

AUCKLAND HEALTH RESEARCH ETHICS COMMITTEE (AHREC)

18/04/2023

Dr Amy Chan
Pharmacy

Re: Request for amendment of Ethics Approval (Our Ref. AH1159): Amendments approved

The Committee considered the amendment request for your study entitled "**Opioid use after surgery and trauma in New Zealand**".

Approval was granted for the following amendments:

1. To extend the project for a further three years.
2. To provide a revised Study Protocol to reflect the exact wording used in the published protocol in BMJ Open. Changes include clarifying index date, adding oral morphine equivalent calculation to compare different opioid exposures, and adding 'modifiable' and 'other' covariates.
3. To include Prof Chris Frampton as a collaborator.
4. To include a detailed description of regression analysis, Wald test, Quantile regression, and assessment for proportional assumption in survival analysis.
5. To include additional sensitivity analysis treating ethnicity as a binary variable (Māori vs Non-Māori) for the primary outcome.
6. To include additional sensitivity analysis for secondary outcome all-cause mortality to extend follow-up time.
7. To include supplementary analyses for primary and secondary outcomes.

The ethics approval for this project expires on **15/04/2026**.

Further amendments to the approved project: Should you need to make any further changes to the approved project, please follow the steps below:

- Send a request to the AHREC Administrators to unlock the application form (using the Notification tab in the Ethics RM form).
- Make all changes to the relevant sections of the application form and attach revised documents (as appropriate).
- Change the Application Type to "Amendment request" in Section L.
- Add a summary of the changes requested in the text box.
- Submit the amendment request (PI/Supervisors only to submit the form).

If the project changes significantly, you are required to submit a new application.

The Chair and the members of AHREC would be happy to discuss general matters relating to ethics approvals. If you wish to do so, please contact the AHREC Ethics Administrators at ahrec@auckland.ac.nz in the first instance.

Additional information:

- Do not forget to fill in the 'approval wording' on the Participant Information Sheets, Consent Forms and/or advertisements, giving the dates of the initial approval and the reference number before you use them or send them out to your participants.

All communications with the AHREC regarding this application should indicate this reference number: **AH1159**.

AHREC Administrators

Auckland Health Research Ethics Committee