monash Health participant.
3. Any unforeseen events that might affect continued ethical acceptability of the project.
4. Any expiry of the insurance coverage provided in respect of sponsored trials.
5. Discontinuation of the project before the expected date of completion, giving reasons.
6. Any change in personnel involved in the research project including any study member resigning from Monash Health and/or the study team.

At the conclusion of the project or every twelve months if the project continues, the Principal Investigator is required to complete and forward an annual progress report to the Committee.

Reminders to submit annual progress report forms will be forwarded to the researcher.

The Coordinating Principal Investigator is responsible for notifying Principal Investigators. The Coordinating Principal Investigator and Principal Investigators should forward a copy of this letter to their site's Research Governance Office.

Approved documents

Documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Human Research Ethics Application	HREC/91163/MonH-2023-354364(v5)	10/2/2023
Study Protocol	4.0	31/1/2023
Victorian Specific Module	2	25/1/2023
Participant Information and Consent form	4	09/2/2023
Patient Letter	3.0	09/2/2023
Workbook for TWIRL study/Case Report Form	-	-

Site Specific Assessment (SSA)

SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

The completed Site Specific Assessment Form and a copy of this ethics approval letter must be submitted to the Research Governance Office for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

If you should have any queries about your project, please contact the Research Support Services team via email research@monashhealth.org or telephone. The contact list for team members is available via: https://monashhealth.org/research/research-support-services/.

Please note that if arranging meetings or contacting team members by phone, our availability is between 9:00am – 4:00pm. Upon prior arrangement, we may be able to assist outside of these

times. We recommend emailing research@monashhealth.org in the first instance, to allow the most appropriate team member/s to provide advice.

The HREC wishes you and your colleagues every success in your research.

Yours sincerely,

Katharine Mahoney
HREC Executive Officer

Cc: Celine Shi

All post-approval submissions for this study must be made via ERM. Upon uploading to ERM, the researcher must also send an email to research@monashhealth.org with the Monash Health Reference Number and ERM Project ID, to notify the Research Support Services team of the submission.

Checklist: Post-ethics approval requirements that must be met before a research project can commence at a study site.

Please ensure that as a PI (including the CPI) the following are completed at each study site.

Requirements	**Yes/No/NA**
Ethics approval notification The PI must send a copy to the RGO at that study site.	Yes
HREC Review Only Indemnity The PI must forward a copy of the signed HREC Review Only Form of Indemnity to the RGO at that study site.	N/A
CTN Acknowledgement for Commercially Sponsored Studies The PI must forward a copy of the CTN Acknowledgement to Research Support Services.	N/A
CTN Lodgement for Collaborative Group/Investigator Driven Studies The PI or nominated delegate is requested to make an appointment with the Monash Health Research Support Services team via research@monashhealth.org so that the lodgment may be completed by both the investigator and Research Support Services. The banking details for payment to the TGA will need to be brought along to this appointment, in order to finalise notification to the TGA. The fee for lodging a CTN is $390.	N/A
SSA authorisation notification The PI must forward the SSA form and attached documents (e.g., CTRA) to the RGO so the authority approving the conduct of the trial at that site, can complete and sign.	Yes
Radiation If applicable, the RGO must contact the Radiation Safety Officer so that the study may be notified to the Victorian Department of Health's Radiation Team.	N/A
Other Commonwealth statutory requirements Ensure compliance with the following e.g., Office of the Gene Technology Regulator; NHMRC Licensing Committee.	N/A