

## (Updated) 2019/ETH03266: Notification of Request for extension of HREC Approval and General Amendment (160847) - Approved

no\_reply@regis.health.nsw.gov.au <no\_reply@regis.health.nsw.gov.au>

Thu 5/16/2024 3:35 PM

To:enquiries <enquiries@sydneyentclinic.com>

Cc:Raquel Alvarado <Raquel@sydneyentclinic.com>;Christine Choy <christine@sydneyentclinic.com>

(Updated 16 May 2024) Date of Decision Notification: **16 May 2024**  
**Greater than low risk review pathway**

Dear Professor Richard Harvey,

Thank you for submitting an Amendment for the following study; **2019/ETH03266**: The effect of biologic medication on patients with nasal polyp eosinophilia

The Amendment has been reviewed on 16 May 2024, by the Executive Officer as delegated by the HREC Chair and has been approved.

The following documentation is included in this approval:

Notification of General Amendment\_7Mar2024

Response Cover Letter\_3May2024

Study protocol: Version 6, 03 May 2024 (tracked and clean)

Participant Information Sheet & Consent form: Version 4, 03 May 2024 (tracked and clean)

Noted:

HREA: code AU/1/E8B3311, submission date 28 January 2018

eCTN study detail form\_2024

With regard to Study Extension request, the HREC can only grant a maximum of 5 years extension at a time. This was discussed with the SVH Research Office Manager, Dr Pamela Blaikie and the study is approved 5 years **from the last expiration date. The new expiration date for this study is now 5 APRIL 2028**. If the study requires to extend, please submit another amendment close to this date.

It is noted that the St Vincent's Hospital Human Research Ethics Committee is constituted in accordance with the National Statement on Ethical Conduct in Human Research, 2023 (NHMRC).

**This email constitutes ethical and scientific approval only.**

**While it is noted that St Vincent's Public Hospital is only providing lab services to the study, a Site General Amendment form will need to be submitted to the St Vincent's Hospital Research Governance Officer to check the Service Agreement if this is still valid and if not, it needs to be replaced with a new agreement. You are not required to upload this form or the ethics approved documents into the site form but you will need to identify this approved amendment form ID 160847.**

**Please also submit an updated CTN to the TGA with regard to the addition of Dupilumab.**

Yours Sincerely,

Geraldine Bicol (On behalf of the St Vincent's Hospital Human Research Ethics Committee)  
Research Officer | St Vincent's Health Network  
Translational Research Centre | 97-105 Boundary Street Darlinghurst NSW 2010  
Email: [svhs.research@svha.org.au](mailto:svhs.research@svha.org.au)