NSW GOVERNMENT Health
Sydney Local Health District

CONFIDENTIAL

Mr Robert Cockburn
Unit 3
36 Hampden Road
ARTARMON NSW 2064
Sent by email to tracproductions@gmail.com

Dear Mr Cockburn,

Re: Complaint Regarding Research Study: *Role of home telemonitoring of lung function using the Forced Oscillation Technique in assessing and predicting asthma control: a pragmatic, observational trial* (HREC number HREC/17/CRGH/177)

I am writing in response to your request for a copy of the investigation report into your complaint in advance of our meeting to be held on 29 October 2019.

As you are aware, the investigation was undertaken in accordance with the SLHD Policy Directive – *Responding to Allegations of Research misconduct* – SLHD_PD2014_008. In accordance with this policy, the investigation has been undertaken under obligations of confidentiality.

Whilst there is an obligation to provide complainants with relevant parts of the investigation report that address their role and opinions in the investigation, as well as disclose the relevant findings of the report, it is not normal practice to disclose the full investigation report. This is because such reports may contain information considered confidential by the respondents to the complaint and individual staff members, as well as information not directly relevant to the complainant's concerns.

Notwithstanding the above, at this stage I can advise you of the findings of the report with respect to each of the allegations made, as well as the recommendations. These are as follows:

Summary of Findings

The Panel's findings are as follows:

- **Allegation 1**, that the research study was an undisclosed commercial clinical trial, including the allegation that the trial is a part of the TGA user registration process for maker Restech which could subsequently permit the Resmon's general sale and use in Australia, **is not substantiated.** The Panel finds that the study did not fall within the National Health and Medical Research Council (**NHMRC**) definition of a

commercial clinical trial and there was no evidence before the Panel to support a conclusion that Restech was seeking to use the study as part of a TGA registration process.

- **Allegation 2**, that the manufacturer Restech srl was attempting to market the device through the vehicle of a clinical trial, **is not substantiated** as there was no evidence before the Panel to indicate that Restech was engaged in such a strategy.

- **Allegation 3,** that there was an alleged failure by the Woolcock Institute researchers to disclose conflicts of interest in that the researchers were undertaking the research study on behalf of Restech srl and not as an investigator-initiated research study, **is not substantiated.** The Panel finds that the study was investigator-initiated, and that it was not being undertaken on Restech's behalf. Accordingly, there was no conflict of interest of the kind stated in this allegation.

- **Allegation 4,** that the devices used in the research study were installed incorrectly by the relevant research assistants who disregarded the warnings outlined in the operations manual and had insufficient training, **is not substantiated.** The Panel found no evidence that the devices had been incorrectly installed, or that the researchers who installed the devices lacked adequate training. Additionally, expert testing found no evidence of radio frequency interference when used at the separation distance suggested by Mr Cockburn's evidence.

- **Allegation 5,** that there was an alleged failure by the researchers to disclose a previous study published on the ClinicalTrials.gov website (https://clinicaltrials.gov/ct2/show/NCT01552031) which identified patients having difficulties using the devices being used in the research study, **is not substantiated** as there was no obligation to provide either potential participants or individuals who had been recruited to the study with information about the earlier study, and the difficulties referred to were not a finding of the previous study.

- **Allegation 6,** whether the Participant Information Statement had false claims or omissions, **is partially substantiated.** The Panel finds that the Participant Information Statement omitted some information that ideally should have been included, but did not find that it contained any false statements.

- **Allegation 7,** whether the devices were not properly registered or approved for use in Australia as part of this research study or otherwise. Alternatively, whether the devices were used outside of their registered or approved indication as part of the research study, **is not substantiated.** The Panel finds that use of the Resmon Pro Diary was appropriately covered by an application made by the researchers under the Clinical Trials Notification (**CTN**) Scheme, and use of the Spiro PD was permitted on the basis that it had been registered at the time the devices were purchased by the company that onsold them to the Woolcock Institute.

- **Allegation 8,** whether all required information was provided to the Human Research Ethics Committee with regard to the use of the devices, **is substantiated.** The Panel found that additional information should have been provided to the HREC regarding the devices used in the trial and the contractual relationships with the Woolcock Institute and Restech.

- **Allegation 9,** whether appropriate information was included in the approved Participant Information Statement and Consent Form in accordance with the National Statement, **is substantiated.** Certain additional information (as specified in **Part 4.6** of this Report) should have been included in the Participant Information Statement.

  Part 4.6 specifies the following additional information

  - *The fact that this was a clinical trial being conducted under the CTN Scheme using a device that was not necessarily registered for use in Australia (and a brief explanation about how the CTN Scheme allows the use of unregistered devices in clinical trials).*
  - *The name of the Forced Oscillatory Technique device (i.e. the Resmon Pro Diary).*
  - *That the performance of Resmon Pro Diary was part of the test of the trial (see correspondence between Restech and Woolcock).*
  - *The involvement of Restech in the trial, including: their support via supplying the Resmon Pro Diary; the fact that the data being transferred to Milan will be going to Restech and will be available to the company in a de-identified form despite Restech not being listed as investigators on the trial; that Restech may derive financial benefit from the results of the trial, and the fact that the information generated by the trial will be jointly owned by the Woolcock and Restech;*
  - *The difficulties that some participants may experience when undertaking spirometry in a home setting; and*
  - *Details of who to contact for advice or assistance in the case of any adverse event or any other difficulties that may be encountered by a participant in the trial.*

- **Allegation 10,** whether the Human Research Ethics Committee review of the research study was consistent with the National Statement and other regulatory requirements, **is partially substantiated.** Given the Panel's findings in relation to Allegations 6 and 9, the need for additional information to have been included in the Participant Information Statement was a matter that should have been identified by the HREC and followed up with the researchers prior to approving the study.

- **Allegation 11** that any adverse events involving the complainant were not reported to the Ethics Committee or were not managed appropriately in accordance with the Australian Code for the Responsible Conduct of Research, **is not substantiated.** The Panel found that the researchers had satisfied the reporting obligations that were applicable to Mr Cockburn's circumstances.

- **Allegation 12** whether the Woolcock Institute or Sydney Local Health District inappropriately withheld the following information that was requested by the participant:

  a. The user approval status of the devices used in the study, and

b. Copies of the full study protocol.

is partially substantiated. The Panel finds that information requested by Mr Cockburn in relation to the registration status of the Resmon Pro Diary and Spiro PD should have been provided to him. However, there was no obligation to provide him with a copy of the full study protocol.

The Panel finds that there was a failure to fully comply with the standards set out in the National Statement, in as much that insufficient information was provided to potential participants and those who had been recruited to the study. The omissions include information regarding the nature of the devices to be used in the trial, the registration status of the trial, the experimental nature of the use of devices in the trial, the interests, including potential commercial interests, of a third party (i.e. Restech) in the trial, and the transfer and use of data generated by the trial to, and by, Restech. Responsibility for these omissions lies with the research team and the Human Research Ethics Committee.

The Panel did not find any breaches of Australian Research Code, the applicable Therapeutics Goods Act, or NSW Ministry of Health research policies. Nor did the Panel find any conduct amounting to research misconduct as defined in the Australian Research Code.

Recommendations

The Panel recommends that:

1. Its findings as set out in **Parts 2** and **4** of this Report are brought to the attention of the Sydney Local Health District (SLHD), Woolcock Institute (WI) and Mr Robert Cockburn;

2. A revised Participant Information Statement for this trial is prepared to include the information that has been identified by the Panel as being omitted from the original Participant Information Statement associated with this trial.

3. Participants enrolled in this trial are provided with the opportunity to confirm their consent for the trial in light of the new Participant Information Statement, and the knowledge that Restech have an interest in the trial and that their data, though de-identified, will be shared with a third party.

4. The WI and SLHD review their processes to ensure that the experimental nature of all elements of trials are disclosed to potential participants

5. That WI and the SLHD Concord HREC review their processes to ensure that important information regarding commercial interests are revealed to potential participants in clinical studies, in keeping with the National Statement and Good Clinical Practice;

6. That WI ensure that information regarding the nature of their relationship with partners in trials are communicated to the HREC in a timely fashion;

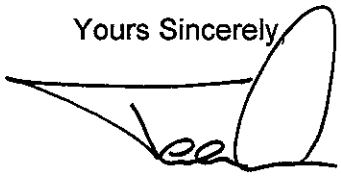
7. That WI and the HREC ensure that details of all therapeutic goods and devices to be used in trials are included in applications and where relevant and appropriate, in Participant Information Statements;

8. That WI and the HREC ensure that appropriate emergency contact details are provided to participants for particular studies.

Please review the above findings and recommendations. I am happy to receive any comments you have regarding these findings.

I appreciate that you have raised your concerns about this trial with SLHD and look forward to meeting you next week to discuss the investigation and your suggestions for system improvement.

Yours Sincerely,



Dr Teresa Anderson
Chief Executive
Date: 25-10-19