



Draft Report: Sydney Local Health District, University of Sydney and Woolcock Institute Response to Potential Breaches of the *Australian Code for the Responsible Conduct of Research*

1. INTRODUCTION

- 1.1 The Australian Research Integrity Committee (ARIC) has conducted a review of the process undertaken by the University of Sydney (the University), the Sydney Local Health District (SLHD), and the Woolcock Institute in response to an investigation into potential breaches of the *Australian Code for the Responsible Conduct of Research, 2007* (the Code) concerning Associate Professor Cindy Thamrin, Dr Claude Farah, Professor Gregory King, Professor Helen Reddel, Professor Matthew Peters and Dr Farid Sanai (the respondents) in the following research project:

Role of home telemonitoring of lung function using the Forced Oscillation Technique in assessing and predicting asthma control: a pragmatic, observational trial

- 1.2 The management and investigation of the matter was undertaken by SLHD.
- 1.3 Mr Robert Cockburn (the applicant) was not satisfied with the process undertaken to investigate his concerns.
- 1.4 The applicant requested that ARIC review the process used to investigate this matter.
- 1.5 ARIC's task is to review the process undertaken by SLHD, as the lead institution to investigate the allegations, and determine whether it was consistent with the 2007 Code and relevant SLHD policies and procedures, which include *SLHD_PD2014_008: Responding to Allegations of Research Misconduct* (SLHD research misconduct policy).
- 1.6 ARIC does not review the merits of any allegations of potential breaches of the Code.
- 1.7 The panel responsible for this ARIC review is Ms Patricia Kelly (Chair), Ms Julie Hamblin, Emeritus Professor Alan Lawson, and Mr Michael Chilcott. The ARIC Chair sought declarations of interest from members of the panel at the commencement of its review and at subsequent meetings. A declaration of interest was declared by one member. The other members of the panel agreed that the declared interests had no bearing on the current matter and did not constitute a current conflict of interest.
- 1.8 The ARIC panel met on 24 February 2022 and 19 May 2022 via Zoom to consider this matter and subsequently communicated by email to finalise this Draft Report.

2. BACKGROUND

- 2.1 [REDACTED]
- 2.2 ARIC understands that the applicant agreed to participate in a clinical trial conducted by the Woolcock Institute. The trial was approved by the SLHD Human Research Ethics Committee at the Concord Repatriation General Hospital (HREC).
- 2.3 On 5 December 2018, the applicant suffered an adverse event after using one of the two home testing devices that were installed into his home the previous day.
- 2.4 On 10 April 2019 the applicant lodged a 22-page complaint to SLHD. In summary, the applicant's complaint was that the study was an undisclosed commercial clinical trial of an unapproved device; that the malfunctioning of the two devices caused him physical harm; that the study information sheet and consent forms approved by the HREC contained false claims and/or omissions; and that the study did not have risk information or emergency plans in the event of an adverse event.
- 2.5 SLHD conducted an independent investigation into the matter.
- 2.6 The SLHD investigation panel included: Professor Ben Canny, Ms Kerry Rehn, Professor David Barnes and Associate Professor Phillip Clifton Bligh.
- 2.7 The SLHD panel was asked to make findings of fact in relation to 12 allegations. The report found:
 - 2.7.1 7 allegations were not substantiated.
 - 2.7.2 3 allegations were partially substantiated.
 - 2.7.3 2 allegations were substantiated.
- 2.8 The SLHD panel found there was a failure to comply with the *National Statement on the Ethical Conduct in Human Research 2007* (the National Statement). The SLHD panel found that the Participant Information Statement omitted information that should have been included and that given these findings the Human Research Ethics Committee should have identified the need for additional information and followed this up with the researchers prior to approving the study. However, the SLHD panel found that these omissions did not amount to a breach of the Code or research misconduct.
- 2.9 The SLHD investigation panel finalised its report in September 2019.
- 2.10 The outcome from the investigation was communicated to the applicant on 25 October 2019. SLHD acted on all of the recommendations made by the investigation panel.
- 2.11 On 29 October 2019 Dr Teresa Anderson, Chief Executive of SLHD, met with the applicant to discuss the investigation report and findings.
- 2.12 On 30 December 2019, the University was advised of the investigation findings.
- 2.13 The University reviewed the findings from the SLHD investigation and did not take any further investigative action.
- 2.14 On 24 April 2021 the applicant contacted the University requesting a further inquiry into his matter. On 17 May 2021, the University advised the applicant that as an inquiry had already been conducted by the SLHD, the University would not investigate the matter further. The applicant requested that the University reconsider this decision and the University again advised the applicant that further investigation was not warranted and SLHD had confirmed that all of the recommendations resulting from the investigation were actioned.

3. REQUEST FOR REVIEW

- 3.1 On 2 October 2021 the applicant lodged a request for an ARIC review. His request for review was lodged 12 weeks and 3 days after receiving the final notification from the University of Sydney informing him that it would not undertake further review of the matter. The applicant's request for ARIC review was accepted outside the standard 12-week timeframe outlined in the *ARIC Framework* at the discretion of the Chair, taking into account the applicant's ongoing health issues.
- 3.2 The applicant claimed that:
- 3.2.1 The SLHD investigation was inadequate and failed to properly investigate the matter.
 - 3.2.2 The Terms of Reference for the investigation were kept confidential until after the panel interview.
 - 3.2.3 The SLHD investigation panel had conflicts of interest.
 - 3.2.4 The University subsequently refused to investigate the matter after the SLHD investigation had been completed.
 - 3.2.5 The University and the SLHD were unfair and biased.
 - 3.2.6 The University's staff deceitfully, deliberately, recklessly and negligently breached Code obligations of community trust, honesty, rigour, transparency, fairness, respect and accountability under its Principles of responsible research, Responsibilities of Institutions and Responsibilities of researchers.
- 3.3 On 4 November 2021 the Chair accepted the request for review. Consistent with the ARIC Framework, the Chair convened a panel.
- 3.4 The NHMRC Funding Agreement¹ requires Administering Institutions to ensure that research and any investigation or inquiry into potential breaches of the Code is conducted in accordance with the Code.

4. THE REVIEW BY ARIC

- 4.1 After ARIC assessed this request for review, the ARIC Secretariat contacted the University on 18 November 2021 seeking information about the review of the matter. The request for information included the applicant's original complaint to the SLHD and relevant correspondence, policies and procedures used to process the complaint, information on how the SLHD panel managed conflicts of interest, information on the funding sources for the project, a response to the concerns raised by the applicant, a timeline of the SLHD's actions from receipt to finalisation of the complaint, and any other information that would assist ARIC in understanding the processes used to respond to the applicant's complaint. On 25 November 2021 the University requested an extension to provide a response. The Chair agreed to an extension and the University provided a response on 10 December 2021 and SLHD provided its response on 20 December 2021.
- 4.2 On 22 March 2022 ARIC contacted SLHD with a request for further information. On 31 March 2022 SLHD requested an extension to provide a response. The Chair agreed to an extension and SLHD provided its response on 22 April 2022.

¹ <https://www.nhmrc.gov.au/funding/manage-your-funding/funding-agreement>

4.3 ARIC reviewed and considered the material provided by the University, SLHD and the applicant.

5. ARIC'S FINDINGS

- 5.1 ARIC considered each of the matters raised by the applicant and all of the associated material and submissions received from the applicant, the University and SLHD.
- 5.2 With the exception of the issues outlined below, ARIC is satisfied that the process undertaken by SLHD and the University to manage and investigate the applicant's complaint was consistent with the requirements of the 2007 Code and SLHD's research misconduct policy.
- 5.3 ARIC notes that it was appropriate at the time of the initial inquiry for SLHD to manage and investigate the complaint under the 2007 Code.
- 5.4 ARIC notes SLHD's thorough, careful and efficient approach to the complaint and the rigorous investigation of the allegations.
- 5.5 Specific observations in relation to each of the applicant's grounds for seeking an ARIC review are set out below.

The applicant's claims that the SLHD investigation was inadequate and failed to properly investigate the matter

and

The applicant's claims that the University's staff deceitfully, deliberately, recklessly and negligently breached Code obligations of community trust, honesty, rigour, transparency, fairness, respect and accountability under its Principles of responsible research, Responsibilities of Institutions and Responsibilities of researchers.

- 5.6 ARIC considers that the SLHD's investigation of the applicant's complaint was overall consistent with the 2007 Code and SLHD's research misconduct policy, which is based on the 2007 Code.
- 5.7 The 2007 Code requires that after a preliminary assessment, the designated person determines whether a *prima facie* case of research misconduct exists and should be investigated. In this matter, the designated person determined that a research misconduct inquiry should be undertaken.
- 5.8 Section 4f of the SLHD research misconduct policy outlines that if a research misconduct inquiry proceeds, the Chief Executive (CE) must appoint
an investigation panel using either internal and/or external investigators.
The more serious the allegation of misconduct, the more likely it is that an external investigation will be conducted.
- 5.9 ARIC notes that SLHD proceeded with an independent investigation panel which included an independent inter-state expert Chair (Professor Ben Canny), a representative from Northern Sydney Local Health District (Professor Phillip Clifton Bligh), a representative from Sydney Local Health District (Professor David Barnes), and a representative from the University of Sydney (Ms Kerry Rehn).
- 5.10 In identifying appropriate cases for an external panel, the 2007 Code outlines the need to consider 'the potential consequences for the accused, the accuser, other parties and institutions in the event that the allegations(s) were to be upheld; and the need to maintain public confidence in research'.

- 5.11 As the determination of the seriousness of the matter is at the discretion of the institution involved, establishing a panel that is a mix of internal and external members is acceptable under the 2007 Code and SLHD's research misconduct policy.
- 5.12 ARIC considers it reasonable for SLHD to determine that the panel would be comprised of a combination of internal and external panel members.
- 5.13 SLHD's research misconduct policy at section 4 g-i includes further detail on how an investigation should proceed if the institution determines that an investigation is needed:
- g) Upon completion of its tasks, the research misconduct inquiry must advise the CE of its findings of fact and what, if any, research misconduct has occurred.
 - h) The CE must then determine the actions to be followed.
 - i) Subsequent actions may, as appropriate, include informing relevant parties of the outcome and correcting the public record of the research.
- 5.14 The above conditions were all met by SLHD.
- 5.15 SLHD's research misconduct policy at section 3.3 states that the complainant will have the opportunity to:
- o testify before the Investigating Officer and/or Investigation Panel;
 - o review portions of the reports pertinent to their allegations or testimony;
 - o be informed of the results of the investigation; and
 - o be protected from harassment, victimisation or any other form of reprisal by the respondent or any other employees.
- 5.16 Section 6.5 of the research misconduct policy states that 'The CE will provide the complainant with those portions of the investigation report that address the complainant's role and opinions in the investigation. The report should be modified, as appropriate, based on the complainant's comments, but only in so far as errors of fact, validated by the Panel, are identified.'
- 5.17 The above conditions were all met by SLHD. The applicant was consulted prior to the terms of reference being finalised, the applicant was interviewed by the panel, received the transcript from the interview for comment and was provided with a summary of the results of the investigation. ARIC has not seen any evidence to suggest that the applicant experienced harassment, victimisation or any other forms of reprisal by the respondent or any other employees of SLHD.
- 5.18 ARIC notes that on 5 July 2019 SLHD emailed the applicant and gave him an extension to provide comments on the transcripts in response to his advice that he would be unable to meet the deadline of 7 July 2019. SLHD also indicated in that email that, should he require further time to review the transcripts, to let them know.
- 5.19 [REDACTED]
- 5.20 ARIC notes SLHD's advice that all of the recommendations made by the investigation panel have been carried out.
- 5.21 While SLHD's communication with the applicant gave him sufficient information or reasons for the outcome of the investigation and it met the requirements of the 2007 Code and SLHD's research misconduct policy, it is ARIC's view that SLHD could have provided the applicant with the full investigation report.
- 5.22 It is ARIC's view that best practice is to provide the full investigation report to the complainant for comment if the complainant agrees to confidentiality, noting that

in some cases it may be appropriate to redact confidential information. A summary should only be provided in exceptional circumstances. Members agreed that in this matter providing the full report to the applicant would have provided him with the detailed reasoning for the findings.

The applicant's claims that the Terms of Reference for the investigation were kept confidential until after the panel interview

5.23 Section 6.1 of SLHD's research misconduct policy states:

The Terms of Reference must be approved by the CE and for joint investigations the CE as well as the University delegate before they are given to the Chair of the Investigation Panel. The Terms of Reference must also be sent to the respondent.

If it becomes apparent during the Investigation Panel's deliberations that there are additional instances of possible misconduct that would justify broadening the scope of the investigation beyond the initial allegations, then the Chair of the Investigation Panel can approach the CE regarding a change of its Terms of Reference.

- 5.24 The 2007 Code does not require that an investigation panel's Terms of Reference are to be provided to the complainant.
- 5.25 SLHD's research misconduct policy does not include a requirement to provide the complainant with a copy of the investigation panel's Terms of Reference.
- 5.26 ARIC notes the emails between the complainant and SLHD staff in May 2019 where, amongst other things, the applicant was provided with the opportunity to comment on the list of allegations prior to the panel interview.
- 5.27 SLHD initially listed 10 allegations that were being investigated and the applicant was advised that he would be invited to a face-to-face interview.
- 5.28 On 23 May 2019, the applicant sent a further email to SLHD and included two extra allegations that were not included in the previous list.
- 5.29 On 24 May 2019 SLHD sent the applicant an email addressing his previous concerns and clarified that the list of allegations had been amended and extended to 12:
- 5.29.1 That the research study was an undisclosed commercial clinical trial, including the allegation that the trial was a part of the TGA user registration process for maker Restech which could subsequently permit the Resmon's general sale and use in Australia.
 - 5.29.2 That the manufacturer Restech Srl was attempting to market the device through the vehicle of a clinical trial.
 - 5.29.3 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.
 - 5.29.4 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.
 - 5.29.5 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.

- 5.29.6 Whether the Participant Information Statement had false claims or omissions.
- 5.29.7 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.
- 5.29.8 Whether all required information was provided to the Human Research Ethics Committee with regard to the use of the devices.
- 5.29.9 Whether appropriate information was included in the approved Participant Information Statement and Consent Form in accordance with the National Statement.
- 5.29.10 Whether the Human Research Ethics Committee review of the research study was consistent with the National Statement and other regulatory requirements.
- 5.29.11 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.
- 5.29.12 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.
- 5.30 ARIC notes the list of allegations that was provided to the applicant for comment is substantially the same as the allegations listed in the Investigation Report's Terms of Reference.
- 5.31 ARIC also notes that SLHD has advised that the Terms of Reference were also presented to the applicant at the time of the panel interview.
- 5.32 Page 2 of the Investigation report states that the applicant was provided with the specific allegations in the terms of reference and he was given the opportunity to comment on them prior to being finalised.
- 5.33 It is ARIC's view that the Terms of Reference, and specifically the list of allegations, for the investigation were not kept confidential from the applicant. However, it would have been preferable to have provided him with the full Terms of Reference document prior to his attendance at the panel interview.

The applicant's claims that the SLHD investigation panel had conflicts of interest

- 5.34 Section 6.2 of SLHD's research misconduct policy states that the panel should consist of at least three individuals who do not have real or apparent conflicts of interest in the case.
- 5.35 On 22 May 2019 SLHD sent an email to the applicant providing a thorough response to the applicant's concerns about the proposed panel including clarification that the panel membership is

in accordance with the management of allegations of research policy which requires persons with proper expertise in research conduct, ethical review, governance and legal, as well as expertise in the relevant clinical field.

- 5.36 Members noted SLHD's response to ARIC advising that the investigation panel members did not declare any conflicts of interest, including the statement that 'Professor David Barnes declared he had no conflicts of interest with any of the research team with respect to the research study including other activities which might have impacted his role to act independently as a panel member for the investigation.'
- 5.37 ARIC is aware from the transcript of the interview provided by the applicant that there was a lengthy discussion about professional and personal interests of investigation panel members. However these declarations were not overtly detailed in the investigation report.
- 5.38 ARIC notes that ideally these low-level professional relationships between panel members and investigators on the research project, or panel members' institutional affiliations, should have been included in the Investigation report. These declarations should not have prevented participation on the panel.
- 5.39 It is ARIC's view that the applicant has not provided any evidence that demonstrates any of the investigation panel members had a conflict of interest that would compromise the outcome of the investigation.
- 5.40 Members agreed that the investigation panel's declarations of interest met the requirements of the 2007 Code, however, best practice would have been for the relationships to have been declared, recorded and the decision about how to manage any potential conflicts communicated to the applicant.

The applicant's claims that the University subsequently refused to investigate the matter after the SLHD investigation had been completed

- 5.41 ARIC notes that the University did not undertake a review of the matter because SLHD had already managed and investigated the matter and the University determined that SLHD's investigation was thorough and further investigation not warranted. The University wrote to the applicant on 17 May 2021 advising that the University did not propose to take any further action.
- 5.42 ARIC notes that the applicant wrote to the University again on 19 May 2021 requesting that the decision be reconsidered.
- 5.43 The University advised that the correspondence from the applicant did not contain new allegations or additional evidence. The University advises that it contacted the Woolcock Institute and SLHD to ensure that all of the recommendations outlined in the investigation report had been actioned.
- 5.44 On that basis, the University wrote to the applicant on 7 July 2021 informing him that the University had been advised that all of the recommendations had been actioned and the University would not take any further action.
- 5.45 It is ARIC's view that the University's decision to refuse to investigate the matter after the SLHD investigation was reasonable. Furthermore, ARIC considers that conducting two investigations into the same matter by different institutions is not best practice, in accordance with the Investigation Guide's recommendation at 8.1 that

Institutions should cooperate if there is a potential breach of the Code to ensure that only one investigation is conducted.

The applicant's claims that the University and SLHD were unfair and biased

5.46 ARIC notes the applicant's claims that the University and SLHD were unfair and biased in how they managed and reviewed this matter and found no evidence to support these claims.

5.47 Having considered all the documents provided, it is ARIC's view that SLHD appropriately managed the review of the applicant's complaint which included a thorough investigation.

6. [REDACTED]

7. [REDACTED]

8. [REDACTED]

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