FINAL MINUTES 205th Session

Council of the National Health and Medical Research Council Tuesday, 22 September & Wednesday 23 September 2015 University House, Canberra

Attendance:

Prof Bruce Robinson AM Chair

Prof Kathryn North AM Chair, Research Committee

Prof Ian Olver AM

Chair, Australian Health Ethics Committee

Prof Graeme Samuel AC

Prof Chris Baggoley AO

Commonwealth Chief Medical Officer (CMO)

Dr Jeannette Young PSM

Chair, Australian Health Ethics Committee

Commonwealth Innovation Advisory Committee

Commonwealth Chief Medical Officer (CMO)

Dr Kerry Chant PSM CHO, NSW

Prof Paddy Phillips PSM CMO Medical Officer, SA

Prof Dinesh Arya CHO, NT
Prof Gary Geelhoed CHO, WA
Prof Michael Ackland A/g CHO, VIC
Dr Paul Kelly CHO, ACT

A/Prof Tony Lawler Principal Medical Advisor, TAS

Ms Karen Carey

Prof David Story

Member with expertise in consumer issues

Member with expertise in professional
and post-graduate medical training

Prof Jonathan Carapetis Member with expertise in Public Health

Prof Ingrid Scheffer AO Member
Prof Elizabeth Sullivan Member

Apologies

Prof Sharon Lewin Chair, Health Translation Advisory Committee
Prof Michael Kidd AM Member with expertise in health care 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

Observers

Mr Mark Cormack

Adj Prof Debra Thoms

Department of Health

Department of Health

Prof Villis Marshall AC Australian Commission on Safety and Quality in Health Care

Prof Helen Zorbas AO Cancer Australia

Ms Lisa McGlynn Australian Institute of Health and Welfare (Wednesday only)

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 Julie Glover A/g Executive Director, Research Programs

Prof Davina Ghersi Senior Principal Research Scientist

DAY ONE

WELCOME

The CEO opened the 205th Session of Council at 1.30pm and welcomed attendees to the first meeting of the 2015 - 2018 NHMRC triennium. The CEO acknowledged the Ngunnawal People as traditional owners of the land upon which the meeting was held.

The CEO welcomed new Chair Prof Bruce Robinson for the 2015-2018 triennium.

The Chair noted apologies from Prof Lewin, Prof Kidd, Prof Eades and Prof Crabb, and noted that Dr Young would be attending on Day Two only and welcomed the observers. The Chair confirmed that the meeting was quorate.

The Chair reminded attendees that everything discussed at the meeting was to be held 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.

Prof Olver informed Council that he would be available to participate in the discussion on PSA Testing and Early Management of Test-Detected Prostate Cancer (item #9) however as he was on the PSA guideline group he would remove himself from voting on this issue.

There were no questions on notice for the Office of NHMRC, and Members did not ask for any "for noting" items be raised for discussion.

Council **ADVISED** the Chair that the draft Session Report of the 204th Session of Council was accepted as a true and accurate record of proceedings. There were no questions on notice.

Members introduced themselves and their current work.

1. INDUCTION

Ms Samantha Robertson provided Council members with an induction, including information on:

- Governance and Legislation of the NHMRC
- Structure of the NHMRC and roles of the CEO, Council, Committees and staff
- Stakeholder and Communication activities
- Meeting Procedures
- Committee Meeting Administration
- NHMRC Administration and Accountability requirements

Council **NOTED** the Induction and agreed to it being recorded by video for members unable to attend this meeting.

2. OVERVIEW FROM THE NHMRC CEO

Prof Kelso provided Council with a strategic overview for the coming three years under five broad headings:

- the role of Council in providing strategic advice to the CEO;
- an overview of the Australian research environment, including the challenges faced by the burden of complex and chronic disease, key priority areas, and the implications for NHMRC;

- the role of NHMRC in funding research, drafting guidelines, promoting research integrity and ethics, and providing other guidance to the Australian community;
- the funding issues faced by NHMRC including falling success rates and pressure to do more with less; and
- major initiatives for NHMRC to tackle this triennium, including managing the funding challenges, protecting and building investment in health and medical research, and focusing on the long term objective of improving the health of all Australians.

Members flagged their perceptions of the key challenges facing Council over the coming triennium, including:

- understanding NHMRC's role in supporting the quality of care paradigm, in particular around end of life care management and reducing unnecessary interventions;
- avoiding unnecessary duplication of research efforts overseas;
- providing guidance to private philanthropists seeking to fund high quality research to ensure the best value for money;
- encouraging commercialisation through the universities, and in particular contributing to an improvement in commercial literacy within the sector;
- balancing the award of funding based on excellence and merit, whilst ensuring equity of resource allocation, or the benefits from funding, across all States and Territories;
- ensuring that pilot research funded by NHMRC is optimised with saleability in mind, to maximise the potential benefit to the community of such research;
- considering the potential for research translation at the point of assessing research funding applications, to increase the likelihood of the benefits for consumers being realised through translation;
- continuing to invest in a broad spectrum of research, from research at the clinical interface to fundamental biomedical discoveries that may not be directly translatable into clinical practice, but which may inform improvements in clinical care in the longer term;
- upholding the tenets of peer review for assessing research quality, whilst considering other important factors alongside excellence, including research priorities;
- balancing investigator driven research schemes against research funding strategically targeted towards identified areas of priority;
- ensuring synchronicity between the MREA and MRFF; and
- continuing to promote gender equality, including consideration of the next steps.

The Chair thanked Prof Kelso for the detailed overview and led Members in a discussion on the strategic environment with the CEO.

Council **NOTED** the overview from the NHMRC CEO.

3. CORPORATE PLAN

This item was addressed in the Induction and the Overview from the NHMRC CEO earlier in the agenda.

Council **NOTED** the NHMRC Corporate Plan 2015-2016 and **NOTED** that further opportunities to update the Plan will occur in 2016.

DAY TWO

1. WELCOME AND GENERAL BUSINESS

The Chair welcomed attendees to day two of the first meeting of the 2015 - 2018 NHMRC triennium. The Chair acknowledged the Ngunnawal People as traditional owners of the land upon which the meeting was held. The Chair welcomed Dr Jeannette Young and Ms Lisa McGlynn (AIHW) who were unable to attend Day One of the meeting.

The Chair reminded attendees that everything discussed at the meeting was to be held 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.

2. ONHMRC: STRATEGIC PRIORITIES - INVESTMENT

Dr Julie Glover introduced the item and summarised the key issues likely to impact the investment of the Medical Research Endowment Account (MREA) during the triennium. Key issues included the plateauing of MREA funding for the forward estimates, the recent Fellowships consultation, the unsustainable nature of current application and peer review processes, the potential cross-over or alignment of the MREA with the Medical Research Future Fund (MRFF), and current government initiatives such as the Boosting the Commercial Returns from Research Action Agenda and the Australian Science and Research Priorities, and their associated practical challenges.

The Research Committee (RC) Chair highlighted that many of these issues were considered by the previous RC, and some were long-standing issues from previous triennia.

The members of Council outlined a number of issues that should be considered when determining the strategy for investing the MREA. These included:

- Wastage in current peer review process, and opportunities to improve process for both applicants and peer reviewers
- Opportunities to improve funding schemes, through evaluation, consideration of best-practice and development of new models
- Potential impact of MRFF on MREA funding priorities, particularly given anticipated focus of MRFF on industry/commercialisation and strategic priorities
- Importance of embedding indigenous and minority groups in research
- Consideration of NHMRC's role in workforce planning

The CEO indicated that the office was intending to undertake a comprehensive review of funding schemes that took into consideration the potential impacts of any proposed changes. During this process the CEO would seek advice from Council and Principal Committees, and also carry out extensive consultation with the research sector.

The Chair summarised discussions that a strategic review, led by the office, should build on the work of previous triennia, adhere to a tight timeline, and engage the research community (particularly young investigators). The Chair proposed engaging with Council by bringing forward papers to future meetings that outline proposals developed by ONHMRC in consultation with RC.

COUNCIL:

- ADVISED the CEO on the identified key strategic issues to be considered over the next triennium;
 and
- ADVISED the CEO to work with the Chairs of Research Committee, Health Innovation Advisory Committee and Health Translation Advisory Committee to develop a strategic approach to

addressing these issues during the triennium.

3. NHMRC'S STRATEGIC DIRECTION IN INNOVATION AND COMMERCIALISATION

Mr Alan Singh provided Council with an overview of NHMRC's activities in promoting innovation and commercialisation in health and medical research. These encompassed three themes, funding schemes, commercial literacy and recognition of industry experience. Mr Singh highlighted the success of the Development Grants scheme in terms of forming commercialisation partnerships. He also mentioned the Translation Advancement Incentive in Research Fellowships, the industry Career Development Fellowship, Partnership Projects and a workshop held in conjunction with the Department of Industry and Science (then Commercialisation Australia).

Members considered the paper and suggested areas where NHMRC and the Health Innovation Advisory Committee (HIAC) could contribute in promoting collaboration between researchers and industry. This included "match-making" researchers with industry partners and educating researchers about working with industry and commercialising research findings.

Council:

- ADVISED the CEO on issues for HIAC's consideration; and
- ADVISED the CEO to work with the Chair of HIAC to develop a work plan for the triennium

4. ONHMRC: STRATEGIC PRIORITIES - TRANSLATION

Mr Alan Singh provided an overview of NHMRC's broad legislative remit in translation, and the schemes, advice and mechanisms used. The number of NHMRC's translation-focused activities has grown strongly over the past triennium. Internationally, other research funders have also been working to improve translation and the body of knowledge is still growing.

Members noted the strategic priorities in translation incorporated into the NHMRC Corporate Plan. Members discussed the need to emphasise collaborations and partnerships, and to bridge cultural and communication divides by involving other parties early in research (eg policy makers and experts in translation). Opportunities were highlighted, eg that the Advanced Health Research and Translation Centres allow a structural approach to be taken; or capitalising on review of MBS items or interest in disinvestment. Members also noted the importance of reaching people outside the health system, including treasuries and politicians. It was suggested that an evaluation of the Research Translation Faculty, as one of NHMRC's flagship translation activities from the previous triennium, would be worthwhile.

Council:

- ADVISED the CEO on issues for HTAC's consideration
- **ADVISED** the CEO to work with the Chair of HTAC to develop a strategy for research translation for NHMRC.

5. RESEARCH INTEGRITY

Ms Robertson spoke to a paper and presentation that had been provided to Council about NHMRC's role in research integrity. Ms Robertson provided an overview of NHMRC's role in ensuring research integrity in Australia, including the three national research ethics standards, and a summary of NHMRC's current and future activities in this area.

Following the presentation, members commented on the importance of ensuring standardised processes for the management of research misconduct matters across institutions. There was a sense that misconduct matters were not currently being managed consistently and the complexity of managing misconduct matters

was also noted. The value of developing a best practice guide for the management of research misconduct was discussed.

Members also raised issues relating to the importance of single ethical review of multi-centre research, noting that NHMRC had done work in this area over many years. Members discussed the fact that difficulties were arising with the authorisation of clinical trials research that needed to occur following an ethics review through institutional research governance processes. The work that NHMRC was undertaking with the University of Tasmania which aimed to develop a nationally consistent and timely site specific assessment process was noted. The Department of Health was supportive of this work.

Council:

- NOTED and discussed the range of activities that NHMRC is involved in to assure research integrity; and
- ADVISED on any other relevant matter the CEO may wish to pursue as part of NHMRC's program of work around research integrity.

6. MEMBERS TO SPEAK ON THEIR EXPECTATIONS OF COUNCIL

Members were asked to discuss the major themes and issues they would like to address in the 2015-18 triennium. These included:

Council Agenda

- Make full use of the extraordinary wealth of skill, expertise and experience of all members of Council for strategic input and reflection on the big issues
- Enable the Council agenda to be a good balance of operational and strategic discussion at every meeting.
- Enable input from all Council Members on topics for major discussion at Council meetings
- Use Council members as an extension of the office in times of limited resources
- Leverage off the goodwill of State and Territory and Commonwealth officers to tackle complex and difficult issues
- Report to Council on key issues arising from States and Territories through CHOs
- Maximise the benefits of the Department of Health and NHMRC relationship
- Support the CEO in delivering her vision and translating it into practice
- Ensure a strong relationship with the safety and quality agenda

Promotion of NHMRC

• Exert influence and promote the brand and value of NHMRC

Public Health

- Increase NHMRC's impact in the public health space
- NHMRC to continue issuing statements on public health issues as they are extremely valuable to the states and territories to guide research, health care and public health approaches. Council to think about what these issues are for the future and address them appropriately

Population and Indigenous Health

- Population health guidelines
- Indigenous capacity building in mainstream research
- Examine the impact of the population footprint on the planet and sustainability

Consumer Needs

- Awareness of community priorities and alignment with the research priorities
- Increase the value the consumer receives from the MREA through translation

- Assist researchers to increase the value they receive from consumer participation
- Move towards a more collaborative and outcomes focused engagement with the community

Research Translation

- Research Translation keeping pace with the policy world
- Encourage research translation into policy areas

Investment

- Transition of the MRFF to dovetail with NHMRC funding to cover the full spectrum of research
- Look at areas for future investment. Investment may require disinvestment in other areas.
- Focus on the next generation of researchers and representation of women in HMR build security
- Strategies to support high quality research

Collaboration

- Ensure there is a culture of collaboration
- Leverage philanthropy
- Innovative models of funding eg. leveraging the not-for profit sector, partnerships, co-funding etc.

Other Strategic Priorities

- Items identified in the McKeon Report
- Address what Health and Medical Research will look like in the future
- Increasing research literacy
- Data and big data, especially data linkage
- Continuation of the work of the Academic Health Centres
- Implementation of the recommendations of the IMRI review
- Embedding research in clinical practice
- Re-examine current gold standards can we do things differently?
- What does success look like? Are we adding value? Are we assessing that appropriately?
- Engaging researchers in the safety and quality space
- Can we embed research in the accreditation standards?

Council **NOTED** the items Members would like addressed in the 2015-18 triennium.

7. FUNDING RECOMMENDATIONS

Dr Julie Glover introduced the papers and apologised for the lateness of the paper due to Research Committee meeting on 18 September 2015.

Dr Glover noted that conflicts and potential conflicts would be dealt with scheme by scheme and that members with a conflict on Project Grants would not need to leave the room.

Research Committee at its 18 September meeting recommended funding for schemes as described in the tabled paper.

Project Grants commencing 2016

Funding for 516 applications with a total budget of \$419,719,973 and an overall funded rate of 13.8%. This includes 19 Indigenous health related applications (which comprise 5.33% of the overall budget) and 33 New Investigator applications.

• Development Grants commencing 2016

Funding for 24 applications, with a total budget of \$14,142,311 and an overall funded rate of 25.26%.

Targeting Call for Research into Preparing Australia for the Genomic Revolution in Health Care commencing 2016

Due to conflicts of interest, Prof North, Prof Carapetis and Prof Scheffer left the room for this discussion. Council noted additional reporting requirements for this grant.

Funding for one application with a total budget of \$25,000,000.

Research Fellowships commencing 2016

Funding for 69 applications, with a total budget of \$55,654,700 and an overall funded rate of 24%.

• Practitioner Fellowships commencing in 2016

Due to conflicts of interest, Prof Scheffer left the room for this discussion.

Funding for 15 applications with a total budget of \$7,299,065 and an overall funded rate of 29.4%.

Career Development Fellowships (CDFs) commencing in 2016

Funding for 55 CDF applications plus the Minister's Medal, with a total budget of \$23,965,192 and an overall funded rate of 11.9%.

Early Career Fellowships commencing 2016

Funding for 112 applications, with a total budget of \$36,443,764 and an overall funding rate of 22%.

• Translating Research Into Practice (TRIP) Fellowships commencing 2016

Funding for 13 applications, with a total budget of \$2,278,939 and an overall funded rate of 25%.

Partnership Projects Cycle #1 commencing 2015

Funding for eight applications, with a total budget of \$6,757,914 and an overall funded rate of 38%.

Centres of Research Excellence (CRE) Applications commencing 2015

Due to conflicts of interest, Prof North, Prof Carapetis, Prof Olver and Prof Scheffer left the room for this discussion.

Funding for 15 applications with a total budget of \$36,826,721 and an overall funded rate of 17.2%.

NHMRC-National Natural Science Foundation of China (NSFC) Joint Call for Research to Enhance Prediction and Improve the Treatment of Type 2 Diabetes in China and Australia commencing 2016

Funding for seven applications with a total budget of \$4,072,105 and an overall funded rate of 58%.

Prof North confirmed that RC viewed the full reports from community observers at the September meeting.

The Chair thanked and congratulated Prof North, ONHMRC, RC and all involved in the peer review processes.

Council

• **SUPPORTED** the funding recommendation listed at <u>Attachments B to L</u>, as advised by Research Committee to a total value of \$632,160,684;

- NOTED that relinquished offers will be reallocated to the next ranked highest applicant(s) from the same category considered fundable, provided that these replacement offers do not change the overall expenditure;
- **ADVISED** the NHMRC's CEO to submit the funding recommendations at <u>Attachments B to L</u> to the Minister for approval;
- **NOTED** the summary of community observers' reports at **Attachment M**; and
- NOTED that a detailed breakdown of funded grant data will be tabled at a subsequent meeting.

Action Item: A presentation on peer review processes (including how funding is allocated to each scheme and how scoring consistency is maintained between panels) to be placed on the next Council agenda.

Action Item: ONHMRC to bring back data on these funding recommendations to the next Council meeting.

8. APPROVAL OF THIRD PARTY GUIDELINES

Mr Singh introduced revised procedures for Council consideration of third party clinical practice guidelines seeking NHMRC approval, to be introduced in 2016. The procedures have been developed in response to previous Council's concerns about the volume of material associated with clinical practice guideline submissions and its capacity to consider some highly specialised clinical topics. They are also designed to assist Council to perform its legislated functions in relation to third party guidelines: scrutiny of public consultation and providing advice to the CEO.

Mr Singh outlined the main differences as follows:

- A guidelines sub-committee will be established comprising members of Council, topic experts, guideline developer representatives and experts in guideline development.
- The guideline sub-committee will report to Council out-of-session and will advise it to either:
 - advise the CEO to approve the guideline(s), or
 - to consider the guideline(s) at a full session of Council.
- NHMRC approval of third party guidelines will henceforth apply only to guideline recommendations
 and not to other supporting material such as evidence summaries and narrative commentary. This
 will allow developers to update the supporting material without public consultation and re-submit to
 Council. Updates to recommendations will still require public consultation and Council scrutiny.
- Mr Singh asked Council to note that the discussion paper Better informed health care through better clinical guidelines is about to be released for targeted consultation. The paper forms part of the NHMRC's guideline improvement work plan and proposes a new standard for guideline development in Australia.

Dr Kelly noted that some clinical guidelines (such as the Immunisation handbook) have a significant public health component, and he advised that these should only be considered at full sessions of Council.

Council:

- AGREED to the revised procedures for clinical practice guidelines; and
- **NOTED** the release of the *Better informed health care through better clinical guidelines* for targeted consultation.

9. CLINICAL PRACTICE GUIDELINES PSA TESTING AND EARLY MANAGEMENT OF TEST-DETECTED PROSTATE CANCER

Mr Singh introduced the guideline, advising that Professors Olver and Marshall were members of the guideline development committee. He noted that the guidelines offered evidence based advice to medical practitioners and men about PSA testing and of management of prostate cancer, but did not advocate a PSA screening program.

Mr Singh outlined the extensive consumer involvement and consultation in the development of the guidelines, and the extensive multi-disciplinary representation on the guideline development group.

He advised that, in line with the new procedures for third party guideline approval outlined in agenda item 8, Council is asked to consider the substantive guidelines as being only the recommendations on pages 7 to 17 of Attachment D: the remaining material is to be considered as supporting material and will not be subject to NHMRC approval.

Professor Olver advised that the guidelines were developed to clearly differentiate between evidence and opinion.

Professors Olver and Marshall left the room as members discussed the guidelines.

Professor Baggoley advised that the Department of Health strongly supports the adoption of the guidelines, observing that the guidelines make sensible recommendations in an area characterised by often rancorous debate.

Dr Chant fed back some minor comments on the guidelines from the Cancer Institute of NSW.

Council **ADVISED** the CEO to approve the *PSA testing and early management of test detected prostate cancer clinical practice guidelines*, comprising the recommendations on pages 7 to 17 of Attachment D.

10. DRAFT PRINCIPLES FOR ACCESSING AND USING PUBLICLY FUNDED DATA FOR HEALTH RESEARCH

Ms Robertson updated Council on the additional consultation with jurisdictions made in response to members' request at the June 2015 session. Professor Louisa Jorm, Chair of the NHMRC Data Reference Group (DRG), joined the discussion via teleconference. Professor Jorm provided additional history about the work and consultations underpinning the Data Access Principles, and reiterated that they are high level principles only and do not mandate specific actions of researchers or custodians. The term 'data' refers to government agency held data as well as other publicly funded data that may be held by a range of government and non-government agencies. Importantly, the data includes health and 'non health related' data, as in many instances non health related data such as housing or employment data are integral to quality public health research.

Ms Karen Carey warned of possible 'push back' from consumer groups on the release of the Data Access Principles, over concerns about possible privacy breaches caused by data linkage once researchers have greater access to data. Professor Carapetis reported that to date there have been no breaches of privacy in Australia, and that this is a strong indicator that the existent structures to support privacy are working. Professor Carapetis advised mentioning this fact in a preamble to the Data Access Principles. To further support this, Professor Geelhoed reported that consumer groups had recently indicated they were supportive of better use of their data for the purposes of improving health outcomes. Professor Jorm agreed, and went further to say that there have been no reports of researchers breaching privacy worldwide, and that there are obvious incentives for researchers not to do so.

There was a discussion regarding the use of data for commercial interest, and how data custodians could be better supported to deal with such requests to manage any possible risks. Professor Jorm responded that it is the role of the various ethics committees approving the research to ensure the research use of data is carried out in accordance with the National Statement on Ethical Conduct in Human Research (and this aligns with Principle 3 (b) of the Data Access Principles regarding researcher responsibilities).

Dr Young expressed concern that individual state legislation was still not captured in Appendix A of the Data Access Principles. Professor Jorm replied that the DRG considered this request, but declined to add these legislation links as it would make the document very lengthy, and maintaining currency would be an issue. Ms Robertson agreed; and suggested that reference to the legislation, as well as links to the state and territory health departments, could be provided on the NHMRC webpage that would host the Data Access Principles.

Ms Carey asked for Ms Carol Bennett to be acknowledged, as Ms Carey has only just recently taken the position on the DRG previously held by Ms Bennett.

Council:

- ADVISED that the Data Access Principles be released; and
- ADVISED that there were no additional comments on the Communication Plan and Consumer Guide

11. WATER QUALITY ADVISORY COMMITTEE: WORK PRIORITIES FOR 2015-18

Ms Robertson introduced the item. NHMRC proposes to consult on the work plan and priorities for NHMRC's Water Quality Advisory Committee for the current triennium.

Ms Robertson explained that NHMRC is the author of the recreational water guidelines and contributes to the health aspect of the recycled water guidelines. Consideration of whether these guidelines require review is overdue.

There was some discussion about the use of recycled grey water on food crops.

NSW noted that reviewing the 1996 chemical fact sheets is a priority for NSW. New and emerging chemicals such as perfluorinated chemicals, chemicals associated with unconventional gas mining and endocrine disruptors where discussed.

ACT noted that it would like the work on developing a cyanobacteria alert framework to be a higher priority than 'low'.

Council

- ADVISED on the draft priorities areas for further work; and
- NOTED NHMRC will write to stakeholders to seek input on priorities areas for the triennium.

12. AUSTRALIAN DRINKING WATER GUIDELINES – AMENDMENTS: ROUNDING AND PARENT COMPOUNDS/METABOLITES

Ms Robertson introduced the item and explained that the suggested additions to the Australian Drinking Water Guidelines did not change any existing processes, just provided clarification.

NSW requested an example of trailing zeroes to be included in the text to assist staff in the field.

Victoria raised concerns regarding the rounding of analytical values due to their accuracy and precision being determined by the testing laboratory. It was not the intent of the changes to require analytical results to be rounded to one significant figure, only to describe the approach to developing guideline values and for users

to be aware of the level of precision when comparing guideline values with monitoring results. Additional text will be added to make it clear that that regulators can provide guidance on determining exceedances.

Council **ADVISED** the CEO to consult publically on the proposed amendments.

13. CHAIRS REPORT

The Chair thanked members for the high quality discussion and engagement held over the past two days, and the secretariat for a well organised meeting.

Council **NOTED** the Chairs Report.

14. STANDING REPORT ON THE STATUS OF ETHICS GUIDELINES AND PUBLICATION AND STANDARDS FOR RESEARCH

Council **NOTED** the update on ethical guidelines and publications.

15. STANDING ITEM: STATUS OF GUIDELINES IN CLINICAL PRACTICE AND PUBLIC HEALTH

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

16. STANDING ITEM: INITIATIVES FOR ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH UPDATE

Council **NOTED** the update provided on the initiatives for improving Aboriginal and Torres Strait Islander health addressed in this paper.

17. UPDATE ON NHMRC'S CLINICAL TRIALS REFORM WORK

Council **NOTED** the updates provided on and the work NHMRC is doing to transform the clinical trials environment.

18. JURISDICTIONAL REPORT

Council **NOTED** the information provided.

19. DEVELOPING NORTHERN AUSTRALIA INITATIVE

Council **NOTED** key elements and next steps in implementing the Developing Northern Australian Tropical Disease Research initiative.

20. OUT OF SESSION ITEMS

Council **NOTED** the outcome of the two Out of Session activities between the 204th and 205th sessions of Council.