

Johnson, Catherine

From: no_reply@regis.health.nsw.gov.au
Sent: Monday, 2 September 2019 1:17 PM
To: Day, Fiona
Cc: Medical Oncology Research Ethics
Subject: 2019/ETH12056: Application HREA - Approved

Date of Decision Notification: 02 Sep 2019

Dear Dr Day

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2019/ETH12056: Palliative Oesophageal Cancer Chemoradioimmunotherapy (PALEO): A multicentre Phase II clinical trial

This project was considered by the **Hunter New England Human Research Ethics Committee** at its meeting held on **2/09/2019** and was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007).

This project has been Approved to be conducted at the following site/s:

- Calvary Mater Newcastle Hospital

The following documentation was reviewed and is included in this approval:

- HREA (Version 3 dated 26 August 2019)
- Response Letter to HNEHREC Requirements (dated 28 August 2019)
- PALEO Protocol (Version 2.4 dated 27 June 2019)
- MIMS Full Prescribing Information Anzatax (Paclitaxel) (MIMS revision date 1 July 2019)
- MIMS Full Prescribing Information Opdivo (Nivolumab) (MIMS revision date 1 July 2019)
- MIMS Full Prescribing Information Carboplatin Injection (MIMS revision date 1 January 2018)
- Master Information for Participants (Version 1.1 dated 27th August 2019)
- Scored Patient-Generated Subjective Global Assessment (PG-SGA) (©2015 v3.22.15)
- EORTC QLQ- C30 (version 3.0) (©1995)
- EORTC QLQ-OES18 English Questionnaire (©1999)
- CMN Radiation Dosimetry Report (signed 17 July 2019, 19 July 2019 and 23 July 2019)

[Application Documents](#) - (Please note : Due to security reasons, this link will only be active for 14 days.)

It is noted that the Hunter New England Human Research Ethics Committee is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC).

The approval is for a period of **5 years from the date of this e-mail (02 Sep 2019)** , on condition of the submission of Annual Reports.

We wish you all the best with the project and remind you that any changes to the application and safety reports will need to be submitted and reviewed by the approving HREC prior to implementation.

This email constitutes ethical and scientific approval only.

This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution under whose auspices the research will be conducted at that site.

This HREC is constituted and operates in accordance with the National Statement on Ethical Conduct in Human Research (2007). The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

Please contact us if you would like to discuss any aspects of this process further, as per the contact details below. We look forward to managing this application with you throughout the project lifecycle.

Kind regards

Debbie Madden

Ethics Administration Officer

Research Ethics & Governance Office

Hunter New England Local Health District

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