



TRIM Ref: SD15/

**Re: DISCOVERY Study**

My apologies for the delay in replying to your correspondence of 1 February 2016.

A significant number of the questions you have asked are in relation to the actions of the University of NSW and I therefore advise that these matters should be directed to the University of NSW.

With regard to actions taken by the RPAH Human Research Ethics Committee when informed of the allegation concerning preclinical data relevant to the DISCOVERY Trial, I refer to my previous correspondence to yourself on this matter dated 6 January 2016.

I have again reviewed all the documentation relating to the allegation and the HREC's decision not to halt the study, and am satisfied that (a) the information provided to us was reliable, (b) even if proven, the allegation would have had no bearing on the safety profile or the potential scientific validity of the study, and (c) **it was not necessary for information regarding the allegation to be provided to the study participants.**

As you would be aware, a HREC is frequently required to make judgements about providing information to participants when new findings from animal studies or clinical trials arise during the course of a study. In doing so, it must balance the benefits of providing all information of possible relevance, no matter how minor, against the risks of causing needless anxiety for the participants. In this case, **the HREC did not consider the allegation to be of sufficient substance to outweigh the risk of causing unwarranted anxiety, and no change to the information and consent documents was recommended.**

With regard to the communications between the various parties and the HREC, it may be helpful to outline the usual process. The HREC normally only communicates with the Principal Investigator (who in this case was the senior clinician running the trial, A/Professor Fergal Moloney). All relevant correspondence with the sponsor, funding agency, DSMB, Clinical Research Organization, regulatory agencies, etc is conducted via the PI. In this particular case, Professor Field informed me directly that an allegation involving a UNSW co-investigator had been made, a step he was technically not obliged to take, but one which I appreciated nevertheless. Appropriately, specific details of the allegation were put before the HREC Executive by the PI and a senior co-investigator, accompanied by Professor Khachigian.

With regard to commercial interests, I should point out that in clinical trials it is commonplace for sponsors to have intellectual property interests in the agent being studied. As was the case here, it is the role of the HREC to ensure that information regarding sponsorship and any conflicts of interest that clinicians running the trial may have is divulged to participants.

I believe all parties have acted correctly and responsibly in this matter. If you disagree and wish to raise a complaint regarding RPAH Human Research Ethics Committee, this should be directed to either the Chief Executive Sydney Local Health District, level 11 KGV Building, Missenden Road Camperdown NSW 2050, or to the National Health and Medical Research Council GPO Box 1421, Canberra ACT 2601.

I now consider this matter closed, and do not intend to enter into any further correspondence.

Yours sincerely

A handwritten signature in black ink, appearing to be 'Alister', written in a cursive style. A thin line extends from the bottom of the signature down towards the text below.

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

2 May 2016