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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

THE SENATE

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL AMENDMENT BILL 2006

(Circulated by authority of the Minister for Health and Ageing, the Honourable Tony Abbott MP)

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL AMENDMENT BILL 2006

OUTLINE

The purpose of this Bill is to amend the *National Health and Medical Research Council Act 1992* to introduce new governance arrangements and to clarify accountability and reporting functions for the National Health and Medical Research Council (the NHMRC), as announced by the Minister for Health and Ageing on 7 September 2005.

The governance model enacted in this Bill provides the NHMRC with financial and operational autonomy while maintaining its independent statutory responsibility for expert health and medical research advice to the Government.

The amendments enacted through this Bill address the governance issues identified in three major reviews:

- Sustaining the Virtuous Cycle For a Healthy, Competitive Australia: Investment Review of Health and Medical Research Final Report, Australian Government, December 2004;
- Governance of the National Health and Medical Research Council; Audit Report No. 29 2003-04, Australian National Audit Office, February 2004; and
- Review of Corporate Governance of Statutory Authorities and Office Holders, June 2003.

The Bill implements opportunities identified in the above reports for both improving the governance of the NHMRC and for improving Australia's health and medical research outcomes through a more accountable and independent NHMRC.

The proposed amendments to the NHMRC Act:

- strengthen the independence of the NHMRC;
- ensure a continued focus on scientific and technical expertise. Previously, the Council of the NHMRC was responsible for both governance matters and expert scientific advice. The new division of responsibility between the CEO and the Council ensures that the Council can focus on expert scientific advice, whilst the CEO will have day to day responsibility for the overall operation of the agency;
- clarify the reporting lines of the CEO and Council. NHMRC's previously cumbersome accountability framework had three concurrent lines of reporting (including the Minister for Health and Ageing, the Secretary of the Department of Health and Ageing and the Council itself). The proposed changes will streamline these reporting lines by providing for the Chief Executive Officer to report directly to the Minister for Health and Ageing, while keeping the Secretary of the Department of Health and Ageing informed;
- do not affect the level of funding the Australian Government has allocated for health and medical research;
- streamline some of the existing provisions to make them more reader friendly and to clarify their intent (for example, appointment processes); and

• include detailed transitional provisions to ensure a smooth transition to the new arrangements.

Under the existing arrangements, the Council is established as a statutory body corporate. Staff of the NHMRC are officers of the Department of Health and Ageing made available to the Council via an arrangement under subsection 45(2) of the Act. The new arrangements establish the NHMRC as a statutory agency. The CEO will be responsible for the primary functions of the agency, with the Council advising and providing guidelines and recommendations to the CEO. The CEO will directly engage the staff of the agency, with the CEO and staff constituting a Statutory Agency for the purposes of the *Public Service Act 1999*. It is proposed that the NHMRC will also become a prescribed agency for the purposes of the *Financial Management and Accountability Act 1997*.

The governance arrangements as provided for in the Bill are illustrated on page 3.

FINANCIAL IMPACT STATEMENT

The financial impact of this Bill is outlined below:

• minor transitional costs are required in order to establish the NHMRC as a statutory agency (approximately \$0.3 million in 2005-06);

Change to NHMRC Departmental Expenses

2005-06	2006-07	2007-08	2008-09
(\$m)	(\$m)	(\$m)	(\$m)
+0.3	0.0	0.0	

- ongoing costs of the NHMRC, as a separate entity, are to be appropriated separately from within the Department's existing budget allocations; and
- minor ongoing resources will be provided to the Department to support integrated policy advice on health issues that are addressed by the NHMRC (for example: human cloning, stem cell research, severe acute respiratory syndrome (SARS) and avian flu virus).

Change to Department of Health and Ageing Departmental Expenses

2005-06	2006-07	2007-08	2008-09
(\$m)	(\$m)	(\$m)	(\$m)
+0.4	+0.5	+0.5	+0.5

PROPOSED NEW NHMRC GOVERNANCE STRUCTURE



NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL AMENDMENT BILL 2006

NOTES ON CLAUSES

Clause 1—Short title

This clause provides that the Act may be cited as the *National Health and Medical Research Council Amendment Act 2006*.

Clause 2—Commencement

This clause provides that sections 1 to 3 of the Bill commence on the day that the Bill receives Royal Assent. Schedule 1, Parts 1, 2 and 4 commence on the later of the day after the Bill receives Royal Assent or 1 July 2006. Schedule 1, Part 3 cannot commence until after the commencement of item 34 of Schedule 1 to the *Financial Framework Legislation Amendment Act (No. 1) 2006* but, dependent on that legislation commencing, Schedule 1, Part 3 will commence on the latest of the commencement of that Act, 1 July 2006, or the day after the NHMRC Amendment Act 2006 commences.

Clause 3—Schedule(s)

This clause provides that each Act that is specified in a Schedule to this Bill is amended or repealed as set out in the applicable items in the Schedule concerned and any other item has effect according to its terms.

SCHEDULE 1—AMENDMENTS

PART 1—AMENDMENT OF THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL ACT 1992

Item 1

This item amends section 3 of the NHMRC Act which describes the object of the Act. The item amends subsection 3(2) by replacing the word "Council" with the word "NHMRC". This reflects the new structure of the agency whereby the NHMRC comprises the CEO, the Council, committees and the staff of the NHMRC (see new section 5B).

Items 2 to 30

These items amend section 4 which sets out the definitions for words used in the Act. The amendments delete words and terms that are no longer used in the Act and insert new definitions for terms such as "CEO", "Embryo Research Licensing Committee of the NHMRC" and "interim guidelines".

Item 31

This item repeals Part 2 of the NHMRC Act. Part 2 of the NHMRC Act currently:

- a) establishes the Council as a statutory body corporate;
- b) sets out the functions of the Council (these become the functions of the CEO set out in the new section 7, with the functions of the Council set out in the new section 21);
- c) describes processes for the making of ethics guidelines (these processes are substantially retained in a new section 10);
- d) provides for the Minister to refer matters to the Council (which is provided for in the new section 5D); and

e) provides for the Minister to give directions to the Council (which is provided for in the new section 5E).

Item 31 inserts a new Part into the NHMRC Act, being *Part 2—The National Health and Medical Research Council.*

PART 2—THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

In summary, this new Part establishes the NHMRC and details those matters that the Minister may refer to the NHMRC and the matters on which the Minister may give directions to the NHMRC.

Section 5B—Establishment of the NHMRC

This section establishes the NHMRC and provides that the NHMRC comprises the CEO, Council and committees (including Principal Committees and working committees) and the staff of the NHMRC.

Section 5C—Function of the NHMRC

This section provides that the function of the NHMRC (other than the CEO) is to assist the CEO in the performance of his or her functions.

Section 5D—Reference of matters to the CEO, Council and Principal Committees by the Minister

Subsection 5D(1) provides that the Minister may refer to the CEO, the Council or a Principal Committee (other than the Embryo Research Licensing Committee of the NHMRC), any matter within the scope of the CEO, Council or Principal Committee's functions.

Subsection 5D(2) provides that the CEO, Council or Principal Committee must deal with a matter referred by the Minister.

Subsection 5D(3) has been inserted to assist readers by clarifying that an instrument under subsection (1) is not a legislative instrument within the meaning of section 5 of the *Legislative Instruments Act 2003*.

Section 5E—Minister may give directions to the CEO, Council and Principal Committees Currently subsection 10(1) enables the Minister to issue written directions to the Council as to the performance of its functions or the exercise of its powers.

This provision replaces the current subsection 10(1) and provides that the Minister may give written directions to the CEO, the Council or a Principal Committee (other than the Embryo Research Licensing Committee of the NHMRC) as to the performance of the functions or powers of those bodies. The CEO, Council or a Principal Committee must comply with directions given by the Minister.

The directions given by the Minister must be of a general nature only and the Minister is not entitled to direct the CEO, Council or Committees in relation to the allocation of research funds or the treatment of particular scientific, technical or ethical issues. This retains the current restrictions on the Minister's power to give directions.

Subsection 5E(4) provides that any directions given by the Minister must be tabled in Parliament. This continues to ensure a high level of transparency and public accountability.

Subsection 5E(5) is included to clarify that a direction given by the Minister is not a legislative instrument within the meaning of section 5 of the *Legislative Instruments Act 2003*.

Item 32

This item repeals the former heading of Part 3 and replaces it with a new heading "Part 3 - The Chief Executive Officer".

Item 33

This item repeals Divisions 1 and 2 of Part 3 (which dealt with powers of the Council and public consultation) and replaces these Divisions with two new Divisions.

Division 1 of Part 3 currently sets out the powers and duties of the Council. The powers and duties of the Council have changed as a result of the new governance arrangements and are now detailed in a new Part 4 (The Council and committees of the NHMRC). The Division previously also provided for the publication of a timetable and procedures to assist the Council to make recommendations to the Commonwealth on the application of the Medical Research Endowment Account. This is now provided for in a new section 8.

Division 2 of Part 3 currently deals with public consultation. The essence of these provisions is retained in the new Division 2 of Part 3 (as described below).

DIVISION 1—ESTABLISHMENT AND FUNCTIONS

Section 6—The Chief Executive Officer

This section provides that there is to be a Chief Executive Officer (CEO) of the NHMRC.

Section 7—Functions of the CEO

This section sets out the functions of the CEO. These are based on, and retain, the previous functions of the Council of the NHMRC but have been amended to reflect the new governance arrangements.

The functions of the CEO, as set out in subsection 7(1) are:

(a) in the name of the NHMRC, to inquire into, issue guidelines on, and advise the community on, matters relating to:

(i) the improvement of health; and

- (ii) the prevention, diagnosis and treatment of disease; and
- (iii) the provision of health care; and
- (iv) public health research and medical research; and
- (v) ethical issues relating to health; and

(b) to advise, and make recommendations to, the Commonwealth, the States and Territories on the matters referred to in paragraph (a);

(c) to make recommendations to the Minister on expenditure;

(i) on public health research and training; and

(ii) on medical research and training;

including recommendations on the application of the Account (being the Medical Research Endowment Account); and

(d) any other functions conferred on the CEO in writing by the Minister; and

(e) any other functions conferred on the CEO by the Act, the regulations or any other law; and

(f) any functions incidental to any of the foregoing.

A note is included at the bottom of subsection 7(1) to direct the reader's attention to section 82 which enables the Minister to delegate additional functions to the CEO.

Subsection 7(2) has been inserted to assist readers by clarifying that an instrument under subsection (1) is not a legislative instrument within the meaning of section 5 of the *Legislative Instruments Act 2003*.

Section 8—Timetables and procedures to assist CEO make recommendations on application of Account

Subsection 8(1) provides that a timetable and procedures to assist the CEO to make recommendations to the Minister on the application of the Medical Research Endowment Account must be published each financial year. This is consistent with current requirements whereby a timetable and procedures are developed to assist Council to make recommendations to the Commonwealth. Under the new governance arrangements it will be the CEO who ultimately makes the recommendations to the Minister (with the advice of Council).

Subsection 8(2) clarifies that the timetable and procedures are not legislative instruments within the meaning of section 5 of the *Legislative Instruments Act 2003*.

DIVISION 2—REGULATORY RECOMMENDATIONS AND GUIDELINES

Subdivision A—Regulatory recommendations made, and guidelines issued, by CEO

Section 9—CEO to only make regulatory recommendations and issue guidelines as developed by Council

Subsection 9(1) provides that the CEO may only make a regulatory recommendation or issue guidelines precisely as developed by the Council and provided to the CEO. In the case of human research guidelines, these must be issued as developed by the Australian Health Ethics Committee (AHEC) and provided to the Council.

A note under subsection 9(1) directs readers to subsection 14(1) which provides that the CEO may make interim regulatory recommendations or interim guidelines without the advice of Council for matters of urgency and describes the processes to be adopted for the development of interim guidelines or interim regulatory recommendations in urgent circumstances.

Subsection 9(2) clarifies that the CEO retains the discretion not to make a particular recommendation or issue particular guidelines merely because they have been provided to him or her by Council. This enables the CEO to seek clarification from Council on any issues in the guidelines or regulatory recommendation prior to publishing final guidelines or a regulatory recommendation.

Subsection 9(3) clarifies that regulatory recommendations and guidelines are not legislative instruments within the meaning of section 5 of the *Legislative Instruments Act 2003*.

Section 10—Human research guidelines

This section describes the process in relation to the development and issuing of human research guidelines.

Subsections 10(1) to 10(3) provide that the CEO must issue human research guidelines. These subsections provide that the Council may only give the CEO human research guidelines precisely as developed by AHEC. However, the Council is not obliged to provide the CEO with such guidelines merely because they have been provided by AHEC. This enables the Council to ask questions of AHEC once the Council has received the guidelines and for AHEC to subsequently make any necessary amendments to the guidelines before representing them to the Council for presentation to the CEO.

Subsection 10(4) provides that human research guidelines must be tabled in Parliament within 15 sitting days of the guidelines being issued by the CEO.

Section 12—Consultation about regulatory recommendations

Section 12 describes the consultation process that must be undertaken by the Council in relation to regulatory recommendations. In essence, the Council must:

- consult in accordance with the section;
- publish a notice stating its intention to provide a regulatory recommendation to the CEO and inviting people to make submissions;
- prepare a draft of the regulatory recommendation and publish a notice inviting submissions on the draft (or if the Council does not intend to make a regulatory recommendation to the CEO, publish a notice stating that it no longer proposes to provide the recommendation to the CEO); and
- have regard to any submission received before providing the recommendation to the CEO.

This process essentially reflects the current process adopted by Council with the only differences being:

- the section no longer refers to "prescribed activities". No activities have ever been prescribed for the purposes of this provision in the past and is not considered necessary to retain this mechanism under the new governance arrangements; and
- necessary changes are made to reflect the fact that Council will no longer be making regulatory recommendations but rather will be providing regulatory recommendations to the CEO.

Section 13—Consultation about guidelines

Section 13 details the consultation process to be undertaken by the Council about guidelines. In summary, the consultation process currently undertaken by the Council in relation to publishing guidelines is retained. That is, the Council must prepare a draft of the guidelines, publish a notice containing a summary of the guidelines and calling for submissions and have regard to any submissions made.

The main change is that the Council will no longer issue guidelines itself but will provide guidelines to the CEO who has the function of issuing the guidelines under section 7.

Section 14—Interim regulatory recommendations and guidelines

Section 14 previously related to the Council taking interim action as a matter of urgency. This is replaced with a new and revised section 14 which allows the CEO to issue urgent guidelines and regulatory recommendations, without receiving them from the Council, if the CEO considers that the matter must be dealt with urgently. After issuing such interim guidelines, the CEO must publish a notice setting out, among other things, a summary of his or her reasons for taking the action and a summary of the recommendation or guidelines and an invitation for people to make submissions. This essentially retains the current process that is adopted by Council if they issue urgent interim regulatory recommendations or guidelines.

Subsections 14(3) and (4) set out a similar process for when the Council considers that a matter is urgent and wishes to provide the CEO with a regulatory recommendation or guidelines without first undertaking the usual consultation processes. Again, the existing safeguards are retained.

Subsections 14(5) and (6) describe the same process to enable AHEC to provide human research guidelines to the Council without prior consultation in urgent circumstances.

Subsections 14(7) and (8) provide that if the CEO makes an interim regulatory recommendation or issues interim guidelines, the Council must (within 30 days after the end of the consultation period) advise the CEO whether to confirm, vary or revoke the recommendation or guidelines. In the case of human research guidelines, AHEC must advise the CeO to confirm vary or revoke and the Council may only advise the CEO in accordance with the advice offered by AHEC.

Subsection 14(9) provides that if the CEO fails (within 45 days after the end of the consultation period) to confirm, vary or revoke the interim regulatory recommendation or guidelines (in accordance with the Council's advice) then the recommendations or guidelines are treated as being revoked. This retains the default position that is currently described in the NHMRC Act in relation to when the Council issues urgent, interim guidelines or regulatory recommendations.

Section 14AA—Consultation requirements do not apply to revoking guidelines

This section provides that the Council may, without undertaking consultation, advise the CEO to revoke guidelines other than human research guidelines. In relation to human research guidelines, AHEC may, without undertaking consultation, advise the Council to advise the CEO to revoke human research guidelines. This is a new section establishing a process for revoking guidelines, where no specified process previously existed.

Subdivision B—Guidelines approved by CEO

Section 14A—Approval by CEO of guidelines for third parties

This section continues to enable the approval of guidelines developed by third parties. The consultation requirements of this section are not changed. The difference is that instead of the Council approving guidelines developed by third parties, the CEO (on the advice of the Council) will approve guidelines developed by third parties. This will not affect the ability of third parties to continue to publish guidelines and to note that they have been approved or endorsed by the NHMRC.

Subdivision C—Other provisions about consultation

Section 14B—Consultation may be dispensed with in certain circumstances

This section retains the intent of the existing section 14B, but makes minor amendments to remove the reference to "a proposed prescribed activity" (consistent with the removal of this terminology throughout this legislation) and to change cross-references to renumbered sections of the Act. The Bill retains the previous circumstances in which the Council may dispense with, or modify, consultation requirements.

Section 15—CEO must develop procedures

The existing section 15 is replaced by a new section 15 that requires that the CEO (rather than the Council) must develop and publish procedures to assist people to make submissions in relation to regulatory recommendations or guidelines. This is consistent with governance changes.

Items 34 to 39

These items amend section 16 which deals with strategic plans. The amendments replace the references to "Council' with references to "the CEO".

Item 40

This item amends subsection 17(1). Currently this provision requires the Council to give the Minister a written review evaluating the Council's success in implementing its strategic plan. This is amended so that the CEO, rather than the Council, must provide such a report to the Minister.

Items 41 to 43

These items amend section 18 (approval, commencement and tabling of strategic plans) by replacing the references to "Council" with references to "the CEO".

Items 44 to 51

These items amend section 19 which deals with variation of strategic plans. References to "Council" are replaced by references to "the CEO".

Item 52

This item repeals the existing Part 4 of the NHMRC Act (which relates to the constitution and operations of the Council) and replaces it with a new Part which establishes and describes the new functions of the Council.

PART 4—THE COUNCIL AND COMMITTEES OF THE NHMRC

DIVISION 1—THE COUNCIL OF THE NHMRC

Section 20—Establishment of the Council of the NHMRC

Section 20 establishes the Council of the NHMRC and the new membership of the Council. A note at the end of section 20 refers readers to Part 5 which describes the appointment, terms and conditions of the Chair and other members of the Council.

Section 20 provides that the Council must have a core of 19 members and may have up to 24 members.

Section 21—Functions of the Council

This section describes the functions of the Council which are:

- a) to provide advice to the CEO in relation to the performance of his or her functions; and
- b) any other functions conferred on the Council in writing by the Minister after consulting the CEO; and
- c) any other functions conferred on the Council by this Act, the regulations or any other law.

A note at the end of the section refers readers to section 82 which provides that the CEO may delegate functions to the Council.

Subsection 21(2) clarifies that instruments under 21(1) (b) are not legislative instruments within the meaning of section 5 of the *Legislative Instruments Act 2003*.

Section 22—Meetings of the Council

Section 22 provides that the Chair of the Council must convene at least one Council meeting in each financial year. This replaces the requirement, previously in subsection 30(1), that the Chair of the Council must convene at least one Council meeting in each calendar year.

A note at the end of section 22 refers readers to section 40, which allows the CEO to determine other matters in relation to Council meetings.

Item 53

This item repeals the previous heading of Part 5 (Committees) and replaces it with a reference to Division 2—Principal Committees. The effect of this is to put all the provisions relating to the Council and all the committees in one consolidated Part (Part 4).

Item 54

This item inserts a note after subsection 35(1) to clarify that matters relating to the constitution, functions and members of the Embryo Research Licensing Committee of the NHMRC are addressed in the *Research Involving Human Embryos Act 2002*.

Item 55

This item amends existing paragraph 35(2)(d) to clarify that the Minister may confer additional functions on the Research Committee only after consulting with the CEO.

Item 56

This item adds a new function to the functions of the Research Committee, namely any other functions conferred on the Research Committee by the Act, the regulations or any other law.

A note at the end of subsection 35(2) refers readers to section 82, which enables the CEO or Council to delegate functions to the Research Committee.

Item 57

This item repeals subsection 35(3) which prescribes the functions of AHEC and replaces it with a new subsection describing the functions of AHEC. The revised wording clarifies that AHEC will also have functions conferred by the Act, regulations or any other law. This is consistent with the functions of both the Council and the Research Committee.

A note is also included at the end of the subsection clarifying that the CEO or Council can delegate functions to a Principal Committee including AHEC. This reflects current practice.

Item 57 also repeals subsection 35(4) which required guidelines for the conduct of medical research involving humans issued by Council to be tabled in Parliament. This requirement has been included at section 10 with all other references to the development of guidelines for human research.

Item 58

Currently paragraph 35(6)(b) provides that AHEC must have a chairperson who is not a member of the Research Committee. This item retains this requirement and also requires that AHEC must have as its Chair a person who is a member of the Council. This is the same requirement as is in place for all other Principal Committees. For other Principal Committees this requirement is described in subsection 35(9) as amended by Item 62 of these amendments.

The requirement that AHEC must not have more than one Research Committee member (paragraph 35(6)(a)) is retained.

Item 59

This item inserts two new notes at the end of subsection 35(6). The notes refer readers to Part 5 which sets out the appointment, terms and conditions of AHEC members including the Chair and to subsection 35(10) which provides that in certain circumstances the Chair of AHEC may not be a member of Council.

Items 60 and 61

These items amend subsection 35(7) by requiring that the Minister consult the CEO before determining the name or functions of any new Principal Committee. A note at the end of the subsection reiterates that the CEO or Council may delegate additional functions to a new Principal Committee as provided for in section 82.

Item 62

Subsection 35(9) currently requires that a Principal Committee (other than AHEC) be constituted by a Chairperson and other members appointed by the Minister.

This item replaces this subsection with a new subsection that provides that a Principal Committee comprises a Chair, who must be a member of the Council, and the members appointed by the Minister. This section does not apply to AHEC because although the same rules apply to AHEC (that is, AHEC members are also appointed by the Minister and the Chair of AHEC must also be a member of Council), this is done through different sections of the Act.

The item also inserts a new subsection 35(10) that provides that the Chair of a Principal Committee can be a person who is not a member of Council if the Minister considers that no members of Council have appropriate expertise and provided that another member of the Principal Committee is a member of the Council. This ensures that there is always Council membership on Principal Committees (as is currently the case).

Item 63

Item 63 amends subsection 35(11) to remove the requirement for the Minister to gazette the constitution of a Principal Committee upon establishment. The requirement to gazette the establishment and functions of any new Principal Committee remains unchanged.

Item 64

This item repeals subsection 35(12) and (13). These subsections provide that members of Principal Committees must be appointed on a part-time basis and for a period not exceeding three years. Equivalent provisions have now been moved to Part 5 of the Act.

A new subsection 35(12) has been inserted to clarify that instruments under section 35 are not legislative instruments within the meaning of section 5 of the *Legislative Instruments Act 2003*.

Item 65

This item replaces the word Chairperson with the word Chair in paragraph 36(1)(a) consistent with current legislative drafting practice.

Item 66

This item repeals subsections 36(3), (4), (5) and (6). The provisions relating to the appointment of AHEC members have been moved to Part 5.

Item 67

This item repeals sections 37 to 44. These sections related to the Executive Committee (which no longer exists), arrangements for working committees (which have been moved to a new Division) and remuneration and conditions of Council and Committee members (which have also been moved to another Part).

Item 68

This item inserts two new Divisions at the end of Part 5.

DIVISION 3—WORKING COMMITTEES

Section 39—Working committees

Section 39 provides that the CEO may establish working committees and that working committees comprise the members appointed by the CEO and have the functions determined by the CEO. Subsection 39(4) enables the CEO to abolish working committees.

Subsection 39(5) clarifies that determinations made by the CEO under section 39 are not legislative instruments within the meaning of section 5 of the *Legislative Instruments Act 2003*.

DIVISION 4—CEO'S DETERMINATIONS OF COUNCIL AND COMMITTEE PROCEDURES ETC.

Section 40—CEO's determinations of Council and committee procedures etc.

Section 40 provides that the CEO may determine the manner in which the Council or committees carry out their functions and the procedures to be followed by the Council or committees (including Principal Committees and working committees).

Item 69

This item repeals existing Parts 5A (Chief Executive Officer) and 6 (Staff, consultants and work arrangements) and inserts a new Part 5 and a new Part 6. The new Part 5 relates to appointments, terms and conditions and the new Part 6 relates to staff, consultants and work arrangements. Following is a description of each section within these new Parts.

PART 5—APPOINTMENTS, TERMS AND CONDITIONS

Section 41—Appointments

Section 41 of Part 5 describes the appointment process for the CEO, the Chair of the Council and Principal Committees, and the members of Council, Principal Committees and working committees.

Subsection 41(1) provides that the Minister must appoint the CEO, Chair and other members of Council, the Chair and other members of all Principal Committees (excluding the Embryo Research Licensing Committee) and the Commissioner of Complaints. The Embryo Research Licensing Committee is excluded to avoid potential conflict with the *Research Involving Human Embryos Act 2002* which makes provision for the appointment of the Chair and members of that Committee.

Before making any of these appointments, the Minister must consult appropriately.

Subsection 41(2) provides that the CEO must appoint members of working committees.

Subsections 41(3) and (4) provide that the CEO must be appointed on a full-time basis and that all other appointments are on a part-time basis only.

Subsection 41(5) provides that the CEO can be appointed for a maximum of five years and all others can be appointed for a maximum of three years. However, the CEO, all other Chairs and other members of Council and committees may be reappointed for further terms. This is permitted under the *Acts Interpretation Act 1901*.

Section 42—Acting appointments

Section 42 details arrangements for acting appointments. Previously, acting arrangements for the Chair of Council, members of Council, the Chairs of Principal Committees, the Commissioner and the CEO were spread across several different sections. This new section consolidates all acting arrangements into one section. In essence, if the Minister has made an appointment the Minister may also appoint a person to act temporarily in that position during any vacancy.

The section places some constraints on the Minister in terms of who may be appointed to act in the positions. For example, if there is a vacancy in the office of Chair of the Council another member of Council must be appointed. If there is a vacancy for the position of Chief Medical Officer for a State or Territory, the Minister may make an acting appointment provided that the person has appropriate expertise and has been nominated by the Minister that has primary responsibility for health in the relevant State or Territory.

Subsection 42(4) clarifies that actions taken by people acting in positions are not invalidated merely because, for example, there was an irregularity in the appointment.

Section 42A—Disclosures of interest

Section 42A describes processes relating to disclosures of interest. In summary, before starting to hold office, the CEO must disclose any potential conflicts of interest to the Minister. A member of Council or a Principal Committee must disclose any interests to the CEO.

If a member of Council or a Principal Committee realises that they have a potential conflict of interest in relation to a matter to be considered, they must disclose the nature of the interest to the Chair of the Council (or the Chair of the committee) at a meeting of the Council (or committee). If a member has disclosed an interest they must not be present when the Council or any committee considers the matter or take part in any decision, unless the Chair of the Council or the committee has otherwise determined. The disclosure must also be recorded in the Minutes.

This reflects the current practice.

Section 43—Remuneration and allowances

This section effectively consolidates the separate provisions in the Act relating to the remuneration of the CEO, Chair of the Council, members of the Council, members of all committees and the Commissioner of Complaints.

Section 43 provides that the CEO, Chair of the Council, members of the Council, members of all committees and the Commissioner of Complaints are to be paid the remuneration and allowances determined by the Remuneration Tribunal or, in the event that no such remuneration or allowances are determined by the Remuneration Tribunal, the remuneration and allowances that are prescribed.

The section provides that the CEO and Chair of the Council are to be remunerated by way of a yearly amount and all members of Council and committees are remunerated by sitting fees. This reflects the current practice.

Subsection 43(3) provides that if a member of the Council or a Committee is also an employee of the Commonwealth, a State or a Territory (or performing the duties of an office established under a Commonwealth, State or Territory law) then they are not entitled to remuneration under this Act. The exception is the Chair of the Council who may receive remuneration (despite being employed by the Commonwealth, State or a Territory) if agreed by the Minister. This retains the current practice.

Subsection 43(6) clarifies that the section has effect subject to the *Remuneration Tribunal Act 1973*.

Section 44—Leave of absence

Section 44 provides that the Minister may grant the Commissioner of Complaints or CEO leave of absence on terms and conditions determined by the Minister and that the CEO may do the same in respect of members of the Council and all committees (including the Chairs).

Section 44A—Resignations

Section 44A provides that people appointed under the legislation (for example, the Council members, CEO, Principal Committee members and working committee members) may resign their appointments by giving notice to the Minister or CEO (whoever made the appointment).

Section 44B—Terminations of appointments

Section 44B consolidates the termination provisions currently set out in sections 28, 44 and 77 of the Act. Section 44B provides that, in relation to people appointed under subsection 41(1) or (2), the Minister or CEO (whoever made the appointment) may terminate the appointment for misbehaviour or for physical or mental incapacity.

The Minister or CEO must terminate the appointment in the circumstances detailed. This includes, for example, where the holder of the office becomes bankrupt or fails to comply, without reasonable excuse, with an obligation to disclose an interest. Appointments must also be terminated if the member is absent without approved leave of absence or (in the case of Council or committee members) is absent from 3 consecutive meetings without approved leave of absence.

This section further provides that if the Minister or CEO terminates an appointment then the Minister or CEO must give the holder of the office a written notice informing the holder of the office of the termination and setting out the reasons for the termination.

These provisions are consistent with the existing provisions relating to termination of appointments, noting that the grounds on which Council and committee members can have their appointments terminated have been made consistent.

Section 44C—Other terms and conditions

This section provides that the CEO and the Commissioner hold office on the terms and conditions (if any), in relation to matters not covered by the Act, that are determined by the Minister.

PART 6-STAFF, CONSULTANTS AND WORK ARRANGEMENTS

Section 45—Staff of the NHMRC

This section provides that the staff of the NHMRC are to be people engaged under the *Public Service Act 1999* and that for the purposes of that Act, the CEO and the staff of the NHMRC together constitute a Statutory Agency and the CEO is the Head of that Statutory Agency.

Section 46—Consultants

This section, which is included for the avoidance of doubt, provides that the CEO may engage consultants to perform services for the CEO related to the CEO's functions.

Section 48—CEO may make arrangements relating to various matters

This section revises the wording of the current section 48 to take account of the new structure and governance arrangements for the NHMRC.

This section provides that the CEO may make arrangements with the chief officer of a State or Territory Department or authority for the services of officers or employees of that Department or authority to be made available to the NHMRC. The CEO may also make arrangements with the chief officer of a State or Territory Department or authority for officers or employees of a Department or authority and the CEO, the members of Council or committees, or the staff of NHMRC, to co-operate in the performance of their functions.

The CEO may make arrangements with the chief officer of a state or Territory Department or authority relating to any matter within the scope of the CEO's functions, including arrangements for the CEO to undertake activities on behalf of a State or Territory Department or authority. This reflects current arrangements for the Council.

Subsection 48(3) clarifies that arrangements under this section are not legislative instruments within the meaning of section 5 of the *Legislative Instruments Act 2003*.

Item 70

Section 51 deals with the purposes of the Medical Research Endowment Account. This item inserts a note at the end of subsection 51(1) which directs people's attention to paragraph 22(1)(a) of the *Acts Interpretation Act 1901* which provides that person includes a body politic or corporate as well as an individual.

Item 71

This item amends subsection 51(2) to delete the reference to 51(2A) which is repealed as a result of Item 73.

Item 72

This item replaces the word "Council" with the word "CEO" in subsection 51(2). The effect of this is that conditions of assistance are determined by the Minister on the advice of the CEO rather than the Council. It is, however, anticipated that the CEO would first seek the advice of Council.

Item 73

This item repeals subsection 51(2A).

Item 74

This item repeals section 54. Section 54 deals with old transitional provisions for the Medical Research Endowment Fund. These provisions were necessary when the old *Medical Research Endowment Act 1937* was repealed and are no longer necessary.

Items 75 to 78

These items replace the references to "Council" with references to "CEO" in paragraphs 56(2)(a) and (b), paragraph 61(1)(e), section 62 (including in the heading) and paragraph 64(3)(a).

Item 79

Section 64 deals with co-operation with the Commissioner of Complaints. This item replaces the word "Council" with the word "NHMRC" in paragraph 64(3)(c).

Item 80

This item replaces paragraph 64(3)(f) with an updated paragraph consistent with the new section 48. This amendment does not alter the intent of this provision.

Items 81 to 84

These items replace "Council" with "CEO" in paragraphs 66(c) and (d), subsection 67(1) and subsections 67(2) and (3). These amendments do not alter the intent of these provisions.

Item 85

This is a minor technical amendment that replaces "it" with "CEO" in paragraphs 67(3)(a) and (b).

Item 86

This is a minor technical amendment that replaces "its" with "CEO's" in paragraph 67(3)(b).

Item 87

This item amends section 68 by requiring the Commissioner of Complaints to give a written report to the CEO at the end of the financial year. Previously the Commissioner was required to give the report to the Council at the end of each calendar year.

Item 88

This item repeals the existing heading of Division 3 (which referred to the appointment, terms and conditions of the Commissioner of Complaints) and replaces it with a new heading that refers to "Administrative arrangements for Commissioner". This is because all of the appointment provisions for the Commissioner of Complaints are now included in Part 5 along with the appointment provisions for Council and committees.

Item 89

This item replaces section 69 which currently describes the appointment of the Commissioner of Complaints with a new section 69.

Section 69 – Commissioner must have appropriate experience

The new section 69 provides that a person must not be appointed as the Commissioner of Complaints unless he or she has appropriate expertise.

Previously the Minister could only appoint a person who had expertise in scientific research, medical research or public health research. However, it may be just as appropriate for a Commissioner of Complaints to have experience in, for example, mediation or dispute resolution. Therefore this provision has been amended to ensure greater flexibility and ensure that the best person for the position can be appointed based on appropriate expertise.

A note is included at the end of section 69 which refers readers to Part 5 for the appointment, terms and conditions of the Commissioner of Complaints.

Item 90

This item repeals sections 70 and 71 which related to the terms and conditions of appointment of the Commissioner of Complaints and the period of the Commissioner's appointment. These provisions are now included in Part 5.

Item 91 and 92

Section 72 of the NHMRC Act deals with the Commissioner of Complaints entering into arrangements with the Secretary of the Department for the provision of Departmental staff to the Commissioner. This item amends this section to enable the Commissioner to make the same arrangements with the CEO of the NHMRC in respect of the staff of the NHMRC.

Item 93

This item repeals sections 73, 74, 75 and 77. These provisions (relating to acting appointment, leave of absence, remuneration and allowances for the Commissioner and termination of appointment) have been incorporated into Part 5.

Item 94

Section 80 of the NHMRC Act describes the arrangements for treatment of confidential commercial information. Subsection 80(1) sets out relevant definitions. This item replaces those definitions with new definitions for "information provider" and "NHMRC officer". The changes do not affect the operation of the provision but merely ensure that all of the references to the new CEO, staff of the NHMRC and Council members are appropriate.

The item also amends subsection 80(2) which sets out the offence relating to disclosure of confidential commercial information. Again, the changes do not affect the substantive operation of the provision but reflect the new governance arrangements.

Item 95

This item repeals subsection 80(5) and replaces it with a new subsection that reflects the new governance arrangements. The substance of the provisions (which related to the Chairperson of the Council dealing with confidential commercial information and now deal with the CEO of the NHMRC dealing with confidential commercial information) have not been affected.

Item 96

This item deletes "Chairperson" and substitutes "CEO" under subsections 80(7), (8) and (9).

Item 97

Currently paragraph 80(9)(d) deals with the Chair of the Council permitting disclosure of certain information to certain people for the purposes of arrangements made under sections 40 or 48.

This item repeals paragraph 80(9)(d) and replaces it with an updated paragraph clarifying that this provision applies to persons assisting under arrangements made by the CEO under new section 48. This does not affect the intent of this paragraph. Persons assisting the Embryo Research Licensing Committee of NHMRC are excluded from this provision.

Items 98 and 99

These items make minor amendments to subsection 80(9) and paragraph 80(11)(b) to delete references to a repealed section.

Item 100

This item repeals section 81 (protection from civil actions). The NHMRC is to become legally part of the Commonwealth in so far as it will no longer be incorporated. This has a number of consequences which diminish the need for section 81. For example, the Commonwealth has various policies whereby it indemnifies employees and those acting in an official capacity on behalf of the Commonwealth (such as Committee members). The Commonwealth is also able to arrange indemnity insurance through Comcover.

Items 101 and 102

Currently subsection 82(1) provides that the Minister may delegate the power of the Minister under section 23 to the Secretary of the Department. This item amends that subsection by providing that the Minister may delegate to the CEO all or any of the Minister's powers or functions under section 42 (acting appointments) in relation to members of the Council (including the Chair).

Subsections 82(2) and (3) are also amended to ensure that the CEO may delegate powers or functions to the Council, or a committee (other than the Embryo Research Licensing Committee of the NHMRC) or a member of the staff of the NHMRC. The Council can also delegate to the Chair of the Council or a committee (other than the Embryo Research Licensing Committee of the NHMRC). A Principal Committee may delegate to a working committee (including a power or function delegated to it by the CEO or the Council).

Item 103

A minor amendment is made to subsection 82(4) to insert "the CEO," after "the Minister," (wherever occurring). The effect of this is to ensure that a delegate must exercise a power delegated by the CEO in accordance with any directions of the CEO. This is consistent with procedures in relation to delegations from the Minister, the Council or a Principal Committee.

Items 104 to 106

Section 83 relates to the content of annual reports of the NHMRC. Item 104 repeals subsection 83(1) and replaces it with a new provision. The old provision required the Council to give a report on the operation of the Council to the Minister each calendar year. The new section requires that the CEO is to provide a report on the operations of the NHMRC to the Minister at the end of each financial year.

Paragraph 83(2)(c) is amended to omit "Council" and substitute with "CEO". Paragraphs 83(2) (d), (e), (f) and (g) are amended to update the reference to the "Council" with a reference to the "CEO". The specifically identified content of the annual report remains unchanged.

Item 107

This item deletes "Council" and substitutes it with "CEO" in paragraphs 83(2)(h) and (i).

Item 108

This item repeals section 84. Section 84 relates to exemption from taxation, an issue that is no longer relevant with the change in status of the NHMRC from body corporate to prescribed agency under the *Financial Management and Accountability Act 1997*.

Item 109

This item repeals Part 10. Part 10 contained the old transitional arrangements that were necessary when the NHMRC legislation was introduced in 1992. These are no longer in use.

PART 2 - AMENDMENT OF OTHER ACTS

Australian Institute of Health and Welfare Act 1987 Item 110

This item amends the reference in subsection 16(3) of the *Australian Institute of Health and Welfare Act 1987* from "National Health and Medical Research Council" to "CEO of the National Health and Medical Research Council".

Food Standards Australia New Zealand Act 1991 Items 111 and 112

These items replace the references to the "National Health and Medical Research Council" in the *Food Standards Australia New Zealand Act 1991* with references to "CEO of the National Health and Medical Research Council" in subsection 3(1) (paragraph (b) of the definition of appropriate government agency) and paragraph 40(1)(e).

Freedom of Information Act 1982 Item 113

This item replaces the second reference to the "National Health and Medical Research Council" in the *Freedom of Information Act 1982* with a reference to "Council of the National Health and Medical Research Council" (Division 1 of Part II of Schedule 2).

National Health Act 1953

Item 114

This item inserts "CEO of the" before "National Health and Medical Research Council" in subsection 73EA(1) of the *National Health Act 1953*.

Privacy Act 1988

Item 115

This item inserts "CEO of the" before "National Health and Medical Research Council" in subsections 73(2) and (3), 95(1) and 95A(1).

Research Involving Human Embryos Act 2002 Item 116

This item inserts "CEO of the" before "NHMRC" in section 8 (paragraphs (a) and (b) of the definition of proper consent) of the *Research Involving Human Embryos Act 2002*.

Item 117

This item repeals paragraphs 13(2)(a), (b), (c) and (d) and replaces them with the correct cross-references to the new sections in the NHMRC Act.

Item 118

Subsection 13(5) refers to "A determination by the NHMRC under paragraph 38(b)(vi)". This is replaced with a reference to a determination made by the NHMRC under "section 42A".

Items 119 to 121

These items replace the references to "NHMRC" with references to "CEO of the NHMRC" in subsection 18(2) second occurring, paragraph 21(4)(c) and subsection 47(1).

Therapeutic Goods Act 1989 Item 122

Subsection 3(1) (paragraph (a) of the definition of ethics committee) is amended to replace "National Health and Medical Research Council" with "CEO of the National Health and Medical Research Council".

PART 3—AMENDMENT CONDITIONAL ON THE FINANCIAL FRAMEWORK LEGISLATION AMENDMENT ACT (NO. 1) 2006

National Health and Medical Research Council Act 1992 Item 123

This item omits "Chief Executive Officer or to an APS employee in the Department" from subsection 82(1A) and substitutes "CEO or to a member of the staff of the NHMRC".

PART 4—TRANSITIONAL PROVISIONS

DIVISION 1—PRELIMINARY

Item 124

This item sets out the definitions used in this Part. The key definitions include:

asset means:

(a) any legal or equitable estate or interest in real or personal property, whether actual, contingent or prospective; and

(b) any right, power, privilege or immunity, whether actual, contingent or prospective.

commencement time means the time when this Part commences.

instrument:

- (a) includes:
 - (i) a contract, deed, undertaking or agreement; and
 - (ii) a notice, authority, order or instruction; and
 - (iii) an instrument made under an Act or regulations; and
 - (iv) regulations; but
- (b) does not include an Act.

new law means the *National Health and Medical Research Council Act 1992* as in force immediately after the commencement time.

old law means the *National Health and Medical Research Council Act 1992* as in force immediately before the commencement time.

old NHMRC means the National Health and Medical Research Council established by the old law.

DIVISION 2—ASSETS, LIABILITIES AND LEGAL PROCEEDINGS

Item 125

This item vests the assets of the old NHMRC in the Commonwealth. This occurs automatically without any conveyance, transfer or assignment and the Commonwealth becomes the successor in law in relation to these assets.

Item 126

This item vests the liabilities of the old NHMRC in the Commonwealth. This occurs automatically without any conveyance, transfer or assignment and the Commonwealth becomes the successor in law in relation to these liabilities.

Item 127

This item enables registration of certificates relating to vesting of land and sets out the circumstances under which this item is applicable.

Item 128

This item provides that if any asset other than land vests in the Commonwealth under this Division and a certificate is lodged with an assets official and is signed by the Minister (identifying the asset and stating that the asset has become vested in the Commonwealth), then the assets official may deal with, and give effect to, the certificate as if it were a proper and appropriate instrument for transactions in relation to assets of that kind.

The assets official may also make such entries in the register as are necessary having regard to the effect of this Part.

Item 129

This item allows for the substitution of the Commonwealth for the old NHMRC in the event of any proceedings, to which the old NHMRC was a party, pending in any court or tribunal immediately before the commencement time.

Item 130

This item provides for the transfer of any records or documents that were in the custody of the old NHMRC or a committee immediately before commencement, to be transferred to the custody of the CEO at or after commencement time.

DIVISION 3—REFERENCE TO, AND THINGS DONE BY OR IN RELATION TO, OLD NHMRC

Item 131

This item allows for the preservation of existing instruments by providing that references to the old NHMRC can be taken to be references to the CEO or Commonwealth, and that references to staff of the old NHMRC, however described, can be taken to be references to the staff of the NHMRC.

Item 131(4) permits the Minister, by writing, to vary the above provisions, under certain circumstances.

Item 131(5) permits variations through regulations in certain specified circumstances.

Item 131(6) provides for the preservation of instruments relating to the Medical Research Endowment Account in circumstances where functions once carried out by the Department are now carried out by the NHMRC and the CEO certifies this to be the case, in writing.

Item 131(7) assists the reader by clarifying that a determination under subitem (4) or a certificate under subitem (6) is not a legislative instrument within the meaning of section 5 of the *Legislative Instruments Act 2003*.

Item 132

This item provides that:

- things done by the NHMRC are taken to be done by the CEO. However, this is not taken to change the time at which the thing was actually done. The item also provides that the Minister may, by writing, determine that this is not the case in relation to a specified thing done by the old NHMRC or that it applies as if the reference to the CEO were a reference to the Commonwealth, the Council or a Principal Committee. Such a determination is not a legislative instrument;
- the regulations may also provide for a thing to be taken to have been done by, or in relation to, a person or body other than the Commonwealth, the CEO, the Council or a Principal Committee; and
- a thing done by AHEC under a provision of Part 3 of the old law has the effect from that time as if it were done under Part 3 of the new law. However, this is not taken to change the time at which the thing was actually done.

Item 133

This item provides that an instrument made or given under the old law and specified in the table (as in force immediately before the commencement time) continues to have effect from the commencement time as if it were made or given under the corresponding provision of the new law specified in the table contained in this item.

DIVISION 4—COMMITTEES AND COMMISSIONER

Item 134

This item provides that a Principal Committee established under the old law (and in existence immediately before the commencement time) continues in existence, at the commencement time, as if it were established under section 35 of the new law. Item 134(2) provides that where the name or functions of a Principal Committee were determined under the old law (and in force immediately before the commencement time) then that instrument continues in force under the new law. This means that Principal Committees will have continuity of operation. The members of the Principal Committee will however need to be appointed.

Item 135

This item provides that a working committee established under the old law (and in existence immediately before the commencement time) continues in existence, at the commencement time, as if it were established under section 39 of the new law. In addition, item 135(2) provides that a person who was a member of the working committee continues to be a member of the working committee after 1 July 2006. This is necessary in order to ensure that the work of working committees, including in relation to consideration of grant applications, can continue.

Item 136

This item provides that the person who is Commissioner of Complaints continues in that office after the new legislation commences. The terms and conditions also continue.

DIVISION 5—REPORTING OBLIGATIONS

Item 137

This item provides that sections 68 and 83 of the new NHMRC Act apply in relation to the financial year ending on 30 June 2007 and later financial years. Those sections apply in relation to the financial year ending on 30 June 2007 as if that financial year also included the period starting on 1 January 2006 and ending on 30 June 2006. In effect this means that the first annual report of the new agency will be for the eighteen month period 1 January 2006 to 30 June 2007.

DIVISION 6-MISCELLANEOUS

Item 138

This item provides that no stamp duty or other tax is payable under a law of a State or Territory in respect of, or anything connected with, the transfer of an asset or liability under this Part or the operation of this Part in any other respect.

Item 139

The effect of this item is that it allows consultation for the first appointment to each office under subsection 41(1) to take place before the new Act commences. This enables the Minister to consult on the appointment of the Council members and AHEC members, and Chairs of the Principal Committees prior to the new arrangements taking effect. This means that when the new arrangements take effect, the appointments of the Council, Principal Committee Chairs, and members of AHEC, can be finalised quickly in order to ensure continuity.

Item 140

This item provides that if a provision of this Part would result in an acquisition of property from a person other than on just terms, the Commonwealth is liable to pay that person reasonable compensation.

If the parties cannot agree on the amount of compensation, the person may institute proceedings for the recovery of reasonable compensation, as determined by the court. This item ensures consistency with the Constitutional requirement that acquisition of property by the Commonwealth must be on just terms.

Item 141

This item provides that a document that appears to be a certificate made or issued under a particular provision of this Part is taken to be such a certificate and is taken to have been properly given (unless the contrary is established).

Item 142

This item enables the Minister to delegate powers and functions under this Part to the Secretary of the Department or the CEO of NHMRC.

The Secretary or CEO must comply with any directions from the Minister when exercising or performing powers or functions under a delegation and the powers or functions delegated must not be sub-delegated.

Item 143

This item enables regulations to be made to give effect to this Part. The regulations may prescribe matters of a transitional nature (including prescribing any saving or application provisions) relating to the amendments or repeals made by this Part.