

MINUTES
209th Session
Council of the National Health and Medical Research Council
2-3 November 2016
NHMRC Offices, Canberra

Attendance:

Prof Bruce Robinson AM	Chair of Council
Prof Kathryn North AM	Chair, Research Committee
Prof Ian Olver AM (day 2, via video, for item 22)	Chair, Australian Health Ethics Committee
Prof Graeme Samuel AC	Chair, Health Innovation Advisory Committee
Prof Sharon Lewin	Chair, Health Translation Advisory Committee
Prof Sandra Eades	Member with expertise in the health needs of Aboriginal persons and Torres Strait Islanders
Ms Karen Carey (via video)	Member with expertise in consumer issues
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 Jonathan Carapetis	Member with expertise in Public Health
Prof Ingrid Scheffer AO	Member
Prof Elizabeth Sullivan	Member
Prof Brendan Murphy	Commonwealth Chief Medical Officer (CMO)
Dr Jeannette Young PSM	Chief Health Officer (CHO), QLD
Dr Jan Fizzell	Representing CHO, NSW
Prof Paddy Phillips PSM	CMO, SA
Dr Hugh Heggie	A/g CHO, NT
Prof Charles Guest	CHO, VIC
Prof Tony Lawler	Principal Medical Advisor, TAS
Dr Vanessa Johnston	Representing CHO, ACT

Apologies

Prof Gary Geelhoed	CMO, WA
Dr Kerry Chant PSM	CHO, NSW
Dr Paul Kelly	CHO, ACT
Prof Michael Kidd AM	Member with expertise in health care training

Observers

Mr Graeme Barden	Department of Health
Mr Barry Sandison	Australian Institute of Health and Welfare

NHMRC Staff

Prof Anne Kelso AO	CEO
Mr Tony Kingdon	General Manager
Ms Samantha Robertson	Executive Director, Evidence, Advice and Governance
Mr Alan Singh	Executive Director, Research Translation
Dr Tony Willis	Executive Director, Research Programs
Mr Tony Krizan FCPA	Executive Director, Corporate Operations and Information

1. WELCOME

The Chair opened the 209th Session of Council at 1pm and welcomed attendees to the fifth 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 apologies from Professors Gary Geelhoed and Michael Kidd, and Doctors Kerry Chant and Paul Kelly, and noted that Ms Karen Carey was participating in the meeting via video conference. The Chair welcomed the observers and confirmed that the meeting was quorate.

The Chair introduced the new Chief Commonwealth Medical Officer, Prof Brendan Murphy.

The Chair reminded attendees that everything discussed at the meeting was to be held or regarded as confidential and invited members to declare any interest that may be a potential or actual conflict of interest at the start of the session and before discussion of relevant items.

The Chair advised that he has joined the board of QBiotics.

No other interests were declared.

Council **ADVISED** the Chair that the draft Session Report of the 208th 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.

2. CEO REPORT

Professor Anne Kelso provided Council members with the NHMRC CEO Report. Discussion with Council members included:

- The Structural Review of NHMRC's Grant Program (the Structural Review) – to be discussed at item 4.
- Medical Research Future Fund – the Australian Medical Research Advisory Board (AMRAB) is completing the strategy and priorities for consideration by the Minister.
- Research Grants Management System (RGMS) – NHMRC has acknowledged the need to replace the current RGMS in the next few years. NHMRC recently sought expressions of interest to develop and implement an improved grant management system.
- A new priority-setting framework for Targeted Calls for Research – the expert advisory group is now preparing the Draft 2016 Roadmap for targeted consultation.
- Advanced Health Research and Translation Centres (AHRTC) – NHMRC has recently invited further applications for recognition as an NHMRC AHRTC. Applications for recognition as a Centre for Innovation in Regional Health also opened at this time.

Council **NOTED** the CEO Report.

3. CHAIR'S REPORT

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

4. STRUCTURAL REVIEW OF NHMRC'S GRANT PROGRAM

Mr Alan Singh provided an update on the review, including the outcome of the consultation, the alternative model developed by the Expert Advisory Group (EAG) and the feedback from Research Committee (RC). Prof Kelso explained the key aims of the review:

- Decrease the burden on applicants and peer reviewers – this requires capping arrangements and five year funding packages, equivalent to a number of smaller Project Grants

- Ensure support for early and mid-career researchers (EMCRs) – further consideration will need to be given to allocating budgets to different parts of the sector
- Increase creativity and innovation – the reduced emphasis on track record for Ideas Grants will provide more opportunities for innovative research.

Members provided the following comments about the EAG's proposed model:

- Modelling of the potential impacts will be critical to determining an alternative model.
- The five-year grant duration should increase creativity.
- If possible, any changes to peer review should be announced at the same time as the new model.
- Diversity should be encouraged; it could be built-into track record assessment for both People and Ideas Grants.
- Concern was expressed about excluding postdoctoral researchers from Ideas Grants – many early career researchers are ready to lead teams; some may have research experience from another discipline before obtaining a PhD; NHMRC should reconsider the approach of defining career levels based on the time from award of a PhD.
- There needs to be clarity about how the funding packages will work (e.g. how diverse teams will divide the funding). Applicants should still be required to submit a budget, for purposes of transparency and assessment of value for money.
- Concern was expressed about the potential impact on Indigenous researchers and those without a strong track record, given 50% of MREA allocation would focus on track record and project/ideas schemes would be reduced to 30% of the MREA.
- It was queried whether Ideas Grants should be capped as this may discourage creativity.
- Stricter capping may result in people submitting applications for 'safe' research.
- Consider whether the model helps researchers make the step from being a part of a team grant to having their own grant.
- Assessment criteria for Ideas Grants do not appear to address high-risk/high-return research.
- Centres of Research Excellence should be retained in some form.
- Strategies for co-funding should be developed. When evaluating the outcomes of research, outcomes from co-funded research should be compared with that which is not co-funded.

Prof North advised that a number of the issues (such as capping) had been considered by Research Committee (RC) in previous triennia. RC considers that the situation is now different, as the higher numbers of applications and lower success rates need to be addressed. Prof North emphasised that the challenge is to reduce the burden of the application process while continuing to fund the best research within the same level of MREA funding. Prof North provided feedback from RC's discussion:

- Overall, there is support for the progress of the review. The consultation provided detailed insights about perceived advantages and disadvantages.
- Some numbers in the model need further consideration – e.g. 30% of the MREA to People Grants may need to be reviewed, given that they will include a research package.
- Financial modelling and modelling of the impact of capping will be important.
- Potential 'gaming' and cost-shifting must be addressed.
- Alternative methods of assessing track record need to be considered, including incorporating experience of researchers in different disciplines.
- Team Grants enhance Program Grants by encouraging multidisciplinary teams and diversity.
- The model must support Aboriginal and Torres Strait Islander health research/researchers.
- Implementing the model would be a whole-of-system change, which should be evaluated.

Council **DISCUSSED** and **ADVISED** on the broad features of a possible new alternative grant program model.

5. RESEARCH COMMITTEE (RC) REPORT

Prof North provided Council with an update on the key agenda items from the RC meeting on 27-28 October 2016 which included:

- Funding Recommendations
- Project Grants and Career Development Grants and the need to look at the legal implications in considering how to deal with gender inequity.

Prof North advised she attended the Global Alliance for Genomics and Health (GA4GH) meeting in Canada, noting it was a great opportunity to see what different countries are rolling out in genomic medicine, and how data are shared across borders. The next step is to start sharing tools and to meet with groups working across the different initiatives.

Council **NOTED** the RC Report.

6. FUNDING RECOMMENDATIONS

Dr Tony Willis introduced this item by reminding Council that due to the procedural nature of funding recommendations they will normally be dealt with out of session. However, as Research Committee met the previous week, it was expedient to bring these recommendations to this meeting.

Dr Willis explained that these funding recommendations were for the Postgraduate Scholarships (PGS), Program Grants and Translating Research into Practice (TRIP) Fellowships funding schemes. The recommendations presented are based on advice received by the CEO from Research Committee for a total of 97 grants and \$115,678,461.

Council **SUPPORTED** the funding for:

- 74 PGS to a total value of \$7,000,000 commencing in 2017
- 10 Program Grants to a total value of \$106,374,900
- 13 TRIP Fellowships to a total value of \$2,303,561.

Council **ADVISED** the CEO to submit these funding recommendations to the Minister for Health and Aged Care.

Action Item: ONHMRC to forward this recommendation for consideration by the Minister.

FUNDING RECOMMENDATIONS (late paper – Partnership Projects)

Professor Eades left the room due to a conflict of interest.

Dr Willis explained that this funding recommendation was for the Partnership Projects funding scheme. The recommendation presented is based on advice received by the CEO from Research Committee for a total of 13 grants and \$9,705,357. Dr Willis highlighted the leveraged funds from partner organisations.

Council **SUPPORTED** the funding for:

- 13 Partnership Projects to a total value of \$9,705,357 commencing in 2016.

Council **ADVISED** the CEO to submit these funding recommendations to the Minister for Health and Aged Care.

Action Item: ONHMRC to forward this recommendation for consideration by the Minister.

7. STRATEGIC ANALYSIS OF NHMRC'S 2016 GRANT PROGRAM

Dr Willis presented the overview of NHMRC funding outcomes across all schemes finalised to date in 2016, including success rates against the organisation's current strategic priorities and against gender of applicants.

Council noted the data and discussed the following issues:

- Considering strategic priorities in the context of alignment with the MRFF is critical
- The analysis would be strengthened by consumer perspectives of activities and outcomes of NHMRC funded research.

Council discussed the possibility of inviting the Minister for Health and Aged Care to attend a future meeting, to discuss the MRFF and its alignment with the MREA.

Council **NOTED** the information provided.

Action Item: ONHMRC to draft a discussion paper considering NHMRC's strategic priorities in the context of alignment with the MRFF

Action Item: ONHMRC to consider how to use consumer perspectives to strengthen this analysis.

Day Two of the 209th Session

Note: the order of the agenda was amended to enable item 22 to be discussed as the first item, to facilitate Prof Olver in videoconferencing into the meeting.

8. PRESENTATION: MR BARRY SANDISON – AUSTRALIAN INSTITUTE OF HEALTH AND WELFARE (AIHW) – UTILISATION OF AVAILABLE DATA SETS

Mr Sandison provided Council with a presentation on the AIHW data sets and gave an overview of future directions.

Mr Sandison described the AIHW's role as an independent entity that provides baseline data across a range of indicators. He noted the importance of these data in establishing an evidence base for policy and research. He further noted the considerable potential to expand the national evidence base through better integration of data and identification of gaps in the collection of data. For example, there is limited cross-over between health and welfare data sets, including such things as burden of disease, hospital admissions, homelessness and domestic violence.

The potential to use unstructured data, such as social media, was also discussed. This may provide opportunities to access a far greater range of information than currently available.

Council **NOTED** the presentation provided by Mr Sandison.

9. DATA STRATEGY

Mr Tony Krizan provided an update on NHMRC's work towards an NHMRC data strategy. The ONHMRC is currently working towards an enhanced system that will strengthen the reporting of outcomes from NHMRC grants. Better integration and use of HMR data across government, the research sector and industry have the potential to enhance HMR outcomes and streamline the administration of the grant system.

Council **NOTED** the paper. A further update on this work will be provided to Council in 2017.

10. MEDICAL RESEARCH FUTURE FUND

Council **NOTED** the progress toward implementation of the MRFF and **NOTED** that disbursements from the MRFF may utilise the capacity of the National Health and Medical Research Council (NHMRC).

11. MREA UPDATE

The total amount available for new commitments in 2016 is \$874.7 million. Of this, the total presented to Council during 2016 was \$828.9 million.

The total under-commitment in 2016 was \$45.8 million, of which \$37.1 million will be made available for distribution in 2017, and \$8.7 million is carry-over commitment due to timing lags.

The total amount available for new commitments in 2017 may be as high as \$876.8 million, including all under-commitments carried forward from 2016.

Council **NOTED** the information provided.

12. PCIC REPORT/INITIATIVES FOR ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH

Prof Sandra Eades introduced the paper and drew members' attention to the 2017 Research Translation Symposium and the 2016 Translating Research into Policy and Practice (TRIPP) Forum. She added that Council Chairperson Prof Bruce Robinson and HIAC Chairperson Prof Graeme Samuel attended the TRIPP Forum held in May. The report of outcomes will potentially feed into work on the NHMRC's Aboriginal and Torres Strait Islander Road Map 3.

PCIC have been working on the development of Road Map 3 and will seek to include new initiatives such as genomics.

Prof Eades highlighted the Targeted Call for Research process and open public consultation, from which 66 completed submissions were received. After examining past research, along with alignment of other priorities such as the National Aboriginal and Torres Strait Islander Plan 2013-2023, a final list of three priorities was tabled with Research Committee. Two were recommended - mental health and ageing well - for funding. Mental health includes gambling related harm and culturally informed research. Ageing well covers premature ageing of the Indigenous population and living with chronic disease.

Council members congratulated Prof Eades on the process and the report.

There was discussion on the People Support scheme, setting of the internal target and the importance of PhD and non-PhD pathways for Aboriginal and Torres Strait Islander researchers. Increased support from the philanthropic sector for Indigenous doctorates could be pursued.

Early career researchers could be more targeted, with more opportunities offered and a consolidation of research skills. An example was given of a recent Clinical and Scientists Symposium which identified role models and targeted individuals

Council **NOTED** the PCIC report.

13. HEALTH INNOVATION ADVISORY COMMITTEE (HIAC) REPORT

Prof Graeme Samuel provided Council with an update on the main agenda items discussed at the HIAC meeting on 5 October 2016 which included:

- Examining the hurdles in commercialisation for the translation of research into health outcomes
- The Development Grants process
- Potential for engaging the philanthropic sector.

Council **NOTED** the HIAC Report.

14. HEALTH TRANSLATION ADVISORY COMMITTEE (HTAC) REPORT

Prof Sharon Lewin provided Council with an update on the main agenda items discussed at the HIAC meeting on 14 September 2016 which included:

- NHMRC's Clinical Trials Framework
- NHMRC Research Translation Strategy.

Prof Lewin noted that a Working Group, chaired by Prof Steve Webb, on Clinical Trials and Large Studies has been formed to develop a framework for NHMRC assessment and funding of clinical trials and other large studies.

Council **NOTED** the HTAC Report.

15. AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF RESEARCH

Ms Samantha Robertson provided members with an update on the review of the *Australian Code for the Responsible Conduct of Research 2007* (the Code). The Code is under review by its three authors, NHMRC, Universities Australia (UA) and the Australian Research Council (ARC), with the assistance of the Code Review Committee (CoRC). The Code has been re-drafted into a principles-based document along with guides and other supplementary material to support implementation of the Code by institutions and researchers. The first comprehensive guide on the investigation and management of potential breaches of the Guide (the Guide) has been developed with the assistance of the Better Practice Guides working group.

Ms Robertson described the major changes between the current Code and the draft Code and Guide. Members noted the two draft documents were sent to key stakeholders in October 2016 seeking high level comments on the broad direction of these two documents and to promote the upcoming public consultation. Members were advised that comments received to date from the pre-consultation communication have been positive. The one exception has been feedback from the Australian Research Integrity Committee (ARIC), which is concerned that the new approach in the Guide weakens research integrity standards because it is not mandatory. Issues that have been raised during these meetings will be addressed in a Frequently Asked Questions (FAQs) document to be released as part of public consultation. Ms Robertson explained that once public consultation has opened, NHMRC, ARC and UA will conduct webinars to explain the new approach and inform consultation submissions.

Members asked if this approach was consistent with other countries. Ms Robertson explained there is no one consistent approach to research integrity; however, most countries rely on a range of self-regulated models. Ms Robertson explained that Canada also has a principles-based approach. Once public consultation has commenced on the Code and Guide, additional guides, for example on authorship and data, will be developed to allow for better adaptation of the Code and support institutions in being more transparent and accountable.

Council **ADVISED** that the draft principles-based Code and draft Guide be released for public consultation.

16. NHMRC JOINT STATEMENT ON VITAMIN K FOR NEWBORN BABIES (AND INFORMATION FOR PARENTS)

Ms Robertson introduced the item by recalling that Council members had advised in March 2016 that the 2010 Joint Statement may require review. Since March, staff had investigated the currency and use of the resource by:

- Seeking feedback from the four colleges involved in developing the original Joint Statement (the Royal Australian College of General Practitioners, the Royal Australasian College of Physicians, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and the Australian College of Midwives)
- Reviewing relevant international guidance
- Scanning Australian jurisdictional policies and advice on the topic.

The four colleges agreed that, while the advice within the 2010 Joint Statement is still current, it would be desirable to update it to reference more recent evidence, to clarify the context of service delivery and to align it nationally and internationally. Members noted that jurisdictional policies and/or guidelines on Vitamin K administration reveal references to be out of date, and that there also seems to be inconsistency in the recommended dose.

Members AGREED that the 2010 Joint Statement should be updated and that, of the revision options available, Option 2 provided the best value for money to do so. This would involve an approach similar to the 2010 revision, where staff would work with the four colleges and additional stakeholders as required. Prof Carapetis suggested consideration of the option of working with a postgraduate student to undertake an in-house literature review of evidence post-2010 and to update the Joint Statement.

As the Joint Statement is essentially a guideline, it will require a public consultation process following the drafting of the revised version.

Council **ADVISED** the NHMRC CEO on the approach to be used to update the 2010 Joint Statement on Vitamin K and the accompanying brochure providing information for parents.

17. AUSTRALIAN AND NEW ZEALAND NUTRIENT REFERENCE VALUES – UPDATE TO FLUORIDE AI AND UL VALUES FOR INFANTS AND YOUNG CHILDREN

The Chair welcomed Ms Janis Baines, Chair of the Fluoride Expert Working Group, and Louise Cook and Susannah van der Straaten from the Australian Department of Health to the meeting for this item.

Ms Robertson introduced the item noting it as a third party guideline developed by the Australian Government Department of Health in collaboration with the New Zealand Ministry of Health. It was noted that a new Methodological Framework had been established to allow for the responsive updating of priority nutrients. This work had undergone methodological review to ensure it met NHMRC's standards on guideline development. A second methodological review was also completed to ensure the proposed recommendations followed the methodology, and were transparent and complete. Public consultation was held in late 2015 and the final revised document underwent independent review from one national and two international experts.

Ms Robertson explained that this pilot was limited to the revision of relevant fluoride Nutrient Reference Values (NRVs) for infants and children up to 8 years of age as this was identified as the critical at-risk group for this nutrient. Resource limitations were also a factor in this decision. The revised recommendations see an almost doubling of current Upper Level recommendations to reflect the evidence on Australian and New Zealand fluoride intake and the low prevalence of dental fluorosis in children. It was noted that this change may be a point of contention, especially with anti-fluoride lobbyists. Ms Robertson also noted that the proposed changes to NRV recommendations have no implications for current drinking water standards in Australia and New Zealand. No issues specific to Aboriginal and Torres Strait Islander people or Maori and Pacific Islander people were identified.

A Member requested clearer justification for the removal of the Adequate Intake value and discussion regarding alignment with policy statements relating to infant formula be included in any dissemination material.

The Chair asked if there were any further comments or objections, and none were received.

Council **ADVISED** the CEO to approve the draft *Australian and New Zealand Nutrient Reference Values for Fluoride (Adequate Intake (AI) and Upper Level of Intake (UL) values for infants and young children)*, being the recommendations on pages 48 to 51 of Attachment A.

Action item: Clearer justification for the removal of the Adequate Intake value and discussion regarding alignment with policy statements relating to infant formula to be included in any dissemination material.

18. AUSTRALIAN DRINKING WATER GUIDELINES – FUNDING FOR REVIEW OF CHEMICAL FACTSHEETS

Ms Robertson introduced the item. NHMRC is currently prioritising the ADWG chemical fact sheets published in 1996 for review, minor updating or archiving. The chemical fact sheets are an essential resource for states and territories in their role as water regulators. She outlined a proposed partnership approach with jurisdictions. The Department of Agriculture has previously used a similar approach to prioritise a review of the Fresh and Marine Water Guidelines. In developing the process NHMRC has consulted with several key stakeholders including the enHealth Water Quality Working Group, the Water Services Association of Australia (WSAA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Pesticides and Veterinary Medicines Authority (APVMA). Members were asked for comment on the attached list of chemicals for review.

Members requested that this prioritisation be considered through the enHealth committee and then brought back to Council. At this time, a funding approach between the jurisdictions and NHMRC needs to be considered.

Council **ADVISED** on the proposed approach for the review of the Australian Drinking Water Guidelines chemical factsheets.

Action: The fact sheet prioritisation to be considered by the CMO/CHOs through enHealth. The outcome of those discussions are to be brought back to Council for consideration.

19. CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF COMMUNICATION AND SWALLOWING DISORDERS FOLLOWING TRAUMATIC PAEDIATRIC BRAIN INJURY

The Chair introduced the item and welcomed A/Prof Angela Morgan, in her capacity as Chair of the guideline development group, who was invited to answer any questions Council had concerning the guideline. Prof North declared a competing interest as Director of the Murdoch Childrens Research Institute and A/Prof Morgan's employer.

Mr Singh introduced the item and outlined the process by which the guideline was developed, noting that it is the first allied health led guideline to be considered by NHMRC. He reported that the guideline had been subject to methodological and clinical review. While the methodological reviewer noted that consumers were not involved in the development of the evidence based recommendations, consumer involvement was apparent throughout the rest of the guideline development process. Mr Singh noted that the guideline had in the view of NHMRC met the necessary development procedures and requirements.

Prof Anthony Lawler, as Council spokesperson, endorsed the high quality of the guidelines.

Council **ADVISED** the CEO to approve the draft *Clinical Practice Guideline for the Management of Communication and Swallowing Disorders following Traumatic Paediatric Brain Injury*

20. MEDICAL CANNABIS INFORMATION PAPER

Ms Robertson introduced the paper and invited comment as to whether Council saw the need for NHMRC to undertake an assessment of the published evidence on the effectiveness of cannabis and cannabis derived products for the treatment of clinical conditions.

It was noted that some states are conducting clinical trials on the use of medicinal cannabis for the management of conditions and symptoms associated with cancer and children with epilepsy. In light of the changes to Commonwealth legislation, doctors are now able to apply to state and territory health departments to seek approval to prescribe certain cannabis-based products for certain medical conditions. A number of states are convening their own expert advisory panels to develop guidance on access, approval and prescription.

The Department of Health outlined the review of the literature that the Therapeutic Goods Administration has commissioned to provide initial guidance and advice for state and territories. There was general consensus that the quality of the research evidence currently available was poor. Good quality clinical trials comparing cannabis to other available medications are required and currently being established.

Council **ADVISED** that given current activity in this area NHMRC should not undertake a systematic review of the literature at this time.

21. PERFLUOROCTANE (PFAS) INFORMATION PAPER

Ms Robertson outlined that NHMRC has had numerous enquiries as to whether a health value will be developed for PFAS in the Australian Drinking Water Guidelines (ADWG). Currently states and territories are relying on the interim value developed by enHealth. The Department of Health has commissioned the Food Standards Australia and New Zealand (FSANZ) to develop a health guideline value for food. Assuming its work is undertaken in a manner that aligns with current evidence based processes used for the ADWG, the work could be utilised to develop a health guideline value for drinking water. NHMRC is working with FSANZ on this issue.

States and territories noted that the extent of PFAS contamination is still unknown. There is a need for consistent messaging on the management of the issue and community concern given the lack of evidence regarding human health effects. The Australian Health Protection Principal Committee has been considering the advice developed by enHealth.

Council **DISCUSSED** the current issues and activities related to per- and poly-fluoroalkyl substances (PFAS). Council **NOTED** that NHMRC is working with FSANZ, with the aim of using the guideline value for food to develop a value for drinking water.

22. ART GUIDELINES

Prof Ian Olver joined the meeting via teleconference and gave Members an overview of the process to revise the draft *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research*.

Prof Olver advised that:

- The review of the clinical practice section (Part B) of the ART guidelines began in April 2013.
- The draft guidelines had been developed on the advice of an expert Working Committee, including persons with relevant knowledge and expertise in ethics, reproductive technology, reproductive law and regulation, religion and consumer issues.
- Two public consultations have been conducted and the submissions received provided a range of community views. All submissions have been considered by the Working Committee.
- The review of Part B had necessitated revision to the introduction (Part A) of the guidelines and editorial changes to the research guidelines (Part C).

- The draft guidelines identify guiding principles to inform the conduct of clinicians. These principles are supported by practical guidelines for clinicians to include in their standard operating procedures.
- The draft guidelines come from a position of respect, balancing the interests and wellbeing of all relevant parties in a manner that minimises harm and maximises the benefit to each party.
- The ART guidelines, in conjunction with state/territory law, create a robust framework for the practice of ART in Australia. Where there are discrepancies between the legislation and the guidelines, the legislation takes precedence.
- The ART guidelines address a range of complex issues that are both contentious and ethically challenging. While some issues may challenge one's personal beliefs or morals, the integrity of the guidelines requires that the guiding principles are consistently applied to all issues.
- AHEC considered the advice of the Working Committee and approved the draft guidelines on 3 August 2016.

The following issues were discussed:

- Paragraph 3.7. The suitability of Guiding Principle seven was queried, given that 95 per cent of ART is provided by the Private Sector.
- Whether the guidelines did enough to address the dispute over the acceptability of social egg freezing.
- Paragraph 5.2.4. It was queried whether this paragraph provided enough information on infection control. Members noted that, ethically, it was necessary for clinics to have infection control policies and procedures in place; however practical or mandatory guidelines for infection control were a matter for clinical practice guidelines.
- Paragraph 6.3. Concern was raised about the implications of supporting the donation of an embryo known to be affected by a genetic condition, disease or abnormality and whether this position was in the best interest of the child and upheld Guiding Principle 2. Members were advised of AHEC's justification for such a position, noting that it would be on a case-by-case basis, with all parties required to consider the implications that the condition might have on the quality of life of the person born, and that informed consent was required from each adult party. Members noted that an embryo affected by a condition that would severely limit the quality of life of the person who would be born would not be eligible for donation.
- Paragraph 8.13. Members discussed concerns that sex selection for non-medical purposes would see fertile individuals or couples accessing ART and that this may result in unnecessary adverse impacts on the person born, given the potential risks ART poses. Members noted that this issue was raised during public consultation and was considered by AHEC.
- Paragraph 8.13. Concerns were raised about AHEC's conclusion that there is an ethical difference between a desire to introduce variety to the existing sex ratio of offspring within a family and the desire to design the sex of the offspring based on the preferential selection of a particular sex due to an individual's or couple's cultural or personal bias, influences or desires.
- Whether it was ethical to include an upper age limit in the ART guidelines. Members noted that the draft guidelines do not include an upper age limit for access to ART services; however, clinics are required to provide individuals with information about risks and success rates, taking into account the age of the individual.

Members **NOTED** that the ART guidelines cover a range of complex issues, and **AGREED** to seek further advice from AHEC on the issues of sex selection for non-medical purposes, an upper age limit for access to ART services and social egg freezing.

Action item: ONHMRC to prepare agenda paper for AHEC.

23. AUSTRALIAN HEALTH ETHICS COMMITTEE (AHEC) REPORT

Council **NOTED** the AHEC Report.

24. JURISDICTIONAL REPORTS

Council **NOTED** the issues discussed at the 13 July 2016 pre-Council meeting between the NHMRC CEO, the Chair of Council and the Commonwealth, State and Territory Chief Health Officers (CHOs). These issues included:

- The review of the *Australian Code for the responsible conduct of research*
- NHMRC Clinical Trials initiatives
- The NHMRC-funded Centre of Research Excellence in Infectious Disease Emergency Response Research
- The revision of the 2009 *Australian Guidelines to Reduce Health Risks from Drinking Alcohol*
- Evidence regarding the relationship between the National Emergency Access Target (NEAT), improved 4 hr compliance and decreased mortality
- E-cigarettes
- Medicinal cannabis.

25. STANDING REPORT ON THE STATUS OF ETHICS GUIDELINES AND PUBLICATIONS AND STANDARDS FOR RESEARCH

Council **NOTED** the update on the status of ethical guidelines.

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

Council **NOTED** the current activity in relation to clinical and public health guidelines.

27. UPDATE ON FUNDING SCHEMES

Council:

- **NOTED** the application data for funding rounds;
- **NOTED** the status update on funding schemes; and
- **NOTED** the outcome data for Grant Announcements.

28. UPDATE ON THE BOOSTING DEMENTIA RESEARCH MEASURE

Council **NOTED** progress on implementation of the Boosting Dementia Research Initiative.

29. UPDATE ON CLINICAL TRIALS REFORM

Ms Robertson updated members on NHMRC's clinical trials reform work, providing an overview of nine initiatives that have been delivered, or are close to delivery. She indicated that current budget funding for these initiatives ends at the end of the financial year.

Ms Robertson made reference to the Minister for Health's May 2016 announcement of an additional \$7 million to improve Australia's clinical trial landscape and sought advice from Council on areas of potential focus to provide advice to the Minister in considering further areas of reform.

Dr Jan Fizzelle stated that further work to improve the Australian clinical trial landscape was welcome, noting that NHMRC should ensure there is no duplication in effort. Ms Robertson noted that NHMRC has been working closely with NSW Health and across a number of groups in the clinical trial sector to minimise duplication.

The Chair stated that the various clinical trials initiatives being delivered have the potential to drive innovation, but the timely start-up of clinical trials remains paramount. He also noted that there may be some cost barriers to clinical trials taking place due to the overhead costs charged by institutions.

Members raised the following issues:

- The potential for Advanced Health Research and Translation Centres (AHRTCs) to improve Australia's clinical trial landscape
- The difficulties in obtaining funding for 'orphan clinical trials'
- Focusing on commercially sponsored clinical trials may not address existing barriers to investigator-initiated trials. It was also noted however that commercially sponsored clinical trials save the health system money.
- Investigator-initiated trials need access to governance and management support and it is important that institutions have clarity around their role as trial sponsors.

Council:

NOTED NHMRC activities to fulfil requirements of Commonwealth Government budget funding measures to expedite clinical trials reforms in Australia.

NOTED a new proposal going to COAG Health Council which will utilise an election commitment of \$7 million.

ADVISED on NHMRC's suggestions for further work to pursue in the context of the COAG reforms.

30. OUT-OF-SESSION PAPERS

Council **NOTED** the outcome of the Out-of-Session activity between the 208th and 209th sessions of Council.

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 would be held in Canberra on 15-16 March 2017.

The meeting closed at 2.15pm.