# ANTHUR RODNISOM & HEDDERWICKS EIGHARY

1992

# THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

SENATE

## NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL BILL 1992

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health, Housing and Community Services, the Honourable Brian Howe MP)

THIS MEMORANDUM TAKES ACCOUNT OF AMENDMENTS MADE BY THE HOUSE OF REPRESENTATIVES TO THE BILL AS INTRODUCED

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#### NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL BILL 1992

## GENERAL OUTLINE

This Bill establishes the National Health and Medical Research Council (the Council) as a body corporate. It outlines the role the Council is to play in advising the Commonwealth, the States and Territories and the Australian community.

The Bill provides the Council with functions that are designed to enable it to continue its existing role in providing advice, issuing guidelines and making recommendations in relation to the improvement of health, health and medical research, public health, health care and health and medical ethics.

The Bill provides for the Council to have the independence from the Government that the community expects having regard to its role and status while also providing for its accountability to the public, the Commonwealth, and the States and Territories.

The Council is required to prepare triennial strategic plans in consultation with the Minister setting out how the Council proposes to address the major health issues it sees as arising. The Plans are to include a national strategy for medical research and public health research. These plans are to be tabled in Parliament, and Council is to review its performance against the Plans.

The Council is also required to consult persons or bodies in relation to any action it proposes to take to issue guidelines or make a recommendation that would require State legislation in order to be effective. The Minister is empowered to provide written directions of a general nature to the Council.

The Council is empowered to publish advice on any matter relevant to its functions.

The Bill provides for the members of Council and its Principal Committees to be appointed by the Minister after consultation with the relevant bodies. The qualifications and attributes for members of the Council are set out in the Bill and the bodies to be consulted in relation to appointments to Council are to be prescribed in regulations.

The Bill provides for the manner in which Council will carry out its functions and makes provision for Council to determine these matters for the Principal Committees.

Much of the work of Council is carried out on an honorary basis by expert working groups and panels. The Bill provides for Principal Committees to establish working committees, panels, etc to enable this invaluable tradition to continue. Provision is made in the Bill for the staff, and facilities for the Council to be provided by the Department of Health, Housing and Community Services, which may also engage consultants on behalf of the Council.

The Bill also provides for the establishment and management of the Medical Research Endowment Fund and in doing so replaces the provisions of the Medical Research Endowment Act 1937. The Bill provides for the repeal of that Act. It also provides for the creation of an office of Commissioner of Complaints. The Commissioner is empowered to investigate complaints relating to applications for grants funds for medical research and teaching and public health research and teaching.

The Bill provides for the Council to provide an Annual Report which is to be tabled in Parliament.

The Bill provides for the existing Council members and Principal Committees to continue and for the continuation of the business of the Council and its committees.

#### FINANCIAL IMPACT STATEMENT

Establishing the Council as a statutory body is of itself largely cost-neutral and will have no impact on total Council expenditure.

#### THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL BILL 1992

#### NOTES ON CLAUSES

#### Part I - PRELIMINARY

#### Clause 1 - Short Title

This clause is a formal requirement and provides for the Act to be cited as the National Health and Medical Research Council Act 1992.

#### Clause 2 - Commencement

This Clause provides that the Act will come into operation on a day or days to be proclaimed or 6 months after it receives Royal Assent, which ever is the sooner.

#### Clause 3 - Object of the Act etc.

Consistent with the existing role of the Council, this clause provides that the object of the Act is to make provision for a national body to pursue activities to raise the standard of health of all Australians, to foster the development of consistent health standards between the various States and Territories, to foster medical and public health research and training, and to foster consideration of ethical issues relating to health. This clause also provides that the Council adopt a policy of public consultation on health matters.

#### Clause 4 - Interpretation

This clause is the interpretation section of the Act. particular note are the following definitions: "Council" means the National Health and Medical Research Council; "appointed member" in relation to the Council means a member of the Council who has been appointed to the office, and in relation to a committee means a member of a committee who has been appointed to that office; "NHMRC Order" means the Order in Council under which the NHMRC previously operated; "regulatory recommendation" means a recommendation of the Council that is intended to be given legal effect in a State by legislation of that State; and "Fund" means the Medical Research Endowment Fund. For the purposes of the Act, the term "reviewable action" means: action taken by the Council in relation to a recommendation made to the Commonwealth under paragraph 7(1)(c); action taken by the Medical Research Committee in relation to a recommendation made to Council under paragraph 35(2)(a); unreasonable delay by the Council or the Medical Research Committee in relation to its consideration of an application for funding; or the failure or refusal by the Council or the Medical Research Committee to make a recommendation in relation to an application for funding.

#### Clause 5 - Act to bind Crown

This clause provides for this Act to bind the Crown in right of the Commonwealth and each State and Territory.

#### Part 2 - ESTABLISHMENT AND FUNCTIONS OF THE COUNCIL

#### Clause 6 - Establishment

This clause establishes the Council as a body corporate that may sue and be sued.

#### Clause 7 - Functions of the Council

This clause reflects the present functions of the Council in providing for it to have the following functions:

- a) To inquire into, and issue guidelines on, and advise the community, the Commonwealth and the States and Territories on, matters relating to:
  - i) the improvement of health;
  - ii) the prevention, diagnosis and treatment of disease;
  - iii) the provision of health care;
    - iv) public health research and medical research; and
    - v) ethical issues relating to health.
- b) To advise and make recommendations to, the Commonwealth, the States and Territories on the matters referred to in a) above;
- c) To make recommendations to the Commonwealth on expenditure on public health research and training and medical research and training including the application of the Medical Research Endowment Fund.
- d) Any functions incidental to any of the foregoing.

Subclause (2) provides that, subject to the direction of the Minister, the Council has the general administration of this Act.

#### Clause 8 - Ethics Guidelines

This clause requires the Council to issue guidelines under clause 7 for the conduct of medical research involving humans, and that in issuing the guidelines the Council is to take into account the recommendations of a Principal Committee established under subclause 35(3) for purposes that include the making of such recommendations.

A Committee established under subclause 35(3) will be a Principal Committee other than the Medical Research Committee.

## Clause 9 - Reference of matters to Council by the Minister

This clause empowers the Minister to refer matters (that fall within the functions of Council) to the Council, and stipulates that the Council must deal with any matter referred to it by the Minister.

### Clause 10 - Minister may give directions to the Council

This clause empowers the Minister to give directions of a general nature to the Council. Subclause (2) provides that the Minister is not entitled to direct the Council to allocate research funds to a particular person, organisation State or Territory, nor direct the Council on how it treats a particular scientific, technical or ethical issue. Subclause (3) provides that the Council must comply with any direction given by the Minister under subclause (1). The Minister is to table in each House of the Parliament particulars of, and the reasons for, any direction within 15 sitting days after giving the direction and details of any direction given under this clause are to be included in the Council's annual report (see clause 82).

#### Part 3 - POWERS AND DUTIES OF THE COUNCIL

#### Clause 11 - Powers of the Council

This clause provides that the Council may do all things necessary in relation to performing its functions. It empowers the Council to (as provided in subclause (2)) accept gifts, grants, bequests, and act as trustee of money vested in Council on trust; prepare and publish papers and reports relating to the functions of Council; and perform any other functions or duties as authorised by the Act.

## Clause 12 - Consultation by Council

This clause provides that the Council must consult persons or bodies as soon as practicable after it decides to make a regulatory recommendation, issue guidelines or engage in any other prescribed activity. Subclause (2) provides that the Council must publish a notice in the prescribed form, informing of its intention to make a recommendation, issue guidelines, or engage in any other prescribed activity, and inviting interested persons or bodies to make submissions relating to the matters within the time specified in the notice.

Subclause (3) provides that the submissions are to be duly considered and the Council must then either a) prepare a draft of the recommendation or guidelines or activity, or an outline of the activity, and publish it in a notice in the prescribed form, inviting submissions relating to the draft or outline, or b) publish a notice in the prescribed form informing that it no

longer intends to make the recommendation, issue the guidelines or engage in the prescribed activity.

This clause is to ensure that there is appropriate consultation on these important matters. This consultation process follows recommendations made by the Administrative Review Council which examined the Council's procedures and reported to the Government in 1990.

# Clause 13 - Consultation may be dispensed with or modified in certain circumstances

This clause provides that Council may dispense with the consultative measures, or any part of the consultative process provided in clause 12, if Council is satisfied that the proposed regulatory recommendation, proposed guidelines or prescribed activity is of minor significance. Subclause (2) provides that notice of Council's reasons for dispensing with the measures is to be published.

This clause ensures that Council may perform its functions in as timely and efficient a manner as is possible, without compromising the nature or level of consultation.

# Clause 14 - Council may take interim action as a matter of urgency

This clause provides that the Council may take interim action, temporarily by-passing the consultative measures outlined above, if the Council considers it a matter of urgency to make a regulatory recommendation or issue guidelines. If this occurs, and as provided in subclause (2), the Council must publish, within 30 days, a notice detailing reasons why the matter was considered urgent, detailing the nature of the recommendation or quidelines, and calling for submissions from interested persons or bodies in accordance with the consultative measures outlined in the notice. Subclause (3) provides that the Council must consider any submissions received in terms of subclause (2) and within 30 days after the period specified in terms of subclause (2), must confirm, vary or revoke the interim recommendation or guidelines. If the Council does not take action in terms of subclause (3) within the 30 day period, it will be taken to have revoked the interim recommendations or guidelines. This is provided in subclause (4).

## Clause 15 - Council must develop procedures

This clause provides that Council must develop and publish procedures to assist persons or bodies to present submissions relating to proposed regulatory recommendations or guidelines. This clause is included to ensure that all interested parties are able to effectively participate in this consultation process.

### Clause 16 - Strategic plans

This clause provides that the Council must develop, and prepare in writing, a strategic plan that details Council's assessment of the major national health issues that are likely to arise during the period of the plan, and the manner in which the Council proposes to deal with these issues during the period. The strategic plans must also, as provided in subclause (2), contain a national strategy for medical research and health research.

Before preparing the strategic plan, the Council must consult with the Minister.

The first such strategic plan to be presented must relate to the period commencing on the proclaimed day of this Act, and ending on 30 June 1994, with subsequent strategic plans being prepared in relation to consecutive three year periods. This is provided in subclauses (4) and (5).

Subclause (6) provides that each strategic plan must be laid before each House of the Parliament within 15 sitting days after it is received by the Minister.

#### Clause 17 - Review of each plan

This clause provides that, no later than 6 months before the end of a strategic plan, the Minister must receive from the Council a written review evaluating the Council's success in implementing the strategic plan. Each review must also be laid before each House of Parliament within a specified time.

## Clause 18 - Delivery and commencement of strategic plans

This clause provides that the first strategic plan must be given to the Minister no later than one month after the proclaimed date of this Act. The Council has already prepared a strategic plan for the triennium 1991-1993 which will form the basis for the first strategic plan under this provision. Subclause (2) provides that this strategic plan will come into force on the day it is given to the Minister. Each subsequent strategic plan must be given to the Minister before the end of the period of the previous strategic plan, must include a review of the previous strategic plan, and will come into force immediately after the end of the immediately preceding plan.

#### Clause 19 - Variation of strategic plans

This clause provides that the Council may, from time to time, review the current strategic plan in order to determine whether variations are required. Any variation can only occur after the Council has consulted with the Minister. Any variation to the strategic plan must be given to the Minister and laid before each House of Parliament within 15 sitting days after it is received by the Minister.

#### Part 4 - CONSTITUTION AND MEETINGS OF THE COUNCIL

## Clause 20 - Constitution of the Council

This clause provides that the Council consists of:

- (a) the Chairperson;
- (b) the Secretary to the Council;
- (c) each person who is, or acting as, the Chairperson of a Principal Committee and who is not a member of the Council because of any other paragraph;
- (d) an officer of each State or Territory health instrumentality nominated by the Minister having administrative responsibility for the instrumentality concerned;
- (e) an officer of the Department nominated by the Minister;
- (f) a person:
  - (i) nominated by the Aboriginal and Torres Strait Islander Commission (ATSIC); and
  - (ii) having knowledge of the health needs of Aboriginals or Torres Strait Islanders;
- (g) a person with expertise in health care training;
- (h) a person with knowledge of professional medical standards and expertise in post-graduate medical training;
- (i) a person with a background in, and knowledge of, the medical profession;
- (j) a person with a background in, and knowledge of, the nursing profession;
- (k) an eminent scientist:
  - (i) who has knowledge of public health and medical research issues; and
  - (ii) who has no current connection with the Council;
- a person with a background in, and knowledge of, the trade union movement;
- (m) a person with a background in, and knowledge of, business;
- (n) a person with a background in, and knowledge of, consumer issues;
- (o) a person with knowledge of the needs of users of social welfare services;
- (p) a person with knowledge of environmental issues;
- (q) no more than 3 other persons with expertise relevant to the functions of the Council.

This membership reflects the current membership of the Council.

#### Clause 21 - Appointment of members

This clause provides that, with the exception of the Secretary to the Council, members are Ministerial appointees. The Chairperson is to be appointed only after consultation with members of the Australian Health Ministers Conference has occurred, and the Minister is satisfied that the person has the relevant expertise.

Subclause (3) of the clause outlines the consultative arrangements for the appointment of Council members through the calling of nominations for appointment from relevant peak bodies and organisations. These peak bodies and organisations correspond in nature to the background, knowledge or expertise required of the member, (as detailed in clause 20) and are to be prescribed in regulations. This clause also provides that any appointed member, other than the Chairperson, must be appointed on a part-time basis only, while the Chairperson may be appointed as a full-time or part-time member.

An appointed member holds office for a period not exceeding three years, but is eligible for reappointment.

Clause 85 ensures that the current members of Council continue in office until December, 1993.

#### Clause 22 - Secretary to the Council

This clause provides that the Secretary to the Council be a Senior Executive Service Officer within the Department of Health, Housing and Community Services, appointed to that position by the Secretary to the Department. The Secretary to the Council is the executive officer of the Council as well as being a member of the Council. This clause ensures that appropriate links between the Council and the Department of Health, Housing and Community Services are maintained.

## Clause 23 - Acting appointments

This clause empowers the Minister to appoint an acting Chairperson or acting member of Council, should the substantive Chairperson or member be absent. Subclause (3) provides that an acting member must have the necessary background and knowledge as provided under clause 20. This clause is included to ensure that business of the Council may continue in the absence of the Chairperson or one of the members, with the full range of expertise available to it.

# Clause 24 - Remuneration and allowances of Chairperson of the Council

This clause provides that the remuneration of the Chairperson shall be determined by the Remuneration Tribunal or, in the absence of a determination, prescribed by regulation. Allowances are to be as prescribed. If the Chairperson is employed on a full-time basis by or in connection with a Commonwealth, State or Territory government body no remuneration is payable under this Act unless the Minister otherwise directs.

This clause is subject to the Remuneration Tribunal Act 1973.

## Clause 25 - Remuneration and allowances of other Council members

This clause provides that remuneration, by way of sitting fees, to members of Council, other than the Chairperson, is to be in accordance with the determinations of the Remuneration Tribunal. If no such determination exists, the levels of remuneration are to be prescribed. Allowances are to be as prescribed. Subclause (2) provides that members who are under the employment of State, Territory or Commonwealth government bodies on a full-time basis are not entitled to this remuneration, while subclause (3) provides that this clause is subject to the Remuneration Tribunal Act 1973.

#### Clause 26 - Leave of absence

This clause provides a) the recreation leave entitlements of a full-time Chairperson and b) that the Minister may grant leave of absence, other than recreation leave to a full-time Chairperson, on terms and conditions set by the Minister, and that the Chairperson may grant such leave of absence to a member, on terms and conditions set by the Chairperson.

#### Clause 27 - Resignation

Members may resign by providing written notice to the Minister.

#### Clause 28 - Termination of appointment

The Minister may terminate the appointment of a member of Council for misbehaviour or physical or mental incapacity. The Minister must terminate the appointment of a member for specified matters including the bankruptcy of the member. Subclause (4) provides that the Minister must provide the member with written notice of their termination of appointment, setting out the reasons for the decision.

#### Clause 29 - Disclosure of interests

This clause provides that the Chairperson and members of Council are to provide written notice, within a month of appointment, of any interest they may have relating to any activity of Council. This clause also provides that the Chairperson or any member with an interest in a particular issue is to be absent during Council's consideration of that issue, unless otherwise determined by the Minister or the Chairperson respectively.

#### Clause 30 - Meetings of Council

This clause provides that the Chairperson must convene at least one Council meeting in each calendar year and may convene such other Council meetings as required to perform the functions of Council effectively. If the Chairperson receives a request signed by at least ten members of Council, a Council meeting must

be convened. The Clause provides that the Chairperson must preside at all meetings if present. If the Chairperson is absent, a member nominated by the Chairperson is to preside at that meeting.

### Clause 31 - Quorum

This clause provides a quorum for Council to be a majority of members. If Council is to make a regulatory or interim regulatory recommendation, the quorum must include a majority of the State and Territory members. Should a Commonwealth, State or Territory member, or the ATSIC member be unable to attend, another nominee of the Minister, the Minister with administrative responsibility for the State or Territory health instrumentality concerned, or ATSIC, as the case may be is deemed to be representative of that absent member.

## Clause 32 - Conduct of meetings

This clause provides that Council regulates meetings as it considers appropriate and that a record of Council proceedings is kept.

## Clause 33 - Council may determine a matter without a meeting

This clause empowers the Council to determine a method by which its members may agree to a resolution without a meeting. The method for this must be agreed by members. A resolution will also be considered passed if, without a meeting being held, a majority of members that would constitute a quorum indicate agreement with the resolution.

#### Clause 34 - Voting

This clause provides that a question arising at a Council meeting is to be determined by a majority of the members present and voting. The presiding member has a deliberative vote and has the casting vote, should there be an equality of votes.

#### Part 5 - COMMITTEES

#### Clause 35 - Principal Committees

This clause provides for the Minister, after consultation with the Council, to establish Principal Committees of the Council. Because of the specific requirements of the Medical Research Endowment Fund, the Minister is required to establish a Principal Committee called the Medical Research Committee, whose functions are to advise and make recommendations to the Council on the application of the Medical Research Endowment Fund, to monitor the use of assistance provided from the Fund, to advise the Council on matters relating to medical research including the

quality and scope of such research in Australia, and such other functions as the Minister from time to time determines.

Subclause (3) empowers the Minister to establish such other Principal Committees as the Minister thinks are necessary in order to assist Council to carry out its functions. As provided in subclause (5) the Minister must determine the name and functions of a Principal Committee established under subclause (3), after due consultation with the Council (as provided in subclause (7)).

Subclause (4) provides that a Principal Committee established under subclause 35(3) for purposes which include the making of recommendations to the Council in relation to guidelines on the conduct of medical research involving humans is not to be chaired by a member of the Medical Research Committee and is not to have more than one member of that Committee on its membership.

Subclause (6) provides that a Principal Committee must be constituted by a Chairperson, and such other members (whether members of the Council or not) as the Minister considers appropriate.

Clauses 87 and 88 act to continue the existing Principal Committees of the Council. These are the Medical Research Committee, the Health Care Committee, the Public Health Committee, the Public Health Research and Development Committee and the Australian Health Ethics Committee.

#### Clause 36 - Executive Committee

This clause empowers the Council to establish an Executive Committee, consisting of the Chairperson of Council, the Chairpersons of the Principal Committees, the Secretary to the Council, and such other Council members as the Council determines. The functions of an Executive Committee are to act on behalf of the Council as its executive organ; to keep under regular consideration the work of Council and its Principal Committees, and to ensure implementation of their decisions; to advise the Council on the organisation of the work of the Council and its Principal Committees; and to perform other functions that the Council may, from time to time, determine.

# Clause 37 - Matters concerning a Principal Committee or the Executive Committee to be determined by the Council

This clause provides that Council may determine the manner in which a Principal Committee or an Executive Committee carries out its functions, and the procedures under which the meetings are conducted. This clause is included to ensure that the Council has suitable control over the work of its reporting committees.

## Clause 38 - Working committees

This clause provides that a Principal Committee may establish working committees as necessary to assist in the carrying out of its functions. The clause stipulates that the Principal Committee must determine the functions of the working committee, procedures under which its meetings are conducted and the manner in which the working committee undertakes its functions. This clause is included to ensure that the Principal Committees retain a suitable level of control over the work of their working committees and the parameters in which they operate.

### Clause 39 - Arrangements to assist committees

This clause provides that the Chairperson of a Principal Committee or a working committee may enter into an arrangement for a person or persons to help the committee carry out its functions. Subclause (2) provides that such arrangements may be on such terms and conditions (other than those relating to remuneration and allowances) as the Chairperson thinks appropriate. This provision enables the Council to continue to draw upon the assistance of a wide range of people to assist it in its work.

# Clause 40 - Remuneration and allowances of committee members and others

This clause provides that remuneration to committee members is to be in accordance with the determinations of the Remuneration Tribunal. If no such determination exists, the levels of remuneration are to be prescribed. Allowances are to be as prescribed. The clause also provides that members who are in the full-time employment of State, Territory or Commonwealth government bodies are not entitled to this remuneration.

#### Clause 41 - Leave of absence for committee members

This clause provides the granting of leave arrangements for Chairpersons and members of Principal Committees, the Executive Committee and appointed members of working committees. The terms and conditions of such grants of leave are to be determined by Chairperson of Council (for Chairpersons and members of Principal Committees and members of an Executive Committee) or by the Chairperson of the Principal Committee (in terms of leave for members of working committees).

#### Clause 42 - Resignation of committee members

This clause provides that notice of resignation being tendered by members of Principal Committees, working committees and the Executive Committee must be made to the appropriate authority. Members of Principal Committees must notify the Minister, appointed members of the Executive Committee must notify the

Chairperson of Council, and members of working committees must notify the Chairperson of the Principal Committee that established the working committee.

## Clause 43 - Termination of appointment of committee members

This clause provides that the appropriate authority may terminate the appointment of a member of a Principal Committee, the Executive Committee or a working committee for misbehaviour or incapacity. The appropriate authority for Principal Committee members is the Minister, for appointed members of the Executive Committee it is the Chairperson of Council, and for the working committees it is the Chairperson of the relevant Principal Committee. The clause details criteria for termination of appointment.

#### Part 6 - STAFF, CONSULTANTS AND WORK ARRANGEMENTS

#### Clause 44 - Staff of the Council

This clause provides that staff of the Council must be persons employed under the Public Service Act 1922. The Council may make arrangements with the Secretary to the Department for staff to be provided to the Council.

## Clause 45 - Engagement of consultants

This clause provides that the Council may arrange with the Secretary to the Department to engage suitably qualified or experienced consultants, on terms and conditions determined by the Secretary to the Department.

#### Clause 46 - Council may arrange provision of facilities

This clause provides that the Council may make arrangements with the Secretary to the Department for the provision of appropriate facilities.

# Clause 47 - Council may make arrangements relating to various matters

This clause provides that the Council may make arrangements with heads of Commonwealth, State or Territory Departments or Authorities for the making available of staff or resources to assist Council undertake its functions. The Council may make arrangements with heads of State or Territory Departments or Authorities relating to any matter within the scope of Council's functions, for the Council to undertake activities on behalf of that State or Territory Department or Authority.

#### PART 7 - MEDICAL RESEARCH ENDOWMENT FUND

### Clause 48 - Establishment of Medical Research Endowment Fund

This clause provides for a fund, known as the Medical Research Endowment Fund, to be established. The clause also provides that income received from the investment of money of the Fund forms part of the Fund, and that the Fund is a Trust Account for the purposes of Section 62A of the Audit Act 1901.

#### Clause 49 - Payments into Fund

This clause provides that money appropriated by Parliament, and any gifts or bequests, are to be paid into the trust account known as the Medical Research Endowment Fund.

## Clause 50 - Purposes of the Fund

This clause provides that the Medical Research Endowment Fund is to be applied to provide assistance to Commonwealth, State or Territory Departments, universities, institutions, or persons engaged in medical research and training in medical research and for any other prescribed purpose. This clause also provides that any assistance is provided subject to such conditions as the Minister, acting on the advice of the Council, determines.

This clause is included to ensure that money in the Medical Research Endowment Fund is used for the purposes for which it was established.

Subclause (3) provides that a grant of assistance must not be provided under subparagraphs (1)(a)(i), (ii) or (iii) unless the recipient agrees to comply with guidelines in force under clause 7 relating to the conduct of medical research involving humans.

## Clause 51 - Application of gifts or bequests

This clause provides that any money held by the Minister for Finance, or accepted by the Minister for Finance, for the purposes of the Fund, is not to be dealt with except in accordance with the obligations of the Minister for Finance. The clause also provides that separate accounts are to be kept for any money which is to have a separate application.

#### Clause 52 - Money repaid to Commonwealth

This clause provides that money repaid to the Commonwealth is to be paid into the Fund.

## Clause 53 - Transitional provision - Medical Research Endowment Fund

This clause provides that the <u>Medical Research Endowment Act 1937</u> be repealed, and money in the existing Fund become money in the Fund covered by this Act. This is a formal clause arranging for this Act to replace the provisions of the existing <u>Medical</u> Research Endowment Act 1937, which prescribes the uses of the Fund.

## Part 8 - COMMISSIONER OF COMPLAINTS

## Clause 54 - Commissioner of Complaints

This clause provides that an office of Commissioner of Complaints is to be established.

#### Clause 55 - Functions of Commissioner

This clause provides that the functions of the Commissioner are to investigate complaints concerning applications for funding for medical and public health research in accordance with the grounds for complaint specified in clause 57 and other conditions set out in the Bill, and summarised below. It provides that the Commissioner is not to inquire into the merits of a recommendation or decision, but rather the processes adopted by the Council or its delegates and committees in dealing with an application.

This enables the Commissioner to inquire into complaints concerning the processes for deciding applications for funds and provides an avenue of redress where there are valid grounds for complaint.

It is intended that this process for investigating complaints will be relatively informal in its procedures relying on the expertise and experience of the Commissioner and the co-operation of the Council. Access to the Ombudsman and the Administrative Decisions (Judicial Review) Act 1977 remains for people who are not satisfied with the outcome of a complaint to the Commissioner of Complaints.

## Clause 56 - Who may complain

This clause provides that anyone whose interests are affected and with grounds for complaint (as provided at clause 57) may complain.

#### Clause 57 - Grounds for complaint

The grounds for complaint relate to reviewable actions, and are as follows:

- (a) that the action involved a breach of the rules of natural justice;
- (b) that the action was induced or affected by fraud;
- (c) that there was no evidence or other material to justify the action;
- (d) that an irrelevant consideration was taken into account in relation to the action;
- (e) that a relevant consideration was not taken into account in relation to the action;
- (f) that in the course of the action a discretionary power was exercised for a purpose other than the purpose for which the power is conferred;
- (g) that the action involved the exercise of a discretionary power in bad faith;
- (h) that, in the course of the action, a personal discretionary power was exercised at the direction of another person;
- (i) that the action involved the exercise of a discretionary power in accordance with a rule or policy without regard to the merits of the particular case;
- (j) that the action involved any other exercise of power in a way that constitutes abuse of the power.

It is not intended that the Commissioner investigate the scientific merits of matters and differing scientific judgements are not a ground for complaint.

## Clause 58 - How to make a complaint

This clause provides that a complaint to the Commissioner about a reviewable action must be in writing, be signed by the complainant, describe the action complained about, specify the nature and grounds for the complaint, and be lodged with the Commissioner.

## Clause 59 - Commissioner to investigate complaints

This clause provides that all complaints must be investigated, except in instances as set out in clause 60.

## Clause 60 - Discretion not to investigate

This clause provides that in certain circumstances, an investigation need not be launched, or an investigation may be discontinued. These circumstances are if, in the Commissioner's opinion, the complaint relates to a decision or event that took place, and was made apparent to the complainant, more than twelve months earlier, or that the complaint is frivolous, vexatious, or made in bad faith, or if a partial investigation reveals that the complaint is not justified or if the complainant has not approached the Council and it would be reasonable for it to do so.

Subclause (2) provides that in any of these situations, the Commissioner must give the complainant written notice of the decision, outlining the reasons for the decision (as prescribed at subclause (3)).

The Commissioner of Complaints may also decide against investigating a complaint, or to discontinue an investigation, if that complaint would have been better placed with the Privacy Commissioner. Again, in this circumstance, the complainant must be informed in writing of the Commissioner's decision. The Commissioner in this instance must transfer the complaint to the Privacy Commissioner along with any information or documents relating to the investigation. The complainant is to be informed in writing by the Commissioner of the transfer of the complaint to the Privacy Commissioner. Any complaint transferred is taken to be a complaint under Part V of the Privacy Act 1988.

### Clause 61 - Council to be informed of investigation

This clause provides that the Commissioner must inform the Council of the impending investigation, prior to the investigation being commenced.

#### Clause 62 - Procedure of Commissioner

This clause provides that the investigation is to take place in private, and in such a manner that the Commissioner sees fit.

#### Clause 63 - Co-operation with Commissioner

This clause provides that the Council, members of the Council, its committees and staff, consultants and other persons assisting a committee of Council, must co-operate with the Commissioner and provide any assistance requested by the Commissioner. In particular a person must provide information or documents requested by the Commissioner and answer any questions that the Commissioner has reasonable grounds for believing are relevant to the investigation.

## Clause 64 - Immunity from Penalty

This clause provides immunity from any penalty or liability under Commonwealth, State or Territory law or common law, which would otherwise arise from the provision to the Commissioner of Complaints, of information, documents or records, to a person who provides such information, documents or records at the request of the Commissioner of Complaints.

## Clause 65 - Reports by Commissioner

This clause provides that the Commissioner must report to the Council about a complaint, if an investigation about the reviewable action has concluded that the action was affected by one of the grounds of complaint set out in clause 57.

#### Clause 66 - Recommendations

This clause provides that the Commissioner may make recommendations to Council, regarding an investigation. The recommendation may include: reconsideration of an action; a particular step to be taken to minimise, rectify or alter the effects of an action; that the decision involved in the action to be revoked or varied; that reasons be given for a decision involved in the action; and that some other thing should be done in relation to the action. This clause further provides for a copy of the Commissioner's report under clause 65 to be supplied to the complainant, for the Council to take appropriate action following its receipt of the report, and for the Council to advise the complainant of any action it proposes to take and its reasons for taking any such action.

## Clause 67 - Annual report of Commissioner

This clause provides that the Commissioner must provide Council with a written annual report of the Commissioner's activities during the year. This should be provided as soon as practicable after the end of each calendar year.

## Clause 68 - Appointment of Commissioner

This clause provides that the Commissioner of Complaints is to be appointed by the Minister, and should have a background and expertise in scientific research, medical research or public health research.

## Clause 69 - Terms and conditions of appointment of Commissioner

This clause provides that the Commissioner is to be appointed on a part-time basis, and that the Commissioner holds the office on terms and conditions that the Minister determines in writing.

## Clause 70 - Period of Commissioner's appointment

The term of appointment is such as determined by the Minister not exceeding 3 years, and specified in the Commissioner's instrument of appointment, and may be renewed.

## Clause 71 - Commissioner may enter arrangement with Department

This clause provides that the Commissioner may make arrangements with the Secretary to the Department for the services of officers and the provision of appropriate facilities.

#### Clause 72 - Acting appointment

This clause provides that the Minister may appoint a person to act as the Commissioner due to a vacancy in the office or when the Commissioner is unable to attend to duties of the office.

Subclause (2) provides that anything done by a person purporting to be Commissioner is not invalid merely because the occasion for the appointment had not arisen; there was a defect or irregularity in, or in connection with, the appointment; the appointment had ceased to have effect; or the occasion for the person to act had not arisen or had ceased.

#### Clause 73 - Remuneration and allowances

This clause provides that remuneration for the Commissioner of Complaints is in accordance with the determinations of the Remuneration Tribunal, or if no relevant determination exists, then such remuneration as is to be prescribed. The allowances of the Commissioner are as prescribed. Subclause (2) provides that this section has effect subject to the Remuneration Tribunal Act 1973.

#### Clause 74 - Leave of absence

This clause provides that the Minister may grant leave of absence to the Commissioner, under terms and conditions that the Minister determines.

# Clause 75 - Disclosure of interests of Commissioner in relation to investigation

This clause provides that the Commissioner must disclose any interest that the Commissioner has in a particular complaint to the complainant and the Minister, and should only continue to investigate the complaint if the complainant and the Minister agree that the Commissioner continue.

This clause also provides that, where the Commissioner discloses any such interest, the Minister may appoint a person to perform the functions of the Commissioner in respect of the complaint.

### Clause 76 - Termination of appointment of Commissioner

This clause empowers the Minister to terminate the appointment of the Commissioner of Complaints for misbehaviour or incapacity or if the Commissioner becomes bankrupt, applies to take the benefit of any law for the relief of bankrupts or insolvent debtors, compounds with his or her creditors to make an assignment of his or her remuneration for their benefit; or, without reasonable excuse is absent except on leave of absence granted under clause 74; or, fails, without reasonable excuse, to comply with the obligation imposed by clause 75.

Subclause (3) provides that the Minister must inform the Commissioner of the termination of his appointment in writing, setting out the reasons for the termination.

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### Clause 77 - Commissioner to protect personal information

This clause provides that the Commissioner must not disclose or make record of any information about a person that the Commissioner has had access to in the performance or exercise of the Commissioner's function. The clause also stipulates that this information should not be made available to any court, tribunal, authority or any other person, except for the purposes of this Bill.

#### Clause 78 - Protection from civil actions

This clause provides that no civil proceedings may be brought against the Commissioner or a person acting under clause 71 in relation to loss, damage, or injury of any kind suffered by a person in the course of the prescribed functions and duties of the Commissioner.

#### Part 10 - MISCELLANEOUS

#### Clause 79 - Confidential commercial information

This clause provides that members of Council and its reporting committees, staff of Council and consultants employed by Council, and persons assisting a committee or Commissioner must not (except in specific instances) disclose any confidential commercial information. The clause also prescribes the specific instances where this information may be, or must be, disclosed.

#### Clause 80 - Protection from civil actions

This clause provides that no civil action may be brought against a member of Council in relation to loss, damage, or injury of any kind suffered by a person in the proper performance of their functions and powers.

## Clause 81 - Delegation

This clause empowers the Council to delegate all or any of its powers to any or all of the following: a Principal Committee; the Executive Committee; the Secretary to the Council and for Principal Committees to delegate to working committees. Any delegation will continue in force despite a change in membership of the Council.

This clause also provides that the Minister may delegate powers to the Secretary of the Department.

#### Clause 82 - Annual Reports

This clause provides that the Council must, as soon as practicable after the end of each year, provide the Minister with

a written report of its operations during that year. The Report must include details of Council membership; the functions and composition of each Principal Committee; details of all regulatory recommendations and interim regulatory recommendations made by Council during that year; details of guidelines issued by Council during the year; details of any recommendation made by Council to the Commonwealth; details of any matters referred to Council by the Minister and a copy of the Commissioner of Complaint's annual report; details of any action taken by the Council in response to the Commissioner's recommendations contained in the report. This report is to be laid before each House of Parliament by the Minister within 15 sitting days after the Minister receives it.

## Clause 83 - Exemption from taxation

This clause provides that the Council is not subject to any taxation laws of the Commonwealth or of a State or Territory. This clause enables regulations to be made which remove this exemption in respect of a specified taxation law.

### Clause 84 - Regulations

This clause is a formal requirement empowering the Governor-General to make regulations as required for the carrying out of, or giving effect to, this Act. This clause is a formal requirement ensuring that the Act is implemented to its fullest effect.

## Part 11 - TRANSITIONAL

## Clause 85 - Existing Council membership

This clause provides that existing members of the Council continue their appointment until 31 December 1993. This date represents the end of the current triennium. Members are appointed on a triennial basis, and this clause is included to allow existing members to serve the full term of their initial appointment.

## Clause 86 - Existing Council activities

This clause provides that any issue before the Council or receiving attention of Council or its reporting committees retains its current status and continues to receive attention. This clause is included to ensure that the matters before Council are continued to be dealt with after implementation of this Act.

## Clause 87 - Existing Medical Research Committee

This clause provides that members of the Medical Research Committee are entitled to continue their appointment until

31 December 1993, the end of the current triennium and the end of their existing appointment period. It also provides for actions of the Committee taken or commenced before this Bill is enacted to continue after the enactment.

#### Clause 88 - Other existing Principal Committees

This clause provides that members of existing Principal Committees are entitled to continue their appointment until 31 December 1993, the end of the current triennium and the end of their existing appointment period. It also provides for actions of the Committees taken or commenced before this Bill is enacted to continue after the enactment.

#### Clause 89 - Existing Ethics Guidelines

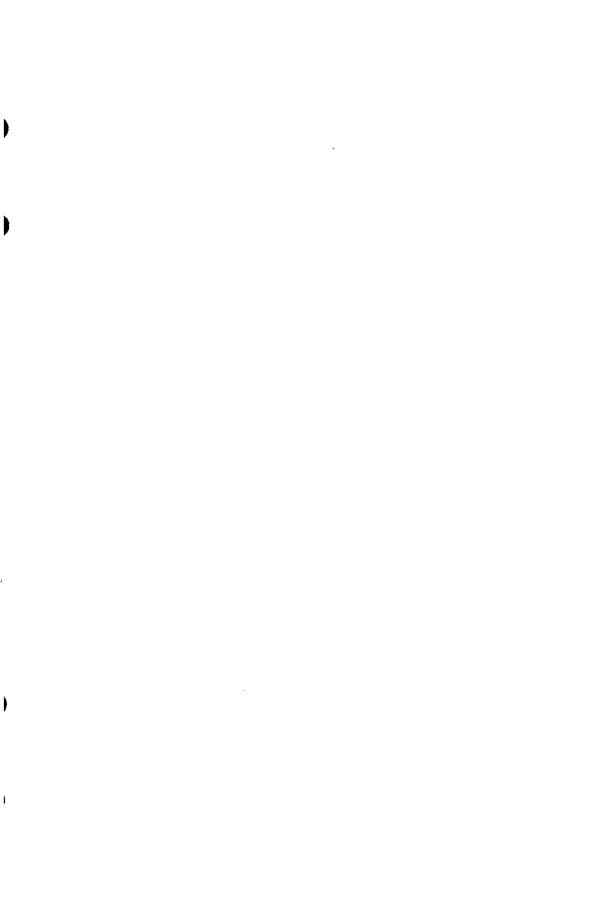
This clause provides for the "NHMRC Statement on Human Experimentation and Supplementary Notes", the current guidelines for the conduct of medical research involving humans, to have effect as if they had been made under subparagraph 7(1)(a)(v) in compliance with clause 8.

### Clause 90 - References in other laws to NHMRC Statement etc.

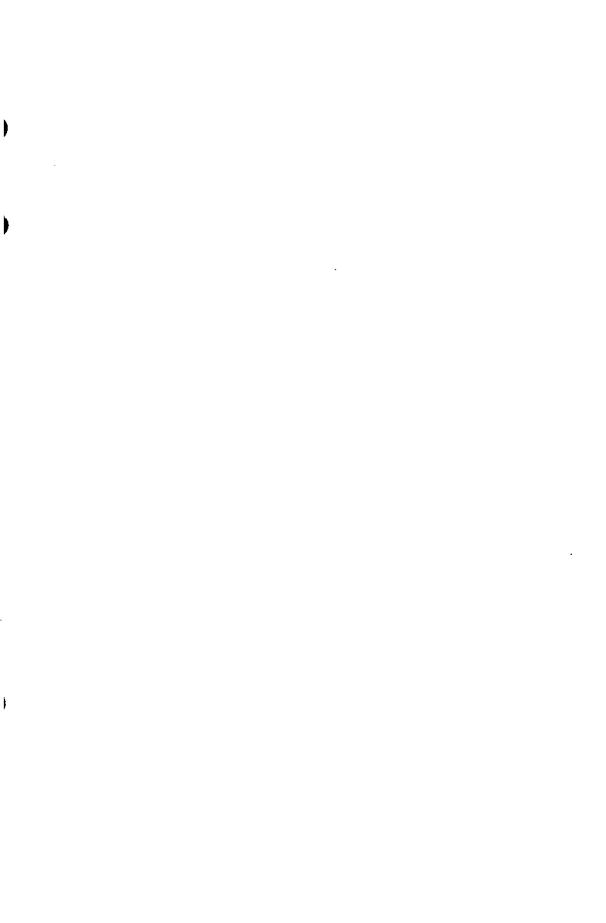
This clause provides that in any Commonwealth law, or in any document issued under such a law, a reference to the NHMRC Statement of Human Experimentation and/or Supplementary Notes is to be treated as a reference to the whole guidelines, or the relevant guidelines within those guidelines, in force or taken to be in force from time to time, under subparagraph 7(1)(a)(v), that relate to the conduct of medical research involving humans.

This clause will enable the Guidelines for the Protection of Privacy in the Conduct of Medical Research to continue in force after the day of proclamation of the National Health and Medical Research Council Bill 1992.

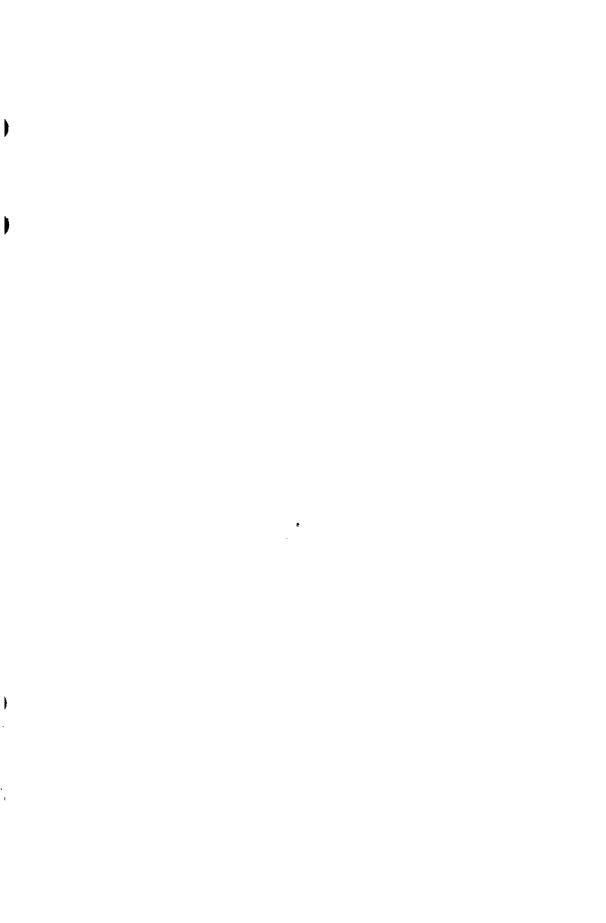
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