



Re: DISCOVERY Trial

My apologies for the delay in replying to your letter of 14 October 2015 regarding the above matter.

The DISCOVERY trial was approved by the RPAH Human research Ethics Committee in July 2010 with stringent conditions of approval appropriate for a Phase I (first in human) trial. In March 2011, the Executive of the HREC met with the senior clinical investigators and Professor Khachigian at their request. Professor Khachigian had been asked by UNSW to provide the HREC with details of an allegation made by a former employee together with relevant documentation.

After due consideration of the nature of the allegation and examination of the pre-clinical data in question, the Executive of the HREC was satisfied that, even if proven, the allegation would have had no bearing on the safety profile or on the potential scientific validity of the study. The clinical investigators concurred with this conclusion.

A detailed written summary of the allegation and the relevant documentation were provided to the HREC at its next meeting in April 2011. Based on this documentation and the opinion of the Executive, the HREC recommended that the trial be allowed to continue and that no further action be taken pending finalisation of the UNSW investigation.

In the period July to September 2011, Professor Field kept the HREC advised of progress of the investigation.

A copy of a letter sent by Professor Field to Professor Khachigian in February 2012 summarizing the outcome of the investigation was subsequently provided to the HREC, advising that there was no case of research misconduct, and that nothing had been found to question the integrity of the data underpinning the trial.

Thank you for your enquiry.

Yours sincerely

Chairman
Ethics Review Committee
Sydney Local Health District (RPAH Zone)

13 January 2016