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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

SENATE

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL BILL 1992

SUPPLEMENTARY EXPLANATORY MEMORANDUM

Further Amendments to be moved
on behalf of the Government

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



**NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL BILL 1992
SUPPLEMENTARY EXPLANATORY MEMORANDUM**

GENERAL OUTLINE

The proposed amendments relate to the relationship between the NHMRC and the Australian Health Ethics Committee (AHEC), a Principal Committee of the NHMRC, when ethical issues relating to the conduct of medical research involving humans are being considered.

The amendments require the establishment of a Principal Committee called the Australian Health Ethics Committee (AHEC) whose specified functions are to advise the NHMRC on ethical issues relating to health and to develop and recommend guidelines on the conduct of medical research involving humans which must be issued by the NHMRC. The NHMRC would be required to issue these guidelines without amendment.

The proposed amendment expressly provides for the categories of membership of AHEC and requires consultation with relevant organisations before the appointment of members to the Committee.

The Bill also provides for the "NHMRC Statement on Human Embryo Experimentation and Supplementary Notes" to be the guidelines on medical research involving humans until amended or replaced. The proposed amendment relates to the content of Supplementary Note 4 which deals with in vitro fertilisation and embryo transfer, and deletes Supplementary Note 4 from this provision.

FINANCIAL IMPACT

These amendments have no financial impact.

NOTES ON AMENDMENTS

- (1) Clause 8, page 5, omit subclause (2), lines 29 to 32 and substitute subclauses (2) and (3):

Subclause (2) requires that the guidelines for the conduct of medical research involving humans be issued by the Council precisely as developed and provided to it by the Principal Committee known as the Australian Health Ethics Committee.

Subclause (3) provides that, in developing guidelines for the conduct of medical research involving humans, the Australian Health Ethics Committee is required to conduct consultations in accordance with the provisions of clauses 12, 13 and 14 and in accordance with the procedures for which clause 15 provides. These consultations would be expected to include the NHMRC.

- (2) Omit and substitute clause 35, subclause (1), page 17, lines 15 and 16:

This amendment requires that the Minister establish a Principal Committee, to be known as the Australian Health Ethics Committee.

- (3) Insertion after clause 35, page 17, subclause (2):

This amendment specifies that the functions of the Australian Health Ethics Committee are to advise the Council on ethical issues relating to health, to develop and give the Council guidelines for the conduct of medical research involving humans, and such other functions as the Minister from time to time determines.

- (4) Clause 35, page 17, subclause (4), omit and substitute line 29 and omit lines 30 to 32

This amendment is as a consequence of the proposed amendment to subclause 35(1) and specifies the Australian Health Ethics Committee.

- (5) Insertion after clause 35, page 17, subclause (5):

This amendment provides for the Australian Health Ethics Committee to be constituted as provided in subclause 35A rather than as determined by the Minister in accordance with subclause 35(6).

- (6) Insertion at clause 35, page 17, line 39:

This is a consequential amendment which excludes the Australian Health Ethics Committee from the constitution expressly provided under subclause 35(6). Its proposed constitution is provided in proposed clause 35A.

- (7) Insertion after clause 35, page 18, subclause 7, paragraph (a):

This amendment ensures that the Minister can not determine any functions of the Australian Health Ethics Committee additional to those provided in paragraphs (2A)(a) or (b) without consulting with the Council.

- (8) Insertion at clause 35, page 18, subclause (7), line 10:

This amendment does not require the Minister to consult with the Council before determining the number of members to be appointed to the Australian Health Ethics Committee as it is intended that the membership of that Committee be specified in proposed clause 35A.

- (9) Insertion at clause 35, page 18, subclause (7), line 12:

This amendment does not require the Minister to consult with the Council before determining the qualifications or attributes of members to be appointed to the Australian Health Ethics Committee as it is intended that these be specified in proposed clause 35A.

- (10) Insertion at clause 35, page 18, subclause (8), line 17:

This amendment requires the Minister to publish, in the "Gazette", a notice of the establishment, functions and constitution of the Australian Health Ethics Committee within 30 days from the day on which the Minister establishes, or is taken to have established, that Committee.

- (11) Insertion after clause 35, page 18:

Subclause 35A(1) expressly provides for the constitution of the membership of the Australian Health Ethics Committee and to be as follows:

- (a) the Chairperson;
- (b) a person with knowledge of the ethics of medical research;
- (c) a person who has expertise in law;
- (d) a person who has expertise in philosophy;
- (e) a person who has expertise in religion;
- (f) a person with experience in medical research;
- (g) a person with experience in public health research;
- (h) a person with experience in social science research;
- (i) a person with experience in clinical medical practice;
- (j) a person with experience in nursing or allied health practices;
- (k) a person with knowledge of the regulation of the medical profession;
- (l) a person with understanding of health consumer issues;
- (m) no more than 2 other persons with expertise relevant to the functions of the Committee.

Subclause 35A(2) provides that the membership of the Australian Health Ethics Committee must include individuals who collectively have membership of all the other Principal Committees.

Subclause 35A(3) provides that the Minister must appoint the members of the Australian Health Ethics Committee.

Subclause 35A(4) provides that the Minister must consult relevant peak organisations before appointing a member to the Australian Health Ethics Committee.

- (12) Insertion at clause 89, page 39, line 33:

This amendment ensures that the current guidelines for the conduct of medical research involving humans as provided in the the "NHMRC Statement on Human Experimentation and Supplementary Notes", with the exception of Supplementary Note 4, have effect as if they had been made under subparagraph 7(1)(a)(v) in compliance with clause 8.

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