

MINUTES
214th Session
Council of the National Health and Medical Research Council
27-28 June 2018
NHMRC Offices, Canberra

Attendance:

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| Prof Bruce Robinson AM | Chair of Council |
| Prof Kathryn North AM | Chair, Research Committee |
| Prof Ian Olver AM | Chair, Australian Health Ethics Committee |
| Prof Sharon Lewin | Chair, Health Translation Advisory Committee (via video) |
| 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 AM | Member with expertise in Public Health (via video) |
| Ms Karen Carey | Member with expertise in consumer issues |
| 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 |
| Dr James Williamson | CMO representative, WA |
| Prof Paddy Phillips PSM | CMO, SA |

Observers

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| Prof Con Michael AO | Chair, Embryo Research Licensing Committee |
| 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 |
| Mr Barry Sandison | Observer, Australian Institute of Health and Welfare |
| Dr Nick Hartland | Observer, Department of Health |
| Ms Erica Kniepp | Observer, Department of Health |

Apologies

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| Prof Graeme Samuel AC | Chair, Health Innovation Advisory Committee |
| Prof Ingrid Scheffer AO | Member |
| Prof Elizabeth Sullivan | Member |

NHMRC Staff

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| Prof Anne Kelso AO | CEO |
| Mr Tony Kingdon | General Manager |
| Dr Tony Willis | Executive Director, Research Quality and Priorities |
| Mr Alan Singh | Executive Director, Research Translation |

Dr Julie Glover
Mr Tony Krizan FCPA

Executive Director (A/g), Research Programs
Executive Director, Corporate Operations and Information

1. WELCOME

The Chair, Professor Bruce Robinson, opened the 214th Session of Council at 1pm and welcomed attendees to the tenth and final 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 Graeme Samuel, Prof Ingrid Scheffer and Prof Elizabeth Sullivan. The Chair noted that Prof Ian Olver was travelling internationally and would join the meeting only for certain items over the two days. The Chair confirmed that the meeting was quorate and welcomed the observers to the meeting.

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 with 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 213th 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 March, April and May 2018.

Professor Kelso highlighted the following items:

- Mental Health Research Roundtable
- US-Australian Cancer Moonshot Roundtable
- Restructure of Office of NHMRC
- Health and medical research funding in the Federal Budget, and
- Work of the advisory committee on myalgic encephalomyelitis/chronic fatigue syndrome

Council **NOTED** the CEO Report.

3. CHAIR'S REPORT

Professor Robinson briefed Council on the invitations he had received as Council Chair. Professor Robinson also briefed the Council on elements of his work as Chair of the MBS Review, which is considering how services can be aligned with contemporary clinical evidence and practice and improve health outcomes for patients.

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

4. PRINCIPAL COMMITTEE INDIGENOUS CAUCUS (PCIC) END OF TRIENNIUM REPORT

Professor Eades highlighted the many achievements of PCIC and NHMRC in Indigenous health research this triennium, as set out in the agenda paper. She noted that this work still needs to translate into improved health outcomes for Aboriginal and Torres Strait Islander communities, and that it may benefit NHMRC to build relationships with, or otherwise respond directly to, the priorities of Indigenous communities where health outcomes are particularly poor. The other priority for next triennium would be the training and development of Indigenous researchers.

Council **NOTED** the PCIC end of triennium report.

5. AUSTRALIAN HEALTH ETHICS COMMITTEE (AHEC) REPORT

Professor Ian Olver presented the Australian Health Ethics Committee (AHEC) end of triennium report and provided an update on the final meeting for the 2015-2018 triennium. Key outputs over the triennium included:

- activities are part of the rolling review of the National Statement on Ethical Conduct in Human Research, 2007, including: an update and release of the revised Section 3, an update and targeted consultation for the review of Section 4, and planning for the review of Section 5.
- a revision of Part B of the Ethical guidelines for the use of assisted reproductive technology in clinical practice and research, 2017
- consideration of ethical issues raised by new technologies as outlined in the discussion 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* (see Item 27).

Council **NOTED** the AHEC end of triennium report.

6. HEALTH INNOVATION ADVISORY COMMITTEE (HIAC) REPORT

Dr Julie Glover presented the Health Innovation Advisory Committee (HIAC) end of triennium report on behalf of Prof Samuel. A key focus of the final meeting for the 2015-2018 triennium was Aboriginal and Torres Strait Islander health. The Committee agreed that progression of the Aboriginal and Torres Strait Islander Term of Reference should be a priority for the 2018-2021 triennium.

Other priorities for the next triennium include:

- continuing to advise NHMRC on opportunities to partner with the philanthropic sector
- identifying and advising NHMRC on the “next big thing” in health and medical research, for example, data science and digital health
- undertaking a review of the Development Grant scheme
- monitoring the impact of the framework for the assessment of track record on outcomes for the new grant program.

The Committee noted its achievements in advising on policy changes to the Development Grants scheme to target applications with the highest commercial potential, and developing resources (including the Innovation webpage) to support researchers interested in the innovation/commercialisation pathway.

Council **NOTED** the HIAC end of triennium report.

7. HEALTH TRANSLATION ADVISORY COMMITTEE (HTAC) REPORT

Professor Sharon Lewin presented the end of triennium report for the Health Translation Advisory Committee (HTAC) and provided Council with an update on the items that were discussed at the 15 June 2018 meeting. These included:

- priorities for the next triennium
- clinician researcher career pathways
- measuring and reporting the impact of clinical practice guidelines and the Guidelines for Guidelines project
- the NHMRC Data Strategy
- the work of the Working Group on Clinical Trials and Cohort Studies
- the Advanced Health Research and Translation Centres and the Centres for Innovation in Regional Health
- the NHMRC Research Translation Strategy and embedding research into health delivery.

Professor Kelso noted that the work HTAC commenced to improve the understanding of the career pathways of clinician researchers is an important project for the next triennium and is of interest to other Principal Committees. HTAC's work on defining the impact of NHMRC funded research and the Guidelines for Guidelines project were also noted as important work undertaken during the triennium.

The Chair thanked Professor Lewin and acknowledged the work of HTAC over the triennium.

Council **NOTED** the HTAC Report.

8. CCAG END OF TRIENNIUM REPORT

Ms Karen Carey informed Council that CCAG provided valuable advice on NHMRC initiatives, informed by a broad range of community perspectives. Ms Carey highlighted many achievements throughout the triennium including:

- Finalisation of the NHMRC/Consumers Health Forum of Australia joint *Statement on Consumer and Community Involvement in Health and Medical Research*; and
- Production of guidance documents on a range of topics such as principles of community expectations and consumer value, measuring alignment with consumer expectations, measuring effectiveness of consumer involvement, measuring impact of research and important elements of research track record.

Council **NOTED** the CCAG End of Triennium Report.

9. MREA UPDATE

Mr Tony Krizan presented an update of the MREA Budget for 2018. The total amount available for new commitments in 2018 is \$794.3 million, as advised by Council in March 2018.

There were no changes to the 2018 MREA allocations from the advice received from Council in March 2018.

Council **NOTED** the MREA update.

10. 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 NHMRC 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: The Office of NHMRC to contact Administering Institutions to advise how NHMRC will handle data breaches. NHMRC will also include an article on data management in the Tracker publication.

10A. OUTCOME REPORTING CASE STUDY DEVELOPMENT

NHMRC provided an update on the development of the Outcome Reporting app. Two draft case studies were presented as examples of the work towards greater reporting capability. Mr Tony Krizan noted that meta-analysis of case studies will be possible and return on investment modelling capability will be built into the next phase of this work.

NHMRC Council discussed the two case study examples provided and noted its support for this work. The development of a new capability to allow researchers and Administering Institutions to report on long term outcomes from NHMRC investment was welcomed.

Council **NOTED** the outcome reporting case study development.

11. NEW GRANTS MANAGEMENT SOLUTION (SAPPHIRE)

Mr Tony Krizan presented an update on the New Grants Management Solution (Sapphire) implementation.

Council **NOTED** the Sapphire Update.

12. RESEARCH COMMITTEE (RC) END OF TRIENNIUM REPORT

Professor Kathryn North provided Council with an update on RC's triennium, highlighting the CEO's leadership, particularly as an ambassador for NHMRC. Positive outcomes for the triennium included:

- advice on the implementation of the new grant program
- development of a framework around strategic priorities, and
- the use of portfolio representatives and the use of videoconferencing to allow for additional meetings.

For the next triennium, RC proposed that there be a continued focus on building Aboriginal and Torres Strait Islander researcher capacity, encouraging women to remain in health and medical research, and building capacity in health services research. The evaluation of NHMRC's new grant program will be a major focus for the next RC.

Professor North noted the improvement in communication by NHMRC with the research sector.

Council **NOTED** the RC End of Triennium Report.

13. FUNDING RECOMMENDATIONS

Mr Alan Singh presented the following funding recommendations to Council for consideration:

Career Development Fellowships (CDF)

Council **SUPPORTED** RC's recommendation to fund 55 new CDFs, including three CDFs from the strategic priority area budget, totalling \$24,421,140.

Council **NOTED** that some additional Fellowships may be funded from the Medical Research Future Fund (MRFF) via the Next Generation Clinical Researchers program.

Early Career Fellowships (ECF)

Council **SUPPORTED** RC's recommendation to fund 115 new ECFs, including five ECFs from the strategic priority area budget, totalling \$37,701,386.

Centres of Research Excellence

Clinical Research Stream

Council **SUPPORTED** RC's recommendation to fund six new CREs totalling \$14,983,873.

Population Health Research Stream

Council **SUPPORTED** RC's recommendation to fund four new CREs totalling \$9,963,364.

Health Services Research Stream

Council **SUPPORTED** RC's recommendation to fund six new CREs totalling \$14,979,988.

Research Fellowships (RF)

Council **SUPPORTED** funding for 78 RFs commencing in 2019 and 23 sixth year extensions, totalling \$62,091,044 as recommended by RC.

Practitioner Fellowships (PF)

Mr Singh clarified that the cost of \$215,992 to fund the next ranked application was in addition to the scheme underspend of \$271,901 as per Attachment B.

Mr Singh advised Council that additional PFs may be funded from the Department of Health MRFF Next Generation Clinical Researchers program.

Council **SUPPORTED** funding for 14 PFs commencing in 2019, totalling \$7,428,099, as recommended by RC.

Development Grants

Council **SUPPORTED** funding for 20 Development Grants commencing in 2019, totalling \$14,490,799 as recommended by RC.

Targeted Call for Research (TCR) into Social and Emotional Wellbeing and Mental Health for Aboriginal and Torres Strait Islander Peoples from Early Life to Young Adults (SEWB)

Mr Alan Singh presented the funding recommendation for the Targeted Call for Research into Social and Emotional Wellbeing and Mental Health for Aboriginal and Torres Strait Islander Peoples from Early Life to

Young Adults (SEWB TCR) and asked Council to support RC's recommendation to fund 5 new grants under this call, totalling \$5,521,141.

Council **SUPPORTED** funding for 5 TCR grants into SEWB commencing in 2018, totalling \$5,521,141 as recommended by RC.

Action Item: The Office of NHMRC to submit these funding recommendations to the Minister for Health.

14. THE AUSTRALIAN IMMUNISATION HANDBOOK (10TH EDITION)

The Chair introduced the item and advised that Mr Alan Singh and Professor Brendan Murphy would speak to this item on the Australian Immunisation Handbook (the Handbook).

Mr Singh informed Council that the Acting Chief Medical Officer had written to Professor Kelso to request NHMRC approval of changes to the recommended use of meningococcal and Haemophilus influenzae type B vaccines and a new digital version of the Handbook.

Mr Singh outlined the rationale for the changes and the process for approval noting that this is the last time that changes will be approved under this process as a proposal for a new approval process will be considered in agenda item 15. He reported that the changes had been released for a 31 day public consultation and that the Office of NHMRC is satisfied that the public consultation process meets the requirements for NHMRC approval.

Mr Singh outlined the changes to the digital edition of the Handbook noting the separation of recommendations from the supporting text which aligns it with other third party guidelines. Members discussed clinicians' access to the Handbook in areas with limited internet service. Professor Murphy noted that the Department of Health did not intend to revert to a printed copy of the Handbook, but advised that the Department of Health would consider ways to make the Handbook available to users with limited internet access.

Ms Carey noted that the digital version of the Handbook is easy to navigate, is written in plain English and will be able to be used by consumers.

Professor Lawler discussed the difference between a statement that recommends or strongly recommends a course of action noting that clarity in this area would assist practitioners with vaccine recommendations that are not funded under the national immunisation program.

Council **ADVISED** the CEO to approve changes to the recommended use of meningococcal and Haemophilus influenzae type B vaccines, being recommendations on pages 3-4 of Attachment A.

Council **ADVISED** the CEO to approve the digital version of the Australian Immunisation Handbook to be launched by the Department of Health in July 2018.

15. AUSTRALIAN IMMUNISATION HANDBOOK: A NEW APPROVAL PROCESS

The Chair introduced the item and invited Mr Singh to speak to the proposed approval process for the Handbook.

Mr Singh described the differences between the current and the proposed Handbook approval process. He noted that the new process requires Members' approval of recommendations only which aligns it with other third party guidelines. He informed Council that they will be notified of any supporting text changes of interest but in general the supporting text won't be submitted for Council consideration. Members agreed that the new process was reasonable and sensible.

Council **AGREED** to rescind the NHMRC procedures and requirement for approval of the Australian Immunisation Handbook (Attachment A).

Council **AGREED** to the new process for NHMRC approval of the Australian Immunisation Handbook.

16. UPDATE TO CLINICAL GUIDELINES FOR STROKE MANAGEMENT 2017

The Chair introduced the item and invited Mr Geraint Duggan to provide an overview of the development process for the amended recommendation for the Clinical guidelines for stroke management 2017. Mr Duggan noted that the Stroke Foundation had become aware of new evidence that changed a recommendation in the NHMRC approved Clinical guidelines for stroke management 2017. The Stroke Foundation released the draft recommendation changes for public consultation in April 2018 and received three submissions.

Mr Duggan noted that the Stroke Foundation has discussed the amendment with all states and territories and, while the Northern Territory does not currently have the ability to implement the update to practice, the Stroke Foundation is working with the Northern Territory on this. Professor Geelhoed noted that Western Australia does not have the resources to implement the change but is in talks with their state stroke network to address this.

Council **ADVISED** the CEO to approve the amended recommendation on the timing of endovascular thrombectomy in the Clinical guidelines for stroke management 2017 as developed by the Stroke Foundation.

Day Two of the 214th Session

17. MEDICAL RESEARCH FUTURE FUND (MRFF) UPDATE

Dr Nick Hartland provided Council with an update on 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.

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

Dr Tony Willis provided an update on the implementation of NHMRC's new grant program. He highlighted the invaluable input from Council and the Principal Committees, particularly Research Committee, in assisting NHMRC to implement the new grant program during the past 18 months. He also acknowledged and thanked the members of Council who had participated in the working groups which had also assisted NHMRC to develop key elements of the new grant program.

Dr Willis noted two key achievements since the previous Council meeting:

- preparing the grant guidelines for each of the new schemes, which are currently undergoing Government approval processes – Department of Finance risk assessment and the Minister for Health's approval to release the grant guidelines, and
- NHMRC's active consultation and communication with the research sector, most recently including the CEO's webinar on 26 April 2018.

In noting that the Taskforce was concluding, he outlined one of the final tasks is the development of an evaluation framework to enable assessment of the new grant program relative to its objectives and also to monitor for any unintended consequences.

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

19. PROGRESS REPORT AGAINST 2017-18 STRATEGIC PRIORITIES

Members were asked to note an end of triennium progress report describing achievements against the strategic priorities in the *NHMRC Corporate Plan 2017–2018*.

Council **NOTED** the report against the strategic priorities and that further discussion of some of the items covered in the report would also be included in the next agenda item.

20. REFLECTIONS ON THE TRIENNIUM ACHIEVEMENTS FROM CEO

Prof Kelso provided her reflections of the triennium, highlighting the key stakeholders who drive the work of NHMRC, and how their needs, and NHMRC, have evolved over the triennium:

- A greater focus on **Community** has seen increased consumer participation earlier in decision making processes, for example, as observers in peer review and in the development of questions for targeted calls for research. NHMRC had also increased its community accessibility with an expanded social media profile and ongoing involvement in educative forums, including parliamentary inquiries.
- The innovation, science and commercialisation agenda of the **Government** has had a positive impact on health and medical research in Australia with the establishment of the Medical Research Future Fund to augment traditional funding streams. NHMRC continued to work collaboratively with funding peers to maximise the complementarity of all funding streams and minimise the impact of a leaner public service.

- By introducing a modernised funding framework, developed in consultation with the **Research Sector** and with guidance from Council and PCs, NHMRC will remain responsive to the changing profile of the Australian health and medical research sector. Along with the more intuitive Sapphire grant management system and streamlined peer review processes, NHMRC has set the foundation in this triennium for a stable and sustainable sector in the future.

In parallel to the substantial change agenda implemented over the triennium, NHMRC continued to deliver on its core business, recommending grant and funding investments of over \$2.7 billion (with \$2.5 billion in payments made over the period), supporting collaborative peer review processes and third party grants for the sector. NHMRC also continued to work on its translation agenda, with an ongoing focus on strategic priority areas including gender equality, improved Indigenous health outcomes and practical health services research.

Prof Kelso noted that the core lessons from the triennium, including the benefits of early community and consumer involvement, harnessing technology to work efficiently with less, not losing sight of the human factors and bringing the sector on the change management journey with NHMRC, will underpin the way NHMRC does business in the future.

Members **NOTED** the presentation and thanked NHMRC staff and executive for their work over the triennium.

21. UPDATE ON DEVELOPMENT OF 2018-19 CORPORATE PLAN

Members were advised that earlier input from Council and Principal Committees has been considered in the development of the draft plan and that progress towards meeting legislative timeframes for publication and tabling was currently on track.

Council **NOTED** the update on the development of the *NHMRC Corporate Plan 2018–2019*.

22. UPDATE ON MHRAC

Dr Tony Willis provided Council with an update on key agenda items from the Mental Health Research Advisory Committee (MHRAC) meetings held from November 2017 – June 2018.

Key agenda items included:

- Minister for Health's announcement of the Mental Health Million Minds Mission (Mission) following the Department of Health's (DoH) roundtable on 5 March 2018:
 - the Mission is to be funded by the Medical Research Future Fund to a total value of \$125 million over 10 years
 - the purpose of the Mission is to assist a million people who might otherwise not be part of mental health research and clinical trials
 - initial priorities include eating disorders, youth mental health and Aboriginal and Torres Strait Islander mental health
- MHRAC's consideration of gaps and priorities identified from funding analyses presented by the Office of NHMRC, and
- Opportunities for the Office of NHMRC and MHRAC to contribute to related work being undertaken by the DoH in finalising the Roadmap for the Mission and with the National Mental Health Commission's development of a National Strategy for Mental Health Research as part of the *Fifth National Mental Health and Suicide Prevention Plan*.

Council **NOTED** that MHRAC is to be extended for a further six months as it explores key themes for future NHMRC investment in health and medical research, as part of its advice to NHMRC's CEO.

23. EVALUATION OF THE BOOSTING DEMENTIA RESEARCH INITIATIVE

Council noted the proposed evaluation of the Boosting Dementia Research Initiative (BDRI). Members asked for clarification on Intellectual Property (IP) ownership, contractor expertise and whether the evaluation will be made widely available. Members were informed that NHMRC will 'own' all IP created through the evaluation, and the contractor conducting the evaluation will be guided by two advisors with expertise in program evaluation. It was noted that the final evaluation report will be primarily for internal use; however, the Office of NHMRC will consider making it publically available.

Council **NOTED** the proposed evaluation of the Boosting Dementia Initiative.

24. PUBLICATION OF PER- AND POLY-FLUOROALKYL SUBSTANCES (PFAS) FACT SHEET IN THE AUSTRALIAN DRINKING WATER GUIDELINES

Mr Alan Singh introduced the item. He noted that Council had considered this item in March 2018 after public consultation feedback was incorporated into the fact sheet. Following Council's advice the Environmental Health Standing Committee was consulted again. The fact sheet reflects that additional consultation.

Members approved publication of the PFAS fact sheet in the Australian Drinking Water Guidelines (ADWG), but noted that should international advice change significantly then the fact sheet should be urgently updated.

Members discussed communication of the guidance and agreed that, given the target audience of the fact sheet is water utilities and regulators, no additional communication activities were required. NHMRC will advise key stakeholders consulted during the development of the fact sheet of its publication.

Council **ADVISED** the CEO to publish the proposed per- and poly-fluoroalkyl substances chemical fact sheet for inclusion in the Australian Drinking Water Guidelines.

Action Item: The Office of NHMRC to seek CEO approval to publish the fact sheet.

25. RECREATIONAL WATER PER- AND POLY-FLUOROALKYL SUBSTANCES (PFAS) GUIDANCE: PUBLIC CONSULTATION ADVICE

Mr Alan Singh introduced the item. He noted that Council had considered this item in March 2018 and had advised that NHMRC consult further with the Environmental Health Standing Committee. Additional consultation with the Environmental Health Standing Committee was undertaken. This resulted in the NHMRC Water Quality Advisory Committee revising the methodology for calculating the recreational water guideline values, and reformatting the fact sheet to align with the PFAS fact sheet in the Australian Drinking Water Guidelines.

Council **ADVISED** the CEO to release the recreational water guideline for a 45 day public consultation.

Action item: The Office of NHMRC to seek CEO approval to release the guidance for public consultation.

26. EMBRYO RESEARCH LICENSING COMMITTEE (ERLC) END OF TRIENNIUM REPORT

Professor Michael, Chair, Embryo Research Licensing Committee (ERLC), provided Council with the annual update on activities of ERLC over the last 12 months and briefed on major achievements over the triennium. These included:

- Development of an information 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*.
- Issuing two new licences under the legislation, and 101 licence variations.
- Release of six biannual Reports to Parliament on the operation of the *Research Involving Human Embryos Act 2002* and licences issued under the Act (Reports 26 to 31).
- Updated information kit for licence applicants (4th edition, 2018).

Professor Michael noted that one licence application remained under review and briefed Council on ERLC's decision to review the required skills and competencies of embryologists seeking to undertake activities under a licence in the new triennium.

Council **NOTED** the ERLC End of Triennium Report.

27. ERLC DISCUSSION PAPER: CONSIDERATION OF EMERGING TECHNOLOGIES IN LIGHT OF THE AUSTRALIAN EMBRYO RESEARCH LEGISLATION

Professor Michael and Dr Willis presented the issues paper, *Consideration of emerging technologies in light of the Prohibition of Human Cloning for Reproduction Act 2002 and Research Involving Human Embryos Act 2002*, noting that since it was last seen by Council in July 2017, it had been subject to an external review and minor revision of scientific/technical content. It was noted that an AHEC/ERLC subgroup had also considered various ethical issues arising from this work and developed a preliminary statement on same.

Professor Michael briefed the Committee on the release, on 27 June 2018, of the report from the Senate Community Affairs References Committee's inquiry into Mitochondrial Donation, noting that this report may raise additional issues that need to be considered within the context of the paper.

Council **APPROVED** a revised resolution that accepted the content of the emerging technologies paper as scientifically valid and helpful, but noted that time would be required to consider if additional issues should be considered as a result of the report from the Senate Community Affairs References Committee's inquiry into Mitochondrial Donation.

28. A GUIDELINES FOR ASSESSMENT AND DIAGNOSIS OF AUTISM SPECTRUM DISORDERS IN AUSTRALIA: A MINIMUM NATIONAL STANDARD

The Chair introduced the item and welcomed Professor Andrew Whitehouse, chair of the guideline research executive, and Dr Kiah Evans, guideline project co-ordinator, (both via videoconference) who had been invited to attend Council to answer Members' questions.

Mr Duggan gave an overview of the document, *A guideline for the assessment and diagnosis of autism spectrum disorders in Australia: A minimum national standard development process noting the extensive consultation undertaken*. He noted that the guideline had been released for a 43-day public consultation and had been subject to methodological and clinical expert reviews. He noted that the timing of the methodological review was unusual but advised that the Office of NHMRC was satisfied that the guideline's recommendations had met the requirements for NHMRC approval.

Professor Sandra Eades, as Council Discussant, also noted the extensive consultation process undertaken and the inclusion of many experts from the clinical, disability and rural health sectors. She identified a concern for children who are not easily diagnosed and the potential for delayed or missed access to services. She noted this guideline will assist to reduce the number of children in this category. Members also noted concerns with over-diagnosis and treatment in this area and the need for assessment and diagnostic rigour.

Members discussed the resource implications of this guideline and questioned the meaning of the term 'minimum national standard'. Professor Whitehouse noted that the development team consulted extensively to address and minimise the impact of resource implications. He noted the term 'minimum national standard' was used to align the diagnostic practices of clinicians throughout Australia where significant variability currently exists. He noted that the term does not indicate a minimum treatment standard, nor does it describe a process that prevents access to support services.

Members noted the very comprehensive process undertaken to develop the guideline. Professor Whitehouse agreed to remove the term 'minimum national standard' from the guideline's title.

Council **ADVISED** the CEO to approve *A guideline for the assessment and diagnosis of autism spectrum disorders in Australia*, being the recommendations on pages 2 to 25 of Attachment A.

29. INTERNATIONAL EVIDENCE-BASED GUIDELINE FOR THE ASSESSMENT AND MANAGEMENT OF POLYCYSTIC OVARY SYNDROME 2018

The Chair introduced the item and welcomed Professor Helena Teede, guideline lead, (via videoconference) who had been invited to attend Council to answer Members' questions.

Mr Duggan gave an overview of the development process and noted that this guideline is an update of the 2011 NHMRC approved, *International Evidence-based guideline for the assessment and management of polycystic ovary syndrome*. Mr Duggan reported that the guideline had been released for public consultation and had been subject to methodological and clinical expert reviews. He advised that the Office of NHMRC was satisfied that the recommendations in the guideline had met the procedures and requirements for NHMRC approval.

The Chair invited Professor Teede to speak to the guideline. Professor Teede noted that the guideline development group only sought NHMRC approval for this international guideline. Professor Teede also noted that 70 experts from around the world collaborated to develop the guideline.

The Chair invited comments from Council members and Professor Con Michael noted that this is a very welcome guideline as polycystic ovary syndrome is commonly over-diagnosed and over-treated in young women. Professor Teede noted that the guideline has tightened diagnostic criteria, which should assist in reducing over-diagnosis. She noted that a summary paper will be published in three international journals and an editorial in *The Lancet* following NHMRC approval.

Council **ADVISED** the CEO to approve the *International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2018*, being the recommendations on pages 6 to 24 of Attachment A.

30. GUIDELINE FOR THE MANAGEMENT OF KNEE AND HIP OSTEOARTHRITIS

The Chair introduced the item and welcomed Professor David Hunter, the Co-chair of the guideline's working group, (via videoconference) who had been invited to attend Council to answer Members' questions.

Mr Duggan gave an overview of the guideline's development process and noted that the guideline was an update of the 2009 guidelines developed by the Royal Australian College of General Practitioners (RACGP). The current update is intended for general practitioners in primary care treating symptomatic patients. Mr Duggan noted that the draft guideline was released for a 30 day public consultation to which the RACGP received 32 submissions and had been subject to a methodological and two expert reviews. He advised that the Office of NHMRC was satisfied that the guideline's recommendations had met the requirements for NHMRC approval.

Dr Hugh Heggie, as the Council discussant for the guideline, noted the importance of the guideline for safe effective care and that it had been a pleasure to read the guideline. He noted that while the guideline is

directed to general practitioners it could be used by allied health and other specialists who provide care for symptomatic patients.

Professor Hunter noted the amount of work which went into the guideline and his appreciation of the opportunity to have the guideline considered by Council.

Professor Kidd excused himself from the vote as a past president of the RACGP.

Council **ADVISED** the CEO to approve the *Guideline for the management of knee and hip osteoarthritis*, being the recommendations on pages 10 to 18 of Attachment A.

31. JURISDICTIONAL REPORT

Council **NOTED** the jurisdictional report.

32. 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.

33. REPORT ON STATUS OF GUIDELINES IN CINICAL PRACTICE AND PUBLIC HEALTH

Council **NOTED** the report on the status of guidelines in clinical practice and public health.

34. NHMRC COMMUNICATIONS UPDATE

This item was removed from the agenda.

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 213th and 214th sessions of Council.

OTHER BUSINESS

Members were asked to provide feedback on their experience of the 2015-18 triennium. A range of logistical and strategic matters were discussed:

- Members felt that the NHMRC papers were of a very high quality; however Members said that the size of some guidelines could prohibit Members' ability to meaningfully contribute to discussions. It was noted that the Office, in consultation with CHOs, is currently working on a process to streamline guideline consideration by Council that will be brought forward in the new triennium. It was noted that the allocation of a Council Discussant for each guideline had proven to be very effective in the past and that Members would welcome this approach in the future.
- Members considered that meeting length and frequency were sufficient to allow the agenda to be realised. Members felt that a mid-triennium review would be beneficial to maintaining momentum.
- Members considered that Funding Recommendations could be considered out of session; this would allow greater flexibility in funding approval cycles in the new triennium, which would fit well with the accessibility objectives of the new grant program.

- Members reiterated the discussion at the 213th session, that greater opportunity to consider matters of strategic importance to the health and medical research sector would be beneficial. This would be in the context of the NHMRC mandate and guided by the CEO's strategic objectives.
- Members highlighted that Council dinners could present an opportunity to brief Members on issues of strategic importance, which could underpin blue-sky discussions.

CLOSE OF MEETING

The Chair thanked the Secretariat and staff of the Office for their work in preparing the high quality papers and their support for the meetings throughout the triennium.

The Chair and CEO thanked Members for their service to Council and to NHMRC.

The meeting was closed at 2.30pm.