NSW GOVERNMENT
The Hon. Brad Hazzard MP
Minister for Health and Medical Research

Mr Robert Cockburn
Email: tracproductions@gmail.com

Our ref M19/5293

Dear Mr Cockburn

Thank you for your emails about informed consent for clinical trials involving medical devices. I appreciate you taking time to raise this issue based on your own experience.

As your previous correspondence states, the National Statement on Ethical Conduct in Human Research covers consent requirements for clinical trials. NSW, like all Australian states, requires all research to comply with the National Statement. This ensures that all clinical trials, regardless of whether they are in a public or private facility, or where in Australia they occur, are subject to the same ethical requirements.

I am informed that the investigation into your concerns did not conclude that the devices in the study were used outside of the authority of the Therapeutic Goods Administration (TGA) Act. However, the investigation did find that certain additional information should have been included in the patient information statement about the use of devices under the TGA Clinical Trial Notification Scheme, the role of an overseas company with a commercial interest supporting the trial, use of the patient data, possible complications undertaking spirometry at home, and details of emergency contacts.

I will ask that the findings from your particular case are shared with Human Research Ethics Committees (HREC) across NSW at the next HREC Roundtable. Additionally, the Office for Health and Medical Research will write to the Chairs of the NSW HRECs to remind them of the importance of ensuring that all essential information relevant to a patient's consent is communicated in the Patient Information Consent form.

Thank you again for writing and for your continued advocacy on this issue. If you would like more information, please contact Dr Tim Sinclair, Acting Chief Executive, Sydney Local Health District, on 9515 9641.

Yours sincerely

06 JAN 2020

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