

From: no_reply@regis.health.nsw.gov.au
To: Christopher.Grainge@hnehealth.nsw.gov.au
Cc: [Douglas Dorahy](#)
Subject: 2019/ETH01248: Amendment - Addition of Site - Approved
Date: Wednesday, August 7, 2019 3:37:37 PM

Date of Decision Notification: 08 Aug 2019

Dear Dr Grainge

2019/ETH01248: A Randomized Open-Label, Phase 1b Study of the Safety of Pirfenidone Solution for Inhalation (AP01) in Patients with Idiopathic Pulmonary Fibrosis (ATLAS Study)

The Amendment has been reviewed by the Executive Officer as delegated by the Hunter New England Human Research Ethics Committee and has been approved for the following:

- Addition of Nepean Hospital, Westmead Hospital and Concord Repatriation General Hospital as study sites
- Addition of Dr Benjamin Ng as principal investigator at Nepean Hospital
- Addition of Professor John Wheatley as principal investigator at Westmead Hospital
- Addition of Dr Elizabeth Veitch as principal investigator at Concord Repatriation General Hospital

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).

This decision will be ratified at the next meeting of the Committee to be held on 21 August 2019.

This email constitutes ethical and scientific approval only.

Please Note: This is your approval, you will no longer receive a formal letter.

Please contact us if you would like to discuss any aspects of this process further, at HNELHD-HREC@health.nsw.gov.au.

Kind regards

Debbie Madden
Ethics Administration Officer
Research Ethics & Governance Office
Hunter New England Local Health District
Ph: 02 49855929
Email: Debbie.madden@health.nsw.gov.au