

DRAFT MINUTES
213th Session
Council of the National Health and Medical Research Council
20-21 March 2018
NHMRC Offices, Canberra

Attendance:

Prof Bruce Robinson AM	Chair of Council
Prof Kathryn North AM	Chair, Research Committee
Prof Ian Olver AM	Chair, Australian Health Ethics Committee
Prof Graeme Samuel AC	Chair, Health Innovation Advisory Committee (day two only)
Prof Sharon Lewin	Chair, Health Translation Advisory Committee
Prof David Story	Member with expertise in professional and post-graduate medical training
Prof Brendan Crabb AC	Member with expertise in health research & medical research issues
Prof Sandra Eades	Member with expertise in the health needs of Aboriginal persons and Torres Strait Islanders
Prof Michael Kidd AM	Member with expertise in health care training
Prof Jonathan Carapetis	Member with expertise in Public Health (via video)
Ms Karen Carey	Member with expertise in consumer issues
Prof Ingrid Scheffer AO	Member
Prof Elizabeth Sullivan	Member
Prof Brendan Murphy	Commonwealth Chief Medical Officer (CMO)
Professor Anthony Lawler	CMO, TAS
Dr Kerry Chant PSM	Chief Health Officer (CHO), NSW
Dr Jeannette Young PSM	CHO, QLD
Dr Hugh Heggie	CHO, NT
Prof Charles Guest	CHO, VIC
Dr Paul Kelly	CHO, ACT
Prof Gary Geelhoed	CMO, WA
Prof Paddy Phillips PSM	CMO, SA

Observers

Ms Caroline Edwards	Observer, Department of Health
Prof Helen Zorbas AO	Observer, Cancer Australia
Adj Prof Debra Thoms	Observer, Commonwealth Chief Nurse and Midwifery Officer
Prof Villis Marshall AC	Observer, Australian Commission on Safety & Quality in Health Care

Apologies

Mr Barry Sandison	Observer, Australian Institute of Health and Welfare
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NHMRC Staff

Prof Anne Kelso AO	CEO
Mr Tony Kingdon	General Manager
Ms Jillian Barr	A/g Executive Director, Evidence, Advice and Governance
Mr Alan Singh	Executive Director, Research Policy & Translation
Dr Julie Glover	A/g Executive Director, Research Programs

Dr Tony Willis
Mr Tony Krizan FCPA

Executive Director, Research Strategy & Implementation T'force
Executive Director, Corporate Operations and Information

1. WELCOME

The Chair, Professor Bruce Robinson, opened the 213th Session of Council at 1pm and welcomed attendees to the ninth meeting of the 2015-2018 National Health and Medical Research Council (NHMRC) triennium. The Chair acknowledged the Ngunnawal People as traditional owners of the land upon which the meeting was held.

The Chair noted the apologies of Prof Sharon Lewin and Prof Sandra Eades (both for day one only) and Mr Barry Sandison. The Chair confirmed that the meeting was quorate.

The Chair reminded attendees that everything discussed at the meeting was to be treated as confidential and invited members to declare any interest that may present a potential or actual conflict at the start of the session and before discussion of relevant items. The Chair noted the importance of transparency in the operation of Council and reminded Members of the need to be timely with updating their Disclosure of Interests (DOI).

Council **ADVISED** the Chair that the draft Session Report of the 212th Session of Council was accepted as a true and accurate record of proceedings.

Action Item: Members to ensure that they update their disclosure of interests on the Committee Centre on an as needs basis and before each meeting.

2. CEO REPORT

Professor Kelso provided Council members with an update on the tabled NHMRC CEO Reports for November, December 2017 and January 2018.

Professor Kelso also updated Council on:

- appointment process for the Council and Principal Committees for the 2018-21 Triennium
- progress towards implementing the New Grants Management Solution
- initial rounds of the Medical Research Future Fund and its intersection with NHMRC
- NHMRC's Gender Equality Strategy, and
- 2018 Project Grant statistics.

Council **NOTED** the CEO Report.

3. CHAIR'S REPORT

Professor Robinson briefed Council on the invitations he had received as Council Chair.

Council **NOTED** the Chair's Report.

4. PRINCIPAL COMMITTEE INDIGENOUS CAUCUS (PCIC) REPORT/INITIATIVES FOR ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH

Professor Sandra Eades provided Council with an update on the main agenda items discussed at the PCIC meeting held on 4 December 2017:

- A capacity strengthening workshop is being planned for May 2018 to bring together a number of Indigenous researchers.

- Road Map 3 is being finalised with PCIC and Council should expect to see it before the end of June 2018.
- The Research Translation Symposium was held in November 2017 and well received.
- Several Targeted Calls for Research in Aboriginal and Torres Strait Islander health are proceeding well.
- The Tripartite Agreement with Canada and New Zealand was renewed in December 2017.

PCIC member and invited guest A/Prof Yvonne Cadet-James noted and supported the report to Council.

Council **NOTED** the PCIC report.

5. HEALTH TRANSLATION ADVISORY COMMITTEE (HTAC) REPORT

Professor Lewin provided Council with an update on the main agenda items that were discussed at the 22 February 2018 meeting. These included:

- Clinical researcher pathways
- Measuring and reporting impact
- NHMRC Research Translation Strategy
- Clinical trials and cohort studies
- Implementation science.

Professor Lewin advised that a survey of clinician researchers is in development which will map the career trajectory of NHMRC funded clinician researchers as well as those supported through other mechanisms. The final HTAC meeting of the current triennium will be held on 15 June 2018.

Council **NOTED** the HTAC Report.

6. HEALTH INNOVATION ADVISORY COMMITTEE (HIAC) REPORT

Professor Graeme Samuel introduced the HIAC Report to Council which provides an update on the main items discussed at the HIAC meeting on 7 March 2018.

Professor Samuel highlighted the significant achievements of HIAC, including its commercialisation, philanthropy and industry engagement work, and indicated that a key focus for the next triennium should be implementation of the policy and guidelines developed by the Committee during the current triennium.

Professor Samuel acknowledged that the HIAC Term of Reference focussed on fostering the development and uptake of innovative technologies and practices to improve the health of Aboriginal and Torres Strait Islander peoples had been difficult to progress. A priority for HIAC in the next triennium should be identifying ways that Aboriginal and Torres Strait Islander knowledge can be captured and translated to drive innovation.

HIAC will hold its final meeting for the triennium on 21 June 2018.

Council **NOTED** the HIAC Report.

7. AHEC REPORT

Professor Ian Olver provided Council with an update on the main agenda items that were discussed at the videoconference meeting of 9 March 2018. These included:

- approving the revised Indigenous research ethics guidelines
- noting the revised *Australian Code for the Responsible Conduct of Research (2018)* and *Guide to Managing and Investigating Potential Breaches of the Code*, and
- agreeing to release draft guidance on payment for participation in research for targeted consultation.

Members also received updates on the review of NHMRC's ethical guidelines on organ and tissue donation from living and deceased donors, the review of Section 4 of the *National Statement on Ethical Conduct in Human Research* and the consideration of the ethical issues raised by new gene editing technologies by an AHEC and Embryo Research Licensing Committee working group. The final AHEC for the triennium will be held on 20 June 2018.

Council **NOTED** the AHEC Report.

8. 2018 MREA INDICATIVE BUDGET ALLOCATIONS

Tony Krizan presented the proposed MREA Budget for 2018. These allocations relate to new grant commitments in 2018, for funding to commence from 2019, and represent the final year of funding under the current NHMRC grant program.

The proposed budget totalled \$794.3 million and allocations for the majority of funding schemes were consistent with 2017, with the exception of Program Grants which are not running in 2018.

Members discussed the cessation of the Program Grants funding scheme and were advised that these funds have been re-allocated to other schemes in 2018 and 2019 to support the first year of implementation of the new grant program.

Members noted that the indicative allocation for Project Grants of \$470 million may result in an increased success rate, especially because the number of project grant applications received has decreased from last year. Members were also advised that the indicative allocation includes funding for strategic priorities within the Project Grants scheme.

Council **ADVISED** the CEO to accept the 2018 indicative allocations for the MREA.

9. NHMRC DATA UPDATE

Council noted the Government Data Update paper that outlined the requirement of the Office of the Australian Information Commissioner from July 2018 for Government agencies to commission Privacy Impact Assessments (PIA) for any new data linkage work. NHMRC intends to conduct a PIA to support the New Grants Management Solution and consideration of other data requests for NHMRC grants data, including data on unfunded grant applications. This will ensure that NHMRC decisions on data linkage work comply with the Australian Privacy Principles.

Brief discussion focussed on a related issue, the *Privacy Amendment (Notifiable Data Breaches) Act 2017*. This amended the Privacy Act to establish the Notifiable Data Breaches (NDB) scheme in Australia. The NDB scheme commenced on 22 February 2018 and applies to all agencies and organisations with existing personal information security obligations under the Privacy Act. The NDB scheme introduced an obligation to notify individuals whose personal information is disclosed in a data breach that is likely to result in serious harm. Council members raised the potential need for NHMRC to inform its Administering Institutions of these new requirements.

Council **NOTED** the data update.

Action Item: ONHMRC to consider contacting Administering Institutions to advise how NHMRC will handle data breaches.

10. NEW GRANTS MANAGEMENT SOLUTION (NGMS)

Tony Krizan presented an update on the New Grants Management Solution (NGMS) implementation. The presentation:

- highlighted the business and technical challenges the project seeks to address in accordance with the *Simplified and Consistent Health and Medical Research budget measure in 2014-15* which seeks to reduce the burden on applicants and reviewers, and
- advised that NHMRC had engaged Professor Matt Gillespie to chair the project's Governance Authority and Professor Bronwyn Kingwell to chair the Grants Management Solution Working Group.

Members noted the risks in introducing a new grants system at the same time as the new grant program. ONHMRC acknowledged these risks, but reminded Council that the alternative to a new system would be to use one of the two Grants Hubs administered through other Government departments.

Members stressed the importance of NGMS to the research sector and raised issues of performance, testing, data migration, usability, outcomes reporting and consultation with the sector.

Members were advised that ONHMRC is taking all precautions to ensure the system is successful, and risk management strategies are in place. The system is being designed to be intuitive and easy to use and will undergo rigorous testing. Data from RGMS will be migrated into NGMS.

Council **NOTED** the NGMS Update.

11. RESEARCH COMMITTEE (RC) REPORT

Professor Kathryn North provided Council with an update on the key agenda items from the RC meetings held October 2017 – March 2018. These included:

- Implementation of NHMRC's new grant program including development of scheme specific funding rules
- Outcomes from the Track Record Working Group, Innovation Working Group and Diversity Working Group
- Peer review for the new grant program
- Transition of fellows to the new grant program
- RGMS redevelopment
- Strategic funding priorities.

Professor North also updated Council on the meetings she has attended as the NHMRC representative on the Global Alliance for Genomics and Health.

Council **NOTED** the RC Report.

12. FUNDING RECOMMENDATIONS

All members remained in the room for this discussion.

Dr Julie Glover presented the funding recommendations for Boosting Dementia Research Grants Priority Round 3.

Dr Glover advised Council that Research Committee recommended funding for one Boosting Dementia Research Grant PR3: National Dementia Network application to a total value of \$18,000,000. She noted that two applications were received and following peer review one application was identified for funding.

Council **SUPPORTED** funding for one Boosting Dementia Research Grants PR3: National Dementia Network application to a total value of \$18,000,000.

13. PUBLIC CONSULTATION ON THE REVISED AUSTRALIAN GUIDELINES FOR THE PREVENTION AND CONTROL OF INFECTION IN HEALTHCARE

Ms Jillian Barr presented this item advising that the draft *Australian Guidelines for the Prevention and Control of Infection in Healthcare* (the Guidelines) had been out for targeted consultation in late 2017 with key stakeholders from the public and private healthcare sectors. The new recommendations were well received, particularly those providing guidance for healthcare facilities on the use of disinfection methods such as ultraviolet light. Consultation feedback helped to clarify and improve the draft content.

Professor Jonathon Carapetis enquired about the scope of the information on cardiac catheters. Ms Connor advised that, while the Guidelines provide the core principles of infection prevention and control for accessing and managing intravascular devices, it is the responsibility of the healthcare facility to develop local policies and procedures relevant to their setting and resources.

Professor Gary Geehoeld commended the new practice statement 'It is good practice for all healthcare workers to be vaccinated in accordance with the recommendations for healthcare workers in the Australian Immunisation Handbook' given that around 70% of healthcare workers are not vaccinated appropriately.

Professor Paul Kelly congratulated NHMRC for transitioning the Guidelines to the online format and agreed with Ms Connor that the Guidelines are not prescriptive advice.

Dr Kerry Chant advised that some NSW healthcare facilities have already adopted the use of novel technologies in their hospitals and suggested this would be a good opportunity for clinical data to be collected for these new technologies.

Council **ADVISED** the CEO to release the draft Australian Guidelines for the Prevention and Control of Infection in Healthcare for public consultation.

14. NHMRC STRATEGIC PRIORITIES FOR 2018

Dr Julie Glover presented an update on 2017 Medical Research Endowment Account (MREA) funding outcomes, including success rates against the current strategic priorities and gender of applicants.

Council **NOTED** the 2017 funding statistics and discussed the following:

- The low number of applications submitted by Aboriginal and/or Torres Strait Islander researchers, noting the amendment to the 2018 Research Fellowship scheme Funding Rules
- The role of NHMRC in continuing to build capacity in this important research area
- Providing funds to ensure women across the sector are retained at all career stages, but particularly in the early stages
- The importance of funding opportunities for women in the new grant program.

Members recommended ONHMRC consider an additional strategic allocation for a CRE in health services research due to the key role these centres play in capacity building.

Council **ADVISED** the CEO on the research funding priorities for 2018, as indicated in the table below.

Scheme	Strategic Priorities	2018 Proposed Allocation
Early Career Fellowships (ECFs)	Aboriginal and/or Torres Strait Islander researcher	\$1.0 million for up to three ECFs
	Health services research	\$1.0 million for up to three ECFs
Career Development Fellowships (CDFs)	Aboriginal and/or Torres Strait Islander researcher	\$1.5 million for up to three CDFs
	Health services research	\$1.5 million for up to three CDFs
Research Fellowships (RFs)	Aboriginal and/or Torres Strait Islander researcher	\$2.5 million for up to three RFs
	Health services research	\$2.5 million for up to three RFs
Project Grants	Aboriginal and/or Torres Strait Islander researcher	\$5.0 million
	Health services research	\$5.0 million
	Gender equity (female CIAs)	To be determined once the funded rate is known.
TOTAL		\$20.0 million

15. CORPORATE PLAN

Ms Barr provided an update on the development of the 2018-19 corporate plan. The plan is being fully reviewed to align with the commencement of the new triennium. The input sought from Council at its October 2017 meeting was provided to Principal Committees and a full round of consultations with these committees has now concluded. In accordance with Council's view, committees were satisfied that the three themes of investment, translation and integrity continue to capture NHMRC's work and should be retained. A range of other comments were provided by Principal Committees. ONHMRC staff are considering all feedback.

Members noted that a further update would be provided at the June 2018 meeting along with a progress report against the strategic priorities in the current 2017–2018 corporate plan.

Council **NOTED** the progress on the development of the *NHMRC Corporate Plan 2018-19*.

Day Two of the 213th Session

16. MEDICAL RESEARCH FUTURE FUND (MRFF) UPDATE

Ms Caroline Edwards provided Council with an update of the Medical Research Future Fund and submitted a supplementary paper on the announced MRFF program summary and implementation status report for Council's information.

Council **NOTED** the MRFF update.

17. UPDATE ON THE IMPLEMENTATION OF NHMRC'S NEW GRANT PROGRAM

Dr Willis provided an update on the implementation of NHMRC's new grant program. He noted that a change had been suggested by Research Committee at their 15/16 March 2018 meeting to amend the amount of non-Commonwealth derived salary that can be kept along with an Investigator Grant salary to less than or equal to 20% of the Investigator Grant salary.

Dr Willis also provided an overview of the development of the proposed peer review processes for Investigator, Synergy and Ideas Grant schemes, including an update on the work of the Track Record, Diversity and Innovation Working Groups.

He noted the importance of avoiding a 'tick-box' approach to diversity in the Synergy Grant scheme. The concept of 'innovation and creativity' in the Ideas Grant scheme is based on the National Institutes of Health definition and took into account the *Guide for assessing industry-relevant experience* developed by the Health Innovation Advisory Committee.

Council **NOTED** the update on the implementation of NHMRC's new grant program.

18. STRATEGIC DISCUSSION – PEER REVIEW FOR NHMRC'S NEW GRANT PROGRAM – OUTCOMES FROM CONSULTATIONS

Drs Fiona Leves and Nick Johnson presented an overview of the peer review consultation process and resulting proposed peer review models for Investigator, Synergy and Ideas Grants. They explained that the introduction of the new peer review processes will likely be staged over several funding rounds due to the ICT requirements for implementing the proposed model..

Council supported the proposed application-based models that were presented and discussed different aspects including:

- The need to train assessors, perhaps using online resources
- Whether NHMRC can source five expert assessors per application
- That fewer assessors would increase the burden on individuals
- That assessors should receive feedback on their performance
- That, in the Synergy Grant scheme, there is a tension between naming researchers with outstanding track records vs. early and mid-career researchers
- Consideration of shortlisting Synergy Grant applications based on the Synergy criterion
- That application of a strict conflict of interest policy, as currently framed, will reduce the number of reviewers available
- The potential impact of removing the in-person panel review process on consumer observers – and the possibility that they can be trained as assessors
- The precise meaning of 'Knowledge Gain' and how this is related to scientific quality.

Council **NOTED** the proposed processes for Investigator, Synergy and Ideas Grants, and **ADVISED** on aspects of the processes.

19. STRATEGIC DISCUSSION – CLINICAL TRIALS AND COHORT STUDIES

Professor Davina Ghersi presented the paper and provided Council with an update on the work on clinical trials and cohort studies. A draft paper on cohort studies in Australia and cohort studies funded by NHMRC was presented to Council for comment. The final version of this paper will form the basis for a roundtable discussion scheduled for mid-2018. Council provided a significant amount of feedback to improve the paper including estimations of actual costs of cohort studies (outside NHMRC funding), more information on how samples are shared, models of future cohort studies nationally and internationally, ethics and consent considerations, and cohort study designs. Council also encouraged NHMRC to include discussions on bio-banking, government strategies and the long term vision in supporting cohort studies, and NHMRC partnerships to leverage funds with other departments and industry..

Council **ADVISED** on the draft discussion paper on cohort studies.

20. REPORT ON THE STATUS OF GUIDELINES IN CLINICAL PRACTICE AND PUBLIC HEALTH

Ms Barr provided Council with an update on current work on to clinical and public health guidelines and asked for Council's advice on the relative importance for revision of documents that are approaching five years of age and those approaching ten years of age in 2018. This includes guidelines developed by NHMRC and those developed by third parties and endorsed by NHMRC.

Members raised a number of issues about NHMRC's guideline program, including the framework for identifying which guidelines should be reviewed, and the need for ongoing funding of guidelines.

The Chief Medical Officers emphasised the importance of updating the recreational water guidelines and noted that financial support for this update was being sought through AHMAC. In the event that this bid is not successful, the CMOs asked NHMRC to write directly to them seeking financial assistance.

Council **ADVISED** ONHMRC to bring a paper back to Council outlining a strategic approach to managing, updating and funding the guidelines process.

Action Item: ONHMRC to bring a paper back to Council on the priorities and costings of public health guidelines requiring to be updated.

21. EMBRYO RESEARCH LICENSING COMMITTEE: UPDATE ON THE RELATIONSHIP BETWEEN EMERGING TECHNOLOGIES AND THE AUSTRALIAN LEGISLATION

Ms Barr briefed the Council on the consultations that had occurred with AHEC and CCAG on the draft paper *Consideration of Emerging Technologies in light of the Prohibition of Human Cloning for Reproduction Act 2002 and the Research Involving Human Embryos Act 2002*.

Council noted that AHEC had established a sub-group to explore the ethical principles that underpin the existing legislation and to consider whether those principles would support any of the new technologies being assessed for use in research and clinical treatment in Australia.

Professor Olver highlighted that the subgroup was looking primarily at the mitochondrial and editing techniques, which Council acknowledged made sense given these technologies were more advanced internationally. Ms Carey noted the technical complexity of the paper and that more information would be useful for CCAG to engage fully in the debate.

Council **NOTED** progress of the subgroup and looked forward to seeing the paper at its next meeting.

22. NHMRC GENDER EQUALITY STRATEGY

Dr Ro Mitchell presented the *Draft NHMRC Gender Equality and Action Plan* (the Strategy).

Dr Mitchell noted that NHMRC had done a lot of work on gender equality in health and medical research, including implementing NHMRC's Administering Institutions policy and the Project Grants special initiative in 2017. Dr Mitchell acknowledged that, although progress had been made, more could be done to work towards gender equality in health and medical research.

Dr Mitchell summarised the Strategy and noted that:

- the Strategy is a working document that will evolve over time, particularly the annual 'Action Plan' component.
- Research Council endorsed the Strategy at its March 2018 meeting.
- NHMRC cannot solve the issue of gender equality in health and medical research alone and the Strategy is just one way NHMRC can address the issue.

The Chair noted that the Strategy was a step in the right direction and members provided positive feedback. Members also suggested that:

- references to LGBTQI could be included, and
- the SAGE & Athena SWAN section may need the language amended for clarity and accuracy.

Council **ADVISED** the CEO to publish the Strategy on NHMRC's website.

Action Item: ONHMRC to publish the Strategy on NHMRC's website.

23. GUIDELINES FOR GUIDELINES

Mr Singh introduced this item, advising that the Consumer Participation module, the latest in the 'Guidelines for guidelines' series, has been renamed Consumer Involvement at the request of CCAG when it considered the module at its meeting on 19 March 2018. At that meeting several additional minor changes were requested to ensure consistency with existing NHMRC advice. Mr Singh advised that all the changes requested by CCAG will be made before the module is released for public consultation.

Council **ADVISED** the CEO to release the Consumer Involvement module for public consultation.

24. AUSTRALIAN DRINKING WATER GUIDELINES – REVISED CHAPTER 5: APPROVAL TO RELEASE FOR PUBLIC CONSULTATION

Ms Barr introduced the item highlighting that this advice has been in development since 2009 and is based on feedback from numerous discussion papers, workshops and consultation. Council approval to release the draft revised Chapter 5 and the accompanying technical appendix for a 60 day public consultation is being sought.

Council **ADVISED** the CEO to release the draft Chapter 5 and technical appendix for a 60 day public consultation.

Action item: ONHMRC to seek CEO approval to release guidance for public consultation.

25. PUBLIC CONSULTATION ON SHORT TERM EXCEEDANCE VALUE METHODOLOGIES AND RECREATIONAL WATER PER- AND POLY-FLUOROALKYLATED SUBSTANCES (PFAS) GUIDANCE

Ms Barr introduced this item highlighting that, following feedback from the CHO meeting, the methodology used for the recreational water PFAS guideline would be revised to incorporate advice from the enHealth

PFAS meeting. ONHMRC is seeking Council approval to release guidance on Short Term Exposure Values (STEV) Methodology and Recreational Water per- and poly-fluoroalkylated substances (PFAS) Guidance. Council members recommended (that subject to minor amendments) the CEO release the recreational water PFAS guideline for a 60 day public consultation.

Council **REQUESTED** that the STEV guidance be developed further based on feedback from the enHealth PFAS meeting.

Action items:

- ONHMRC to further develop the STEV guidance prior to seeking Council approval out of session.
- ONHMRC to amend recreational water PFAS guideline document and seek CEO approval to release guidance for public consultation.

26. PUBLICATION OF PER- AND POLY-FLUOROALKY SUBSTANCES (PFAS) IN THE AUSTRALIAN DRINKING WATER GUIDELINES (ADWG)

Ms Barr introduced this item highlighting that eight submissions were received in response to the public consultation and that enHealth was further consulted on a revised fact sheet out of session in early March. Council's approval was being sought to publish the fact sheet in ADWG.

Council **REQUESTED** that enHealth give further consideration to the fact sheet and HBGV and provide feedback to ONHMRC out of session prior to ONHMRC seeking Council feedback out of session.

Action Item: ONHMRC to seek further feedback from enHealth prior to seeking Council approval out of session.

27. NHMRC'S ROLE WITH HUMAN RESEARCH ETHICS COMMITTEES (HRECS)

At its last session, Council requested a paper on NHMRC's oversight of Human Research Ethics Committees (HRECs). Ms Barr presented this paper and a chronology that detailed NHMRC's involvement with HRECs since 1999. Information was also provided about NHMRC's National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-Centre Research (National Certification Scheme).

Council **NOTED** the paper on NHMRC's involvement in HREC registration and certification, as well as NHMRC's planned actions to strengthen the National Certification Scheme and streamline the administration of the existing registration of HRECs.

28. NATIONAL STATEMENT SECTION 3 REVISION – APPROVAL OF FINAL GUIDELINES

Ms Barr introduced this item, outlined the new structure and approach to the revised Section 3 and advised members that AHEC had recommended that the revised Section 3 of the *National Statement on Ethical Conduct in Human Research* be issued by the CEO. Members noted that consequential changes had also been made to Section 5 and the Glossary to align with the changes to Section 3. The Chair noted the importance of the document and sought feedback from members. Members were supportive of the revised Section 3 and advised the CEO to issue the Section.

Council **ADVISED** the CEO to release the revised Section 3 of the *National Statement on Ethical Conduct in Human Research* (National Statement) and accompanying changes to Section 5 and the Glossary.

29. AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF RESEARCH – APPROVAL OF FINAL DOCUMENTS

Ms Barr introduced this item, advising that the revised *Australian Code for the Responsible Conduct of Research* (the Code) and *Guide to Managing and Investigating Potential Breaches of the Code* (the Investigation Guide) have been finalised by the Code Review Committee (CoRC) and Better Practice Guides

working group. Professor Mike Calford (Chair of the CoRC) provided a summary of the development of the Code and Investigation Guide. Ms Catriona Jackson (Deputy CEO of Universities Australia) and Mr Justin Withers (Director, Policy and Integrity at the Australian Research Council) were in attendance.

Members were asked for advice on minor changes to one section of the Investigation Guide that had been proposed by the Board of Universities Australia and another two that had been proposed by Research Committee. The changes were presented in a tabled document, along with a verbal explanation of the rationale for these changes and the support for these changes from the co-authors. Council accepted all proposed changes.

Members discussed whether Figure 1 in the Investigation Guide should indicate that a complaint may require immediate action, for example if there is a risk of harm to humans. It was noted that Sections 8.2 and 8.3 contain information about these circumstances; however, members advised that these circumstances should be referred to earlier in the Investigation Guide (such as in Figure 1).

Council:

- **ADVISED** the CEO to release the *Australian Code for the Responsible Conduct of Research, 2018* (the Code) pending minor changes.
- **ADVISED** the CEO to release the *Guide to Managing and Investigating Potential Breaches of the Code, 2018* (the Investigation Guide).
- **ADVISED** the CEO to revoke the 2007 edition of the Code.
- **NOTED** that parts of the 2007 Code will be provided for reference purposes until they are replaced by new supplementary guidance.

Action Item: NHMRC to add words towards the beginning of the Investigation Guide that refer to Sections 8.2 and 8.3 (such as in Figure 1).

30. INDIGENOUS RESEARCH ETHICS GUIDELINES: REVISION OF VALUES AND ETHICS AND KEEPING RESEARCH ON TRACK

Members were provided with background information about the review and the development of the revised guidelines by an expert working committee. The revised guidelines are:

- *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*
- *Keeping Research on Track II.*

Members noted the evaluation process and extensive consultation that led to the development of the revised guidelines. Members also noted that the revised guidelines now cover all research instead of only health research. The revised guidelines address the recommendations made from the evaluation and the public consultation submissions, with an increased focus on the values and increased emphasis on the links to the *National Statement on Ethical Conduct in Human Research*. Members noted that the revised guidelines were provided to the following committees prior to Council:

- Principal Committee Indigenous Caucus (PCIC)
- Community and Consumer Advisory Group
- Australian Health Ethics Committee (AHEC).

Members noted the supporting recommendations from AHEC and PCIC to release the guidelines.

Members acknowledged the work from the expert working committee and NHMRC staff in completing this revision. Members agreed to recommend to the CEO that the two revised guidelines be released.

Council **ADVISED** that the following revised guidelines be provided to the CEO with the recommendation they be released:

- *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researcher and stakeholders*
- *Keeping Research on Track II*

31. COMPETENCIES FOR AUSTRALIAN ACADEMIC CLINICAL TRIALISTS

Ms Barr introduced this paper and the draft Competencies for Academic Clinical Trialists. Ms Barr outlined the development of the competencies and the recommendation of the Health Translation Advisory Committee (HTAC) to release the documents. Council members supported the release of the competencies and suggested sending them to all medical schools via the Council of Presidents of Medical Colleges and to Deputy Vice-Chancellors of Research.

Council **NOTED** the competencies and the recommendation of HTAC to release the competencies.

32. JURISDICTIONAL REPORT

Council **NOTED** the jurisdictional report.

33. STATUS OF GUIDELINES AND PUBLICATIONS AND STANDARDS FOR RESEARCH

Council **NOTED** the update on the status of ethics guidelines and publication and standards for research.

34. NHMRC COMMUNICATIONS UPDATE

Council **NOTED** the NHMRC communications update.

35. UPDATE ON BOOSTING DEMENTIA RESEARCH INITIATIVE

Council **NOTED** the update on the Boosting Dementia Research Initiative.

36. OUT-OF-SESSION ITEMS

Council **NOTED** the outcomes of the out-of-session activity between the 212th and 213th sessions of Council.

OTHER BUSINESS

Noting that the June meeting would be the final for this Council, the Chair sought preliminary views on learnings from the triennium. This session foreshadowed a more detailed discussion to be held at the June meeting on triennium achievements and work recommended for rolling into the new triennium.

Members acknowledged that reforms to the NHMRC grants and peer review process had necessarily taken significant Council time within this triennium. It was generally acknowledged that these initiatives would add value and diversity to the research sector over the longer term and the Council had appreciated the opportunity to advise the CEO in this regard.

Members indicated a desire to increase opportunities to strategically leverage the diverse expertise on Council to guide its work program. It was noted that linkages between Council and its Principal Committees had proven invaluable to maximising advice to the CEO and that opportunities in research innovation and knowledge translation were an area for increasing future focus.

It was acknowledged that sectoral growth has seen a rapid demand for expert health and medical guidelines in a range of areas. The ability to meet demand for guidelines was offset by resource constraints on the Office. This may result in a future need to determine how NHMRC can (and should) add value in an increasingly crowded health and medical research space.

CLOSE OF MEETING

The Chair thanked the Secretariat and staff of the Office for their work in preparing the papers and their support for the meeting.

The Chair noted that the next Council meeting will be held in Canberra on 27-28 June 2018.

The meeting closed at 3.00pm.