



Australian Government
Department of Health

Ref No: MC19-012973

Robert Cockburn
(tracproductions@gmail.com)

Dear Mr Cockburn

Thank you for your email correspondence of 14 and 28 August 2019 to the Minister for Health, the Hon Greg Hunt MP, regarding the investigation of the Woolcock Institute Clinical trial, and the Australian Register of Therapeutic Goods (ARTG) status of the two medical devices used in the trial. The Minister has asked me to reply.

As advised in Minister Hunt's correspondence with your local Member of Parliament, Mr Trent Zimmerman MP in May 2019, the Therapeutic Goods Administration (TGA) plays a minimal role in the conduct of clinical trials in Australia through the administration of the Clinical Trial Notification (CTN) scheme. Under the CTN scheme, the TGA does not review any data relating to clinical trials, it only provides an avenue for the importation or supply in Australia of unapproved therapeutic goods for use in that trial. However, all clinical trials require Human Research Ethics Committee (HREC) approval before a clinical trial may commence. As a result, HRECs play a central role in reviewing clinical trials that are subject to the therapeutic goods legislation.

In most clinical trials of drugs or devices in Australia, the trial intervention will not yet be approved and listed on the ARTG. Clinical trials generate evidence to inform best-practice ways of improving care or treatment to patients. The outcomes of clinical trials can provide evidence that leads to either the adoption or continuation of effective treatment and care, or the cessation of ineffective interventions.

Information about drugs or devices being trialled, including whether they have been assessed by the TGA, or other regulators internationally would ordinarily be expected to be included in any materials or communication supporting the process of obtaining consent from potential participants in the research. Guidance on requirements for valid consent to participate in research can be found in the National Statement on Ethical Conduct in Human Research at Chapters 2.2 and 3.1 (<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>).

The two medical devices that you are seeking information about (ie. Resmon PRO Diary DEV53 TSIM 16, FOT made by RESTECH Respiratory Technology, Milan; and Spiro-PD made by PMD Healthcare, PA, USA) are not currently included in the ARTG. However, the Resmon product was previously in the ARTG, but its registration was cancelled by the Sponsor on 27 February 2017.

Thank you for bringing your concerns to the Minister's attention.

Yours sincerely

A handwritten signature in dark ink, appearing to read 'Miranda Lauman', with a stylized, cursive script.

Miranda Lauman
Assistant Secretary
Medical Devices Branch
Therapeutic Goods Administration
10 September 2019